

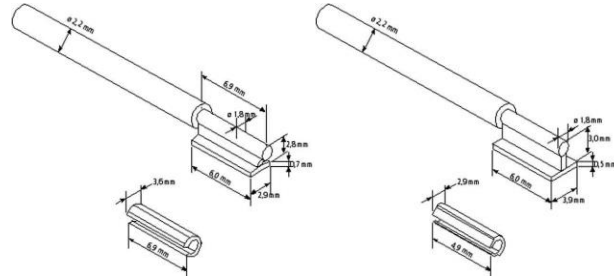
# Attachments (Simplex + Topline)

Date of issue: 01.12.2017

Last revision date: 16.12.2020



\*Application example (with circulating/interlock)



\*Technical drawings

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### 1. User group

The products may only be processed by appropriately qualified personnel in dental laboratories and used by qualified personnel in dental surgery or clinics.

- Dental technicians
- Dentists

### 2. Target patient group

Patients with dental medical indications in the area of the described indications and applications.

### 3. Materials / Components

*Friction sleeves (replaceable) / contact with the patient*

Article	Material
Friction sleeves (Matrices)	PEEK (polyether ether ketone), biocompatible

*Accessories (exclusively for manufacture in dental lab) / no contact with the patient*

Article	Material
Patrice	Polypropylene (burns out without residue)
Duplicate-matrices	Polypropylene (burns out without residue)

### 4. Product description

The accessories (forming parts: patrice, duplicating matrices) are made of polypropylene which burns out without residue. They are integrated into the wax modeling and can be transferred into any dental alloy by means of dental precision casting. The friction sleeves/matrices themselves consist of a high-quality, biocompatible thermoplastic material (PEEK) and can be replaced if necessary.

### 5. Indication

Topline and Simplex attachments are rigid, extracoronal slide attachments for removable partial dentures. The attachments differ slightly in shape and size.

### 6. Contraindication

- Patient's lack of readiness to follow aftercare/recall notices correctly.
- Dental restorations without milled circulation or additional vertical support
- Unilateral free-end dentures as monoreductor

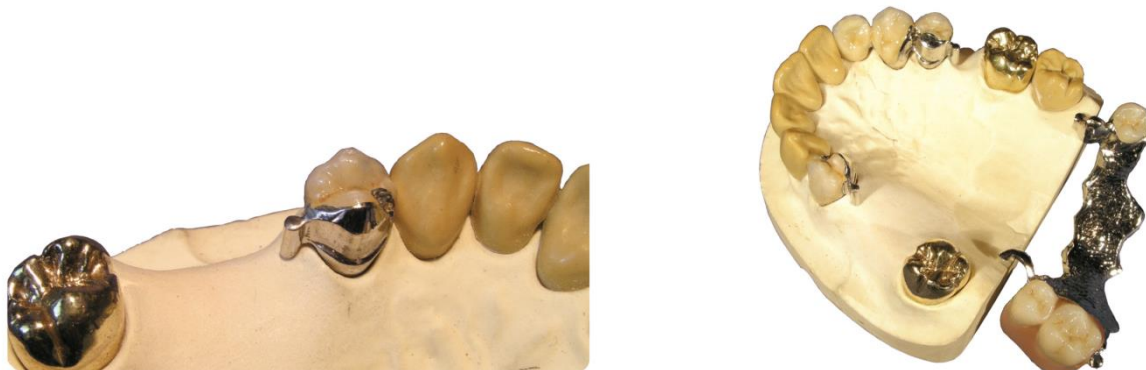
The matrices (PEEK) are not compatible with other similar products.

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### 7. Processing



#### Removable partial dentures

1. The elongated plastic rod of the patrice is fixated into a parallelometer or a parallel milling machine
2. Reserve space in the wax modelling of the crown or bridge for anatomically correct insertion of the plastic attachment
3. Remove the rod with a hot scalpel after fixation of the patrice using wax
4. The patrice is now modelled into the anatomical shape of the crown and existing gaps are filled with modelling wax and cleaned up
5. The wax model can be finished as usual.
6. The different attachments require attaching additional oral parallel milled bracings acting as vertical support. This safeguards the positioning of the prosthesis, the attachment itself only serves as a safeguard for the removal of the prosthesis.
7. The next step consists in working and grinding the prosthesis, if necessary doing ceramic build-up, milling and final polishing. Please note that the extracoronal cylinder/patrice is not cut back too far to avoid an irreversibly loose fitting of the friction sleeve (PEEK).
8. The correctable impression with crown/bridge and rod is cast as master model.
9. For duplication the blue duplicate-matrice is mounted onto the patrice. This acts as a place-marker for the friction sleeves (PEEK) later positioned into the partial framework prosthesis.
10. If necessary, adjust the duplicate-matrice basal to the gingiva.
11. Gaps and slits must be closed and cleaned with modelling wax.  
*We recommend using duplicating silicone for duplication.*
12. The casting is done with investment material
13. The investment model shows the primary part completely in investment material including the duplicating accessory.  
This model must not be changed anymore!
14. The silhouette of the duplicate-matrices must be accurately replicated in the investment
15. Modeling, casting and adjustment work of the partial framework prosthesis is done as usual.  
The cavity in the model casting obtained by the modelling accessory is to be processed with highest accuracy if necessary.
16. The friction sleeve (PEEK) is inserted into the cavity using gentle pressure and minimal friction
17. Simple roughening of the inner surface by sandblasting ensures stable fixation of the friction sleeve.
18. Its length is adjusted to the shape of the gingiva underneath the patrice. The sleeve can then easily be replaced if necessary.

### 8. Protective measures / Warnings

No special hazard known.

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## 9. Residual risks

A possible residual risk can be an insufficient or faulty friction of the friction sleeve (matrices) due to inaccurate processing / manufacturing in the dental lab.

A further residual risk can be a possible contamination due to inappropriate disinfection before inserting/integrating the denture intraorally.

These residual risks are highly unlikely and are not expected in case of appropriate use and handling over the lifecycle of the instrument.

## 10. Disposal

Used and/or defective parts need to be disinfected before disposal to avoid transmission of germs. Please be careful with sharp edges or tips.

After disinfection instruments can be discarded with general clinical waste.

## 11. Notification to competent authorities

Competent national authorities and the manufacturer need to be notified about all serious incidents occurring in the context of the product without delay.



DFS-Diamon GmbH  
Ländenstraße 1  
93339 Riedenburg  
Germany

**CE 0297**

## 12. Symbolerklärungen

Piktogramm	Norm / Richtlinie	Erklärung
	EU RL 93/42/EWG (MDD)	Bestätigung der Produktkonformität, in Bezug auf die genannte europäische Richtlinie sowie die Kennnummer einer benannten Stelle, welche diese Produktkonformität bestätigt hat.
	DIN EN ISO 15223-1 (Bezugsnummer 5.1.1)	Hersteller
	DIN EN ISO 15223-1 (Bezugsnummer 5.1.3)	Herstellungsdatum
	DIN EN ISO 15223-1 (Bezugsnummer 5.4.3)	Gebrauchsanweisung beachten
	DIN EN ISO 15223-1 (Bezugsnummer 5.1.6)	Artikelnummer
	DIN EN ISO 15223-1 (Bezugsnummer 5.1.5)	Fertigungslosnummer, Charge
	-	Hinweis auf ein Medizinprodukt