QualiSense Gold

Instructions for use
MD

QualiSense ADHESIVE T1

Light cure one component bonding agent for the total-etch-technique

Recommendation for Use

ADHESIVE T1 is a simple to use **light cure one component bonding agent.** It is designed for strong bonding of light cure **composites and compomers** to **etched enamel and dentine and to nonprecious and precious metals.**

Its strong adhesion to etched enamel or dentine proceeds on principles similar to that occurring with glassionomer cements. Good, long lasting adhesive strength and good biocompatibility are attained by polycarboxylic acids.

ADHESIVE T1 is compatible with all current brands of visible light cure composite materials. It is ethanol-based and hydrophilic. **ADHESIVE T1** can be used on slightly moist dentine surfaces (wet bonding technique).

If a dual or self-cure bonding system is recommended, the dual cure **ADHESIVE T2** can be applied in a similar way.

Indications

Adhesive for:

- Composite based restorations with light cure composites

Side effects

In singular cases, **ADHESIVE T1** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight **(0.5 - 1.0 mm)** bevel placed in the enamel to increase the surface area for greater bond strength.

3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material (e. g. **CH LINER**).

4. Enamel and Dentine Conditioning

Recommended is the total etch technique. Apply **ETCHING GEL** onto the enamel and dentine surfaces beginning with the enamel bevels. Condition **the enamel for at least 15 seconds and the dentine for 15 seconds.** Deciduous teeth are etched correspondingly longer. Rinse for 20 seconds with water. Dry it in a water-free and oil-free airstream, but do **not desiccate**. A slightly wet dentine surface is important for the function of **ADHESIVE T1**. The etched enamel bevel should have a chalky white appearance.

Etching precaution

It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid etching gel contact with oral soft tissues, eyes, and skin. If accidental contact occurs, flush immediately with copious amounts of water.

For the typical indications of compomers etching is mostly not recommended, but it improves considerably the bonding with tooth material.

5. Application of ADHESIVE T1

Apply **ADHESIVE T1** generously with a brush onto the enamel and dentine surfaces for **30 seconds** with agitation. The material should build a homogeneous layer. Remove excess material carefully.

Dry cautiously with oil free air for about **15 seconds** to remove all volatile components and to disperse the adhesive to an even layer. Do not desiccate the dentine.

Cure the **ADHESIVE T1** layer for **20 seconds** with a suitable dental halogen light unit or an LED **(wavelength 400–500 nm, light intensity min. 1000 mW/cm²)** before application of a second layer of **ADHESIVE T1.**

Note:

If not used immediately, place dispensed **ADHESIVE T1** in subdued light to prevent premature polymerization by incident light. The **ADHESIVE T1** will **not** self cure.

6. Application of a Second Layer of ADHESIVE T1

Apply again the **ADHESIVE T1** as described under **point 5**. and light cure before placement of a light cure composite.

7. Restorative Placement

Apply the restorative material according to the instructions of the manufacturer.

Best results are obtained with application of a thin layer of a light cure flowable composite followed by the application of a moldable composite. Light cure each composite layer separately according to the corresponding user instructions.

Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Storage of ADHESIVE T1

Do **not** store above **25 °C (77 °F)!** Avoid storage in direct sunlight. **Do not use after expiration date.**

Warranty

DS Dental Supply GmbH warrants this product will be free from defects in material and manufacture. DS Dental Supply GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusively remedy and DS Dental Supply GmbH's sole obligation shall be repair or replacement of the DS Dental Supply GmbH product.

Limitation of Liability

Except where prohibited by law, DS Dental Supply GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Keep away from children!

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ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

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QualiSense ISOADHESIVE T1

Light cure filled one component bonding agent for the total-etch-technique

Product description

ISOADHESIVE T1 is a simple to use light cure filled one component bonding agent. It is designed for strong bonding of light cure composites and compomers to etched enamel and dentine.

ISOADHESIVE T1 is compatible with all current brands of visible light cure composite materials. It is ethanol-based and hydrophilic. **ISOADHESIVE T1** can be used on slightly moist dentine surfaces (wet bonding technique).

Indications/Intended use

Adhesive for:

- Restorations with light cure composites and compomers

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight **(0.5 - 1.0 mm)** bevel placed in the enamel to increase the surface area for greater bond strength.

3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of calcium hydroxide material (e. g. **CH LINER**).

4. Enamel and Dentine Conditioning

Recommended is the total etch technique. Apply **ETCHING GEL** onto the enamel and dentine surfaces beginning with the enamel bevels. Condition **the enamel for at least 15 seconds and the dentine for 15 seconds.** (This results in 20–30 seconds etching of enamel and 15 seconds of dentine). Deciduous teeth are etched correspondingly longer. Rinse for **20 seconds** with water. Dry it in a water-free and oil-free airstream, but do **not desiccate**. A slightly wet dentine surface is important for the function of **ISOADHESIVE T1**. The etched enamel bevel should have a chalky white appearance.

> **Etching precaution:**
> It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

For the typical indications of compomers etching is mostly not recommended, but it improves considerably the bonding with tooth material.

5. Application of ISOADHESIVE T1

Apply **ISOADHESIVE T1** generously with a brush onto the enamel and dentine surfaces. Gently agitate **ISOADHESIVE T1** onto all prepared dentine surfaces for at least **10 seconds**. The material should build a homogeneous layer. Remove excess material carefully. Dry cautiously with oil free air for about **1-3 seconds** to remove all volatile components and to disperse the adhesive to an even layer. Do **no** desiccate the dentine.

Light cure the **ISOADHESIVE T1** for **20 seconds** with a polymerization unit **(wavelength range 400-500 nm, light intensity at least 1000mW/cm^2).**

6. Restorative Placement

Apply the restorative material according to the instructions of the manufacturer.

Best results are obtained with application of a thin layer of a light cure flowable composite followed by the application of a moldable composite. Light cure each composite layer separately according to the corresponding user instructions.

Storage

Do **not** store above **25 °C (77 °F)!** Avoid storage in direct sunlight.

Do not use after expiration date.

Additional Notes/Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

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Limitation of Liability

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ARSACO GmbH

V1-04-2021

CE 0482

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QualiSense Gold

Instructions for use
MD

QualiSense ADHESIVE S1

Self-etching light cure adhesive

Recommendation for Use

ADHESIVE S1 is a simple to use **self-etching light curing one component adhesive.** It is designed for strong bonding of **composites** to **enamel and dentin**

ADHESIVE S1 is compatible with all current brands of visible light cure composite restorative materials.

Indications

Adhesive for:

- Composite based restorations with light cure composites

Side effects

In singular cases, **ADHESIVE S1** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection the cavity floor in cases of deep excavations should be covered with a thin layer of calcium hydroxide material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of **ADHESIVE S1**. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight **(0.5 - 1.0 mm)** bevel placed in the enamel to increase the surface area for greater bond strength.

3. Pulp Protection

Cavity floor of deep excavations should be covered with a thin layer of calciumhydroxide material (e.g. CH LINER).

4. Application of ADHESIVE S1

Apply **ADHESIVE S1** with a brush onto the moist enamel- and **dentin** surfaces for **30 seconds** with agitation.

The material should build a homogeneous layer. Air thin gently for **10 seconds** to remove the volatile components and to disperse the adhesive. Then light cure with a suitable dental light unit for **20 seconds** before placement of a composite.

5. Restorative Placement, Cure and Finishing

Apply the restorative material according to the instructions of the manufacturer.

Best results are obtained with application of a thin layer of a light cure flowable composite followed by the application of a moldable composite. Light cure each composite layer separately according to the corresponding user instructions.

Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Storage

Do **not** store above **25 °C (77 °F)**! Avoid storage in direct sunlight. **Do not use after expiration date.**

Warranty

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QualiSense Gold

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QualiSense ADHESIVE S2

Self-etching light cure bonding system

Instructions for Use

ADHESIVE S2 is a simple to use self-etching light curing bonding system. It consists of a self-etching primer **Part A** and a bonding agent **Part B**, that are applied one after the other.

ADHESIVE S2 designed for bonding of light cure composites to enamel and dentine, silicate ceramics, zirconia and non-precious metals. **ADHESIVE S2** is compatible with all visible light cure composite restorative materials

Indications

Adhesive for:

- Composite based restorations with light cure composites

Side effects

In singular cases, **ADHESIVE S2** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of **ADHESIVE S2**. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight **(0.5 - 1.0 mm)** bevel placed in the enamel to increase the surface area for greater bond strength.

3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material (e.g. **CH LINER**).

4. Application of ADHESIVE S2

4.1. Application of Part A

Apply **Part A** using a brush onto the slightly wet enamel and dentin surfaces (as they are usual in clinical procedures) for about 10 seconds with agitation.

The material should build a homogeneous layer. Air thin gently to remove the volatile components and to disperse the adhesive.

4.2. Application of Part B

Apply **Part B** using a brush for about **10 seconds** with agitation. Air thin to remove the volatile components and to disperse the bonding to an even layer until the dentine surface appears slightly dull (the enamel surface remains glossy). Then light cure with a suitable dental halogen light unit or an LED (wavelength 400–500 nm, light intensity min. 1000 mW/cm2) for **20 seconds** before placement of a light cure composite.

Note:
Application of **Part A** and **Part B** can be done with one brush.

5. Restorative Placement

Apply the restorative material according to the instructions of the manufacturer.

Best results are obtained with application of a thin layer of a light cure flowable composite followed by the application of a moldable composite. Light cure each composite layer separately according to the corresponding user instructions.

Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates
- Avoid contact with skin, mucous membrane and eyes
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Storage

Do **not** store above **25 °C (77 °F)!** Avoid storage in direct sunlight.
Do not use after expiration date.

Warranty

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Instructions for use

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QualiSense ADHESIVE T2

Dual Cure Bonding System for the Total Etch Technique

Instructions for Use

ADHESIVE T2 is a simple to use dual cure bonding system consisting of the two components **ADHESIVE T2 Part A** and **ADHESIVE T2 Part B** that were mixed before application. It is designed for strong bonding of **light cure, self-cure and dual cure composites** to etched **enamel and dentine and to non-precious and precious metals**. **ADHESIVE T2** can be also used for priming the root canals before cementation of endodontic posts with self or dual cure composites.

The strong adhesion of **ADHESIVE T2** to etched enamel or dentine proceeds on principles similar to that occurring with glass ionomer cements. Good, long lasting adhesive strength and good biocompatibility are attained by polycarboxylic acids.

ADHESIVE T2 can be used on slightly moist dentine surfaces (wet bonding technique).

Indications

Adhesive for:

- Composite based restorations with light cure, self-cure and dual cure composites

Side effects

In singular cases, **ADHESIVE T2** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of **ADHESIVE T2**. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Application

1. Composite Fillings and Indirect Restorations

1.1. Isolation

Rubber dam is the recommended method of isolation.

1.2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight (**0.5 - 1.0 mm**) bevel placed in the enamel to increase the surface area for greater bond strength.

1.3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping materials (e.g. **CH LINER**).

1.4. Enamel and Dentine Conditioning

Recommended is the total etch technique. Apply **ETCHING GEL** onto the enamel and dentine surfaces beginning with the enamel bevels. Condition the enamel for at least 15 seconds and the dentine for **15 seconds**. (This results in **20–30 seconds** etching of enamel and **15 seconds** of dentine). Deciduous teeth are etched correspondingly longer. Rinse for **20 seconds** with water. Dry it in a water-free and oil-free airstream, but do **not desiccate**. A slightly wet dentine surface is important for the function of **ADHESIVE T2**. The etched enamel bevel should have a chalky white appearance.

Etching precaution

It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid **Etching Gel** contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

1.5. Application of ADHESIVE T2

For light cure composites:

Apply **ADHESIVE T2 Part A** generously with a brush onto the enamel and dentin surfaces for **30 seconds** with agitation. The material should build a homogeneous layer. Remove excess material carefully. Dry cautiously with oil free air for about **15 seconds** to remove all volatile components and to disperse the adhesive to an even layer. Do no desiccate the dentine.

Cure the **ADHESIVE T2 Part A** coating by exposing its entire area to a dental halogen light unit for **20 seconds** before application of a second layer of **ADHESIVE T2 Part A**.

> Notes: Do not rinse off the **ADHESIVE T2 Part A!** If not used immediately, place dispensed **ADHESIVE T2 Part A** in subdued light to prevent premature polymerization by incident light. The **ADHESIVE T2 Part A** will **not** self-cure.

Apply again the **ADHESIVE T2 Part A** generously with a brush onto the adhesive surfaces as described above before placement of a light cure composite.

For self-cure and dual cure composites

One drop of **ADHESIVE T2 Part A** and one drop of **ADHESIVE T2 Part B** were combined in a mixing pallet and mixed for **5-10 seconds** under subdued light.

> Note:
> Do **not** interchange lids of the bottles, because this can lead to a cross-contamination of the liquids.

Apply the **ADHESIVE T2** mixture generously with a brush onto the enamel and dentine surfaces for **30 seconds** with agitation. The material should build a homogeneous layer. Remove excess material carefully. Dry cautiously with oil free air for about **15 seconds** to remove all volatile components and to disperse the adhesive to an even layer. Do no desiccate the dentine.

Cure the **ADHESIVE T2** coating by exposing its entire area to a dental halogen light unit for **20 seconds** before application of a second layer of **ADHESIVE T2.**

Without light cure apply the second layer after drying with oil free air.

Apply again the **ADHESIVE T2** mixture generously with a brush onto the adhesive surfaces as described above before placement of a composite.

It is essential that the primed dentine and enamel surfaces are dry and contaminant free for the application of the composite.

The self-cure or dual cure composite can be applied immediately.

1.6. Application of the Composite

1.6.1. Direct Restorations

Apply the restorative material according to the instructions of the manufacturer.

Light cure restorative materials

Best results are obtained with application of a thin layer of a light cure flowable composite followed by the application of a moldable composite. Light cure each composite layer separately according to the corresponding user instructions.

Self or dual cure restorative materials

Apply a self cure or dual cure composite according to the user instructions. Light cure in case of dual cure composites shortens setting time.

1.6.2. Indirect Restorations

Refer to manufacturer's instructions for application of indirect restorations.

For cementing of the indirect restoration a self cure or dual cure composite cement is applied according to the user instructions.

2. Application of ADHESIVE T2 in Root Canals

2.1. Isolation

Use of a rubber dam to isolate the tooth is strongly recommended.

2.2. Root Canal Preparation

Prepare and clean the root canal according to the instructions of the selected post manufacturer. Dry the root canal but do **not** desiccate.

Etch the root canal with **ETCHING GEL** for **15 seconds** and rinse with water using an endodontic irrigation syringe. Blot the canal dry with soft paper tips, leaving the dentin visibly moist. A slightly wet dentine surface is important for the function of **ADHESIVE T2.**

Etching Precaution

It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

2.3. Application of ADHESIVE T2

One drop of **ADHESIVE T2 Part A** and one drop of **ADHESIVE T2 Part B** were combined in a mixing pallet and mixed for **5-10 seconds** under subdued light.

> Note:
> Do **not** interchange lids of the bottles, because this can lead to a cross-contamination of the liquids.

Apply **ADHESIVE T2** generously with a suitable brush on the prepared root canal walls for **30 seconds** with agitation. The material should build a homogeneous layer.

Remove excess material carefully e.g. with paper points. Dry cautiously with oil free air to remove all volatile components and to disperse the adhesive to an even layer. Do no desiccate.

Optional cure the **ADHESIVE T2** coating by exposing its entire area to a dental halogen light unit for **20 seconds** before application of a second layer of **ADHESIVE T2.**

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2.4. Application of a 2nd Layer of ADHESIVE T2

Apply again the **ADHESIVE T2** generously with a brush onto the adhesive surfaces as described under **2.3.** Optional light cure.

It is essential that the primed dentine and enamel surfaces are dry and contaminant free for the application of the composite.

Proceed immediately with placement of the post.

2.5. Post Cementation

Prepare the post according to manufacturer instructions.

Place the post with a flowable dual cure or self-cure composite (e.g. DC CORE) into the root canal. For post stabilization light cure the coronal part of the cemented post for **20 seconds.**

Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates
- Avoid contact with skin, mucous membrane and eyes
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Storage

Do not store above **25 °C (77 °F)!** Avoid storage in direct sunlight. **Do not use after expiration date.**

Warranty

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QualiSense Gold

Instructions for use
MD

QualiSense DC ADHESIVE S2

Self-etching dual cure adhesive

Recommendation for Use

DC ADHESIVE S2 is a simple to use **self-etching dual cure adhesive** for a durable and strong bonding of **composites**, **compomers and resin modified glass ionomer cements** to **enamel and dentin.**

DC ADHESIVE S2 works optimally under slightly wet conditions.

DC ADHESIVE S2 consists of the components **Part A** and **Part B** that were mixed before application. It is bonding to **dual cure**, **self-cure** and **light cure** composite restorative materials.

Indications

Adhesive for:

- Core build-ups and cementing of posts with dual and self-cure composites (e.g. **DC CORE, NANOCORE ZR**)
- Cementing of posts with dual and self-cure composite cements (e.g. **DC CEM**)
- Cementing of inlays, onlays, crowns and bridges with dual and self-cure composite cements (e.g. **DC CEM**)
- Composite based restorations with **dual cure, self-cure and light cure composites**

Side effects

In singular cases, **DC ADHESIVE S2** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection the cavity floor in cases of deep excavations should be covered with a thin layer of calcium hydroxide material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of **DC ADHESIVE S2**. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Cavity Preparation

Prepare the cavity according to the principles of the **adhesive** restoration technique.

3. Pulp Protection

Cavity floor of deep excavations should be covered with a thin layer of calcium hydroxide material (e.g CH LINER).

4. Application of DC ADHESIVE S2

One drop of **DC ADHESIVE S2 Part A** and one drop of **DC ADHESIVE S2 Part B** were combined in a mixing pallet and mixed for **5-10 seconds.**

Notes: Do not interchange lids of the bottles, because this can lead to a cross-contamination of the liquids.

4.1. Application for Core Build-ups, Cementing of Inlays, Onlays, Crowns and Bridges and for Composite based Restorations

Apply the homogeneous mixture generously with a brush onto the slightly wet enamel and dentin surfaces (as they are usual in clinical procedures) for **30 seconds** with agitation. The material should build a homogeneous layer. Air thin for **10 seconds** to remove the volatile components and to disperse the adhesive. Then light cure for **20 seconds** with a dental halogen light unit or an LED **(wavelength 400–500 nm, light intensity min. 1000 mW/cm2)** and place the restorative material. For a maximal adhesion it is **strongly recommended to use the light cure mode.**

If light cure is absolutely impossible, the adhesive will also cure in the auto cure mode. After application of the adhesive air thin to **remove all volatile components.** There must remain a sticky layer. Then apply the dual cure, self-cure or light cure restorative material directly.

4.2. Application in the Root Canal (Cementing of Posts)

Prepare and clean the root canal with e.g. sodium hypochlorite solution, rinse and remove excess solution from the canal with a soft paper point.

Apply the homogeneous mixture of **DC ADHESIVE S2 Part A** and **DC ADHESIVE S2 Part B** generously with a brush onto the slightly wet root canal walls for **15 seconds** with agitation.
Repeat procedure **1 – 2 times**. All the dentin surfaces must kept wet with the primer over the specified time.

Remove excess **DC ADHESIVE S2** with dry paper points. Dry the root canal cautiously with oil free air for **15 seconds** to remove all volatile components and to disperse the adhesive to an even layer. Light cure all areas that are available for a dental curing unit for **20 seconds.**

5. Restorative Placement, Cure and Finishing

Refer to manufacturer instructions for placement of the dual cure, self-cure or light cure restorative material.

Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Storage

Do **not** store above **25 °C (77 °F)!** Avoid storage in direct sunlight. **Do not use after expiration date.**

Warranty

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Limitation of Liability

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Keep away from children!

For dental use only!

ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense UNIVERSAL ADH
Universal Adhesive

Product description
UNIVERSAL ADH is a simple to use light cure universal adhesive. **UNIVERSAL ADH** can be used with the self-etch technique, with preceding selective enamel etching or with the total-etch technique. It is suitable for moist, wet and dry surfaces. Based on innovative MDP technology **UNIVERSAL ADH** allows an excellent adhesion.
For applications, where light cure cannot be ensured (e.g. in the root canal) **UNIVERSAL ADH** has to be used in combination with **UNI CATALYST**. Please refer to the instructions for **UNI CATALYST.**

Indications/Intended use
Adhesive for the self-etch technique, selective enamel etching or total-etch technique for:

- Direct light cure composite and compomer restorations.
- Core build-ups with light, dual and self-cure composites (e.g. DC CORE, NANOCORE ZR) if light cure of the adhesive is possible.
- Cementing of inlays, onlays, crowns and bridges with light, dual and self cure composite cements (e.g. DC CEM) if light cure of the adhesive is possible.
- Repair of fractured composite restorations

Use UNIVERSAL ADH only with dual cured or self cured composites if light cure of the adhesive is guaranteed.

Performance features
The performance features of the product meet the requirements of the intended use.

Contraindications
In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.
Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group
Persons who are treated during a dental procedure.

Intended users
This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials
Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material come into contact with materials containing eugenol.

Application
1. Isolation
Rubber dam is the recommended method of isolation.

2. Cavity Preparation
Prepare the cavity according to the principles of the adhesive restoration technique.

3. Pulp Protection
For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material **(e. g. CH LINER).**

4. Conditioning with ETCHING GEL (optional)
Selective enamel etching or etching by application of the total-etch-technique can be used to improve the bond to enamel.

> Note:
> Unprepared enamel surfaces must always be conditioned with **ETCHING GEL.**

Etching precaution
It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as described below. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

a. Selective enamel etching
Apply **ETCHING GEL** onto the enamel surfaces and leave in place for at least **15 seconds.** Deciduous teeth are etched correspondingly longer. Rinse for **20 seconds** with water and dry it in a water-free and oil-free airstream. The etched enamel surface should have a chalky white appearance.

b. Total-Etch Technique
Apply ETCHING GEL onto the enamel and dentine surfaces beginning with the enamel bevels. Condition **the enamel for at least 15 seconds and the dentine for 15 seconds**. (This results in 20–30 seconds etching of enamel and 15 seconds of dentine). Deciduous teeth are etched correspondingly longer.
Rinse for 20 seconds with water. Dry it in a water-free and oil-free airstream, but do **not desiccate**.

The etched enamel bevel should have a chalky white appearance.

5. Application of UNIVERSAL ADH
Dispense one or two drops **UNIVERSAL ADH** into a mixing well and use immediately after dispensing.

Close bottle immediately after use.
Apply **UNIVERSAL ADH** with a brush onto the whole enamel and dentine surface in a thin and even layer. Keep the adhesive agitated for at least **20 seconds**. Applying the adhesive on the tooth surface without agitation is inadequate. The material should build a homogeneous layer.
Air thin gently **(at least 5-10 seconds)** to remove the volatile components and to disperse the adhesive until a glossy and uniform layer results. Then light cure with a suitable dental halogen light unit or an LED **(wavelength 400–500 nm, light intensity min. 1000 mW/cm2)** for **20 seconds.**

6. Application of a composite
Refer to manufacturer instructions for placement of the light, dual or self cure restorative material.

Note for direct restorations
Best results are obtained with application of a thin layer of a light cure flowable composite followed by the application of a moldable composite. Light cure each composite layer separately according to the corresponding user instructions.

Storage
Do not store above 25 °C (77 °F)! Protect from direct sunlight. Do not use after expiry date.

Additional informations/Warnings
Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.

- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Disposal
Disposal of the product according to local authority regulations.

Reporting obligation
Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty
DS Dental Supply GmbH warrants this product will be free from defects in material and manufacture. DS Dental Supply GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusively remedy and DS Dental Supply GmbH's sole obligation shall be repair or replacement of the DS Dental Supply GmbH product.

Limitation of Liability
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CE 0482
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QualiSense Gold

Instructions for use
MD

QualiSense POLISH

Prophylaxis powder for polishing and desensitizing of teeth

Product description

POLISH is a powder for the cleaning and polishing of teeth as part of a dental professional prophylaxis treatment of dental enamel and for the relief of tooth sensitivity. **POLISH** removes plaque, soft deposits, and surface stains. The components of **POLISH** are known to encourage remineralization of tooth material.

POLISH is perfect for polishing during prophylaxis procedures. Cleaning with **POLISH** reduces tooth abrasion to a minimum.

POLISH is intended to be used in commercially available air polishing equipment for supra gingival air polishing (e.g. NSK, Acteon, Kavo) or Sylc Jet hand-held devices.

Indications

- Removal of extrinsic stains, e.g. coffee, tea and tobacco
- Plaque removal prior to fluoride treatments
- Prophylaxis of orthodontic patients
- Treatment of hypersensitivity
- Surface preparation prior to bonding and sealing
- Before and after scaling and root planing procedure to reduce sensitivity
- Before and after bleaching procedures

Contraindications

- Do not use **POLISH** for patients with a known allergy to silica.

Precautions

- When using **POLISH** wear protective glasses and cover the patient eyes.
- In case of contact with eyes, rinse with copious amounts of water and consult a physician if necessary.
- Do not use **POLISH** in the gingival area or in the gingival sulcus. Application of **POLISH** with air polishing equipment at high air pressures may cause injury to the gum tissues or an emphysema caused by the introduction of air into the soft tissue spaces.
- Avoid directing **POLISH** on dental prostheses e.g. crowns and bridgework (possible damage of the restoration).
- Avoid directing **POLISH** on orthodontic brackets (it could dull the metal).
- Clean the powder chamber daily to avoid clogging of the powder.
- Please be aware that there are no adequate data for use in pregnant women and children.

Application

1. **POLISH** is intended to be used in the above recommended air polishing equipment or hand-held devices.
2. Shake the bottle well before use and open it by turning the lid counterclockwise.
3. Pour **POLISH** powder into the delivery system (chamber) to the maximum level recommended by equipment manufacturer.
4. **POLISH** should be applied at an air pressure range of approximately 2.8-3.2 bar (40-46 psi). The equipment should be set to a minimum powder flow and powder uptake.
5. If increased cleaning effect is required, increase flow and powder settings accordingly.
6. Following treatment, the patient should not eat or drink for at least 1 hour.
7. **POLISH** can be used on patients who are on a sodium-restricted diet.

Storage

Store at 15 – 25 °C (60 – 77 °F) at a dry place. Opened bottles have to be used up within 3 months and before the expiry date. Do not use if bags/bottles are damaged.

Do not use after expiry date!

Warranty

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Keep away from children!
For dental use only!

ARSACO GmbH

V1-04-2021

CE 0482

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22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense BLEACHING 9%

In Office Bleaching System for Professional Tooth Whitening in Dentistry

Product description

BLEACHING 9% is a self-activating 9% hydrogen peroxide containing bleaching material in a 1:1 syringe. **BLEACHING 9%** is for professional tooth whitening within a dental treatment of vital and non-vital teeth.

Please Note

Tooth whitening products are only to be sold to dental practitioners. The use of the product must be administered by dental practitioner who will have performed a clinical examination. Not to be used on a person under 18 years.

Composition

hydrogen peroxide, glycerin, activator

Indications

Whitening of individual or multiple discolored teeth (vital and non-vital) within a dental treatment. Teeth whitening takes place by oxidative breakdown of organic substances in the enamel.

A medical dental treatment with BLEACHING 9% may be necessary at:

External bleaching

- discoloration caused by medication (e.g. tetracycline or minocycline)

Intra coronal bleaching

- pulp nekrosis and/or consequences of endodontic treatments

External bleaching with BLEACHING 9% is also possible at:

- age-dependent discolorations
- food-related discolorations (e.g. coffee, tea, tobacco, red wine)

Contraindications

Do **not** use **BLEACHING 9%** in the case of:

- pregnant or lactating women
- patients known to be allergic to any of the ingredients
- heavy smokers, except in the case, they don't smoke during the duration of the treatment
- in the presence of teeth which are cervical exposed
- in the presence of crowns and bridges with marginal gaps
- in the presence of untreated caries
- periodontal diseases
- hypersensitive patients

Discontinue treatment if the patient experiences excessive pain sensation.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Warnings

- hydrogen peroxide-contact with the skin, the mucous membrane or with eyes causes irritation. In the case of contact rinse with plenty of water and consult an ophthalmologist (contact with eyes)
- do not swallow
- keep away from children

Hints:

Tooth and gingiva may be sensitive to the bleach gel, in this case reduce the amount of gel used and /or reduce the gel contact-time to tooth. If the symptoms continue check the patient's allergy to the bleach ingredients. It might be necessary to discontinue the treatment.

Preparation of the treatment:

- patient information: possibilities of bleaching risks, side effects and follow-on treatments
- reasons for discolorations, demonstrations of the likely success of bleaching
- preparation of the teeth to be bleached, (professional cleaning, shade determination (photo), removal of tartar, surface contamination any anomalies on the tooth surface)
- The patient, practitioner and assistants must all wear protective eyewear during the application of **BLEACHING 9%.** The practitioner and dental assistants must also wear gloves and a mask. Do **not** allow **BLEACHING 9%** to come into contact with skin, eyes or mucosa.

The application

External bleaching

1. Ensure that the teeth are cleaned thoroughly.
2. Mask the gingiva with **BLEACH DAM** or **BLEACH MASK** (see recommendation for use BleachMask) or protect the gingiva by rubber dam.
3. **BLEACHING 9%** is applied through the mixing tip directly onto the teeth. Before applying discard the first amount (approx. the size of a pea) of the extruded material. Agitate with a dental brush to enhance bleaching activity.
4. After an exposure time up to **20 minutes** remove the bleaching gel by using gauze or a brush and rinse well with water.
5. Remove the gingiva protection.
6. If desired, a fluoridation treatment could be accomplished.
7. Use for every new application a new mixing cannula (the mixed material in the mixing cannula will become ineffective for bleaching purposes after some time).
8. For storage remove the mixing cannula and replace the cap.

Steps 3 and 4 can be repeated twice per visit. If additional bleaching is desired, repeat treatment is possible after one week.

For sensitive-reacting patients reduce the application time or stop if it's too much sensitivity.

Please check the condition of the teeth and the gingiva during the whole bleaching treatment.

Intra coronal bleaching

1. Before starting the bleaching procedure take an X-ray to verify that the root canal filling is closely sealed.
2. First open the entrance to the pulp chamber and to the root canal and remove carefully existing filling material. Ensure that enough space is created in the area of the coronal pulp to accommodate the bleaching gel.
3. The root canal filling should be removed to a maximum depth of ca. **2 mm** below the cervical gingival and should afterwards be tightly covered with a lining material.

Warning:

Remove all carious dentine before application of the bleaching gel!

4. Create a dry working area around the affected tooth. Use o rubber dam is recommended to provide adequate protection against inhalation or swallowing of the highly reactive bleaching gel. For alternative protection of the gingiva apply BLEACH DAM according to the corresponding instructions.
5. Fill **BLEACHING 9%** into the cavity and leave enough space for the temporary restoration. Leave the bleaching gel– depending on the degree of discoloration - up to **3-5 days** in the cavity.

Note:

For storage remove the mixing cannula and replace the cap.

6. During the exposure time of **BLEACHING 9%** seal the cavity with a classical glass ionomer cement **(e.g.GI E)**. Verify occlusal clearance in protrusive and laterotrusive movements. Premature occlusal contacts may fracture the provisional restoration resulting in leakage and loss of bleaching gel with subsequent damage of the mucosa. Instruct the patient to contact a dentist if he feels a leakage or something unusual.
7. After the exposure time remove the bleaching gel carefully from a cavity using a surgical suction cannula.
8. To increase the bleaching effect, step 5 to 7 can be repeated twice.
9. When the tooth has reached the desired shade, remove the bleaching gel and rinse the cavity thoroughly with plenty of water.
10. Seal the cavity with a suitable temporary filling material. The filling should remain in situ for at least **14 days** before a definitive treatment with a composite is possible.

Patient Information:

- In the first two weeks after bleaching teeth may darken slightly. Restorations can be replaced two weeks after finishing the bleaching treatment.
- To reduce the risk of discoloration, avoid staining foods, beverages and tobacco for **24-48 hours** after treatment.

Storage:

Store BLEACHING 9% in the refrigerator at 2-6°C (36-43 °F) to maintain the gel-like consistency. (keep out of sunlight and heat!)

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Dentist Information:

Before each application check the consistency of the material.

BLEACHING 9% is not for laser activated bleaching.

Warranty

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QualiSense Gold

Instructions for use
MD

QualiSense BLEACHING 16%

In Office Bleaching System for Professional Tooth Whitening in Dentistry

Product description

BLEACHING 16% is a self-activating 16% hydrogen peroxide containing bleaching material in a 1:1 syringe. **BLEACHING 16%** is for professional tooth whitening within a dental treatment of vital and non-vital teeth.

Please Note

Tooth whitening products are only to be sold to dental practitioners. The use of the product must be administered by dental practitioner who will have performed a clinical examination. Not to be used on a person under 18 years.

Composition

hydrogen peroxide, glycerin, activator

Indications

Whitening of individual or multiple discolored teeth (vital and non-vital) within a dental treatment. Teeth whitening takes place by oxidative breakdown of organic substances in the enamel.

A medical dental treatment with BLEACHING 16% may be necessary at:

External bleaching

- discoloration caused by medication (e.g. tetracycline or minocycline)

Intra coronal bleaching

- pulp nekrosis and/or consequences of endodontic treatments

External bleaching with BLEACHING 16% is also possible at:

- age-dependent discolorations
- food-related discolorations (e.g. coffee, tea, tobacco, red wine)

Contraindications

Do **not** use **BLEACHING 16%** in the case of:

- pregnant or lactating women
- patients known to be allergic to any of the ingredients
- heavy smokers, except in the case, they don't smoke during the duration of the treatment
- in the presence of teeth which are cervical exposed
- in the presence of crowns and bridges with marginal gaps
- in the presence of untreated caries
- periodontal diseases
- hypersensitive patients

Discontinue treatment if the patient experiences excessive pain sensation.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Warnings

- hydrogen peroxide-contact with the skin, the mucous membrane or with eyes causes irritation. In the case of contact rinse with plenty of water and consult an ophthalmologist (contact with eyes)
- do not swallow
- keep away from children

Hints:

Tooth and gingiva may be sensitive to the bleach gel, in this case reduce the amount of gel used and /or reduce the gel contact-time to tooth. If the symptoms continue check the patient's allergy to the bleach ingredients. It might be necessary to discontinue the treatment.

Preparation of the treatment:

- patient information: possibilities of bleaching risks, side effects and follow-on treatments
- reasons for discolorations, demonstrations of the likely success of bleaching
- preparation of the teeth to be bleached, (professional cleaning, shade determination (photo), removal of tartar, surface contamination any anomalies on the tooth surface)
- The patient, practitioner and assistants must all wear protective eyewear during the application of **BLEACHING 16%.** The practitioner and dental assistants must also wear gloves and a mask. Do **not** allow **BLEACHING 16%** to come into contact with skin, eyes or mucosa.

The application

External bleaching

1. Ensure that the teeth are cleaned thoroughly.
2. Mask the gingiva with **BLEACH DAM** or **BLEACH MASK** (see recommendation for use BleachMask) or protect the gingiva by rubber dam.
3. **BLEACHING 16%** is applied through the mixing tip directly onto the teeth. Before applying discard the first amount (approx. the size of a pea) of the extruded material. Agitate with a dental brush to enhance bleaching activity.
4. After an exposure time up to **20 minutes** remove the bleaching gel by using gauze or a brush and rinse well with water.
5. Remove the gingiva protection.
6. If desired, a fluoridation treatment could be accomplished.
7. Use for every new application a new mixing cannula (the mixed material in the mixing cannula will become ineffective for bleaching purposes after some time).
8. For storage remove the mixing cannula and replace the cap.

Steps 3 and 4 can be repeated twice per visit. If additional bleaching is desired, repeat treatment is possible after one week.

For sensitive-reacting patients reduce the application time or stop if it's too much sensitivity.

Please check the condition of the teeth and the gingiva during the whole bleaching treatment.

Intra coronal bleaching

1. Before starting the bleaching procedure take an X-ray to verify that the root canal filling is closely sealed.
2. First open the entrance to the pulp chamber and to the root canal and remove carefully existing filling material. Ensure that enough space is created in the area of the coronal pulp to accommodate the bleaching gel.
3. The root canal filling should be removed to a maximum depth of ca. **2 mm** below the cervical gingival and should afterwards be tightly covered with a lining material.

Warning:

Remove all carious dentine before application of the bleaching gel!

4. Create a dry working area around the affected tooth. Use o rubber dam is recommended to provide adequate protection against inhalation or swallowing of the highly reactive bleaching gel. For alternative protection of the gingiva apply BLEACH DAM according to the corresponding instructions.
5. Fill **BLEACHING 16%** into the cavity and leave enough space for the temporary restoration. Leave the bleaching gel– depending on the degree of discoloration - up to **3-5 days** in the cavity.

Note:
For storage remove the mixing cannula and replace the cap.

6. During the exposure time of **BLEACHING 16%** seal the cavity with a classical glass ionomer cement **(e.g.GI E)**. Verify occlusal clearance in protrusive and laterotrusive movements. Premature occlusal contacts may fracture the provisional restoration resulting in leakage and loss of bleaching gel with subsequent damage of the mucosa. Instruct the patient to contact a dentist if he feels a leakage or something unusual.
7. After the exposure time remove the bleaching gel carefully from a cavity using a surgical suction cannula.
8. To increase the bleaching effect, step 5 to 7 can be repeated twice.
9. When the tooth has reached the desired shade, remove the bleaching gel and rinse the cavity thoroughly with plenty of water.
10. Seal the cavity with a suitable temporary filling material. The filling should remain in situ for at least **14 days** before a definitive treatment with a composite is possible.

Patient Information:

- In the first two weeks after bleaching teeth may darken slightly. Restorations can be replaced two weeks after finishing the bleaching treatment.
- To reduce the risk of discoloration, avoid staining foods, beverages and tobacco for **24-48 hours** after treatment.

Storage:

Store BLEACHING 16% in the refrigerator at 2-6°C (36-43 °F) to maintain the gel-like consistency. (keep out of sunlight and heat!)

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Dentist Information:

Before each application check the consistency of the material.

BLEACHING 16% is not for laser activated bleaching.

Warranty

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QualiSense Gold

Instructions for use
MD

QualiSense BLEACHING 27%

In Office Bleaching System for Professional Tooth Whitening in Dentistry

Product description

BLEACHING 27% is a self-activating 27% hydrogen peroxide containing bleaching material in a 1:1 syringe. **BLEACHING 27%** is for professional tooth whitening within a dental treatment of vital and non-vital teeth.

Please Note

Tooth whitening products are only to be sold to dental practitioners. The use of the product must be administered by dental practitioner who will have performed a clinical examination. Not to be used on a person under 18 years.

Composition

hydrogen peroxide, glycerin, activator

Indications

Whitening of individual or multiple discolored teeth (vital and non-vital) within a dental treatment. Teeth whitening takes place by oxidative breakdown of organic substances in the enamel.

A medical dental treatment with BLEACHING 27% may be necessary at:

External bleaching

- discoloration caused by medication (e.g. tetracycline or minocycline)

Intra coronal bleaching

- pulp nekrosis and/or consequences of endodontic treatments

External bleaching with BLEACHING 27% is also possible at:

- age-dependent discolorations
- food-related discolorations (e.g. coffee, tea, tobacco, red wine)

Contraindications

Do **not** use **BLEACHING 27%** in the case of:

- pregnant or lactating women
- patients known to be allergic to any of the ingredients
- heavy smokers, except in the case, they don't smoke during the duration of the treatment
- in the presence of teeth which are cervical exposed
- in the presence of crowns and bridges with marginal gaps
- in the presence of untreated caries
- periodontal diseases
- hypersensitive patients

Discontinue treatment if the patient experiences excessive pain sensation.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Warnings

- hydrogen peroxide-contact with the skin, the mucous membrane or with eyes causes irritation. In the case of contact rinse with plenty of water and consult an ophthalmologist (contact with eyes)
- do not swallow
- keep away from children

Hints:

Tooth and gingiva may be sensitive to the bleach gel, in this case reduce the amount of gel used and /or reduce the gel contact-time to tooth. If the symptoms continue check the patient's allergy to the bleach ingredients. It might be necessary to discontinue the treatment.

Preparation of the treatment:

- patient information: possibilities of bleaching risks, side effects and follow-on treatments
- reasons for discolorations, demonstrations of the likely success of bleaching
- preparation of the teeth to be bleached, (professional cleaning, shade determination (photo), removal of tartar, surface contamination any anomalies on the tooth surface)
- The patient, practitioner and assistants must all wear protective eyewear during the application of **BLEACHING 27%.** The practitioner and dental assistants must also wear gloves and a mask. Do **not** allow **BLEACHING 27%** to come into contact with skin, eyes or mucosa.

The application

External bleaching

1. Ensure that the teeth are cleaned thoroughly.
2. Mask the gingiva with **BLEACH DAM** or **BLEACH MASK** (see recommendation for use BleachMask) or protect the gingiva by rubber dam.
3. **BLEACHING 27%** is applied through the mixing tip directly onto the teeth. Before applying discard the first amount (approx. the size of a pea) of the extruded material. Agitate with a dental brush to enhance bleaching activity.
4. After an exposure time up to **20 minutes** remove the bleaching gel by using gauze or a brush and rinse well with water.
5. Remove the gingiva protection.
6. If desired, a fluoridation treatment could be accomplished.
7. Use for every new application a new mixing cannula (the mixed material in the mixing cannula will become ineffective for bleaching purposes after some time).
8. For storage remove the mixing cannula and replace the cap.

Steps 3 and 4 can be repeated twice per visit. If additional bleaching is desired, repeat treatment is possible after one week.

For sensitive-reacting patients reduce the application time or stop if it's too much sensitivity.

Please check the condition of the teeth and the gingiva during the whole bleaching treatment.

Intra coronal bleaching

1. Before starting the bleaching procedure take an X-ray to verify that the root canal filling is closely sealed.
2. First open the entrance to the pulp chamber and to the root canal and remove carefully existing filling material. Ensure that enough space is created in the area of the coronal pulp to accommodate the bleaching gel.
3. The root canal filling should be removed to a maximum depth of ca. **2 mm** below the cervical gingival and should afterwards be tightly covered with a lining material.

Warning:

Remove all carious dentine before application of the bleaching gel!

4. Create a dry working area around the affected tooth. Use o rubber dam is recommended to provide adequate protection against inhalation or swallowing of the highly reactive bleaching gel. For alternative protection of the gingiva apply BLEACH DAM according to the corresponding instructions.
5. Fill **BLEACHING 27%** into the cavity and leave enough space for the temporary restoration. Leave the bleaching gel– depending on the degree of discoloration - up to **3-5 days** in the cavity.

Note:
For storage remove the mixing cannula and replace the cap.

6. During the exposure time of **BLEACHING 27%** seal the cavity with a classical glass ionomer cement **(e.g.GI E)**. Verify occlusal clearance in protrusive and laterotrusive movements. Premature occlusal contacts may fracture the provisional restoration resulting in leakage and loss of bleaching gel with subsequent damage of the mucosa. Instruct the patient to contact a dentist if he feels a leakage or something unusual.
7. After the exposure time remove the bleaching gel carefully from a cavity using a surgical suction cannula.
8. To increase the bleaching effect, step 5 to 7 can be repeated twice.
9. When the tooth has reached the desired shade, remove the bleaching gel and rinse the cavity thoroughly with plenty of water.
10. Seal the cavity with a suitable temporary filling material. The filling should remain in situ for at least **14 days** before a definitive treatment with a composite is possible.

Patient Information:

- In the first two weeks after bleaching teeth may darken slightly. Restorations can be replaced two weeks after finishing the bleaching treatment.
- To reduce the risk of discoloration, avoid staining foods, beverages and tobacco for **24-48 hours** after treatment.

Storage:

Store **BLEACHING 27%** in the refrigerator at 2-6°C (36-43 °F) to maintain the gel-like consistency. (keep out of sunlight and heat!)

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Dentist Information:

Before each application check the consistency of the material.

BLEACHING 27% is not for laser activated bleaching.

Warranty

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Limitation of Liability

Except where prohibited by law, DS Dental Supply GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

For dental use only. Use as directed.

ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense ZN CARBOXYLATE C

ZN CARBOXYLATE C is a zinc polycarboxylate cement based on zinc oxide and polyacrylic acid for cementing of crowns and inlays as well as for cavity linings.

Recommendation for use

Application

A clean, dry glass plate at approx. **20°C (68°F)** and a non-discoloring spatula are recommended for mixing.

The powder/liquid ratio for a suitable **cementing consistency is 2.5/1.0 (w/w)**, for a suitable **lining consistency 2.9/1.0 (w/w)**.

In order to achieve a homogeneous consistency of the cement divide the measured quantity of powder into several portions. Mix the powder in portions quickly into the measured liquid - within 1 minute. The mixture should appear thicker as usual for zinc phosphate cement, yet it is just as easy to work.

Do not add additional liquid during the mixing.

The cementing consistency has been reached when the peak formed on lifting the spatula slowly falls back into the paste. The lining consistency has been reached when on lifting the spatula, the peak drawn out forms a small hook and does not sink back into the paste.

Discard remaining powder or impure liquid. Dentine areas near the pulp must be protected.

The working time **(at 23°C, 72°F)** is approx. **1:30 minutes** (luting consistency) resp. **1:20 minutes** (lining consistency).

The setting time from end of mixing is about **4 minutes (at 37°C)**.

Additional notes

- The mixed cement should never be applied directly onto dentine near to pulp or onto exposed pulp.
- Apply the thinnest possible layer for cementing.
- The cement must be applied to the dry tooth surface and must set without contact to moisture.
- Remove excess material (e.g. of neighbouring teeth, facets) immediately
- Immediately after use, tightly close both liquid and powder bottles to prevent exposure to moisture.
- Clean instruments and glass plate with water before the cement sets.

Zinc polycarboxylate cement can be dissolved using a cement-solving after setting.

Storage

Store dry at room temperature.

Do **not** expose liquid to sunlight and frost.

Do not use after expiry date.

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Keep away from children!

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QualiSense Gold

Instructions for use
MD

QualiSense ZN PHOSPHATE C (normal set)

ZN PHOSPHATE C is classical cement based on zinc oxide and phosphoric acid for cementing of crowns, bridges and inlays, for orthodontic bands and cavity linings.

Recommendation for use

Application

A clean, dry glass plate at ca. **20°C (68°F)** and a non-discoloring spatula are recommended for mixing.

The **powder/liquid ratio** for a suitable cementing consistency is **1.5/1.0 (w/w)**.

In order to achieve a homogeneous consistency of the cement divide the measured quantity of powder into several portions. Mix the powder in portions quickly into the measured liquid - within **1 minute.**

Do **not** add additional liquid during the mixing.

The cementing consistency has been reached when the peak formed on lifting the spatula slowly falls back into the paste.

Discard remaining powder or impure liquid. Dentine areas near the pulp must be protected.

The working time **(at 23°C, 72°F)** is approx. **2:00 minutes**. The setting time from end of mixing is about **7 minutes (at 37°C)**.

Additional notes

- The mixed cement should never be applied directly onto dentine near to pulp or onto exposed pulp.
- Irritations of the pulp may occur following the cementing.
- The cement must be applied to the dry tooth surface and must set without contact to moisture.
- Immediately after use, tightly close both liquid and powder bottles to prevent exposure to moisture.
- The liquid contains phosphoric acid and is corrosive. In case of accidental eye contact immediately rinse with large quantities of water.

Storage

Store dry at room temperature.

Do not use after expiry date.

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QualiSense Gold

Instructions for use
MD

QualiSense DC CEM (MINIMIX)

Dual Cure Composite Cement

Recommendations for Use

DC CEM is a **dual cure** easy flowing microhybrid composite for permanent cementations of inlays, onlays, crowns, bridges and veneers.
DC CEM is a radiopaque and relatively high filled composite of very high strength.
DC CEM is based on methacrylate resin and inorganic filler particles of **0.05-1 µm.** The total filler load is **61 %** and the total filler volume **41 %. DC CEM** meets the requirements of **DIN EN ISO 4049.**

Preparing the MINIMIX-Syringe

Remove the cap of the **MINIMIX-syringe** and throw it away **(do not use it again!)**. It is replaced by a special **1:1 mixing** cannula. Turn the cannula **90° until** it locks in position. The material is now ready for application.

The working time (23°C (74°F)) in the self cure mode is 2:00 minutes from start of mixing.

Note:
Store used syringe with fixed used mixing cannula. Discard the first 2-3 mm (about the size of a peppercorn) of the extruded material. This has to be done for each new mix.

Cementation of Inlays, Onlays, Crowns, Bridges and Veneers

1. Preparing

Prepare the luting side areas of the restoration (inlay, onlay, crown, bridge or veneer) with a suitable bonding agent:

Restorations made from:
- Zirconia with e.g. ZirconPrime M
- Silicate ceramics with e.g. CERAMIC PRIME
- Metal (precious or non-precious metal) with e.g. MetalPrime M

2. Cementing of the indirect restoration

2.1. Cementing of Inlays, Onlays, Crowns and Bridges

Apply a suitable dual cure bonding agent **(e.g. ADHESIVE S2)** to the prepared tooth surface.

For cementing (preparation of the restoration see 1.) apply a uniform coating **(0.5 mm)** of **DC CEM** on the luting side of the inlays, onlays, crowns and bridges and on the primed tooth areas. Seat the restoration under light pressure and retain it in place until the cement has completely cured. Remove excess material. Light cure all marginal areas of the restoration from each direction for **20 seconds** with a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least **1000mW/cm2**. The dual cure cement system will auto cure within 4 minutes.

2.2. Cementing of Veneers

Optional try-in the veneers with a try-in gel. Avoid gingival contact to prevent bleeding. Rinse try-in gel off the enamel surfaces with water. Thoroughly clean the veneer and the prepared tooth with water spray and dry with oil-free air.

Isolate the teeth to be veneered with interproximal strips to protect adjacent teeth (not being veneered) from the etchant and bonding agent.

Apply an etchant **(e.g. ETCHING GEL)** onto the enamel areas to be veneered. Leave the etchant in place for **15 seconds**, and rinse with plenty of water. After drying place a thin coat of suitable bonding agent **(e.g. UNIVERSAL ADH)** as described in the corresponding user instruction before application of **DC CEM.**

Remove matrix strips prior to placing veneers on teeth. This step assures complete and passive seating of the veneer, even in multiples.

After placement of the veneer, light cure for **20 seconds** with a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least **1000mW/cm2** through tooth structures and the veneer material. If the light through the veneer material is **not sufficient** or a light cure cannot be guaranteed to be sufficient,
DC CEM self-cures in **4 minutes**. After curing finish and polish margins in the usual manner.

Additional Notes

- Do not use any resin to adjust viscosity of composite restorative material.
- Do neither store the composite material in proximity of eugenol containing products, nor let the composite allow to come into contact with materials containing eugenol. Eugenol impairs the hardening of the composite.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.

Storage

Do **not** store above **20 °C (68 °F)**. Store unopened material in the refrigerator.

Opened cartridges have to be used up within 3 months.

Do not use after expiry date.

Warranty

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Limitation of Liability

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ARSACO GmbH

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CE 0482

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22607 Hamburg Germany

Distributor: Arsaco GmbH
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QualiSense Gold

Instructions for use

MD

QualiSense UNI LUTE (AUTOMIX 4:1)

Self Adhesive Dual Cure Luting Cement

Product description

UNI LUTE is a self-adhesive dual cure luting cement for permanent cementations.
When **UNI LUTE** is used, conditioning and bonding of the tooth structure are not necessary. **UNI LUTE** is self-neutralizing.
UNI LUTE is based on methacrylate resin and inorganic fillers. The total filler load is **50%** wt, the total filler volume is **45 %**. The mixing ratio based on volume is 4 parts base and 1 part catalyst.

Indications/Intended use

Permanent luting of:
- crowns and bridges made of metal and metal ceramic
- crowns and bridges of reinforced ceramics (e.g. Zirconia)
- all-ceramic crowns and bridges produced by using Cerec®
- inlays and onlays of ceramic, metal and composite
- posts
- metal, metal ceramic and reinforced ceramics (e.g. Zirconia) on implant abutments

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

- Thin all-ceramic restorations of feldspathic ceramic or other low fusing ceramics, veneers, Maryland-bridges
- Pulp capping
- In singular cases, **UNI LUTE** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparing the MINIMIX-Syringe

Remove the **MINIMIX-syringe** from the seal-pack and discard the bag. Note the date of removal on the syringe label.
Remove the cap of the **MINIMIX-syringe** and throw it away **(do not use it again!)**. Squeeze out a small quantity of paste on a mixing pad to equal the base and catalyst paste in the MINIMIX-syringe and discard it.
Attach a **4:1 mixing** cannula and turn **90° until** it locks in position. The Material is now ready for application.
The working time **(23°C (74°F))** in the self cure mode is **1:30 minutes** from start of mixing.

> Note:
> Store used cartridge with fixed used mixing cannula in the dark. Discard a peppercorn-size quantity of material. This has to be done for each new mix.

Pulp protection

Pulp capping with **UNI LUTE** is contraindicated. Cavity floor of deep excavations should be covered with a thin layer of calcium-hydroxide material.

Application

1. Cementation of Inlays, Onlays, Crowns and Bridges

1.1. Preparing

Prepare the luting side areas of the all-ceramic inlays, onlays, crowns and bridges according to manufacturer instructions and primed with a silane priming agent.
The luting side areas of metal, zirconia or composite restorations should be prepared according to manufacturer instructions.

1.2. Cementing of the indirect restoration

1.2.1. Preparation of cavity/tooth stump

For a sufficient retention the height of the prepared stump must be at least 4 mm with a steep preparation angle (maximum 6 degrees).
Prior to final cementation, clean the prepared stump or cavity thoroughly with pumice slurry, rinse with water and slightly dry in 2-3 intervals with oil free air. **Do not overdry!**

1.2.2. Cementing of Inlays, Onlays, Crowns and Bridges

For cementing (preparation of the restoration see 1.1.) apply a uniform coat (0.5 mm) of **UNI LUTE** on the luting side of the inlays, onlays, crowns and bridges and on the prepared tooth areas. Seat the restoration under slight pressure.
Remove excess material after brief light exposure **(approx. 5 sec)**. Light cure all marginal areas of the restoration from each direction (mesio-oral, disto-oral, mesio-buccal, disto-buccal) for **20 seconds** with a polymerization unit **(wavelength range of 400-500 nm and light intensity of at least 1000mW/cm2)**.

2. Cementation of Posts

2.1. Preparing of the root canal

Use of a rubber dam to isolate the tooth is strongly recommended.
Prepare the selected post according to manufacturer directions.
Treat the root canal endodontically and clean it in the usual manner (e.g. with sodium hypochlorite solution, approx. 3%). Rinse with water and dry with paper points.

2.2. Filling of the root canal

Prepare the **MINIMIX-syringe** as described above and attach an Endo-Tip to the mixing cannula. Insert the Endo-Tip as deep as possible into the root canal and apply **UNI LUTE** starting apical. Keep the end of the Endo-Tip in the material to avoid bubbles. When the root canal has been completely filled remove the Endo-Tip from the material.
If necessary apply a thin layer of **UNI LUTE** on the post. Place the post in the filled root canal and hold in position under moderate pressure. Light cure the coronal part of the cemented post for **20 seconds** with a polymerization unit **(wavelength range of 400-500 nm and light intensity of at least 1000mW/cm2)**.

Storage

Store in the original seal-pack at 10- 25 °C. After opening of the seal-pack, use **UNI LUTE** within 6 months and before the end of expiry date. Avoid constantly high humidity. Do **not** store in the refrigerator.
Do not use after expiry date.

Additional Notes/Warnings

- Do not use any resin to adjust viscosity of luting cement.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- Catalyst paste: Contact with eyes may cause severe eye damage. Wear eye protection. In case of contact with eyes rinse immediately with plenty of water and seek medical advice.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Cerec® is not a registered trade mark of DS Dental Supply GmbH
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

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Limitation of Liability

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CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense DESENSITIZER

Instructions for use

DESENSITIZER is a silicone based one component acid protecting varnish with Nano-Fluorapatite, Nano-Calciumfluoride and soluble fluoride.
DESENSITIZER is for protection in cervical regions and free dentine areas after dental treatments. Nano-technology fluorapatite particles are known to enhance remineralization of tooth material.

DESENSITIZER does not require etching. It builds a protective film , that can be replenished, if necessary. The application is easy and time saving.

DESENSITIZER contains **2000 ppm (0,2 %)** fluoride.

Indications

- application after bleaching procedures
- protection of hypersensitive cervicals
- protection after scaling, professional tooth cleaning

Application of DESENSITIZER

Clean the sensitive areas and rinse thoroughly. Gently dry in an oil- and water free air stream.

Before application vigorous shake the bottle with the **DESENSITIZER**. During shaking listen to the bead inside the bottle.
Apply **DESENSITIZER** 2 – 3 times in an even thin layer. Avoid contact of the **DESENSITIZER** with the mucosa.
Let **DESENSITIZER** dry for **1 minute** or dry it gentle in an oil free air stream.

Important remarks

- In the **first 2 hours** after application of **DESENSITIZER** don't eat anything nor brush the teeth.
- Do **not** use **DESENSITIZER** under bridges and other restorative materials.
- The intense smell of **DESENSITIZER** volatizes during drying within **1 minute.**
- **DESENSITIZER** contains ethylacetate. Ethylacetate is highly flammable. Keep away from sources of ignition. Avoid inhalation of ethylacetate vapour. After eye contact rinse out with plenty of water and call an ophthalmologist. After contact with skin, wash with plenty of water and soap.
- Impressions with vinyl silicones can be made earliest 4 weeks after the treatment with **DESENSITIZER**.
- For hygienic reasons the bottle containing **DESENSITIZER** is for single use and for one patient only.

Storage

Do **not** store above **25 °C (77 °F)!**

Do not use after expiration date!

Store **DESENSITIZER** tightly closed in a well ventilated place.

Warranty

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QualiSense Gold

Instructions for use

MD

QualiSense LC DESENSITIZER

Light Curing One Bottle Desensitizing & Adhesive Agent

Product description

LC DESENSITIZER is a light curing dentine adhesive agent, which serves all at once as a desensitizer. It is designed for strong bonding of **composites, compomers** and metals to **enamel and dentine**. The application as a desensitizer in cervical regions and free dentine areas during and after dental treatments anodynes all postoperative pains. **LC DESENSITIZER** does not tan and irritate the tissue and gingiva.

The strong adhesion of **LC DESENSITIZER** to etched enamel or dentine proceeds on principles similar to that occurring with glass ionomer cements. Good, long lasting adhesive strength and good biocompatibility are attained by methacrylate grafted polycarboxylic acids.

The desensitizing **LC DESENSITIZER** has good wetting properties. It is ethanol-based and hydrophilic. Therefore it can be used on slightly moist dentine surfaces (wet-bonding-technique).

LC DESENSITIZER contains 1000 ppm (0,1 %) fluoride.

Indications/Intended use

- Adhesive/Desensitizer for composite based restorations with light cure composites
- Application after bleaching procedures
- Treatment of hypersensitive cervical regions

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

1. Application before Restorations

1.1. Isolation

Rubber dam is the recommended method of isolation.

1.2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight **(0.5 - 1.0 mm)** bevel placed in the enamel to increase the surface area for greater bond strength.

1.3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material **(e. g. CH LINER).**

1.4. Enamel and Dentine Conditioning

Recommended is the total etch technique. Apply **ETCHING GEL** onto the enamel and dentine surfaces beginning with the enamel bevels. Condition **the enamel for at least 15 seconds and the dentine for 15 seconds.** Deciduous teeth are etched correspondingly longer. Rinse for **20 seconds** with water. Dry it in a water-free and oil-free airstream, but do **not desiccate**. A slightly wet dentine surface is important for the function of **LC DESENSITIZER**. The etched enamel bevel should have a chalky white appearance.

Etching Precaution

It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

1.5.Application of LC DESENSITIZER

Apply **LC DESENSITIZER** generously with a brush onto the enamel and dentine surfaces for **30 seconds** with agitation. The material should build a homogeneous layer. Remove excess material carefully. Dry cautiously with oil free air for about **15 seconds** to remove all volatile components and to disperse **LC DESENSITIZER** to an even layer. Do no desiccate the dentine.

LC DESENSITIZER will not self-care. Cure the **LC DESENSITIZER** coating by exposing its entire area to a dental halogen light unit for **20 seconds** before application of a second layer of **LC DESENSITIZER.**

Notes:

Do **not** rinse off the **LC DESENSITIZER!** If not used immediately, place dispensed mixture in subdued light to prevent premature polymerization by incident light.

1.6. Application of a second layer of LC DESENSITIZER

Apply again **LC DESENSITIZER** generously with a brush onto the adhesive surfaces as described under **1.5.** before placement of a light cure composite or an amalgam restoration.

Note:

Because light curing under amalgam restorations is impossible, and the primer does not selfcure it is essential to cure the coating by exposing its entire area to a dental halogen light unit for **20 seconds before** application of the amalgam filling.

1.7. Restorative placement

Refer to manufacturer instructions of restorative materials.

2.Application after bleaching procedures, scaling and in other cases of hypersensitive areas

2.1. Preparation

Clean the sensitive areas and rinse thoroughly. Dry the sensitive area with a cotton pellet or roll to remove excess moisture. Do **not** overdry!

2.2. Application of LC DESENSITIZER

Apply **LC DESENSITIZER** generously onto the enamel and dentine surfaces for **30 seconds** with agitation. The material should build a homogeneous layer. Remove excess material carefully. Dry cautiously with oil free air for about **15 seconds** to remove all volatile components and to disperse the adhesive to an even layer. Do no desiccate the dentine.

Cure the **LC DESENSITIZER** coating by exposing its entire area to a dental halogen light unit for **20 seconds** before application of a second layer of **LC DESENSITIZER.** Apply again **LC DESENSITIZER** as described above and light cure for 20 seconds.

Storage

Do **not** store above **25 °C (77 °F)!**

Avoid storage in direct sunlight.

Do not use after expiration date.

Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

DS Dental Supply GmbH warrants this product will be free from defects in material and manufacture. DS Dental Supply GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusively remedy and DS Dental Supply GmbH's sole obligation shall be repair or replacement of the DS Dental Supply GmbH product.

Limitation of Liability

Except where prohibited by law, DS Dental Supply GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense DC CORE (MINIMIX)

Dual Curing Flowable Microhybrid Composite for Core Build-ups and Cementation of Posts

Instructions for Use

DC CORE is a dual curing radiopaque flowable microhybrid composite based material for core-build-up and cementation of posts. **DC CORE** is also suitable for cementing of crowns and bridges, inlays and onlays. For all indications the use of a dual cure bonding agent (e.g. **ADHESIVES2**) is required before application of the composite.

DC CORE is based on poly- and difunctional methacrylates and inorganic filler particles of **0.05-2.5 µm**. The total filler content is **66 %** by weight and 46 % by volume. Delivered in auto-mixing **1:1 MINIMIX-syringes** it can be easily dispensed and applied directly. **DC CORE** exhibits a short setting time without high heat generation. The dual cure properties enables the dentist, also to carry out cementations and core build ups in cases where a light cure cannot be guaranteed to be sufficient.

DC CORE meets the requirements of **DIN EN ISO 4049**, **type 2**, **class 3.**

Indications

- Core build-ups
- Cementing of posts
- Cementing of crowns and bridges, inlays and onlays

Contraindications

The placement of **DC CORE** is contraindicated if a dry working area or the recommended application technique are not possible. Also do **not** use **DC CORE** if the patient is known to be allergic to any of the ingredients.

Side effects

In singular cases, **DC CORE** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material.

Incompatibility with other materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparing the MINIMIX-Syringe

Remove the cap of the **MINIMIX-syringe** and throw it away **(do not use it again!)**. It is replaced by a supplied **1:1 mixing** cannula. Turn the cannula **90° until** it locks in position. The material is now ready for application.

> Note:
> Store used syringe with fixed used mixing cannula. Discard the first **2-3 mm** of the extruded material. This has to be done for each new mix.

Store used syringe with fixed used mixing cannula in the dark.
The working time **(23°C (74°F))** of **DC CORE** in the self cure mode is **1:30 minutes** from start of mixing.

1. Post Cementation

1.1. Isolation

Use of a rubber dam to isolate the tooth is strongly recommended.

1.2. Root Canal Preparation

Refer to directions of the selected post manufacturer.

Before starting the preparation clean the tooth from residues. Prepare and clean the root canal with e.g. sodium hypochlorite solution, rinse and remove excess solution from the canal with a soft paper tip.

Recommended bonding agents for conditioning are:

- **UNIVERSAL ADH** combination with **UNI CATALYST** according to the self-etch technique
- **ADHESIVE T2**, use dual cure bonding system for the Total-Etch-Technique in combination with **ETCHING GEL**
- **ADHESIVE S2**, a self-etching dual cure adhesive

Apply the bonding agent according to the corresponding instructions.

1.3. Post Cementation

Prepare the selected post according to manufacturer directions.

DC CORE is applied into the prepared root canal and onto the post. Seat the post careful into the canal and maintain firm pressure until the post is seated. **DC CORE** self-cures within **3:30 minutes**. For post stabilization light cure the coronal part of the cemented post for **20 seconds** with a polymerization unit **(wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm2.**

As soon as the **DC CORE** has set proceed with the core-build-up procedure.

2. Core-Build-Up

2.1 Isolation

Use of a rubber dam to isolate the tooth is strongly recommended.

2.2. Cavity Preparation

Remove all existing old restorations and decay from the tooth. If necessary place any pins or posts. Refer to directions of the selected post manufacturer.

2.3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material **(e.g. CH LINER).**

2.4. Application of a Bonding Agent

Recommended bonding agents for conditioning are:

- **UNIVERSAL ADH**, a light cure universal adhesive to be used with the self-etch technique, with preceding selective enamel etching or with the total-etch technique **(if required in combination with UNI CATALYST)**
- **ADHESIVE T2**, use dual cure bonding system for the Total-Etch-Technique in combination with **ETCHING GEL**
- **ADHESIVE S2**, a self-etching dual cure adhesive

Apply the bonding agent according to the corresponding instructions.

> Note:
> It is essential that the primed dentine and enamel surfaces are dry and contaminant free for the application of **DC CORE**.

2.5. Application of DC CORE

Place the mixing cannula directly into the preparation and press out the paste.

DC CORE is automatically mixed when dispensed with slight and even pressure. Filling should occur from bottom upwards to prevent air voids. To facilitate placement of DC CORE place a matrix band around the prepared tooth.

DC CORE may be contoured by using a composite instrument. A flat-ended interproximal carver is recommended.

Place **DC CORE** directly into the preparation and allow the system to self cure for **3:30 minutes**. After that the material should be light-cured **(40 seconds)** with a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least 1000mW/cm2. With this technique an optimum of physical properties will be obtained.
An explorer can be used to test that **DC CORE** has completely set. Remove the matrix not earlier than the material has set.
Final core preparation on **DC CORE** can be carried out by using crown preparation burs.

Additional Notes

- Do **not** use any resin to adjust viscosity of composite restorative material.
- Contact of resin pastes with skin and gingival tissue should be avoided, especially by anyone having known resin allergies.

Storage

Do **not** store above **20 °C (68 °F)**. Store unopened material in the refrigerator.

Opened cartridges have to be used up within 3 months.

Do not use after expiry date.

Warranty

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Limitation of Liability

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Keep away from children!
For dental use only!

ARSACO
ARSACO GmbH

V1-04-2021

CE 0482

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22607 Hamburg Germany

Distributor: Arsaco GmbH
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QualiSense Gold

Instructions for use
MD

QualiSense NANOCORE ZR (MINIMIX)

Dual Curing Flowable Microhybrid Composite for Core Build-ups and Cementation of Posts

Product description

NANOCORE ZR is a dual cure high radiopaque flowable microhybrid composite material with nano particles (nano-zirconium dioxide, nano-calciumfluoride) for core-build-up and cementation of posts. Due to its excellent mechanical properties final crown preparation can be carried out more precise. **NANOCORE ZR** is also suitable for cementing of crowns and bridges, inlays and onlays. For all indications the use of a dual cure bonding agent (e.g. **DC ADHESIVE S2**) is required before application of the composite.
NANOCORE ZR is based on poly- and difunctional methacrylates and inorganic filler particles of 0.02-10 µm. The total filler content is 64 % by weight and 48 % by volume. Delivered in auto-mixing 1:1 MINIMIX-cartridges it can be easily dispensed and applied directly. **NANOCORE ZR** exhibits a short setting time without high heat generation. The dual cure properties enables the dentist, also to carry out cementations and core build ups in cases where a light cure cannot be guaranteed to be sufficient.
NANOCORE ZR meets the requirements of **DIN EN ISO 4049**, type 2, class 3.

Indications/Intended use

- Core build-ups
- Cementing of posts
- Cementing of crowns and bridges, inlays and onlays

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

The placement of **NANOCORE ZR** is contraindicated if a dry working area or the recommended application technique are not possible.
Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with other materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparing the MINIMIX-Syringe

Remove the cap of the MINIMIX-syringe and throw it away (**do not use it again!**). It is replaced by a supplied 1:1 mixing cannula. Turn the cannula 90° until it locks in position. The material is now ready for application.

Note:
Store used syringe with fixed used mixing cannula. Discard the first 2-3 mm of the extruded material. This has to be done for each new mix.

Store used syringe with fixed used mixing cannula in the dark.
The working time (23°C (74°F)) of NANOCORE ZR in the self cure mode is 1:30 minutes from start of mixing.

Application

1. Post Cementation

1.1. Isolation

Use of a rubber dam to isolate the tooth is strongly recommended.

1.2. Root Canal Preparation

Refer to directions of the selected post manufacturer.

Before starting the preparation clean the tooth from residues. Prepare and clean the root canal with e.g. sodium hypochlorite solution, rinse and remove excess solution from the canal with a soft paper tip.
Recommended bonding agents for conditioning are:

- **UNIVERSAL ADH** combination with **UNI CATALYST** according to the self-etch technique
- **ADHESIVE T2** , a dual cure bonding system for the Total-Etch-Technique in combination with **ETCHING GEL**
- **DC ADHESIVE S2**, a self-etching dual cure adhesive

Apply the bonding agent according to the corresponding instructions.

1.3. Post Cementation

Prepare the selected post according to manufacturer directions.

NANOCORE ZR is applied into the prepared root canal and onto the post. Seat the post careful into the canal and maintain firm pressure until the post is seated.
NANOCORE ZR self-cures within **3:30 minutes**. For post stabilization light cure the coronal part of the cemented post for **20 seconds** with a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least 1000mW/cm2.
As soon as the **NANOCORE ZR** has set proceed with the core-build-up procedure.

2. Core-Build-Up

2.1 Isolation

Use of a rubber dam to isolate the tooth is strongly recommended.

2.2. Cavity Preparation

Remove all existing old restorations and decay from the tooth. If necessary place any pins or posts. Refer to directions of the selected post manufacturer.

2.3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material **(e.g. CH LINER).**

2.4. Application of a Bonding Agent

Recommended bonding agents for conditioning are:

- **UNIVERSAL ADH**, a light cure universal adhesive to be used with the self-etch technique, with preceding selective enamel etching or with the total-etch technique **(if required in combination with UNI CATALYST)**
- **ADHESIVE T2**, a dual cure bonding system for the Total-Etch-Technique in combination with **ETCHING GEL**
- **DC ADHESIVE S2**, a self-etching dual cure adhesive

Apply the bonding agent according to the corresponding instructions.

Note:
It is essential that the primed dentine and enamel surfaces are dry and contaminant free for the application of **NANOCORE ZR.**

2.5. Application NANOCORE ZR

Place the mixing cannula directly into the preparation and press out the paste.

NANOCORE ZR is automatically mixed when dispensed with slight and even pressure. Filling should occur from bottom upwards to prevent air voids. To facilitate placement of **NANOCORE ZR** place a matrix band around the prepared tooth.
NANOCORE ZR may be contoured by using a composite instrument. A flat-ended interproximal carver is recommended.
Place **NANOCORE ZR** directly into the preparation and allow the system to self cure for **3:30 minutes**. After that the material should be light-cured **(40 seconds)** with a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least **1000mW/cm2.** With this technique an optimum of physical properties will be obtained.
An explorer can be used to test that **NANOCORE ZR** has completely set. Remove the matrix not earlier than the material has set.
Final core preparation on **NANOCORE ZR** can be carried out by using crown preparation burs.

Additional Notes/Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of the composite.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Color stability meets the requirements of DIN EN ISO 4049.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Storage

Do not store above 20 °C (68 °F). Protect from direct sunlight. Store unopened material in the refrigerator. Opened syringes have to be used up within 3 months. Do not use after expiry date.

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

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ARSACO GmbH

V1-04-2021

CE 0482

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Distributor: Arsaco GmbH
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QualiSense Gold

Instructions for use
MD

QualiSense ETCHING GEL

Thixotropic gel containing 37% phosphoric acid

Product description

ETCHING GEL is a 37% phosphoric acid gel for enamel and dentine with an excellent thixotropy.
Delivered in syringes (2ml or 5ml) with very thin disposable application cannulas it can be applied very easily and safely on only that areas that are really desired to be etched.

Indications/Intended use

Enamel etch or total etch technique for:

- Composite restorations
- Sealing of fissures
- Adhesive cementation of inlays, onlays, crowns and bridges (with suitable composite-cement systems)

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Warnings

ETCHING GEL contains phosphoric acid and is corrosive. Avoid contact with eyes, skin and oral mucosa (safety glasses are recommended for both patients and dentists). After contact with eyes immediately rinse with copious amounts of water for at least 15 minutes and consult a physician/ophthalmologist.
After skin contact immediately rinse with soap and water.

Application

Preparation of ETCHING GEL syringe

Screw off the screw cap and substitute by the application needle. Store the screw cap!

Note:
The application needle might be bend in a slight arc, if desired, to facilitate application.

Handling precaution:
Squeeze out the first small drop on a pad to ensure proper handling and prevent “shooting” out of the etching gel by entrapped air.

Application of ETCHING GEL

Apply **ETCHING GEL** onto the enamel and dentine surfaces beginning with the enamel bevels. Condition the enamel for at least 15 seconds and the dentine for 15 seconds. (This results in 20–30 seconds etching of enamel and 15 seconds of dentine). Deciduous teeth are etched correspondingly longer. Rinse for 20 seconds with water. Dry it in a water-free and oil-free airstream, but do not desiccate. The etched enamel bevel should have a chalky white appearance.

Etching precaution:
It is essential, that etched areas are not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

After use replace disposable application cannula by the screw cap. Discard used application cannula. Application cannulas are for single use only due to hygienic reasons.

Application of Adhesive

Apply the adhesive of your choice (e.g. **ISOADHESIVE T1**) using a brush on the etched salivafree enamel and dentine surfaces according to the instructions of the manufacturer.

Restorative placement, cure and finishing

Refer to manufacturers instructions for placement, curing and finishing of restorative materials.

Storage

Do not store above 25 °C (77 °F). Do not use after expiry date.

Additional Notes

- Avoid contact with gingiva, certain liners (based on glass ionomers) and adjacent teeth.
- Keep away from children!

Composition

37 % phosphoric acid

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Note

The summary of safety and clinical performance of the medical device can be found in the European database on medical devices (EUDAMED – https://ec.europa.eu/tools/eudamed).

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QualiSense Gold

Instructions for use
MD

QualiSense MICROFILL F

Light cure high performance flowable composite with excellent high gloss polishability

Instructions for Use

MICROFILL F is a visible light cure flowable composite for anterior and limited posterior restorations with permanent gloss and toothlike opalescence. Beside its low shrink and low abrasion **MICROFILL F** shows improved mechanical properties. High gloss polishability demands only few efforts. **MICROFILL F** contains dimethacrylate based resins and inorganic fillers **< 0.2 µm**. The total filler content is **57 %** by weight and **48 %** by volume. **MICROFILL F** is radioaque **(140 % aluminium)**

The material properties of **MICROFILL F** meet the requirements of **ISO 4049, type 1, class 2, group 1.**

Indications

- Restorations of class III, IV and V
- Small class I and II restorations
- Lining of cavities

Side Effects

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection the cavity floor in cases of deep excavations should be covered with a thin layer of calciumhydroxide material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste prior to preparation and color matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate **MICROFILL F** shade.

MICROFILL F is shaded according to **VITA®-Shades.**

Cavity Preparation

After isolation (best with a rubber dam) prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material (e.g. **CH LINER**).

Apply a common adhesive for enamel and dentine bonding according to the corresponding manufacturer instructions.

The application of the universal adhesive **UNIVERSAL ADH** is recommended. **UNIVERSAL ADH** can be used in combination with an etching gel (e.g. **ETCHING GEL**) or as a self-etching adhesive. Follow the instructions for **UNIVERSAL ADH**.

Placement of MICROFILL F

Apply **MICROFILL F** in the selected shade. Place it directly from the **APPLIC.-Tip** or by using a suitable instrument. Transparent matrix strips may be used.

Application from syringe:

Screw off the cap of the syringe and substitute it by one of the supplied NeedleTips. After use discard the NeedleTip and attach the cap to the syringe again. NeedleTips are for single use only due to hygienic reasons.

Curing of MICROFILL F

For an optimum result apply **MICROFILL F** in layers of **max. 2 mm**. Light cure each increment separately.

By using a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least 1000mW/cm2, cure each increment separately.

Lighter shades **(e.g. A1, A2, B2) 20 seconds**

Darker shades **(e.g. A3.5) 30 seconds**

Hold the light emission window as close as possible to the filling material.

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs.

Polish to high gloss with polishing discs or polishing brushes.

Storage

Do **not** store above **25°C (77°F)**. Protect from direct sunlight.

Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

APPLIC.-Tips are for single use only due to hygienic reasons.

Additional Notes

- The ambient light of the dental lamp may start polymerization of the composite.
- Do **not** use any resin to adjust viscosity of composite restorative material.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- **VITA®** is a registered trade mark of the **VITA-Zahnfabrik**, Bad Säckingen, Germany.

Warranty

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Keep away from children!

For dental use only!

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V1-04-2021

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QualiSense Gold

Instructions for use
MD

QualiSense NANOHYBRID F

Flowable light cure composite with nano-filler technology

Product description

NANOHYBRID F is a visible light cure flowable **nano-composite for anterior and limited posterior restorations**. Beside its low shrink and low abrasion **NANOHYBRID F** shows improved mechanical properties. **NANOHYBRID F** is also available in **APPLIC.-Tips**.

NANOHYBRID F is based on urethanedimethacrylate resin and inorganic filler particles **<1,0 µm**. The total filler content is **62 %** by weight and **48 %** by volume. Radiopacity of NANOHYBRID F is 150 % aluminium (radiopacity of enamel: ~200 % aluminium, of dentine:~ 100 % aluminium).

The material properties of **NANOHYBRID F** meet the requirements of **ISO 4049, type 1, class 2, group 1.**

Indications/Intended use

- Restorations of class III, IV and V
- Small class I and II restorations
- Lining of cavities

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Application

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and color matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate **NANOHYBRID F** shade.

NANOHYBRID F is shaded according to VITA®-Shades.

Cavity Preparation

After isolation (best with a rubber dam) prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material material (e.g. **NANOHYBRID F**).

Condition and apply a bonding agent according to the manufacturer instructions. The total etch technique with ETCHING GEL and subsequent application of a light cure bonding agent (e.g. **ADHESIVE T1**) is recommended. Otherwise use a self etching bonding agent (e.g. **ADHESIVE S2** or **ADHESIVE S1**) before application of **NANOHYBRID F** .

Placement of NANOHYBRID F

Apply **NANOHYBRID F** in the selected shade. Place it by using a suitable instrument. Matrix strips may be used.

Application from syringe:

Screw off the cap of the syringe and substitute it by one of the supplied NeedleTips. After use discard the NeedleTip and attach the cap to the syringe again. NeedleTips are for single use only due to hygienic reasons.

Curing of NANOHYBRID F

For an optimum result apply **NANOHYBRID F** in **layers of max. 2 mm**. Light cure each increment separately.

By using a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm2, cure each increment as follows:

Lighter shades (e.g. A1, A2, B2) **20 seconds**

Darker shades (e.g. A3.5, B3) **30 seconds**

Hold the light emission window as close as possible to the filling material.

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs. Polish to high gloss with polishing discs or polishing brushes.

Storage

Do not store above 25°C (77°F). Protect from direct sunlight. Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

Additional Notes/Warnings

- APPLIC.-Tips are for single use only due to hygienic reasons.
- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of the composite restorative.
- Avoid contact with skin, mucous membrane and eyes.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- VITA® is a registered trade mark of the VITA-Zahnfabrik, Bad Säckingen, Germany.
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

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Instructions for use
MD

QualiSense SE COMP F

Self-adhesive light cure flowable composite

Product description

SE COMP F is a self adhesive light cure flowable composite for anterior and limited posterior restorations. Beside its good mechanical properties, the physical properties of **SE COMP F** are comparable to conventional flowable composites. The optimized flow behavior enables easy application of the material.
The self adhesives properties of **SE COMP F** require no etching, priming and bonding of enamel and dentine in the restorative therapy. For application as pit and fissure sealant, enamel etching for cleaning the surface is recommended.
SE COMP F is based on methacrylates and inorganic fillers and inorganic filler particles of 0.05-1 µm. The total filler load is 59% and the total filler volume 45%. Radiopacity of **SE COMP F** is 150 % aluminium (radiopacity of enamel: ~200 % aluminium, of dentine:~ 100 % aluminium). The composite material meets the requirements of DIN EN ISO 4049, type 1, class 2, group 1.

Indications/Intended use

- Small class I restorations
- Lining of class I and II cavities
- Pit and fissure sealing
- Extended fissure sealing
- Filling of undercuts

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Application

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste prior to preparation and color matching.
Ascertain the tooth shade while teeth are still moist and select the appropriate **SE COMP F** shade.
SE COMP F is shaded according to VITA®-Shades.

Cavity Preparation

After isolation (best with a rubber dam) prepare the cavity with minimal tooth reduction. If possible, margins should have a slight (0.5 - 1.0 mm) bevel placed in the enamel to increase the surface area for greater bond strength.
For pulp protection areas close to the pulp should be covered with a thin layer of e.g. **CH LINER**. Please refer to the instructions of the product used.

Placement of SE COMP F

Remove the cap from the **SE COMP F** -syringe and attach a NeedleTip.
Squeeze out the first small drop on a pad to ensure safe handling of **SE COMP F**.
After use discard the NeedleTip and attach the cap to the syringe again.
NeedleTips are for single use only due to hygienic reasons.

Small class I restorations and lining of class I and II

Place **SE COMP F** with the NeedleTip in a thin layer directly onto the prepared areas. With the supplied microbrush work it into the entire cavity walls and beveled areas under slight pressure for 20s. Remove excess material around the margins with a microbrush.
Cure **SE COMP F** as follows:
Lighter shades (e.g. A1, A2, B1) 20 seconds
Darker shades (e.g. A3) 30 seconds
After lining of the cavity walls and the beveled areas build the restoration with **SE COMP F** in layers of max. 2 mm.
Light cure each increment separately.
Lighter shades (e.g. A1, A2, B1) 20 seconds
Darker shades (e.g. A3) 30 seconds

Pit and fissure sealing

Clean the enamel with a fluoride-free paste and rinse thoroughly. Dry in a water and oil-free air stream leaving a slightly moist shining surface on the enamel.

> Note:
> In addition to cleaning as described above, etching of enamel with a 37 % phosphoric acid etching gel is recommended. Etch the enamel surface for 15 – 20 seconds, rinse for 10 seconds and dry in a water and oil-free air stream.

Place SE COMP F with the NeedleTip in a thin layer directly onto the prepared areas. With the supplied microbrush work it into the prepared areas under slight pressure for 20s. Remove excess material around the margins with a microbrush.
Cure SE COMP F as follows:
Lighter shades (e.g. A1, A2, B1) 20 seconds
Darker shades (e.g. A3) 30 seconds
Hold the light emission window as close as possible to the filling material.
Check the occlusion and correct, if necessary.

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs.
Polish to high gloss with polishing discs or polishing brushes.

Storage

Do not store above 25°C (77°F). Protect from direct sunlight. Do not use after expiry date.
Close syringe immediately after use to avoid exposure to light.

Additional Notes/Warnings

- The curing times are for Halogen curing lights with a light intensity of min. 500 mW/cm2 or LED curing lights with a light intensity of min.1000 mW/cm2. ansd a wavelength range 400-500 nm.
- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of **SE COMP F**.
- Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- Contact with eyes may cause severe eye damage. Wear eye protection. In case of contact with eyes rinse immediately with plenty of water and seek medical advice.
- VITA® is a registered trade mark of the VITA-Zahnfabrik, Bad Säckingen,
- Germany
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

DS Dental Supply GmbH warrants this product will be free from defects in material and manufacture. DS Dental Supply GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and DS Dental Supply GmbH's sole obligation shall be repair or replacement of the DS Dental Supply GmbH product.

Limitation of Liability

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ARSACO GmbH

V1-04-2021

CE 0482

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22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense FLUORIDE GEL

Recommendation for use

FLUORIDE GEL is a fluoride containing one component varnish with Xylitol. For desensitizing of teeth it is applied on dentin and enamel surface. **FLUORIDE GEL** contains in addition to easy soluble fluorides Calciumfluoride and Fluorapatite. Fluorapatite particles are known to enhance remineralization of tooth material. **FLUORIDE GEL** has a pleasant sweetish taste.

FLUORIDE GEL adheres to wet and dry surfaces and can be applied easily and time saving.

FLUORIDE GEL contains **22600 ppm (2,26 %)** fluoride.

FLUORIDE GEL is designed for the following indications:

- protection and fluoridation of tooth surface
- treatment of hypersensitive teeth
- treatment of exposed dental necks
- sealing of teeth during and/or after orthodontic procedures
- sealing of tooth surface after bleaching
- **FLUORIDE GEL** is for adults and for children over 3 years old

Application of FLUORIDE GEL

Recommended dosage:

For treatment with **FLUORIDE GEL** the following dosage is recommended for a complete dentition:

Teeth of 1. dentition: approx. 0.2 ml **FLUORIDE GEL**

Permanent teeth: approx. 0.4 ml **FLUORIDE GEL**

From experience, the required amount for a complete set of teeth ranges between 0.2 and 0.4 ml **FLUORIDE GEL.**

A strand length of 1 cm on the mixing pad is equivalent to approx. 0.1 ml **FLUORIDE GEL.**

For children from 3 to 6 years ensure that not more than 0.2 ml FLUORIDE GEL is applied.

FLUORIDE GEL should be applied as a thin film on the dental hard tissue. A thick film give no therapeutic advantages but peels off more easily.

Clean the teeth thoroughly from tartar and remove excess moisture and saliva from the areas to be treated. Place **FLUORIDE GEL** on the mixing pad and apply it with the supplied brush on the teeth. The entire surface should be covered with an even thin film. Moisturizing by natural saliva ensures a proper setting of **FLUORIDE GEL.**

Note:
During the first 4 hours after application of **FLUORIDE GEL** avoid solids, alcohol, tooth cleaning with brush and floss.

Close tube immediately after use.

Remarks

- **FLUORIDE GEL** contains natural resins.
- In case of known hypersensitivities (allergic reactions) to natural resins, **FLUORIDE GEL** should not be used.
- Natural resins may inhibit the polymerization and adhesion of composites.
- To prevent the cap to stick, wipe-off any contaminating residues on the screw of the tube with an ethanol-containing cloth.
- **FLUORIDE GEL** is contraindicated in patients with ulcerative gingivitis or stomatitis. **FLUORIDE GEL** is not intended for systemic treatments.
- In case of protecting teeth with **FLUORIDE GEL** during application of orthodontic multi-band technique, the brackets are placed on the teeth **before** the application of **FLUORIDE GEL**.
- In case of hypersensitivity reactions, remove **FLUORIDE GEL** with a soft tooth brush and floss and rinse with warm water.
- On the day of treatment use no other fluoride preparations. Stop treatment with fluoride tablets for several days.
- Do **not** swallow **FLUORIDE GEL**.
- In case of swallowing large amounts of **FLUORIDE GEL** consult a doctor immediately.
- Do **not** use **FLUORIDE GEL** for children under 3 years.

Storage

Do **not** store above **25 °C (77 °F)!**

Do not use after expiration date!

FLUORIDE GEL is available in tubes with **10 ml** and in blister with **0.3 ml** content.

For hygienic reasons **FLUORIDE GEL** in blister is for single use and for one patient only.

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Keep away from children!

For dental use only!

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QualiSense Gold

Instructions for use
MD

QualiSense GI E CEM - Hand-Mix

Classical Glassionomer Luting Cement

Product description

GI E CEM is a **fluoride containing radiopaque** classical strontium glassionomer cement designed for cementing a wide variety of prosthetic appliances and materials. As a glassionomer cement, it features good chemical adhesion and biocompatibility. It bonds to enamel, dentine, non-precious metals and porcelain.

The glassionomer cement is suitable for cementing all types of crowns, inlays, onlays, bridges, endodontic posts and orthodontic bands. It can also be used for amalgam bonding and as liner.

GI E CEM meets the requirements of **DIN EN ISO 9917-1** (Specification for Dental Water based Cements).

Indications/Intended use

- cementing of all types of crowns, inlays, onlays, bridges,
- endodontic posts and orthodontic bands
- liner under composite fillings and amalgam

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

- Pulp capping
- Allergic reactions to glass ionomer cements

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Application

1. Tooth Preparation

Prepare tooth in usual manner. Clean prepared tooth with pumice and water only. Rinse thoroughly and dry, but **do not** desiccate.

By using a cotton pellet apply a dentine conditioner (e.g. **GI CONDITIONER**) **for 20 sec** to remove the smear layer. Rinse the dentine conditioner with water and dry it in an airstream, but **do not** desiccate.

Pulp capping with **GI E CEM is contra indicated**. To deep areas of possible pulpal exposure apply calcium hydroxide liner.

2. Dispensing and Mixing

The **powder/liquid** ratio to achieve a suitable consistency is **1.8 / 1.0.** This can be obtained by mixing of **one scoop (blue colored) of powder and two drops of liquid.**

Note:
The spoon dosage is only an approximate reproduction of the nominal mixing ratio.

For accurate dispensing of **GI E CEM Powder** shake the bottle to loosen the powder. Overfill the spoon with the powder, level the powder by using the collar at the top of the bottle and carry it onto the mixing pad. **Avoid compressing** powder into the spoon with the inside wall of the bottle.

For dispensing of **GI E CEM Liquid** turn the bottle vertically with the tip about 5cm above the mixing pad. Steady your hand and squeeze the bottle gently to dispense the drops. If any bubbles are present, lightly tap the bottle with the fingers holding it. **Discount drops** that contain bubbles and are obviously not full-sized.

Use a small spatula to rapidly mix half the powder into the liquid. Then mix the remaining powder into the mixed paste to achieve a glossy appearance. Total mixing time is **30 sec**.

After use, tightly close both liquid and powder bottles to prevent exposure to moisture.

3. Cementation Technique

Mix the required amount of **GI E CEM**. Coat the prepared bonding surface of the restoration with **1 mm** of cement **(Do not overfill!)** and seat immediately **(working time 1:25 min from start of mixing at 23°C)**. Seat the restoration by using steady, even pressure. Net setting time is about **4:30 min**.

Remove excess cement at the first setting stage.

Maintain isolation until the set of the cement is verified **(approx. 4:30 min).**

Note:
Higher temperatures will shorten the working time, lower temperatures will prolong the working time.

An overextended working time will cause the loss of adhesion to the dental enamel and the dentin.

4. Additional Notes/Warnings

- Do not use GI E CEM with patients who show an allergy to the material. In case of allergic reactions immediately stop the application, and advise the patient to consult a physician. An operator, who has a history of allergy to glass ionomer-cements should not handle GI E CEM.
- Do not allow the liquid or cement mixture to contact the oral tissues or skin. In case of contact, remove the material with absorbent cotton soaked in alcohol and rinse with water.
- Avoid eye contact of the liquid or cement mixture. In case of contact, immediately flush with water and seek medical treatment.
- Do not mix the powder or liquid of GI E CEM with any other glass-ionomer product.
- Shade: universal
- Keep away from children!

5. Storage

Store **GI E CEM** in a cool and dark place at 4-**25 °C (39-77 °F).** Temperature should not exceed **25 °C (77 °F).**

Store protected from moisture.

Do not use after expiry date.

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

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Limitation of Liability

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QualiSense Gold

Instructions for use
MD

QualiSense GI CONDITIONER

Cavity Cleaning Agent

GI CONDITIONER is a mild polyacrylic acid solution designed to clean the cavity and to condition dentine and enamel, thus enhancing the bond between glass ionomer cement and tooth structure.

Contraindications

Do **not** use with patients with known allergic reactions to glassionomer cements. In case of an allergic contact contact to a physician.

Directions for Use

1. After having the tooth prepared apply **GI CONDITIONER** to the bonding surfaces for **20 seconds** by using a cotton pellet or brush.
2. Rinse thoroughly with water and dry gently. Do not desiccate!
3. Now the glassionomer cement can be applied.
4. Close the bottle immediately after use.

Warning

Do **not** allow the liquid to contact the oral tissues or skin. In case of contact, flush immediately with water.

Avoid contact with eyes. In case of contact, immediately flush with water while holding the eyelid open and seek medical advice.

Storage

Store **GI CONDITIONER** in a cool place at 4-**25 °C (39-77 °F).** Temperature should not exceed **25 °C (77 °F).**

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QualiSense GI E - Hand-Mix

Classical Glassionomer Restorative Cement

Recommendations for Use

GI E is a non-sticky condensable esthetic restorative glassionomer cement. Besides its high fluoride content and excellent biocompatibility it has also good chemical bonding to dentine and enamel. Therefore it requires **no** enamel and dentin etching. The early resistance to water uptake permits one visit treatment. Because of its radiopacity it ensures easy postoperative diagnosis.

GI E meets the requirements of: **DIN EN ISO 9917-1** (Specification for Dental Water based Cements). **GI E** is designed for the following indications:

- Deciduous teeth: final restorative for Class I, II and V (according Black)
- Long term restorative in non-load bearing areas of Class I and II and Class V restorations
- Intermediate restorative and sandwich material for heavy stress bearing Class I and II cavities
- Core build-up material

DIRECTIONS FOR USE

1. Tooth Preparation

Clean the cavity preparation with pumice and water. Rinse thoroughly and dry, but **do not** desiccate.

If desired, place a matrix band.

By using a cotton pellet apply a dentine conditioner (e.g. **GI CONDITIONER**) **for 20 sec** to remove the smear layer. Rinse the dentine conditioner with water and dry it in an airstream, but **do not** desiccate.

Pulp capping with **GI E is contra indicated**. To deep areas of possible pulpal exposure apply calcium hydroxide liner.

2. Dispensing and Mixing

The **powder/liquid** ratio to achieve a suitable consistency is **3.6 / 1.0.** This can be obtained by mixing of **one level scoop (blue colored) of powder and one drop of liquid.**

> Note:
> The spoon dosage is only an approximate reproduction of the nominal mixing ratio.

A condensable thick mix is required to minimize abrasive loss, but a glossy surface is also need for strong chemical bond strength. Using the appropriate **powder / liquid** ratio is therefore strongly recommended.

Shake the bottle to loosen the powder. Overfill the spoon with the powder, level the powder for using the collar at the top of the bottle and carry it onto the mixing pad provided. **Avoid compressing** powder into the spoon with the inside wall of the bottle.

Turn the liquid bottle vertically with the tip about **5cm** above the mixing pad. Steady your hand and squeeze the bottle gently to dispense one drop. If any bubbles are present, lightly tap the bottle with the fingers holding it. **Discard drops** that are obviously not full-sized.

After use, tightly close both liquid and powder bottles to prevent exposure to moisture.

Using a spatula, divide the powder into **2 equal parts**. Spread the liquid across the mixing pad and mix the first half with the whole of the liquid for **15 sec**. Add the second part and mix for **15 sec** to obtain a homogenous mixture. **Total mixing time is 30 sec.**

3. Filling

Remove moisture from the cavity surface either with a cotton pellet, or very gently with an air syringe blast. It is essential not to desiccate the dentin and enamel surfaces.

Place the mixed cement with a suitable instrument within the **working time** (**1:20 min. at 23°C or 74°F, from begin of mixing**) into the cavity. Please see to it, that no air bubbles will be incorporated.

Form the material with a placement or forming instrument. Optional use a matrix strip to form the surface.

> Note:
> Slightly wet instruments simplify filling and modelling.
>
> Higher temperatures will shorten the working time, lower temperatures will prolong the working time

Net setting time is about **4 minutes.**

If a matrix strip is placed, don't remove it before end of net setting time.

Immediately after setting, a varnish should be placed onto the surface of the restoration.

4. Finishing

Final finishing and polishing can begin under water spray for about

6 minutes from the start of the mixing by progressing from steel burs at low speed to superfine diamond points. Apply a final coating of varnish to the final finished surface of the restoration and instruct the patient not to expose it to any pressure for one hour.

5. Conclusive Notes

This product is to be applied only by a dental professional in the way as described in the instructions.

Do **not** use **GI E** with patients who show an allergy to the material. In case of allergic reactions immediately stop the application, and advise the patient to consult a physician. An operator, who has a history of allergy to glassionomer-cements should not handle **GI E**.

Do **not** allow the liquid or cement mixture to contact the oral tissues or skin. In case of contact, remove the material with absorbent cotton soaked in alcohol and rinse with water.

Avoid eye contact of the liquid or cement mixture. In case of contact, immediately flush with water and seek medical treatment.

Do **not** mix the powder or liquid of **GI E** with any other glassionomer product.

6. Storage

Store **GI E** in a cool place at **4-25 °C (39-77 °F)**. Temperature should not exceed **25 °C (77 °F)**.

Do not use after expiry date.

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Keep away from children!

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QualiSense Gold

Instructions for use

MD

QualiSense GI R - HandMix

Glass Ionomer Restorative Cement for Permanent Fillings

Recommendations for Use

GI R is a newly developed glass ionomer restorative cement that shows, even in warm and humid climate, an excellent shelf life. **GI R** is resin-free and shows very good biocompatibility.

Indications

- Class I and II restorations in deciduous teeth
- Non-load bearing small class I and class II restorations in permanent teeth
- Intermediate restorations material for heavy stress situations in class I and class II cavities
- Base material for class I and II cavities according to sandwich technique
- Class V and root surface restorations
- Core build-ups

1. Tooth Preparation

Prepare the tooth using standard techniques. Do **not** prepare thin edges.

If desired, place a matrix band.

Apply **GI CONDITIONER** with a cotton pellet for **20 sec** to the bonding surfaces to remove the preparation smear layer. Rinse **GI CONDITIONER** thoroughly with water and dry gently. **Do not desiccate.**

Areas close to the pulp should be covered with a small amount of a calcium hydroxide liner (e.g. **CH LINER**).

2. Dispensing and Mixing

The **powder/liquid** ratio to achieve a suitable consistency is

2.6 /1.0. This can be obtained by mixing **1 level scoop of powder and 1 drop of liquid.**

For accurate dispensing of **GI R Powder** lightly tap the bottle against the hand. Overfill the spoon with the powder, level the powder by using the collar at the top of the bottle and carry it onto the mixing pad provided. **Avoid compressing** powder into the spoon with the inside wall of the bottle.

For dispensing of **GI R Liquid** turn the bottle vertically with the tip about **5 cm** above the mixing pad. Steady your hand and squeeze the bottle gently to dispense the drops. If any bubbles are present, lightly tap the bottle with the fingers holding it. **Discount drops** that contain bubbles and are obviously not full-sized.

Use a small spatula to rapidly mix half the powder into the liquid. Then mix the remaining powder into the mixed paste to achieve a glossy appearance. Total mixing time is **30 sec**.

After use, close both powder and liquid bottles.

3. Filling

Mix the required amount of **GI R** and apply it into the prepared cavity by using a suitable placement instrument.

Please see to it, that no air bubbles will be incorporated.

GI R should be placed in the cavity within the working time **(1:30 minutes from start of mixing at 23 °C or 74°F)**. If desired, a matrix band may be used to form the contour.

Net setting time is about **4 minutes.**

After setting, immediately apply **LC GI COAT** and light cure for **20 seconds.**

Close bottle immediately after use.

If a light cure varnish is not desired, apply **X-FINISH** and gently blow dry.

Close bottle immediately after use.

Note:

Higher temperatures will shorten the working time; lower temperatures will prolong the working time.

An overextended working time will cause the loss of adhesion to the dental enamel and the dentine.

Remove the matrix when the cement has achieved clinical set (approx. **4 minutes** after application)

4. Finishing

Final finishing and polishing can begin from about **6 minutes** after start of mixing. Smooth with fine diamond burs, then polish with finishing and polishing discs with graded grain size.

Spray preparation dust away with water and dry the surface in an oilfree airstream.

Apply a thin layer of **LC GI COAT** to the final finished surface of the restoration. Immediately light cure for **20 seconds.**

Close bottle immediately after use.

If a light cure varnish is not desired, apply **X-FINISH** and gently blow dry.

Close bottle immediately after use.

Instruct the patient not to expose the restoration to any pressure for one hour.

5. Conclusive Notes

The products are to be applied only by a dental professional in the manner as described in this instruction.

Do **not** use the products with patients who show an allergy to the material. In case of allergic reactions immediately stop the application, and advise the patient to consult a physician.

Do **not** allow the liquid or the mixture to contact the oral tissues or skin. In case of contact, remove the material with absorbent cotton soaked in alcohol and rinse with water.

Avoid eye contact of the mixture. In case of contact, immediately flush with water and seek medical treatment.

Do **not** mix the powder or liquid of **GI R** with any other restorative cement components.

6. Storage

Store the products at room temperature. Do **not** use after expiry date.

Warranty

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Keep away from children!

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QualiSense Gold

Instructions for use
MD

QualiSense CH LINER

CH LINER is a radiopaque water-based calcium hydroxide liner.

Recommendations for Use

Indications

- direct capping when the pulp is opened or a pulpotomy is performed
- indirect capping for the treatment of caries profunda
- temporary filling of root canals
- lining of cavities to prevent exposure to acid media when using cements

Contraindications

- Direct pulp capping after exposure of the pulp in carious dentin if:
    - the area of exposure is larger than **1 mm²**
    - a completely dry field cannot be established
    - the treatment of the tooth cannot be completed in one appointment
    - the tooth concerned is already causing discomfort
- direct and indirect pulp capping if the pulp is damaged irreversible
- the material should not be used in patient with a known allergy to any of the ingredients

Application

Clean and dry the cavity. If desired, the application needle might be bend in a slight arc to facilitate the application.

Handling precaution

Squeeze out the first small drop on a pad to ensure proper handling and prevent «shooting» out of the **CH LINER** by entrapped air. This must be done for each new application.

Apply **CH LINER** with a suitable dental instrument in thin layers until the desired thickness is reached. Allow each layer to dry briefly or dry carefully with an oil and water free stream of air. Do not apply to the cavity edges and remove any paste sticking to them. Then proceed with adhesive, underfilling and filling procedures.

For root canal fillings, first prepare and clean the root canal (e.g. hydrogen peroxide **3%** or sodium hypochlorite solution) and insert **CH LINER** paste with a suitable instrument. Avoid overfilling (apical) and trapping of air. It is advisable to inspect the root canal filling by taking an X-ray.

Important Notes

Immediately after use stick the application needle of the syringe through the septum into the Anti-Dry Protector. The chemical and physical properties of the Anti-Dry Protector prevent hardening of **CH LINER** and the Anti-Dry Protector acts also as disinfecting agent for the application tip.

But for the next application it has to be used a new application needle.

Do **not** use hardened paste!

Side-effects

If the root canal is overfilled, discomfort may result (sensitivity for pressure and/or swelling) but, as a rule, this will subside within **24-48 hours.**

Contra-indications or interactions are not known.

Warnings

- When using **CH LINER** wear protective glasses and cover the patient eyes.
- **CH LINER** is irritant. In case of contact with eyes a risk of serious damage to eyes exists.
- Avoid contact with skin, mucous membrane and eyes.
- In case of contact with eyes, rinse with copious amounts of water and consult a physician immediately.
- If accidental skin contact occurs, wash immediately with water.

Storage

Do **not** store at less than **+8° C (46 °F)!**

Do not use after expiry date.

After application stick the needle into the anti-dry protector.

Warranty

DS Dental Supply GmbH warrants this product will be free from defects in material and manufacture. DS Dental Supply GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and DS Dental Supply GmbH's sole obligation shall be repair or replacement of the DS Dental Supply GmbH product.

Limitation of Liability

Except where prohibited by law, DS Dental Supply GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Keep away from children!
For dental use only!

ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense GI LINER SA

Self-adhesive light cure liner

Recommendations for Use

GI LINER SA is a self-adhesive light cure, fluoride-containing liner. The moderately acidic properties of **GI LINER SA** makes it ideally suited to its application as liner, especially when basic MTA cements (e.g. **MTA U**) are used for pulp capping.

When using **GI LINER SA**, prior etching of tooth substance is not mandatory. **GI LINER SA** shows self adhesive properties, therefore application of an adhesive is not absolutely necessary. Nevertheless, application of a light cure adhesive (e.g. **ADHESIVE S1**) improves the bond strength of **GI LINER SA** to dentine and enamel and so guarantees a more reliable bond between tooth structure and **GI LINER SA**.

GI LINER SA is self neutralizing. The flow properties are optimized for easy application. **GI LINER SA** is based on methacrylates and inorganic fillers.

Indications

- Liner under composite fillings
- Covering of MTA cements after pulp capping

Application of GI LINER SA

Store syringe after use again in the seal pack.

1. Liner

Clean the prepared cavity.

Apply **ADHESIVE S1** with a brush onto the moist enamel and dentin surfaces for **30 seconds** with agitation.

The material should build a homogeneous layer. Air thin gently for **10 seconds** to remove the volatile components and to disperse the adhesive. Then light cure with a suitable dental light curing unit for **20 seconds.**

Remove the cap from the **GI LINER SA**-syringe and attach a NeedleTip. Squeeze out the first small drop on a pad to ensure safe handling of **GI LINER SA.**

Apply **GI LINER SA** in a thin layer up to **1-2 mm** below the cavity margin. With a suitable brush work **GI LINER SA** in for **20 seconds**. **30 seconds** after application light cure for **20 seconds** with a dental light curing unit.

Apply a light cure composite according to the user instructions and light cure.

2. Covering of MTA-cement after pulp capping

Apply **MTA U** from the DirectCap over the exposed pulp as described in the corresponding instructions.

Earliest **5 minutes** after the application of **MTA U** place a small amount of **GI LINER SA** and light cure.

Apply **ETCHBOND S1** onto the remaining cavity walls as described under point 2, followed by the application of **GI LINER SA** in a thin layer up to **1-2-mm** below the cavity margin. With a suitable brush work **GI LINER SA** in for **20 seconds. 30 seconds** after application light cure for **20 seconds** with a dental light curing unit.

Apply a light cure composite according to the user instructions and light cure.

Additional Notes

- The curing times are for Halogen curing lights with a light intensity of min. **500 mW/cm2** or LED curing lights with a light intensity of min.**1000 mW/cm2**.
- Do **not** use any resin to adjust viscosity of **GI LINER SA**.
- Neither store **GI LINER SA** in proximity of eugenol containing products, nor allow it to come into contact with materials containing eugenol. Eugenol impairs the hardening of **GI LINER SA**.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- Contact with eyes may cause severe eye damage. Wear eye protection. In case of contact with eyes rinse immediately with plenty of water and seek medical advice.

Storage

Store in the original seal-pack at **10- 25 °C.**

After opening of the seal-pack, use **GI LINER SA** within **6 months** and before the end of expiry date. Avoid constantly high humidity. Do **not** store in the refrigerator.

Do not use after expiry date.

Warranty:

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QualiSense Gold

Instructions for use
MD

QualiSense GI LINER

Radiopaque Resin Based Glassionomer Liner

Recommendations for Use

GI LINER is a light cure, radiopaque resin-based glassionomer liner for light cure composites.

Its field of application is:
- lining of cavities for following filling procedures
- lining of cavities to improve marginal behaviour

Side effects

In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calcium hydroxide material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material come into contact with materials containing eugenol.

Application

Clean and dry the cavity.

Screw off the cap of the syringe and substitute it by one of the supplied NeedleTips. Squeeze out the first small drop on a pad to ensure safe handling of **GI LINER**.

Before applying **GI LINER** paste use of a radiopaque calcium hydroxide liner, (e.g. **CH LINER**) in areas in approximity of the pulp (pulp protection) is recommended. Dentin should be primed with a suitable dentin priming agent (e.g. **ADHESIVE T1**).

Apply then **GI LINER** in a thin layer until the desired thickness is reached. Light cure **GI LINER** for **40 seconds**. Do not apply to the cavity edges and remove any paste sticking to them. Then proceed with light cure composites, (**e.g. MH**).

After use discard the NeedleTip and attach the cap to the syringe again.

NeedleTips are for single use only due to hygienic reasons!

Additional Notes

- Do **not** use any resin to adjust viscosity of **GI LINER**.
- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Storage

Do **not** store above **25 °C (77 °F)**.

Do not use after expiry date.

Warranty

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QualiSense Gold

Instructions for use
MD

QualiSense LC LINER

Light cure radiopaque liner with calcium hydroxide

Product description
LC LINER is a light cure, radiopaque liner with calcium hydroxide.

Indications/Intended use
- indirect pulp capping
- lining of cavities for following filling procedures

Performance features
The performance features of the product meet the requirements of the intended use.

Contraindications
In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.
Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group
Persons who are treated during a dental procedure.

Intended users
This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials
Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material come into contact with materials containing eugenol.

Application
Clean and dry the cavity thoroughly. Avoid contamination

Screw off the cap of the syringe and substitute it by a NeedleTip. After use discard the NeedleTip and attach the cap to the syringe again. NeedleTips are for single use only.

Note:

In direct proximity to the pulp (direct pulp capping) application of an aqueous calcium hydroxide liner **(e.g. CH LINER)** is recommended.

To enhance bonding of **LC LINER** use a bonding agent. Etching and application of **ADHESIVE T1** according to the corresponding instructions is recommended. In areas with a thin dentin layer over the pulp do without bonding (pulp protection).

Apply **LC LINER** in a thin layer (max. 1 mm) and light cure for 40 seconds by using a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm2.

Note:

Avoid placing **LC LINER** on enamel or the margins of the cavity.

After curing apply the filling according to manufacturer instructions.

Storage
Store at **4 - 25 °C (39 - 77 °F)** protected from light and moisture. Close syringe immediately after use.

Do not use after expiry date.

Additional Notes/Warnings
- When using **LC LINER** wear protective glasses and cover the patient eyes.
- Unpolymerized materials may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- In case of contact with eyes, rinse with copious amounts of water and consult a physician immediately.
- Avoid contact with skin. If accidental contact occurs, wash immediately with water.
- Do not use any resin to adjust viscosity of **LC LINER**.
- Keep away from children!

Disposal
Disposal of the product according to local authority regulations.

Reporting obligation
Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty
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Limitation of Liability
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ARSACO GmbH

V1-04-2021

CE 0482

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22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense MH

Light Cure Microhybrid Composite

Product description

MHis a **visible light cure radioaque microhybrid composite** for **anterior and posterior** restorations. It is based on BIS-GMA-resin and inorganic filler particles of 0.05-1.5 µm. The total filler load is 81 %, the total filler volume is 65 %. Radiopacity of **MH** is 200 % aluminium (radiopacity of enamel: ~200 % aluminium, of dentine:~ 100 % aluminium).

The composite meets the requirements of: **DIN EN ISO 4049**, type 1, class 2, group 1.

Indications/Intended use

Restorations of all cavity classes

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Application

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and color matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate **MH** shade.

MH is shaded according to VITA®-Shades.

Cavity Preparation

After isolation (best with a rubber dam) prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material material (e.g. **CH LINER**).

Condition and apply a bonding agent according to the manufacturer instructions. The total etch technique with **ETCHING GEL** and subsequent application of a light cure bonding agent (e.g. **ISOADHESIVE T1**) is recommended. Otherwise use a self etching bonding agent (e.g. **ADHESIVE S2** or **ADHESIVE S1**) before application of **MH** .

Application and Curing of MH

Apply **MH** in the selected shade. **MH** is easy to model. Place it by using a suitable instrument. Matrix strips may be used.

In case of deep and extended cavities best results are obtained with a build-up of a base liner using a light cure resin modified cement (e.g **MODGLASS F**) or a light cure flowable composite (e.g. **SE COMP F**), followed by the application of **MH** .

In case of small cavities **MH** can be applied directly.

For an optimum result apply **MH** in **layers** of **max. 2 mm.** Light cure each increment separately.

By using a polymerization unit (wavelength range 400-500 nm) with a **light intensity of at least 1000mW/cm²**, cure each increment as follows:

Lighter shades (e.g. A1, A2, C2) **20 seconds**

Darker shades (e.g. A3.5, B3) **30 seconds**

Hold the light emission window as close as possible to the filling material.

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs. Polish to high gloss with polishing discs or polishing brushes.

Storage

Do not store above 25°C (77°F). Protect from direct sunlight. Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

Additional Notes/Warnings

- APPLIC.-Tips are for single use only due to hygienic reasons.
- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of the composite restorative.
- Avoid contact with skin, mucous membrane and eyes.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- VITA® is a registered trade mark of the VITA-Zahnfabrik, Bad Säckingen, Germany.
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

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Limitation of Liability

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CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense MICROFILL

Light cure high performance composite with excellent high gloss polishability, for Universal- or Multi-Opacity restorations

Product description

MICROFILL is a light cure composite for anterior and posterior restorations with permanent gloss and toothlike opalescence. **MICROFILL** shows excellent physical properties and good handling features. High gloss polishability demands only little effort. **MICROFILL** contains dimethacrylate based resins and inorganic fillers **< 0.2 µm**. The total filler content is **80 %** by weight and **76 %** by volume. Radiopacity of **MICROFILL** is **230%** aluminium (radiopacity of enamel: **~200 %** aluminium, of dentine:~ **100 %** aluminium). The material properties of **MICROFILL** meet the requirements of **ISO 4049 type 1, class 2, group 1.**

Indications/Intended use

- Restorations of all cavity classes
- Direct veneers
- Repair of ceramic restorations (e.g. veneers, crowns)

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Application

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and color matching.
Ascertain the tooth shade while teeth are still moist and select the appropriate **MICROFILL** shade.
MICROFILL is available in a wide variety of VITA®-Shades and in different opacities.

For easy and time saving esthetic restorations the following Universal Shades are available:

A1 U	B2 U
	BL U (BLEACH)
A2 U	C2 U
A3 U	D3 U
A3.5 U	

For highest esthetic demands the shade layering technique is recommended. A wide variety of shades and opacities are here available:

Dentine	Enamel	Incisal
A1 D	A1 E	
A2 D	A2 E	
A3 D	A3 E	
A3.5 D	A3.5 E	
B1 D	B1 E	
B2 D	B2 E	
C2 D	C2 E	
INT D	A4 E	
	B3 E	
	C3 E	
BL D	BL E	Inc (Incisal))
	BL 0.5 E	T (Transparent)
		T X (Extra Transparent)

Cavity Preparation

After isolation **(best with a rubber dam)** prepare the cavity with minimal tooth reduction.
For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material **(e.g. CH LINER).**
Apply a common adhesive for enamel and dentine bonding according to the corresponding manufacturer instructions.
The application of the universal adhesive **UNIVERSAL ADH** is recommended.
UNIVERSAL ADH can be used in combination with an etching gel (e.g. ETCHING GEL) or as a self-etching adhesive. Follow the instructions for **UNIVERSAL ADH.**

Application and Curing of MICROFILL

Apply **MICROFILL** in the selected shade in increments and light cure.
MICROFILL is easy to model. Place it by using a suitable instrument. Matrix strips may be used.
In case of deep and extended cavities best results are obtained with a build-up of a base liner using a light cure resin modified cement **(e.g. MODGLASS F)** or a light cure flowable composite
(e.g MICROFILL F), followed by the application of **MICROFILL**.
In case of small cavities **MICROFILL** can be applied directly.
For an optimum result apply **MICROFILL** in **layers of max. 2 mm.** Light cure each increment separately.
By using a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least **1000mW/cm2**, cure each increment separately.

Shades	Incremental depth	Cure time
Body, Enamel, Translucent	2,0 mm	20 seconds
Dentine	1,5 mm	40 seconds

Hold the light emission window as close as possible to the filling material.

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs.
Polish to high gloss with polishing discs or polishing brushes.

Storage

Do **not** store above **25°C (77°F).** Protect from direct sunlight.
Do not use after expiry date.
Close syringe immediately after use to avoid exposure to light.

Additional Notes/Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do **not** use any resin to adjust viscosity of composite restorative material.
- Avoid contact with skin, mucous membrane and eyes.
- Unpolymerized MICROFILL may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- **VITA®** is a registered trade mark of the **VITA-Zahnfabrik**, Bad Säckingen, Germany.
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

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QualiSense Gold

Instructions for use
MD

QualiSense NANO CER

Light Cure Microhybrid Composite with Nano-Fillers

Recommendations for Use

NANO CER is a nano-filled visible light cure microhybrid composite for anterior and posterior restorations. It is based on BIS-GMA-resin and inorganic filler particles of **0.05-0.9 µm**. Filler content: **81 % (wt), 70 % (vol.).** The composite material meets the requirements of **DIN EN ISO 4049.**

Indications

Suitable for all cavities.

Side Effects

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and color matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate **NANO CER** shade.

NANO CER is shaded according to VITA®-Shades. It is also available in special shades and bleach shades.

Cavity Preparation

After isolation **(best with a rubber dam)** prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material (e.g. **CH LINER**).

Condition and apply a bonding agent according to the manufacturer instructions. The total etch technique with **ETCHING GEL** and subsequent application of a light cure bonding agent (e.g. **ADHESIVE T1**) is recommended. Otherwise use a self etching bonding agent (e.g. **ADHESIVE S2**) before application of the **NANO CER.**

Application and Curing of NANO CER

Apply **NANO CER** in the selected shade. **NANO CER** is easy to model. Place it by using a suitable instrument. Matrix strips may be used.

In case of deep and extended cavities best results are obtained with a build-up of a base liner using a light cure resin modified cement (e.g. **MODGLASS F**) or a light cure flowable composite (e.g. **LC HI FLOW**), followed by the application of **NANO CER.**

In case of small cavities **NANO CER** can be applied directly.

For an optimum result apply **NANO CER** in layers of **max. 2 mm.** Light cure each increment separately.

By using a polymerization unit with a light intensity of at least **1000mW/cm2,** cure each increment as follows:

Lighter shades **(e.g. A1, A2, C2) 20 seconds**

Darker shades **(e.g. A3.5, B3) 30 seconds**

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs.

Polish to high gloss with polishing discs or polishing brushes.

Storage

Do **not** store above **25°C (77°F).** Protect from direct sunlight.

Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

APPLIC.-Tips are for single use only.

Additional Notes

- Do **not** use any resin to adjust viscosity of composite restorative material.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.
- **VITA®** is a registered trade mark of the **VITA-Zahnfabrik**, Bad Säckingen, Germany.

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QualiSense Gold

Instructions for use
MD

QualiSense NANOHYBRID

Esthetic low shrink light cure composite with nano-filler technology

Instructions for Use

NANOHYBRID is a **visible light cure radiopaque nano-filled composite** for anterior and posterior restorations. Beside its low shrink and low abrasion **NANOHYBRID** shows improved handling features and excellent mechanical properties. **NANOHYBRID** is based on urethanedimethacrylate resin and inorganic filler particles **<1.0 µm**. The total filler content is **82 % (wt)** and **74% (vol).**

The composite material meets the requirements of **DIN EN ISO 4049, type 1, class 2, group 1.**

Indications

Suitable for all cavities.

Side Effects

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Incompatibility with Other Materials

Do **not** use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Preparation of Tooth and Colour Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and colour matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate **NANOHYBRID** shade.

NANOHYBRID is shaded according to **VITA®-Shades**. It is also available in special shades and bleach shades.

Cavity Preparation

After isolation **(best with a rubber dam)** prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material (e.g. **CH LINER**).

Condition and apply a bonding agent according to the manufacturer instructions. The total etch technique with **ETCHING GEL** and subsequent application of a light cure bonding agent (e.g. **ADHESIVE T1**) is recommended. Otherwise use a self etching bonding agent (e.g. **ADHESIVE S2** or **ADHESIVE S1**) before application of the **NANOHYBRID** .

Application and Curing of NANOHYBRID

Apply **NANOHYBRID** in the selected shade. **NANOHYBRID** is easy to model. Place it by using a suitable instrument. Matrix strips may be used.

In case of deep and extended cavities best results are obtained with a build-up of a base liner using a light cure resin modified cement (e.g. **MODGLASS F**) or a light cure flowable composite (e.g. **LC HI-FLOW NANO**), followed by the application of **NANOHYBRID** .

In case of small cavities **NANOHYBRID** can be applied directly.

For an optimum result apply **NANOHYBRID F** in **layers of max. 2 mm.** Light cure each increment separately.

By using a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least **1000mW/cm2**, cure each increment as follows:

Lighter shades **(e.g. A1, A2, C2) 20 seconds**

Darker shades **(e.g. A3.5, B3) 30 seconds**

Hold the light emission window as close as possible to the filling material.

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs.

Polish to high gloss with polishing discs or polishing brushes.

Storage

Do **not** store above **25°C (77°F)**. Protect from direct sunlight.

Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

APPLIC.-Tips are for single use only due to hygienic reasons.

Additional Notes/Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do **not** use any resin to adjust viscosity of composite restorative material.
- Avoid contact with skin, mucous membrane and eyes.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- **VITA®** is a registered trade mark of the **VITA-Zahnfabrik**, Bad Säckingen, Germany.

Warranty

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ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense MTA U - Handmix

Endodontic Repair Cement

Recommendation for Use

1. Indications

- Repair of root perforations during root canal therapy
- Root end filling (retrograde)
- Pulp capping
- Root end filling (orthograde)

2. Contraindications

Not known

3. Side effects

Not known

4. Dispensing and Mixing

The **powder/liquid** ratio **is 2.6/1.0.** This can be obtained by mixing **1 level (blue) scoop of powder and 2 drops of liquid.**

If a thinner or firmer consistency is desired, the mixing ration can be modified slightly:

Mixing ratio (by weight)	2:1	**2,6:1**	3:1
Working time (at 23 °C/74 °F)	3:00 min	**2:00 min**	1:00 min

For root end filling (orthograde) (see 5.4) the recommended mixing ratio is 2:1 (by weight). This can be obtained by mixing **3 level (blue) scoops of powder and 8 drops of liquid.** The mixed material gives a sufficient amount for apexification that can be applied optimally with a suitable application device into the root canal.

For mixing of **MTA U** use a mixing pad that is impervious to water or a glass block of suitable dimension.

For accurate dispensing of **MTA U** powder shake the bottle to loosen the powder. Overfill the spoon with the powder, level the powder with the mixing spatula and carry it onto the mixing pad.

For dispensing of **MTA U** liquid turn the bottle vertically with the tip about 5cm above the mixing pad. Steady your hand and squeeze the bottle gently to dispense one drop at a time. If any bubbles are present, lightly tap the bottle with the fingers holding it. Discount under-sized drops that contain bubbles and are obviously not full-sized. Discount over-sized drops, usually resulting from holding the bottle too close to the mixing pad or squeezing the bottle too hard and/or for too long.

Use a small spatula to rapidly mix all the cement powder in portions into the liquid. The mixed cement should be thixotropic and have a homogeneous consistency. Total mixing time is **30 seconds.**

If desired, a more rigid consistency can be achieved by adding some more powder to the mixture, a more creamy consistency is attained by adding some liquid.

After use, tightly close both liquid and powder bottles to prevent exposure to moisture.

5. Application

5.1. Repair of root perforations

Place rubber dam and clean the root canal system using intra-canal instruments and irrigate with NaOCl. Dry the root canal with paper points and isolate the perforation.

Fill the apical canal space up to the perforation completely with a suitable root canal filling material.

Mix **MTA U** as described under point 4.

Apply **MTA U** with suitable instruments into the perforation site and condense it.

Check the position of **MTA U** in the root canal by an X-ray. If an adequate barrier has not been created, rinse **MTA U** out of the canal and repeat the procedure.

Remove excess moisture with a damp cotton pellet or a paper point.

Place a damp cotton pellet in the access to the root canal and apply a temporary filling material.

Alternatively seal the access preparation with a suitable root canal filling material and seal the cavity with a tight filling.

Both options can be done not before **5 minutes** after placement of the **MTA U.**

MTA U repair material remains as a permanent part of the root canal filling.

5.2. Root End Filling (retrograde)

Create an access to the root-end and resect the root with a surgical bur.

Use an ultrasonic tip to prepare a class I root-end cavity preparation to a depth of 3-5 mm.

Isolate the area and dry the root end cavity with paper points. Achieve hemostasis with suitable methods.

Mix **MTA U** as described under point 4.

Apply **MTA U** with suitable instruments and condense it using a small plugger.

Remove excess cement and clean the surface of the root with a moist piece of gauze.

Confirm placement of the **MTA U** repair material with an X-ray. The **MTA U** repair material remains as a permanent part of the root canal filling.

5.3. Pulp Capping

Place rubber dam and prepare the cavity outline. If caries is present, remove it. Rinse cavity and exposed pulpal areas with a suitable disinfectant.

Mix **MTA U** as described under point 4.

With a suitable instrument apply a small amount of **MTA U** over the exposed pulp and remove excess moisture with a dry cotton pellet.

Not before **5 minutes** after application of **MTA U** place a small amount of a flowable light cure liner (e.g. **GI LINER**) and light cure.

Etch the remaining cavity walls according to the total-etch-technique with **ETCHING GEL** and apply a suitable bonding agent (e.g. **ADHESIVE T1**) according to the corresponding instructions.

Place a light cure composite (e.g. **NANOHYBRID**) according to the instructions and light cure.

Pulp vitality and status should be checked by X-ray at regular intervals.

5.4. Root End Filling (orthograde)

Place rubber dam and clean the root canal system using intra-canal instruments and irrigate with NaOCl. Dry the root canal with paper points.

For disinfection place calcium hydroxide paste in the root canal for one week. Seal the access opening with a temporary filling material.

Mix **MTA U** as described under point 4..

With a suitable instrument apply a small amount of **MTA U** into the apical region and condense it. Create a **3 – 5 mm** barrier of **MTA U**.

Check the position of **MTA U** by an X-ray. If an adequate barrier has not been created, rinse **MTA U** out of the canal and repeat the procedure.

Remove excess moisture with a damp cotton pellet or a paper point.

Place a damp cotton pellet in the access to the root canal and apply a temporary filling material.

Alternatively seal the access preparation with a suitable root canal filling material and seal the cavity with a tight filling.

Both options can be done not before **5 minutes** after placement of the **MTA U.**

MTA U repair material remains as a permanent part of the root canal filling.

Additional remarks

- In the first hour after application handle the placed MTA cement carefully.
- Intraoral application of **MTA U** must be done immediately after mixing to prevent dehydration during setting.
- **MTA U** can cause discoloration. Use **MTA U** only in the root canal and/or the pulp chamber.

Storage

Store **MTA U** at a dry place at 10 – **25 °C (50 °F – 77 °F).**

Do **not** store below **10°C (50 °C)!**

Do not use after expiry date.

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Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense SEALANT

Light cure pit and fissure sealant

Instructions for Use

SEALANT is a light cure single component and fluoride containing methacrylate based pit and fissure sealant; semi-opaque and white.

The white coloration allows controlled application and facilitates visual observation, the semi-opaque colouration is more tooth like.

ETCHING GEL roughens the enamel surface and produces microfine retentions into **SEALANT** can flow. Thus, etching of the enamel increases adhesion of **SEALANT** in fissures, pits and on the tooth surface.

SEALANT meets the requirements of: **DIN EN ISO 6874, class 2.**

Isolation

Rubber dam is the recommended method of isolation.

Enamel etching

The occlusal surfaces of the teeth to be sealed must be thoroughly cleaned. Apply **ETCHING GEL** in the area of the surface and keep the acid off from dentin. Leave the **ETCHING GEL** in place for **30 seconds** and flush than thoroughly with water. Dry with air that is oil and water free. The etched enamel should have a chalky white appearance.

> Etching precaution: It is essential that the etched enamel is not contaminated by anything. If contamination occurs, re-etch, rinse with water and dry as above. Avoid etching gel contact with oral soft tissues, eyes and skin. If accidental contact occurs, flush immediately with copious amounts of water.

During the application of **SEALANT**, the areas should be kept dry with rubber dam.

Application of SEALANT

1. Direct Application with NeedleTips:

Screw off the cap of the syringe and substitute it by one of the supplied NeedleTips.

Press cautiously **SEALANT** in a thin layer directly onto etched areas and - if necessary - spread with a suitable brush.

After use discard the NeedleTip and attach the cap to the syringe again. NeedleTips are for single use only due to hygienic reasons.

2. Application with a brush

Place a small quantity of **SEALANT** onto the tooth and spread with a suitable brush. **SEALANT** should be applied only to the etched areas. Remove excess of material.

By using a polymerization unit **(wavelength range 400-500 nm)** with a light intensity of at least **1000mW/cm2**, cure each segment for **20 seconds.**

After polymerization, adjust occlusion and inspect sealant for complete coverage. In case of incomplete coverage reapply **SEALANT** in the same manner.

Storage

Do **not** store above **25°C (77°F)**. Protect from direct sunlight.

Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

Additional Notes/Warnings

- The ambient light of the dental lamp may start polymerization of the composite.
- Do **not** use any resin to adjust viscosity of the material.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.

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Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense MODGLASS C Hand-Mix

Light Cure Resin Modified Glassionomer Luting Cement

Instructions for Use

MODGLASS C is a light cured resin reinforced glassionomer luting cement. Beside its excellent fluoride release and the excellent biocompatibility as glassionomer cement **MODGLASS C** has also a good chemical bonding to dentine and enamel and to the restoration and a tight seal at the dentinal margins. Because of its radiopacity it ensures easy postoperative diagnosis. **MODGLASS C** meets the requirements of **DIN EN ISO 9917-2.**

Optional: To improve adhesion the light cure bonding agent **MODGLASS P** can be applied.

Indications

Cementing of crowns, bridges, inlays and onlays (all types: metal, resin, ceramic fused to metal and ceramic)

Contraindications / side-effects

- In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used further on.
- Direct and indirect pulp capping

Interaction with other materials

Avoid direct contact with products containing eugenol since eugenol impairs the setting of the material.

1. Tooth Preparation

Prepare tooth in usual manner.

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material (e.g. **CH LINER**) or MTA cement (e.g. **MTA U**). Refer to the corresponding instructions for use.

2. Dispensing and Mixing

The **powder/liquid** ratio to achieve a suitable consistency is

2.0 /1.0. This can be obtained by mixing **one level (blue) scoop of powder and 3 drops of liquid.**

> Note:
> The spoon dosage is only an approximate reproduction of the nominal mixing ratio.

For accurate dispensing of **MODGLASS C** powder shake the bottle to loosen the powder. Overfill the spoon with the powder, level the powder by using the collar at the top of the bottle and carry it onto the mixing pad. Avoid compressing powder into the spoon.

If any bubbles are present in the **MODGLASS C** liquid, lightly tap the bottle with the fingers holding it. Discard drops that contain bubbles and are obviously not full-sized.

For dispensing of **MODGLASS C** liquid turn the bottle vertically with the tip about **5 cm** above the mixing pad. Steady your hand and squeeze the bottle gently to dispense one drop.

Use a small spatula to rapidly mix all the cement powder into the liquid. The mixed cement should be thixotropic and have a homogenous consistency. Total mixing time is **30 seconds.**

After use, tightly close both liquid and powder bottles to prevent exposure to moisture.

3. Cementing

Avoid water and saliva contamination during application and setting of the cement. For a dry working area adequate isolation of the tooth is required.

Prepare the restoration according to manufacturer instructions.

Mix the required amount of **MODGLASS C** and apply into the lumens of the crown or bridge (approx. half) resp. to the bonding surface of inlays or onlays in a thin layer. Seat the restoration immediately **(working time 2:30 min from start of mixing at 23°C).** Net setting time without any light is approx. **4:00 min.**

Remove excess cement at the first setting stage.

Maintain isolation until the set of the cement is verified (ca. 4:00 minutes). Setting can be optimized with **20 seconds** light cure with a suitable dental light cure unit (wavelength range **400–500 nm**, light intensity min. **1000 mW/cm2**).

> Note:
> Higher temperatures will shorten the working time, lower temperatures will prolong the working time.

An overextended working time will cause the loss of adhesion to the enamel and the dentine.

4. Notes/Warnings

- The material can also be used as liner under composite restorations.
- Unpolymerized material may have an irritant effect and can lead to sensitization against methacrylates.
- Avoid contact with skin, mucous membrane and eyes
- If the material comes into contact with skin, remove the material with absorbent cotton soaked in alcohol and rinse with water. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

5. Storage

Store **MODGLASS C** in a cool and dark place at **4-25 °C (39-77 °F).**Temperature should not exceed **25 °C (77 °F).**

Do not use after expiry date.

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ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense MODGLASS F Hand-Mix

Light Cure Resin Modified Glassionomer Filling Cement

Recommendation for Use

MODGLASS F SYSTEM consists of **MODGLASS F** and **GLASS PRIME**.

MODGLASS F is a light cured resin reinforced glassionomer filling cement. Beside its excellent fluoride release and the excellent biocompatibility as glassionomer cement **MODGLASS F** has also good chemical bonding to dentine and enamel and a tight seal at the dentinal margins. Because of its radiopacity it ensures easy postoperative diagnosis.

GLASS PRIME is a light cure bonding agent for dentine and enamel to enhance the bond between light cure resin modified glassionomer cements and tooth structure.

Indications:

- Primary teeth: restorations of Class I, II and V
- Long-term restoration in non-load bearing areas of Class I and II
- Restoration of Class V
- Intermediate restorations
- Sandwich material for heavy stress bearing Class I and II cavities
- Core build-ups

Contraindications / side-effects

In singular cases, **MODGLASS F** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material.

Interaction with other materials

Avoid direct contact with products containing eugenol since eugenol impairs the setting of **MODGLASS F.**

Do **not** mix the powder or liquid of **MODGLASS F** with any other glassionomer product.

1. Tooth Preparation

Prepare the cavity. Rinse thoroughly with water and dry gently, but do not desiccate.

For pulp protection areas close to the pulp should be covered with a thin layer of calciumhydroxide material (e.g. **CH LINER**) or MTA cement (e.g. **MTA U**).

Optional:

To improve adhesion particularly in case of deeper cavities the light cure bonding agent GLASS PRIME can be applied.

2. Dispensing and Mixing

The **powder/liquid** ratio is **3.6/1.0**. This can be obtained by mixing **1 level (lightblue) scoop of powder and 2 drops of liquid.**

Note:

The spoon dosage is only an approximate reproduction of the nominal mixing ratio.

For accurate dispensing of **MODGLASS F** powder shake the bottle to loosen the powder. Overfill the spoon with the powder, level the powder for using the collar at the top of the bottle and carry it onto the mixing pad. Avoid compressing powder into the spoon with the inside wall of the bottle.

For dispensing of **MODGLASS F** liquid turn the bottle vertically with the tip about 5cm above the mixing pad. Steady your hand and squeeze the bottle gently to dispense one drop. If any bubbles are present, lightly tap the bottle with the fingers holding it. Discount drops that contain bubbles and are obviously not full-sized.

Use a small spatula to rapidly mix all the cement powder into the liquid. The mixed cement should be thixotropic and have a smooth consistency and glossy appearance. Total mixing time is **30 sec.**

After use, tightly close both liquid and powder bottles to prevent exposure to moisture.

3. Filling and Finishing

Mix the required amount of **MODGLASS F** and apply it into the prepared cavity by using a suitable placement instrument.

Please see to it, that no air bubbles will be incorporated.

MODGLASS F should be placed in the cavity within the working time **(2:30 minutes from start of mixing at 23 °C or 74°F)**. A transparent matrix may be used.

Cure for **20 sec** with a visible light-curing device **(wavelength range 400–500 nm, light intensity min. 1000 mW/cm2).** Net setting time without any light is approx. **4:00 min.**

In case of cavities with a depth of more than **2 mm** curing in incremental layers is strongly recommended. Cure each layer separately. In order to improve the self-adhesion, this is very important for the first layer of **2 mm.**

Note:

Higher temperatures will shorten the working time, lower temperatures will prolong the working time.

An overextended working time will cause the loss of adhesion to the dental enamel and the dentine.

After **MODGLASS F** has set, remove matrix where applicable and perform finishing under water spray using standard techniques.

Optional: a layer of **GI COAT** can be applied after the finishing and subsequently light-cured for **20 seconds.**

4. Warnings

- This product is to be applied only by a dental professional in the manner as described in this instruction.
- Unpolymerized material may have an irritant effect and can lead to sensitization against methacrylates.
- Avoid contact with skin, mucous membrane and eyes
- If the material comes into contact with skin, In case of contact, remove the material with absorbent cotton soaked in alcohol and rinse with water. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

5. Storage

Store **MODGLASS F** in a cool and dark place at **4-25 °C (39-77 °F)**. Temperature should not exceed 25 °C (77 °F).

Do not use after expiry date.

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V1-04-2021

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Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense MODGLASS P

Primer for use with resin modified glassionomer cements

Recommendation for Use

MODGLASS P is a simple to use primer for dentine and enamel to enhance the bond between light cure resin modified glassionomer cements and tooth structure.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Cavity Preparation

Clean the tooth with flour of pumice and water prior to preparation. Prepare the cavity with minimal tooth reduction. Margins should have a slight **(0.5 - 1.0 mm)** bevel placed in the enamel to increase the surface area for greater bond strength.

3. Pulp Protection

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material material (e.g. **CH LINER**).

4. Application of MODGLASS P

Apply **MODGLASS P** with a suitable brush onto the **moist enamel and dentine surfaces** for **30 seconds** with agitation. The material should build a homogeneous layer. Air thin gently for **10 seconds** to remove the volatile components and to disperse the adhesive. Then light cure with a suitable dental halogen light unit or an LED **(wavelength 400–500 nm, light intensity min. 1000 mW/cm^2)** for **10 seconds**. before placement of a light cure resin reinforced glassionomer cement.

5. Restorative Placement, Cure and Finishing

Refer to manufacturers instructions for placement, curing and finishing of light cure resin reinforced glassionomer cements.

Side effects

In singular cases, **MODGLASS P** may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of **MODGLASS P.** Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates
- Avoid contact with skin, mucous membrane and eyes
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.

Storage

Do **not** store above **25 °C (77 °F)!** Avoid storage in direct sunlight.

Do not use after expiration date.

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QualiSense Gold

Instructions for use
MD

QualiSense SEAL VARNISH – SingleDose

Silicone based one component varnish with Nano-Fluorapatite and Nano-Calciumfluoride

Product description

SEAL VARNISH is a silicone based one component acid protecting varnish with Nano-Fluorapatite and Nano-Calciumfluoride for sealing of teeth. Nano-technology fluorapatite particles are known to enhance remineralization of tooth material.

SEAL VARNISH does not require etching. It builds a protective film, that can be renewed or repaired just as you like, if necessary. The application is easy and time saving.

SEAL VARNISH contains 2000 ppm (0,2 %) fluoride.

Indications/Intended use

- Sealing of teeth where cleaning is difficult due to multi-band technique
- Sealing of teeth when patients are handicapped
- Temporary sealing of restorations with marginal leakage
- Sealing of teeth after bleaching procedures (protection from staining and remineralization)
- Protection of hypersensitive cervicals
- Protection of deciduous teeth
- Protection after scaling and after professional tooth cleaning
- Protection of teeth in pateints susceptible to caries

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

Impressions with vinyl silicones can be made earliest 4 weeks after the treatment with **SEAL VARNISH**.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Application of SEAL VARNISH

The caries-free teeth are cleaned thoroughly with an oilfree paste, polished and dried in an oil- and water free air stream.

Before application vigorous shake the bottle with the **SEAL VARNISH**. During shaking listen to the bead inside the bottle.

Apply **SEAL VARNISH** 2 – 3 times in an even thin layer. Avoid contact of the **SEAL VARNISH** with the mucosa.

Let **SEAL VARNISH** dry for 1 minute or dry it gentle in an oil free air stream.

Important remarks

- In the first 2 hours after application of **SEAL VARNISH** don't eat anything nor brush the teeth.
- In case of protecting teeth with **SEAL VARNISH** during application of orthodontic multi-band technique, brackets are placed on the teeth before the application of **SEAL VARNISH**.
- The intense smell of **SEAL VARNISH** volatizes during drying within 1 minute.
- **SEAL VARNISH** contains ethylacetate. Ethylacetate is highly flammable. Keep away from sources of ignition. Avoid inhalation of ethylacetate vapour. After eye contact rinse out with plenty of water und call an ophtalmologist. After contact with skin, wash with plenty of water and soap.
- For hygienic reasons the bottle containing **SEAL VARNISH** is
- for single use and for one patient only.
- Keep away from children!

Storage

Do not store above 25 °C (77 °F)! Do not use after expiry date!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Warranty

DS Dental Supply GmbH warrants this product will be free from defects in material and manufacture. DS Dental Supply GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusively remedy and DS Dental Supply GmbH's sole obligation shall be repair or replacement of the DS Dental Supply GmbH product.

Limitation of Liability

Except where prohibited by law, DS Dental Supply GmbH will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

ARSACO GmbH

V1-04-2021

CE 0482

Manufacturer: DS Dental Supply GmbH
22607 Hamburg Germany

Distributor: Arsaco GmbH
Schützenstraße11 D66953- Pirmasens Germany

QualiSense Gold

Instructions for use
MD

QualiSense UNI CATALYST

Activator for the universal adhesive UNIVERSAL ADH

Product description

UNI CATALYST is designed as a product for additional and/or extended self etch applications of **UNIVERSAL ADH** for all the special cases, where light cure of the adhesive cannot be ensured (e.g. in the root canal).

The mixture of **UNIVERSAL ADH/ UNI CATALYST** is suitable for moist, wet and dry surfaces.

Indications/Intended use

Adhesive for the self-etch technique for:

- Adhesive cementing of posts (and possibly subsequent core build-up) with dual or self cure composites (e.g. DC CORE, NANOCORE ZR).

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

In singular cases, the material may cause a sensitizing reaction in patients with a hypersensitivity to any of the ingredients. In these cases, the material should not be used.

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the material. Neither store the material in proximity of eugenol containing products, nor let the material allow coming into contact with materials containing eugenol.

Application

1. Isolation

Rubber dam is the recommended method of isolation.

2. Root Canal Preparation

Prepare the root canal appropriate to the selected post.

3. Application of the Adhesive

One drop of **UNIVERSAL ADH** and one drop of **UNI CATALYST** were combined in a mixing pallet and mixed for 5-10 seconds under subdued light.

> Notes:
> Do not interchange lids of the bottles, because this can lead to a cross-contamination of the liquids.

Apply the **UNIVERSAL ADH/UNI CATALYST** mixture with a suitable brush onto the root canal walls for 30 seconds with agitation. Applying the adhesive on the surface without agitation is inadequate. Repeat procedure 1–2 times. The material should build a homogeneous layer.

Remove excess material thoroughly e.g.with paper points.

Air thin gently (at least **5-10 seconds**) to remove the volatile components and to disperse the adhesive until a glossy and uniform layer results.

For optimal adhesion light cure with a suitable dental halogen light unit or an LED (wavelength 400–500 nm, light intensity min. 1000 mW/cm2) for **20 seconds** is recommend.

4. Post Cementing

Prepare the post according to manufacturer instructions.

Place the post with a flowable dual cure or self cure composite into the root canal.

Refer for this and for core build-up to manufacturer instructions of the dual or self cure composite.

Storage

Do not store above 25 °C (77 °F)! Protect from direct sunlight. Do not use after expiry date.

Additional informations/Warnings

- Unpolymerized material may have an irritating effect and may lead to a sensitizing reaction against methacrylates.
- Avoid contact with skin, mucous membrane and eyes.
- If the material comes into contact with skin, immediately wash with water and soap. If the material comes into contact with eyes, immediately rinse with copious amounts of water and seek medical advice if required.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- Keep away from children!

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

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QualiSense MICROHYBRID F

Light Cure Easy Flowable Microhybrid Composite

Product description

MICROHYBRID F is a visible light cure easy flowing radiopaque microhybrid composite for anterior and limited posterior restorations and for sealing. It is based on methacrylate-resin and inorganic filler particles of 0.05-1 µm. The total filler load is 62% and the total filler volume 47%. Radiopacity of **MICROHYBRID F** is 150 % aluminium (radiopacity of enamel: ~200 % aluminium, of dentine:~ 100 % aluminium). The composite material meets the requirements of DIN EN ISO 4049, type 1, class 2, group 1.

Indications/Intended use

- Restorations of class III, IV and V
- Small class I and II restorations
- Lining of cavities
- Sealings

Performance features

The performance features of the product meet the requirements of the intended use.

Contraindications

Irritations resulting from direct contact with the pulp cannot be ruled out. Therefore for pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material.

Patient target group

Persons who are treated during a dental procedure.

Intended users

This medical device should only be used by a professionally trained dental practitioner.

Incompatibility with Other Materials

Do not use in combination with substances containing eugenol because eugenol inhibits the polymerization of the composite. Neither store the composite material in proximity of eugenol containing products, nor let the composite allow coming into contact with materials containing eugenol.

Application

Preparation of Tooth and Color Matching

Clean the tooth with a fluoride-free polishing paste (e.g. flour of pumice with water) prior to preparation and color matching.

Ascertain the tooth shade while teeth are still moist and select the appropriate **MICROHYBRID F** shade.

MICROHYBRID F is shaded according to VITA®-Shades.

Cavity Preparation

After isolation (best with a rubber dam) prepare the cavity with minimal tooth reduction.

For pulp protection areas close to the pulp should be covered with a thin layer of pulp capping material material (e.g. **CH LINER**).

Condition and apply a bonding agent according to the manufacturer instructions. The total etch technique with **ETCHING GEL** and subsequent application of a light cure bonding agent (e.g. **ISOADHESIVE T1**) is recommended. Otherwise use a self etching bonding agent (e.g. **ADHESIVE S2** or **ADHESIVE S1**) before application of **MICROHYBRID F**.

Placement of LC FLOWFILL

Apply **MICROHYBRID F** in the selected shade. Place it by using a suitable instrument. Matrix strips may be used.

Application from syringe:

Screw off the cap of the syringe and substitute it by one of the supplied NeedleTips. After use discard the NeedleTip and attach the cap to the syringe again. NeedleTips are for single use only due to hygienic reasons.

Curing of MICROHYBRID F

For an optimum result apply **MICROHYBRID F** in layers of max. 1 mm. Light cure each increment separately.

By using a polymerization unit (wavelength range 400-500 nm) with a light intensity of at least 1000mW/cm2, cure each increment as follows:

Lighter shades (e.g. A1, A2, B2) 20 seconds

Darker shades (e.g. A3.5, B3) 30 seconds

Hold the light emission window as close as possible to the filling material.

Finishing

Depending on the shape of the area contour with finishing diamonds, flexible grinding discs or carbide burs. Polish to high gloss with polishing discs or polishing brushes.

Storage

Do not store above 25°C (77°F). Protect from direct sunlight. Do not use after expiry date.

Close syringe immediately after use to avoid exposure to light.

Additional informations/Warnings

- APPLIC.-Tips are for single use only due to hygienic reasons.
- The ambient light of the dental lamp may start polymerization of the composite.
- Do not use any resin to adjust viscosity of the composite restorative.
- Avoid contact with skin, mucous membrane and eyes.
- Unpolymerized composite may have an irritant effect and can lead to sensitization against methacrylates.
- Commercial medical gloves do not protect against the sensitizing effect of methacrylates.
- VITA® is a registered trade mark of the VITA-Zahnfabrik, Bad Säckingen, Germany.
- Keep away from children!

Composition

Dimethacrylates, dental glass, silicon dioxide, photo initiators.

Disposal

Disposal of the product according to local authority regulations.

Reporting obligation

Serious incidents according to the EU Medical Devices Regulation that have occurred in connection with this medical device must be reported to the manufacturer and the competent authority.

Note

The summary of safety and clinical performance of the medical device can be found in the European database on medical devices

(EUDAMED – https://ec.europa.eu/tools/eudamed).

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