

## Instructions for use

English - MBK1074-01/24



Bite to Perfection



R-SI-LINE® METAL-BITE®



CE 0482

### Manufacturer :

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### R-SI-LINE® METAL-BITE®

REF MBK1074

#### Product description

R-SI-LINE® METAL-BITE® in automixing cartridges is an extremely fast, extremely hard and precise addition curing registration material on vinyl polysiloxane base. It can be directly and bubblefree syringed onto the occlusal areas.

R-SI-LINE® METAL-BITE® can be applied as a key material e. g. for taking intraoral registrations with needle points and as a material for fixation of bite forks for use with face bows.

R-SI-LINE® METAL-BITE® is scanable and therefore usable for powderfree optical registration of data (antagonist registration).

R-SI-LINE® METAL-BITE® is a registration material based on addition curing vinyl silicones. R-SI-LINE® METAL-BITE® is very suitable for cutting and contouring, inflexible and not crumbly.

Thanks to its thixotropy, undesired flow of R-SI-LINE® METAL-BITE® into dental interstices is prevented and allows an easy removal.

#### Indications/intended use

R-SI-LINE® METAL-BITE® is indicated as

- a bite registration material,
- a key material for taking intraoral registrations with needle points,
- a material for fixation of bite forks for use with face bows and
- as a scanable registration material.

#### Performance features

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

#### Contraindications

Not known.

#### 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. Preparing the auto-mixing cartridge/R-SI-LINE® MIXING PISTOL N

Introduce the auto-mixing cartridge into the MIXING PISTOL N (REF MIP1081) and lock it. Before first use screw off the original cap and dispose it. When screwing on a new mixing cannula the cartridge should be tested if both pastes will be extruded equally. Then screw on the mixing cannula R-SI-LINE® MIXING CANNULA SXN (REF MIK1093). The mixing pistol is ready for application. For direct, broaden application onto the teeth use the R-SI-LINE® BITE-TIPS (REF BRT1000).

##### 2 a. Registration

Before application, a small amount of automatically mixed material (pea size) is squeezed out and immediately discarded. The automatically mixed R-SI-LINE® METAL-BITE® is applied directly to the occlusal areas or to the bite fork for face-bow transfer. The occlusal surfaces should be closed in the desired occlusion within 20 s after the start of application (working time at 23 °C).

After 60 s in the mouth, R-SI-LINE® METAL-BITE® has hardened and can be removed from the mouth.

##### 2 b. Data registration (static, antagonist-registration)

The automatically mixed R-SI-LINE® METAL-BITE® is applied directly onto the prepared occlusal areas. After hardening the registrate will not be removed and will be prepared mesial and distal. Then the mesial, the registrated (of the antagonist) and the distal occlusal area can be optically registered (Scan).

##### 2 c. Data registration (dynamic, FGP-antagonist-registration)

After hardening the registrate will be prepared intraoral mesial and distal and will be reduced to a FGP-table with occlusal informations. Then fresh material will be applied onto this table and excursion movements (trusion movements) will be done. Then the dynamic registration can be scanned (literature >> www.r-dental.com).

The filled MIXING CANNULA functions as a seal until the next application.

#### 3. Articulator

R-SI-LINE® METAL-BITE® allows a visual control during fixing of the gypsum model in the articulator. Registrates made from R-SI-LINE® METAL-BITE® can be stored over months without shrinkage.

#### 4. Desinfection

R-SI-LINE® METAL-BITE® can be disinfected with disinfectant solutions especially for materials based on addition-curing silicones. Please follow the manufacturer's instructions for use.

#### 5. Storage

Do not store above 25 °C (77 °F)! Avoid exposure to sunlight. Do not use after expiry date.

#### Additional notes

Do not use latex gloves because they may inhibit the polymerization of vinyl silicones. Do not touch prepared tooth with latex gloves.

Keep out of the reach of 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.

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#### Warranty

R-dental Dentalmaterialien GmbH warrants this product will be free from defects in material and manufacture. R-dental Dentalmaterialien GmbH makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. The 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 R-dental Dentalmaterialien GmbH's sole obligation shall be repair or replacement of the product.

#### Limitation of Liability

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