SFI-Bar® 2-Implant

Instructions for use

Application, activation, deactivation, repairs and regular servicing of attachments should only be carried out by trained personnel using original instruments and components.
Mechanically cleaning attachments with a toothbrush and toothpaste can cause premature wear and tear of the functional components.

The publication of these instructions renders all previous versions invalid.

The manufacturer disclaims any liability for damage caused by failure to follow these instructions.

Intended Use
The bars manufactured by Cendres+Métaux SA serve as connectors for implant-supported removable dental prostheses.

General instructions

Sterilisation
The SFI-Bar® components are delivered in a non-sterile condition.
All metallic SFI-Bar® components must be sterilised before use.
Steam sterilize at 134 °C for 18 min.

Disinfection
After any fabrication or modification, the prosthetic work, incl. female part component, must be cleaned and disinfected according to national guidelines.
When selecting the disinfectant, it is essential to ensure that:
– it is suitable for cleaning and disinfection of dental prosthetic components.
– it is compatible with the materials of the products to be cleaned and disinfected.
– it has tested efficacy in disinfection.
All parts made of plastic must be disinfected with a high EPA-registered disinfectant prior to use.
Recommended: Cidex® OPA Solution. Strictly follow manufacturer's instructions.

Disinfection of deactivators
070201 Deactivator (macro) must not be sterilised. When sterilising the above deactivator in the autoclave, there is a possibility that his plastic handles may be destroyed.
It is therefore advisable to disinfect according to the section «Disinfection» of these instructions for use.

Warnings
With patients having an existing allergy to one or several elements of the materials contained in any one attachment, this particular product must not be used. With patients suspected of having an allergy to one or several of these elements contained in any one attachment, this product can only be used after preliminary allergological testing and proof of a non-existing allergy.

Please contact your Cendres+Métaux sales representative for further information.

Auxiliary instruments may contain nickel.

– The device has not been evaluated for safety and compatibility in the MR environment.
– The device has not been tested for heating or migration in the MR environment.

These operating instructions are not sufficient for immediate use of the attachment. Knowledge of dentistry and dental technology as well as instruction on the handling of the Cendres+Métaux attachments by an experienced person are required. Training courses are regularly provided by Cendres+Métaux, among others. The activation, deactivation, repair and periodic maintenance of attachments should be carried out solely by specialists. Only original auxiliary tools and parts should be used for this work.

Precautions
– The parts are delivered non-sterile. Proper preparation of the parts before use in patients is explained in the section «Disinfection».
– Ensure the attachment is cleaned regularly to avoid soft tissue inflammation.
– During intraoral use, all products should generally be secured against aspiration.
– No cutting work should be performed in the patient's mouth.
– The male parts must be placed parallel to the direction of insertion.
– Undercuts must be blocked out.

Information about the SFI-Bar® can be found at www.sfi-bar.com

S = Syntax TiAl6 V4 ELI (grade 5)
Ti > 89.478 %, Al 6.0 %, V 4.0 %

E = Elitor®
Au 68.60 %, Pt 2.45 %, Pd 3.95 %, Ag 11.85 %, Cu 10.60 %, Ir 0.05 %, Zn 2.50 %
$T_S - T_L$ 880–940 °C

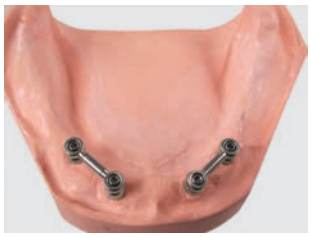

Fig. 1

Rx only

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

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Materials
SFI®-Bar S
(tube bar, fixation screw, large ball joint, small ball joint, half shell ball and implant adapter)

S = Syntax
TiAl6 V4 ELI (grade 5)

Female part asymmetrical E (gold female part)
Integration:
polymerising/bonding E = Elitor®

Indications
The SFI-Bar® is intended to be used with the implant manufacturer's implant to provide support for fixation of overdentures.
Lower jaw:
Connecting 2 or 2x2 implants (Figure 1)
Upper jaw:
Connecting 2x2 implants (Figure 1) in the anterior/premolar region

Immediate loading
The implants (min. 2) in the mandible can be fitted with the SFI-Bar® immediately after implantation, provided the following criteria are met:
– Implant manufacturers permit immediate loading in their system.
– No necessity for simultaneous guided bone regeneration; implants surrounded on all sides by local bone.
– Implant insertion torque min. 35 Ncm.
– All parts are sterilised or disinfected.
– Pull-off strength during osseointegration < 20 N.
– Please refer to instructions for use for the implant manufacturer for additional contraindications for immediate loading.
Note: The study report on immediate loading presented at the 2010 EAO Congress and the current list of the available implant systems are to find on our website www.sfi-bar.com.

Can be fitted directly in the mouth (Chairside):
SFI-Bar® 2-Implant in the lower jaw
SFI-Bar® for 2x2-Implant (Figure 1) in the upper and lower jaw

Contraindications
– Immediate loading SFI-Bar® in the upper jaw.
– Female part T with replaceable retention inserts G on SFI-Bar® 2-Implant.
– Extension of the bar superstructure.
– Implant spans < 8 mm, > 26 mm (Figure 2).
– Implant divergences > 15°.
(Note: If the SFI-Bar® is not aligned with the same plane using the implant adapter, the possibility of compensation of implant divergences is reduced.)
– Use without authorization of the relevant implant manufacturer (list on www.sfi-bar.com).
– Where patients have an existing allergy to one or more elements of the attachment materials.
– Unilateral dentures without transverse support.
– Unwillingness of the patient to correctly follow the aftercare/ recall instructions.
– Patients with bruxism or further uncontrolled para-functional habits.
– Please refer to instructions for use for the implant manufacturer for additional contraindications for immediate loading.

Instructions for use
These instructions were compiled in collaboration with Bonn University, Outpatient Department for Prosthodontics, Propaedeutics and Material Sciences, Director Prof. Dr. med. dent. Helmut Stark, Prof. Dr. med. dent. Karl-Heinz Utz and Dr. med. dent. Stefan Bayer.

Important:
– Assumption: Case planning completed, SFI-Bar® is indicated, implants can be loaded.
– Do not unscrew fixation screw from the screw holder on the ball joint (Figure 3).
– Secure parts to prevent aspiration.
– The procedure is described with the aid of a case study and is applicable to work in the practice and in the laboratory.
Warning: No cutting work in the patient's mouth.

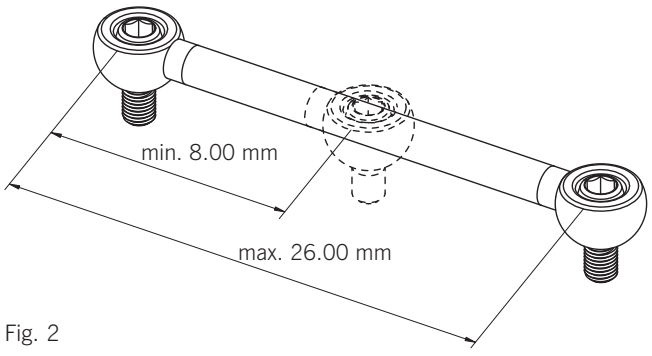


Fig. 2

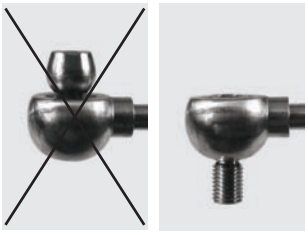
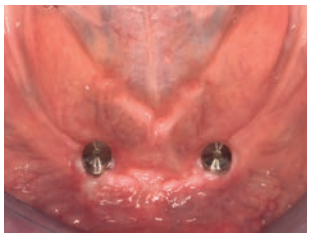


Fig. 3

1. Initial intra-oral situation (Figure 4)
2. Ascertain length of implant adapter by aligning the bar parallel to the occlusal plane at least 1 mm above the gingiva (Figure 5).
3. Tighten implant adapter with screwdriver (Order No. 07000114) and torque wrench (Order No. 07000109) on the implant with the defined torque (Figure 6). The torque details can be found on the package label.
4. Fit tube bar onto the large ball joint (Figure 7).
5. Slide tube bar gauge (Order No. 07000106) onto the tube bar so that the convex part of the gauge can be fitted onto the implant adapter. Tighten holder and attach threads to prevent aspiration (Figure 8).
6. In the mouth, use the hex screwdriver (Order No. 07000115) to screw the large bar joint with fixation screw firmly onto the implant adapter so that the ball joint can still just be moved. Carefully loosen holder. Now the tube bar gauge can be fitted onto the implant adapter by pushing on the tube bar. Press slightly and retighten the holder. The tube bar must fit snugly on the ball joint (Figure 9).
7. Slightly loosen opposite fixation screw and **remove the tube bar with the tube bar gauge from the mouth.** Separate tube bar with cutting disc with a cutting width of 0.30 mm (e.g. Premium Disc No. 1, Order No. 08000101). The cutting disc must abut the flat side of the gauge (Figure 10). Wear protective glasses.
8. Remove flash (Figures 11 + 12).
9. **Prophylaxis:** Seal the cavities and fissures with antibacterial, high-viscosity silicone material (Figure 13).
10. Slide on the second large ball joint and tighten the SFI-Bar® with the fixation screw onto the implant adapter with the defined torque, while protecting against aspiration in the mouth (Figure 14). The torque details can be found on the website www.sfi-bar.com under «Available implant systems» in the data sheet for the relevant implant system.
11. **Control:** The SFI-Bar® is seated tension-free if the pre-mounted restoration can be screwed in on the implant adapter without considerable effort.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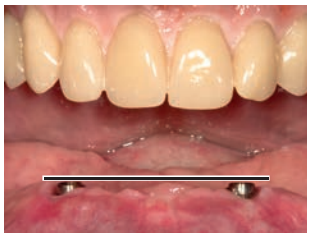
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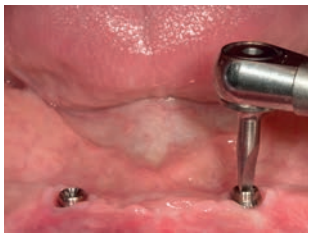
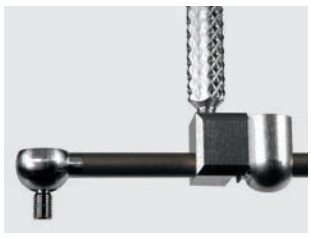


Fig. 6


Fig. 7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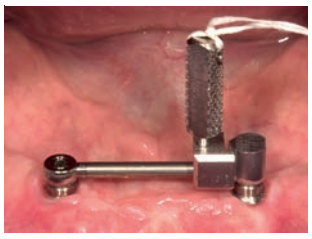


Fig. 9

Fig. 10


Fig. 11

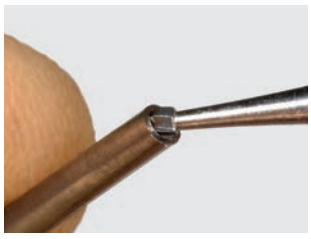


Fig. 12


Fig. 13

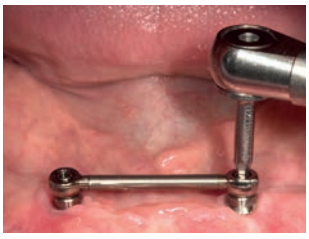


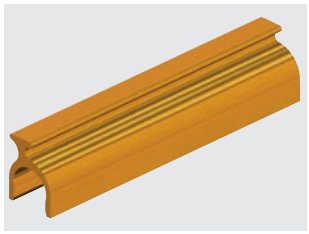
Fig. 14

Integrating the female part directly in the mouth
(The patient has an existing complete denture without any reinforcing framework)

12. Asymmetrical female part E (Order No. 0500 0344), can be activated and shortened as required (Figure 15).
13. In the patient's mouth, measure the whole length of the bar, including support on the arm of the ball joint (Figure 16).
14. Shorten the gold female part as required and remove flash inside and outside (Figure 17). Wear protective glasses.
15. Open the denture lingually and create enough space for the female part (Figure 18).
16. Check in the mouth that the denture does not rock (Figure 19).
17. Temporary insertion of a spacer (Order No. 052 082) between female part and bar before polymerising the resin. The spacer is removed again after integration. Align the asymmetrical retention of the gold female part depending on aesthetic and functional considerations (Figure 20).
18. Then block out undercuts in the area of the SFI-Bar® and the implant adapter (Figure 21).
19. **Important:** Lamellae must be clear of resin up to half-way to ensure the best possible elastic properties over a long service life. This exposure of the lamellae also provides access for activation with a suitable instrument.
20. Attach denture and carefully fix gold female part temporarily with resin. The final integration should be done in the laboratory under optimum conditions for material processing (Figure 22).
21. Ready-integrated female part (Figure 23).
22. Finished denture inserted in the patient's mouth (Figure 24).

Note
We recommend fabricating a customized reinforcing framework when refabricating the denture in the laboratory.

Activation / Deactivation
Use the activator set (Order No. 070 198) for activation by carefully pressing inwards (Figure 25). To deactivate a female part seated too tightly, push the deactivator macro (Order No. 070 201) into the female part (Figure 26) until the desired friction is achieved.
Note: The gold female part is milled and highly stable. This is a great advantage in terms of long-term stability.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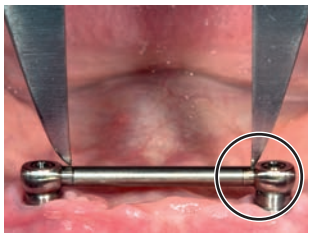
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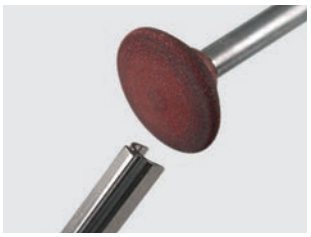
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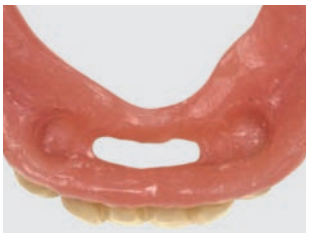
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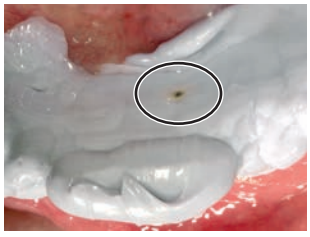
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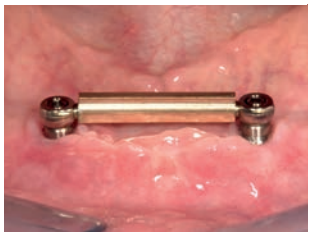
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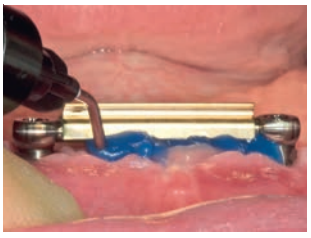
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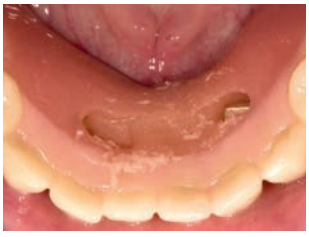
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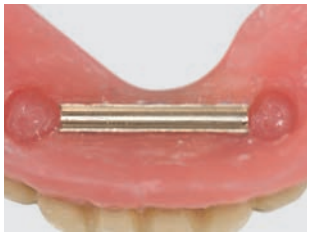
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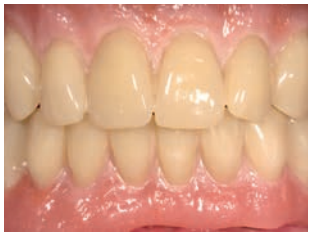
Fig. 24


Fig. 25

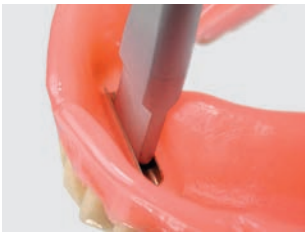
Fig. 26

Aftercare
Inside the mouth, retainers for prosthetic work are more or less exposed to stresses in a constantly changing environment, and hence wear. Wear occurs everywhere in everyday situations and cannot be avoided, only reduced. The intensity of wear depends on the system as a whole. Our endeavour is to use materials that are optimally matched to one another, in order to reduce wear to an absolute minimum. The good fit of the denture on the mucosa has to be checked at least once a year and a lining may have to be provided in order to eliminate swinging movements (overloads), especially in the case of free-end prostheses. We recommend replacing the friction insert (wearing part) at the annual check-up as a precaution.

Patients can obtain information and recommendations about the use, removal and care of prostheses on the patient website at www.cmsa.ch/dental/infos.

Care & cleaning
Ideally you should clean your teeth and your denture after every meal. Cleaning your denture also involves cleaning the connecting element. The gentlest method is to clean the connecting element under running water with a soft toothbrush. For the most thorough cleaning, the denture has to be placed in a small ultrasonic device with a suitable cleaning additive. High-precision attachments must never be cleaned with toothpaste because this can cause damage. You should also be wary of unsuitable cleaning solutions or tablets. These can also damage the high-quality connecting element or interfere with its functioning. The connecting elements fixed in your mouth, e.g. on remaining teeth or on implants, must be cleaned only by using water and a soft toothbrush as well as an interdental brush. Do not use toothpaste in order to avoid premature damage to the connecting element. Ensure the attachment is cleaned regularly to avoid soft tissue inflammation.

Please contact your Cendres+Métaux agency for advice and additional information.

Disclaimer
Upon publication, these instructions for use supersede all previous editions.

The manufacturer is not liable for any damages due to the user disregarding the instructions for use below.

This attachment is part of a comprehensive conception and may only be used or be combined with the corresponding original components and instruments. If this is not the case, any responsibility by the manufacturer will be refused.

In case of complaints the lot number must always be specified.

Markings on the packaging / Symbols

	Manufacturer
	Catalogue number
	Batch code
	Quantity
	Consult instructions for use
Rx only	Caution: US Federal law restricts this device to sale by or on the order of a licensed (healthcare) practitioner.
	Cendres+Métaux products with the CE mark fulfill the requirements of the Medical Device Directive 93/42/EEC.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Caution, consult accompanying documents