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www.cmsa.ch/dental

Instructions for use

#### Participation

This instructions for use was prepared in cooperation with the University of Bern, Clinic for Dental Prosthetics, Priv.-Doz. Dr. Dr. med. dent. N. Enkling, specialist for prosthetics and oral surgery, senior physician and deputy to clinic director Prof. R. Mericske-Stern.

The use, activation, deactivation, repair and periodic maintenance of attachment elements must be carried out exclusively by skilled persons. Only original tools and parts may be used for this work. The mechanical cleaning of attachment elements using a toothbrush and toothpaste may lead to premature wear of the functional parts. The issuing of these instructions for use renders all previous versions invalid. The manufacturer rejects any liability for damages resulting from non-compliance with these instructions for use.

#### Device (trade) Name

SFI-Anchor® D20, SFI-Anchor® D60, SFI-Anchor® CD20

#### **Device Description**

The SFI-Anchor<sup>®</sup> is used for the following clinical situations: **SFI-Anchor<sup>®</sup> D20**:

- Removable, rigidly prosthetics on dental implants.
- Hybrid dentures / Hybrid prosthetics.
- Transversally splinted, unilateral free-end prostheses.
- Partial and free-end prostheses in combination.
- SFI-Anchor® D60:
- Removable, rigidly prosthetics on dental implants.
- Hybrid dentures / Hybrid prosthetics.
- Transversally splinted, unilateral free-end prostheses.
- Partial and free-end prostheses in combination.

#### Mandible:

### (D20, D60)

Anchorage of mandibular (MD) prosthesis on 2 or more implants. **Note:** In case of partial prosthesis only 1 implant if the partial prosthesis is already given primary support via a clasp rest or a rigid attachment.

#### Maxilla: (D20, D60)

Anchorage of maxillary (MX) prosthesis on 4 or more implants, designed as complete prosthesis or also palate-free. **Note:** In case of partial prosthesis only 1 implant if the partial prosthesis is already given primary support via a clasp rest or a rigid attachment.

Rx only



The products carry the CE Mark. See packaging for details.



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#### Angulation overview of the different SFI-Anchor®:

REF no    045.026, 045.027, 045.028, 045.031, 045.032, 045.033, 045.033, 045.029, 045.030, 045.036, 045.034, 045.035, 045.041, 045.042, 045.043, 045.044, 045.045    045.029, 045.030, 045.039, 045.039, 045.034, 045.035, 045.041, 045.042, 045.043, 045.044, 045.045      Picture    Image: state st	Variant	SFI-Anchor <sup>®</sup> D60	SFI-Anchor <sup>®</sup> D20	SFI-Anchor <sup>®</sup> CD20	
Divergence    The SFI-Anchor® D60 can be angled up to 20 degrees mechanically.    The SFI-Anchor® D20 is a straight abutment without mechanical compensation of divergence.    The SFI-Anchor® CD20 is a straight abutment without mechanical compensation of divergence.    The SFI-Anchor® CD20 is a straight abutment without mechanical compensation of divergence.    The SFI-Anchor® CD20 is a straight abutment without mechanical compensation of divergence.    The SFI-Anchor® CD20 is a straight abutment without mechanical compensation of divergence.    The SFI-Anchor® CD20 is a straight abutment without mechanical compensation of divergence.      +    +    +    Additional possibility to compensate divergence up to 10° by the SFI-Anchor® Housing (REF 045.061V4) and by the SFI-Anchor® Retention Insert (REF 045.051, 045.047V4, 045.048V4, 045.049V4, 045.050V4).    =    =      Possibility to restore a divergence up to 30 degrees per implant (60 degrees    Possibility to restore a divergence up to 10 degrees per implant (20 degrees    Possibility to restore a divergence up to 10 degrees per implant (20 degrees	REF no	045.029, 045.030, 045.036, 045.037, 045.038, 045.039,	045.034, 045.035, 045.041, 045.042, 045.043, 045.044,	045.025	
up to 20 degrees mechanically.    abutment without mechanical compensation of divergence.    attachment without mechanical compensation of divergence.      +    +    +    +      Additional possibility to compensate divergence up to 10° by the SFI-Anchor® Housing (REF 045.061V4) and by the SFI-Anchor® Retention Insert (REF 045.051, 045.047V4, 045.048V4, 045.049V4, 045.050V4).    =      =    =    =      Possibility to restore a divergence up to 10° degrees per implant (60 degrees    Possibility to restore a divergence up to 10° degrees per implant (20 degrees	Picture	30° alignment		10° alignment	
Additional possibility to compensate divergence up to 10° by the SFI-Anchor® Housing (REF 045.061V4) and by the SFI-Anchor® Retention Insert (REF 045.051, 045.047V4, 045.048V4, 045.049V4, 045.050V4).      =    =      Possibility to restore a divergence up to 30 degrees per implant (60 degrees    Possibility to restore a divergence up to 10 degrees per implant (20 degrees	Divergence		abutment without mechanical	attachment without mechanical	
SFI-Anchor® Retention Insert (REF 045.051, 045.047V4, 045.048V4, 045.049V4, 045.050V4).      =    =      Possibility to restore a divergence up to 30 degrees per implant (60 degrees    Possibility to restore a divergence up to 10 degrees per implant (20 degrees    Possibility to restore a divergence up to 10 degrees		+	+	+	
to 30 degrees per implant (60 degrees to 10 degrees per implant (20 degrees to 10 degrees (20 degrees between					
to 30 degrees per implant (60 degrees to 10 degrees per implant (20 degrees to 10 degrees (20 degrees between		=	=	=	
		to 30 degrees per implant (60 degrees	to 10 degrees per implant (20 degrees	to 10 degrees (20 degrees between	

### SFI-Anchor® CD20

Additional retention element on CAD/CAM milled dental bars. Materials

#### SFI-Anchor® S

Abutment (male part), Housing (female part).

#### SFI-Anchor® E, G

Retention inserts E, retention inserts, auxiliary instruments G. Auxiliary instruments S

S = Syntax, TiAl6 V4 ELI (Grade 5), Ti > 89.478 %, Al 6.0 %, V 4.0 %; G = Galak, POM, Santoprene, Pekkton®; E = Elitor®; X = steel

Detailed information on the materials and their classification is given in the specific material data sheets and the catalog. See website www.cmsa.ch/dental or the Cendres+Métaux Dental Documentation (available free of charge from all Cendres+Métaux subsidiaries, branches and dealers).

Further information on SFI-Anchor® at www.cmsa.ch/dental

#### Indications for use

The SFI-Anchor<sup>®</sup> D20 and D60 is intended for the fixation of (dental) prostheses to corresponding dental implants. The compatible implant systems are specified in table 1 below.

Table 1: Compatible Implant Systems.

Implant Manufacturer: Institute Straumann

Implant System: ITI Dental Implant System<sup>®</sup> respectively Straumann<sup>®</sup> Dental Implant System Implant line name(s): see below

Standard Ø 4.1 mm Regular Neck (RN)

Standard Ø 4.8 mm Regular Neck (RN)

Standard Plus Ø 4.1 mm Regular Neck (RN)

Standard Plus  $\emptyset$  4.8 mm Regular Neck (RN)

Tapered Effect Ø 4.1 mm Regular Neck (RN)

Bone Level Ø 4.1 mm, Regular CrossFit<sup>®</sup> (RC)

Bone Level Ø 4.8 mm, Regular CrossFit® (RC)

The SFI-Anchor® CD20 is intended as an additional retaining element on CAD/CAM milled dental bars.

#### Contraindication

- Implant divergences  $> 30^{\circ}$ .
- The SFI-Anchor<sup>®</sup> is to be used exclusively with the specific implant systems listed in Table 1.
- In patients with allergies to one or more elements of the attachment materials.
- Use on a single implant.
- Not suitable if fixed connections are require.
- Existing clinical picture in the patient's mouth does not permit the correct use of the SFI-Anchor<sup>®</sup>.
- Lacking cooperation of the patient with respect to follow-up / recall instructions.
- Patients with bruxism or other parafunctional habits.
- Unilateral free-end prosthesis without transversal support.
- Hybrid prostheses supported on one or more root caps.
- For additional contraindications, please refer to the instructions for use from the implant manufacturer.

#### Warnings

Allergies: This product may not be used in patients with allergies to one or more elements of the attachment materials. In patients with suspected allergy to one or more elements of the materials, this product may only be used following allergological clarification and proof of non-existence of an allergy. Auxiliary instruments may contain nickel.

The SFI-Anchor<sup>®</sup> has not been evaluated for safety and compatibility in the MR environment. The SFI-Anchor<sup>®</sup> has not been tested for heating or migration in the MR environment.

#### Spacer

The SFI-Anchor<sup>®</sup> Spacer is slightly oversized versus the original components. This ensures optimal space conditions for later polymerization in the mouth.

**Note:** The Spacer must not be used as a temporary replacement in place of the female part.

These instructions for use are not sufficient for immediate use of the anchors. Dental or laboratory knowledge is required, as well as an introduction to handling the SFI-Anchor<sup>®</sup> by an experienced person.

Information: www.cmsa.ch/dental

#### Precautions

- The processing, activation, deactivation, repair and periodic maintenance of attachment elements of the SFI-Anchor<sup>®</sup> must be carried out exclusively by skilled persons. Only original tools and parts may be used for this work. The mechanical cleaning of the SFI-Anchor<sup>®</sup> using a toothbrush and toothpaste may lead to premature wear of the functional parts.
- The SFI-Anchor<sup>®</sup> components are supplied non-sterile.
  For further information, please see workflow / handling, sterilization / disinfection.
- Secure parts against aspiration.
- No cutting work may be carried out in the patient's mouth.
  (Only concerns injection adapter = SFI-Anchor<sup>®</sup> Aligner)
- The male parts must be aligned parallel to the direction of insertion.
- It is essential to block out undercuts prior to polymerizing the female part.
- Smear male part undercuts with petroleum jelly for better cleaning during polymerization (better removal of excess composite bonding cement).
- Screw in the SFI-Anchor<sup>®</sup> D20 or D60 abutment only once with the correct torque (35 Ncm) for the corresponding dental implant (Table 1).
- In case of immediate loading (observe implant manufacturer's indication), ensure that the tightening torque of the abutment does not exceed the torque of the implant 5 Ncm below implant tightening torque is recommended.
- Ensure that the position of the abutment is not rotated when working with the SFI-Anchor<sup>®</sup> Aligner.
- It is essential to remove excess composite bonding cement.
- Do not use the SFI-Anchor® Spacer as a temporary female part.
- After inserting the retention inserts in the housing, the retention inserts must no longer be rotated in the housing.
- Clean and dry the abutment surface with oil free air prior the cementation with RelyX<sup>™</sup> Unicem or RelyX<sup>™</sup> Unicem 2.
- No pretreatment, like sandblasting or coat (silicate) of the abutment surface is required.
- RelyX<sup>™</sup> Unicem 2 is an Automix and is a dual-curing cement therefore also sensitive to natural or artificial light. The working time is significantly reduced during application under operating lights. Therefore avoid intensive light exposure during application.
- The processing and setting times depend on the ambient and oral temperature. The hardening-time recommendations are based on conditions relevant for practice. As it is the case with every composite cement, the setting of cement slows down significantly at room temperature.
- In case the mucosa is in prolonged contact with RelyX<sup>™</sup> Unicem or RelyX<sup>™</sup> Unicem 2 rinse with plenty of water.
- Start of polymerization after start of mixing 02:30 min.
- End of polymerization after start of mixing 06:00 min.
- For additional Precautions relating to the RelyX™ Unicem and RelyX™ Unicem 2, please refer to the instructions for use from 3M Espe.

#### Side effects

No known side effects if used as intended.

### Workflow / handling

The procedure was described using a patient case and is valid for use in the dental practice and the laboratory.

#### **General information**

- The gingival heights between the SFI-Anchor® D20 and the SFI-Anchor® D60 vary by 1 mm.
- Example: SFI-Anchor<sup>®</sup> D20 H3 = SFI-Anchor<sup>®</sup> D60 H2. - The SFI-Anchor® Aligner (045.057) can be shortened to the existing notch (end of cylindrical diameter) if necessary to simplify application, especially in the posterior region.
- When using the SFI-Anchor® Aligner (045.057), it is essential to check for a correct fit on the abutment and that the Aligner is not rotated around its own axis after placement.
- The SFI-Anchor<sup>®</sup> Block-out spacer (045.053) can be shortened when using abutment heights H1-H2 for better assembly of the female part.
- Make sure that the retention insert is in the correct position before inserting it in the housing. Carefully align the Retention Insert until it is seated in the housing. Once aligned, press the retention insert into the housing until you hear it click and it remains fully engaged at this specific position. The retention inserts must not be rotated once they are fully engaged in the housing.

#### Symbols

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Important information for the specialist i Warning symbol for increased caution

#### Labeling on packaging / symbols

M	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Batch code
QTY	Quantity
ī	Consult instructions for use
Rx only	Attention: According to US federal law, this product may only be sold by or on behalf of a physician.
	Cendres+Métaux SA products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC.
$\otimes$	Do not re-use
NON	Non-sterile
淡	Keep away from sunlight
-	Attention (observe accompanying documents)

#### Recommendation

The use of commercial, mouth-compatible and self-adhesive composite bonding cement RelyX<sup>™</sup> Unicem and RelyX<sup>™</sup> Unicem 2 by 3M Espe is recommended for variant D60. The manufacturer's instructions must be observed.

When fabricating new dentures in the laboratory, we recommend fabricating an individual reinforcement framework.

When using other mouth-compatible composite bonding cements, ensure that these are chemically hardening.

#### Sterilization / disinfection

After any fabrication or modification the prosthetic work, including the female part components, must be cleaned and disinfected according to national guidelines. When choosing the disinfectant, ensure that:

- it is suitable for the cleaning and disinfection of dental prosthetic components.
- it is compatible with the materials of the products to be cleaned and disinfected, and
- it has proven efficacy in disinfection.

All the parts (S, E, G and X) must be disinfected with a high EPAregistered disinfectant prior to use.

Recommended: Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

All metal SFI-Anchor® components (S, E and X) must be sterilized prior to use. Plastic parts are not suitable for steam sterilization and should only be disinfected.

#### Sterilization method

Gravity-displacement steam sterilization cycles for unwrapped nonporous and porous items.

Minimum exposure time and temperature: 10 minutes, 132 °C. Drying time: 1 minute

All parts made of plastic (= G) must be disinfected with a high EPA-registered disinfectant prior to use.

Recommended: Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

#### Processing

Prior placement of the implants is a precondition. It is essential to follow the manufacturer's instructions. Illustrated step-by-step instructions are available on the Cendres+Métaux homepage. www.cmsa.ch/dental

Attention (observe accompanying documents)

### Fabrication of a new Prosthesis D20

Patient Situation Initial clinical picture (Fig. 1).

#### Verify Implant Alignment

Place the SFI-Anchor<sup>®</sup> Abutment planner (045.056 RN or 045.062 RC) onto the Implant (Fig. 2). The SFI-Anchor<sup>®</sup> Abutment planner is specially designed to be positioned onto the specific implant systems listed in Table 1. The SFI-Anchor<sup>®</sup> Abutment planner has an incorporated 10° angle that allows the user to determine whether the implant is at an angle greater than 10° relative to the occlusal plane.

Rotate the SFI-Anchor<sup>®</sup> Abutment Planner 360° (Fig. 3). If the SFI-Anchor<sup>®</sup> Abutment planner passes through the vertical orientation perpendicular to the occlusal plane as it is rotated the implant is less than 10° off axis. Be sure to check the angulation in both the buccal-lingual and mesial-distal planes!

▲ **Note:** A maximum total correction of 10° can be achieved per implant with SFI-Anchor<sup>®</sup> D20. If the implant is greater than 10° off axis the SFI-Anchor<sup>®</sup> Abutment D20 cannot be used. Use of

the SFI-Anchor<sup>®</sup> Abutment D60 should be assessed as described elsewhere in this document. The abutment height can be read off the graduation markings on the SFI-Anchor<sup>®</sup> Abutment planner (Fig. 4). The lowest height for SFI-Anchor<sup>®</sup> Abutment D20 starts at graduation marking 1. Determine the correct height of the SFI-Anchor<sup>®</sup> Abutment D20 (045.031 to 045.035 or 045.041

to 045.045) so the lower edge of the SFI-Anchor<sup>®</sup> Abutment D20 (045.031 to 045.035 or 045.041 and aligned parallel to the occlusal plane.

The following Table gives an overview which SFI-Anchor<sup>®</sup> Abutment D20 height is in correlation with the graduation marking onto the SFI-Anchor<sup>®</sup> Abutment planner.

Graduation marking on the SFI-Anchor <sup>®</sup> Abutment planner (starting near the implant)	SFI-Anchor <sup>®</sup> Abutment D20
1	H1 (045.031, 045.041)
2	H2 (045.032, 045.042)
3	H3 (045.033, 045.043)
4	H4 (045.034, 045.044)
5	H5 (045.035, 045.045)

#### Place the SFI-Anchor<sup>®</sup> Abutment D20

Screw the SFI-Anchor<sup>®</sup> Abutment D20 into the implant by hand and then tighten with the torque ratchet and the SFI-Anchor<sup>®</sup> Screw driver (045.059) to a torque of 35 Ncm. Make sure that the SFI-Anchor<sup>®</sup> Screw driver is correctly seated on the SFI-Anchor<sup>®</sup> Abutment D20 (Fig. 5).

#### Obtain an Impression

Place the SFI-Anchor<sup>®</sup> Impression part (045.054) onto the SFI-Anchor<sup>®</sup> Abutment D20 (Fig. 6) and take a mucodynamic impression.







Fig. 2



Fig. 3









Fig. 6

#### Fabrication of the master model according to state-of-the-art technology

Provide the impression and the SFI-Anchor<sup>®</sup> Analogs (045.055) to the dental laboratory for fabrication of the model. The SFI-Anchor<sup>®</sup> Analogs are inserted into the SFI-Anchor<sup>®</sup> Impression part prior to casting the model.

Once the model is completed insert the SFI-Anchor<sup>®</sup> Housing (045.061) with mounted SFI-Anchor<sup>®</sup> Retention insert, extra-low (045.048) or SFI-Anchor<sup>®</sup> Spacer (045.052) onto the SFI-Anchor<sup>®</sup> Analogs (Fig. 7).

The prosthesis can now be fabricated using conventional technology.

The SFI-Anchor<sup>®</sup> Housing can also be polymerized directly in the mouth if required. It is essential to create sufficient space, mount the Block-out spacer (045.053) on the male part, then place the SFI-Anchor<sup>®</sup> Housing with mounted Retention Insert and Block-out spacer into all undercuts before polymerization (Fig. 8).

⚠ Note: To provide the patient with the most comfort and ease of insertion of the prosthesis, as well as for familiarization with retention in the mouth, it is recommended to fit the prosthesis with an SFI-Anchor<sup>®</sup> Retention insert, extra-low (045.047) first. If the patient demands stronger retention, SFI-Anchor<sup>®</sup> Retention inserts offering greater retention can be placed.

For assembly and disassembly of the retention inserts, see **Assembly and disassembly of retention inserts** instructions elsewhere in this document.



Fig. 7



### SFI-Anchor<sup>®</sup> D20, SFI-Anchor<sup>®</sup> D60, SFI-Anchor<sup>®</sup> CD20

#### Fabrication of a new Prosthesis D60

Patient Situation Initial clinical picture (Fig. 9).

#### Verify Implant Alignment

Place the SFI-Anchor® Abutment planner (045.056 RN or 045.062 RC) onto the implant (Fig. 10). The SFI-Anchor® Abutment planner is designed to be placed onto the specific implant systems listed in Table 1. The SFI-Anchor® Abutment planner has an incorporated 10° angle that allows the user to determine whether the implant is at an angle greater than 10° relative to the occlusal plane. Place the Planner and rotate 360° (Fig. 11). If the SFI-Anchor® Abutment planner passes within 10° of the vertical orientation perpendicular to the occlusal plane as it is rotated the implant is less than 30° off axis. Be sure to check the angulation in both the buccal-lingual and mesial-distal planes! You may use a radiograph to determine the angle of the implant.

 $\Delta$  Note: A total correction of 30° can be achieved per Implant with SFI-Anchor® D60. If the implant is greater than 30° off axis the SFI-Anchor® Abutment D60 cannot be used. Restoration will need to proceed using a different anchoring system or the implant will need to be revised.

Determine the correct height of the SFI-Anchor® Abutment D60 (045.026 to 045.030 or 045.036 to 045.-040) in that the lower edge of the SFI-Anchor® Abutment D60 is at least 1mm above the gingiva and aligned parallel to the occlusal plane (Fig. 11). The lowest height for SFI-Anchor® Abutment D60 starts at graduation marking 2 (Fig. 12).

Repeat for each implant to be restored.

The following Table gives an overview which SFI-Anchor® Abutment D60 height is in correlation with the graduation marking onto the SFI-Anchor® Abutment planner.

Graduation marking on the SFI-Anchor <sup>®</sup> Abutment planner (starting near the implant)	SFI-Anchor® Abutment D60
2	H1 (045.026, 045.036)
3	H2 (045.027, 045.037)
4	H3 (045.028, 045.038)
5	H4 (045.029, 045.039)
6	H5 (045.030, 045.040)

### Place the SFI-Anchor® Abutment D60

Screw the SFI-Anchor® Abutment D60 into the implant with the SFI-Anchor® Screw driver (045.059) and tighten with the torque wrench and the SFI-Anchor® Screw driver to a final torque of 35 Ncm.

Smear male part undercuts with petroleum jelly to ease the removal of any composite bonding cement residues resulting from the filling process (Fig. 13). Repeat for each implant to be restored.





Fig. 10



Fig. 11



Fig. 12





#### Place the SFI-Anchor<sup>®</sup> Aligners

Mount an SFI-Anchor® Aligner (045.057) onto each Abutment. Advance the Aligner firmly until it is in the fixed position on the Abutment, which is seated on the outer contour of the Abutment (Fig. 14) and the filling funnel properly seated in the central filling hole (Fig. 15). The Aligner will be aligned with the axis of the implant when in the fixed position.

 $\Delta$  Note: The SFI-Anchor® Aligner funnel creates a seal with the Abutment filling hole (Fig. 15) to prevent composite bonding cement flowing unexpectedly external to the Abutment and in any undercuts.

Place the injection cannula onto the Aligner attached to the first Abutment to be filled (Fig. 16).  $\Delta$  Note: Be sure to review the working time and cure time of the cement being used. Plan the procedure so that all cement injection occurs within the specified working time and that all final alignment occurs as early as possible during the curing phase. Times for 3M Espe RelyX™ Uni-

Inject composite bonding cement into the SFI-Anchor® Abutment D60 until cement emerges from the two vent holes (Fig 17, Fig. 17a). If the cement leaks from the vent hole stop cement injection.

A Note: Verify that filling is complete prior to removing the injection cannula from SFI-Anchor®

An incorrectly mounted Aligner will be immediately obvious as the cement will leak from the fill hole and out of the Aligner (Fig. 18). In that case remove and discard the SFI-Anchor® Aligner and clean

the Abutment and the gingiva with water, correctly attach a new SFI-Anchor® Aligner and repeat the

- Working time (time from start of mixing until start of polymerization) - Cure time (time from start of mixing to end of polymerization)

Prepare the composite bonding cement per the manufacturer's instructions.

Repeat for each Abutment, be sure not to exceed the cement working time.

Repeat for each SFI-Anchor® Abutment D60.

Prepare and Inject Composite Bonding Cement

cem and RelyX<sup>™</sup> Unicem 2 are as follows:

Aligner.

injection process.



Fig. 14



Fig. 15





Fig. 17





02:30 min.

06:00 min.



#### Alignment of SFI-Anchor® Abutment D60

Carefully tip the SFI-Anchor<sup>®</sup> Aligner in the opposite direction of the implant axis while taking care to not rotate the Aligner. The SFI-Anchor<sup>®</sup> Aligner will find a second position, the movable position, on the Abutment (Fig. 19).

Position each Aligner until it is perpendicular to the occlusal plane. Be sure to verify the alignment in both the buccal-lingual and mesial-distal planes (Fig. 21). It is recommended that each SFI-Anchor® Aligner be kept on each of the SFI-Anchor® Abutments to assure that all of the abutments are aligned in the same orientation (Fig. 21).

▲ Note: An optimal alignment result is achieved by aligning all SFI-Anchor<sup>®</sup> Abutment D60 simultaneously perpendicular to the occlusal plane using the SFI-Anchor<sup>®</sup> Aligner (045.057) by visual confirmation in both the buccal-lingual and mesial-distal planes.

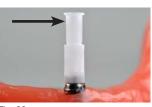
Allow composite bonding cement to fully cure. Follow the manufacturer's instructions.

- ▲ Note: After injecting the composite bonding cement and aligning the abutment, take special care not to move the position of the SFI-Anchor<sup>®</sup> Abutment D60 until the composite bonding cement has cured. After curing of the composite bonding cement, remove the SFI-Anchor<sup>®</sup> Aligners from the Abutments and immediately remove any excess composite bonding cement and petroleum jelly from the male part.
- ▲ Note: If the upper, male portion of an Abutment is able to move after the cementing process, it is likely that the Abutment was not completely filled with cement. Replace the Abutment with a new SFI-Anchor® Abutment D60 and repeat the steps outlined above. Never reuse an Abutment or attempt to inject additional cement into an Abutment that is not properly filled on the first attempt.

This is immediately followed by fabrication of the prosthesis as described in section **Fabrication of a new prosthesis D20** above.



Fig. 19







# D20 and D60 chairside application for existing MD prosthesis in a prosthesis fixed on SFI-Anchor<sup>®</sup> with simultaneous relining (using D60 as example).

#### Confirm Sufficient Room for Housings in Existing Prosthesis

Sufficient space must be available in the prosthetic body for inclusion of the housings. If there is insufficient space, the existing prosthesis should not be revised and a new prosthesis planned.

#### Remove Existing Abutments

Remove existing abutments from the existing implants in the patient's mouth per manufacturer's instructions.

#### Select Appropriate SFI-Anchor® Abutments

Prior to placing the SFI-Anchor<sup>®</sup>, first determine whether the D20 or D60 is appropriate using the SFI-Anchor<sup>®</sup> Abutment planner (045.056) as described above (Fig. 22). If all of the implants are less than 10° out of alignment with the occlusal plane the D20 or the D60 system may be used. If any of the implants is greater than 10° out of alignment, but all implants are within 30° the D60 system must be used.

 $\Delta$  Note: If any of the implants is greater than 30° out of alignment, the SFI-Anchor® Abut-

ment D60 cannot be used. Restoration will need to proceed using a different anchoring system or the implant will need to be revised.

Determine the correct height of the SFI-Anchor<sup>®</sup> Abutment D60 (045.026 to 045.030 or 045.036 to 045.040) in that the lower edge of the SFI-Anchor<sup>®</sup> Abutment D60 is at least 1 mm above the gingiva and aligned parallel to the occlusal plane (Fig. 23).

#### Cementing and Alignment

Follow the same procedure up to and with alignment and polymerization of the SFI-Anchor<sup>®</sup> Abutment D60 as described in section Fabrication of a new prosthesis elsewhere in this document.

#### Obtain Impression

Take impression for relining in the usual manner. For detailed information, please observe impression instructions under section Fabrication of a new prosthesis D20 elsewhere in this document.

#### Modify Existing Prosthesis

The impression is then passed to dental laboratory for fabrication of the model and relining. For detailed information on fabrication of the model and polymerization of the housing, please observe impression instructions under section Fabrication of a new prosthesis elsewhere in this document. Integration of the housing in the patient's mouth is an option (Fig. 24).

#### In case of a new prosthesis, use SFI-Anchor® CD20 as an additional retaining element on a milled bar.

Obtain an impression of the clinical situation in the mouth and fabrication of the master model as specified by the implant manufacturer.

Then fabricate the prosthesis using a conventional wax setup.

The bar is then fabricated using CAD/CAM technology. Please follow the manufacturer's instructions. When modeling the bar in the CAD software, allow for the position of the SFI-Anchor® CD20, a standard thread M2 is required for bar-side fixation.

I Now the SFI-Anchor<sup>®</sup> CD20 (045.025) can be mounted on the milled bar using the SFI-Anchor<sup>®</sup> Screw driver (045.059) (Fig. 25). Tighten the SFI-Anchor<sup>®</sup> CD20 using the torque ratchet the Screw driver to a torque of 35 Ncm.

After assembly of the milled bar with mounted SFI-Anchor® CD20 Abutment and fixed housing on the master model, the prosthesis can be finished according to state-of-the-art technology.







Fig. 23



Fig. 24



#### In case of an existing prosthesis, use SFI-Anchor® CD20 as an additional retaining element on a milled bar.

Obtain an impression with prosthesis according to the implant manufacturer. This is followed by transfer to dental laboratory for fabrication of the model. Fabrication of milled bar with mounted matrix according to description use of SFI-Anchor® CD20 as an additional retaining element on a milled bar for a new prosthesis.

#### Selection of retention inserts.

Four different Pekkton<sup>®</sup> SFI-Anchor<sup>®</sup> Retention inserts are available to achieve the desired prosthesis retention force. The Retention inserts are color-coded and divided into four different retention strengths:

yellow: extra-low red: low green: medium blue: strong

In addition to Retention inserts made of Pekkton<sup>®</sup>, a variant made of precious metal is also available to the user. The retention force of the SFI-Anchor<sup>®</sup> Retention inserts Elitor<sup>®</sup> is similar to that of the Blue (Strong) insert (Fig. 26).

#### Assembly and disassembly of the retention inserts.

The Retention Inserts are placed in the housing using the provided Tool.

- ⚠ Note: Make sure that the Retention insert is in the correct position before inserting it in the housing. Carefully align the Retention insert until it is seated in the housing. Once aligned, press the Retention insert into the housing until you hear it click and it remains fully engaged at this specific position (Fig. 27).
- ▲ Important: Do not rotate the Retention insert after hearing the click! The Retention inserts must not be rotated in the housing. Otherwise, the retention insert is no longer serviceable.

The appropriate side of the tool is used to disassemble the Retention inserts. Forcefully press the appropriate side of the tool into the Retention insert. The Retention insert is disassembled by slightly rotating the Retention insert in the housing while pulling it outward at the same time (Fig. 28).  $\triangle$  **Note:** To provide the patient with the most comfort and ease of insertion of the prosthesis as

well as for familiarization with retention in the mouth, it is recommended to fit the prosthesis with an SFI-Anchor<sup>®</sup> Retention insert, extra-low, first. If the patient demands stronger retention, SFI-Anchor<sup>®</sup> Retention inserts offering greater retention can be placed.

Fig. 28



Fig. 26





#### Handling / follow-up

Retaining elements in prosthetic work are subject to considerable stress in the mouth in a constantly changing environment, and thus are subject to wear over time. Wear is routine and cannot be avoided, only reduced. The amount of wear depends on the overall system. Our endeavors are aimed at using optimally matched materials as far as possible to reduce wear to an absolute minimum. The good fit of dentures on the mucosa is to be checked at least once per year, and relined if required to prevent tilting movement (overload), especially in the case of free-end prostheses. We recommend checking hybrid prostheses at three-monthly intervals initially and to replace the retention inserts if necessary.

#### Insertion and removal of the dentures

Ensure that the dentures do not cant, as any canting can lead to damage. Never place dentures by biting the teeth together. This can lead to damage or even to breaking of the attachment elements. Further information on handling / aftercare of dentures is available in the patient information brochure. www.cmsa.ch/dental. **Insertion:** Hold the denture at both ends, ideally between thumb and forefinger, and place it back in the mouth on the anchors. Search or feel for the correct insertion position and push the denture onto the anchors with gentle, even pressure. Carefully close your jaws and check whether the denture is in its correct final position (Fig. 29).

**Removal:** Hold the denture at both ends, ideally between thumb and forefinger, and slowly, carefully and steadily pull it off the anchors and remove it out of the mouth (Fig. 30).

#### **Cleaning and care**

It is best to clean your teeth and your dentures after every meal. Cleaning of dentures includes cleaning of the connecting element. The most gentle cleaning is achieved by cleaning the connecting element under running water with a soft toothbrush. Most intensive cleaning is achieved when cleaning the dentures in a small ultrasonic device and adding a suitable cleansing agent. Never clean the high precision connecting elements with toothpaste as this could lead to damage. Caution should also be exercised in the case of unsuitable cleansing agents or tablets. This could also damage the high quality connecting element or impair its function. Only clean the connecting parts on the other teeth or implants with water and a soft toothbrush as well as an interdental brush. Do not use toothpaste to avoid damage. Pay attention to regular cleaning of the anchorage to prevent any inflammation of the soft issue. For information and additional tips on caring for the instruments see www.cmsa.ch/dental

For further information, please contact your Cendres+Métaux representative.

#### Traceability of the batch numbers

The batch numbers of all parts used must be documented to ensure traceability.

### Frequently asked questions

### SFI-Anchor® D60

- How do you determine the angle of the implant?

You may use a radiograph to determine the angle of the implant before processing. More details may be found in section «Fabrication of a new Prosthesis D60» within this instructions for use.

– What happens if you accidentally cement on the SFI-Anchor<sup>®</sup> Aligner? What happens if it can not be removed?

It would be very unlikely that this may happen. An incorrectly mounted SFI-Anchor<sup>®</sup> Aligner will be immediately obvious as the cement will leak from the fill hole and out of the Aligner (Fig. 18). In that case remove and discard the SFI-Anchor<sup>®</sup> Aligner and clean the Abutment and the gingiva with water, correctly attach a new SFI-Anchor<sup>®</sup> Aligner and repeat the injection process.

### - Can the SFI-Anchor® Aligner be removed in any case?

The SFI-Anchor<sup>®</sup> Aligner can be removed in any case from the SFI-Anchor<sup>®</sup> D60.

The SFI-Anchor<sup>®</sup> Aligner funnel creates a seal with the Abutment filling hole (Fig. 15) to prevent composite bonding cement flowing unexpectedly external to the Abutment and in any undercuts.

– What are the risks of accidentally flowing?

It would be very unlikely that this may happen. An incorrectly mounted SFI-Anchor<sup>®</sup> Aligner will be immediately obvious as the cement will leak from the fill hole and out of the Aligner (Fig. 18). In that case remove and discard the SFI-Anchor<sup>®</sup> Aligner and clean the Abutment and the gingiva with water, correctly attach a new SFI-Anchor<sup>®</sup> Aligner and repeat the injection process.

#### Disclaimer / disclaimer of liability

The issuing of these instructions for use renders all previous versions invalid. The manufacturer rejects any liability for damages resulting from non-compliance with these instructions for use. This attachment element is part of an overall concept and may only be used or combined with the appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

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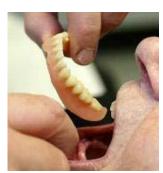




Fig. 30