SFI-Bar® 4-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
070 201 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.

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

T = Pure titanium
Ti > 98.9375 %

G = Galak

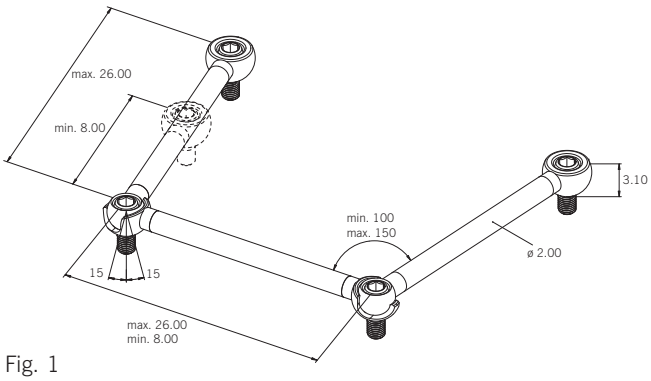

Fig. 1

Rx only

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

CENDRES+ MÉTAUX

Cendres+Métaux SA
Rue de Boujean 122
CH-2501 Biel/Bienne

Phone +41 58 360 20 00
Fax +41 58 360 20 11
info@cmsa.ch

www.cmsa.ch/dental

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

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®

Female part with retention inserts T (titanium female part)
Integration: polymerising/bonding T = Pure titanium

Retention inserts G
G = Galak, mouth-resistant plastic

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 4 implants
Upper jaw:
Connecting 4 implants 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® 4-Implant in the lower jaw, provided the minimum implant distance is > 10 mm and the patient is suitable for lengthy intraoral work. It is imperative to read and follow the handling instructions.

Contraindications
– Immediate loading SFI-Bar® in the upper jaw.
– SFI-Bar® 4-Implant in the upper jaw, applied directly in the patient's mouth.
– Extension of the bar superstructure.
– Implant spans < 8 mm, > 26 mm (Figure 1).
– Implant divergences > 15° (Figure 2).
(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.

The instructions describe the procedure in the laboratory and can be adapted to the intraoral procedure, except for points 6 and 12 of the instructions, points 2 and 3 for titanium female part and points 1 and 2 for gold female part.

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.
– Shortening the pins (Figure 7–11) in case of implant spans < 15 mm will continuously reduce the telescope-type, aspiration-secure retention of parts. The following must be heeded when inserting.
– Before mounting, cement small tube bars to a pin with AGC Cem (FDA Regulation Number 872.3275).
– **Prophylaxis:** Seal the cavities and fissures with antibacterial, high-viscosity silicone material (Figure 12).
– The cohesion of the parts can be increased by coating the pins with silicone.
Warning: No cutting work in the patient's mouth.

1. Ascertain length of implant adapter by aligning the bar parallel to the occlusal plane at least 1 mm above the gingiva (Figure 4).
2. Tighten implant adapter with screwdriver (Order No. 07000114) and torque wrench (Order No. 07000109) in the implant analogue.
3. Detach tube bars from the pre-mounted SFI-Bar® (Figure 5), ensuring that the parts are not mixed up (Figure 6).
4. Use the hex screwdriver (Order No. 07000115) to screw onto the implant adapter, align and tighten the two large ball joints at the end and the pre-mounted parts (small ball joint in the half shell ball) in front (Figure 7).
5. The pins of the ball joint can be shortened, if necessary. Mark the cut-off point. Shorten the length of both pins equally (**Important:** minimum implant distance is 8 mm!). Keep the gap between the two pins as small as possible (Figure 8).
6. Shorten on the model (Figure 9) and remove flash (Figure 10). For laboratory use only. No cutting work in the patient's mouth. Wear protective glasses.
7. Slightly loosen the fixation screws on the ball joint in order to align the pins (Figure 11).
8. Slide tube bar gauge (Order No. 07000106) onto the tube bar and fix by turning the retaining screw (Figure 12).


Fig. 2

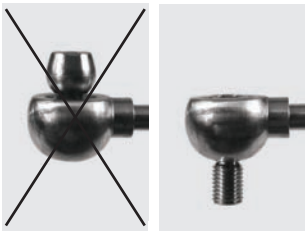
Fig. 3


Fig. 4

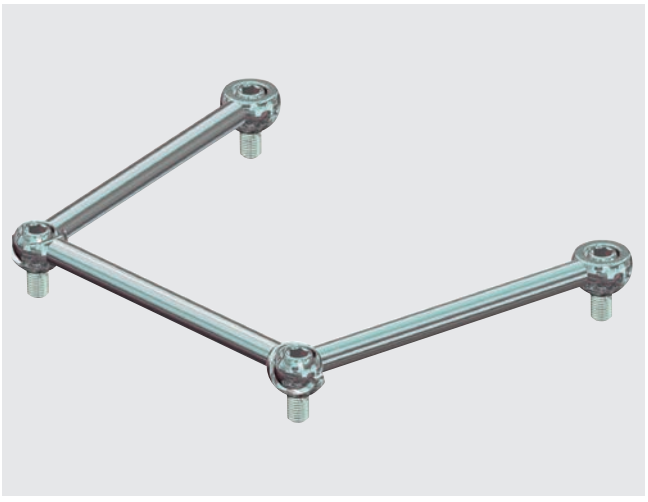
Fig. 5

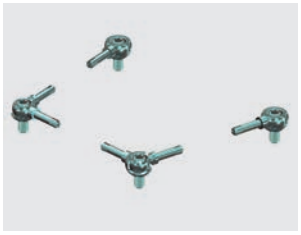
Fig. 6

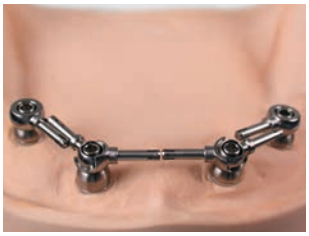
Fig. 7

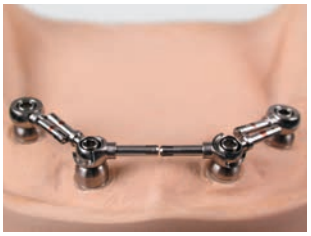
Fig. 8


Fig. 9

9. On the model, slide the tube bar with the tube bar gauge onto the pin of the ball joint until it engages so that the convex part of the tube bar gauge can be fitted onto the implant adapter (Figure 13).
10. Carefully loosen retaining screw. Now the tube bar gauge can be fitted onto the implant adapter by pushing on the tube bar. Press slightly and retighten the retaining screw. The tube bar must fit snugly on the ball joint (Figure 14).
11. Remove tube bar gauge incl. tube bar from the model (Figure 15).
12. 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 16). Remove flash inside and outside. No cutting work in the patient's mouth. Wear protective glasses.
13. Slide the shortened tube bar onto the two ball joints. Tighten fixation screw with hex screwdriver (mounted in Thomas spanner key Order No. 070221) (Figure 17).
14. **Control:** The SFI-Bar® is seated tension-free if the pre-mounted restoration can be screwed in on the implant adapter without considerable effort.
15. Proceed in the same way for the other two tube bars (Figure 18).
16. In the case of small bar components, cement the tube bar with AGC Cem (FDA Regulation Number 872.3275) on one side (Figure 19) to prevent components from falling apart in the mouth when finally mounted.
17. The SFI-Bar® is now ready-mounted on the model and ready for fabrication of the prosthetic reconstruction (Figure 20).

Insertion in the mouth

– Tighten the implant adapter with the screwdriver and the torque wrench with the defined torque while protecting against aspiration in the mouth. The torque details can be found on the package label.
– Tighten the SFI-Bar® with the hex key and the fixation screw on the implant adapter with the defined torque. 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.

Denture fabrication

There are two types of female parts available for the SFI-Bar®.

a) Titanium female part (T) made of pure titanium, which can be activated with replaceable retention inserts in different retaining forces, length 47.5 mm.
   – Order No. 05000358, six retention inserts yellow (low retention) and red (normal retention) are included.
b) Gold female part asymmetrical in Elitor® (gold alloy), lamellae can be activated, length 30 mm.
   – Order No. 05000344.


Fig. 10

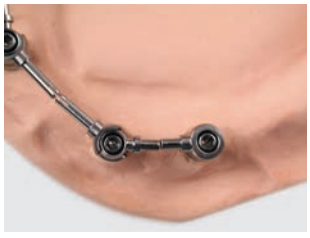
Fig. 11


Fig. 12


Fig. 13

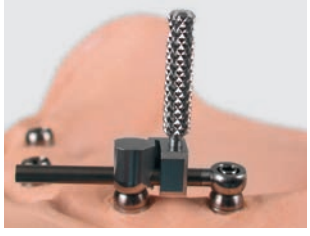
Fig. 14


Fig. 15

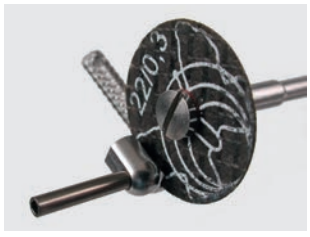

Fig. 16


Fig. 17

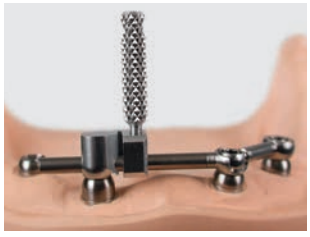
Fig. 18


Fig. 19


Fig. 20

a) Titanium female part

1. Measure the maximum possible tube bar length between the implants, including support on the pins of the ball joint (Figure 21).
2. Place a cutting disc (max. cutting width 0.30 mm) in the groove provided to cut the female part to the possible maximum length. The groove simultaneously acts as the guide for separating with the cutting disc (Figure 22). No cutting work in the patient's mouth. Wear protective glasses.
3. After separation, remove flash inside and outside (Figure 23). No cutting work in the patient's mouth. Wear protective glasses.
4. Then mount 2 retention inserts (except for 1-part) onto both ends of the housing (Figure 24). Mounting as described in «Activation / Deactivation».
5. Attach and block out female parts, duplicate model and fabricate individual reinforcing framework (Figure 25).
6. Finished framework (Figure 26).
7. 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.
8. Then block out undercuts with soft wax in the area of the SFI-Bar® and the implant adapters (Figure 27).
9. The titanium female part must be completely coated with the resin of the denture.
10. Ready-fabricated denture (Figure 28).

Adjusting the retaining force

Removing retention insert

Use the tweezers (Order No. 070 347) to pinch the two lamella ends together. As a result, the insert disengages from the retention and can be removed. Once a retention insert has been removed, it must not be re-used because the retention groove might be damaged. Similarly, a new retention insert must not be used if any damage to the retention groove is noted (Figure 29).

Inserting retention insert

1. Place retention insert on the insert positioner (Order No. 070 00 036). The retention insert is held securely in the instrument by the two side lamellae (Figure 30).
2. Apply slight pressure by pushing on the female part in order to find the correct position of the retention insert (Figure 31).
3. As soon as it engages in the groove, the retention insert is slotted into its final position. This locking in place is tangible and audible (Figure 32).

Note:

– The retention inserts used for processing must not be used for the patient.
– Depending on the retaining force required, several different retention stages may be inserted. So that the patient can quickly get used to handling the new denture, inserts with low retention should be used as little as possible for 2 – 4 weeks.
– Newly inserted retention inserts: the retaining force will self-adjust after about two weeks, but initially it is slightly higher.
– For long female parts, at least place a retention insert at both ends in order to achieve ideal distribution of forces.

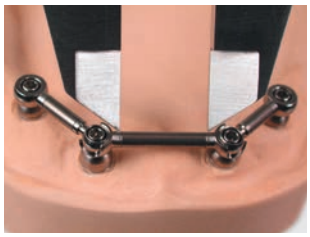
Fig. 21

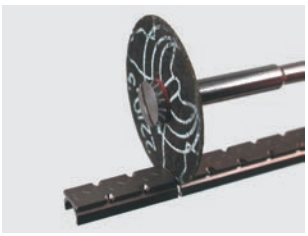
Fig. 22


Fig. 23


Fig. 24


Fig. 25

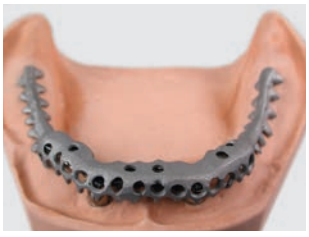
Fig. 26

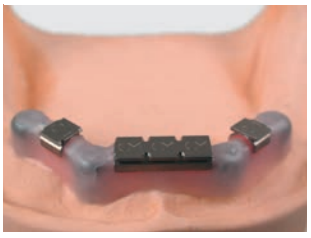
Fig. 27

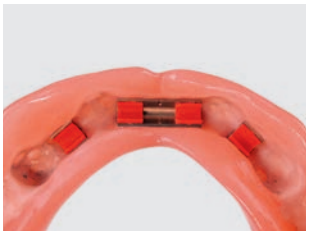
Fig. 28

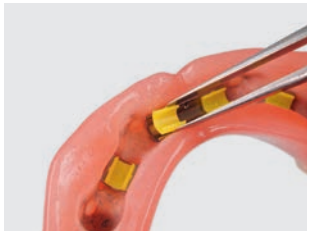
Fig. 29


Fig. 30


Fig. 31

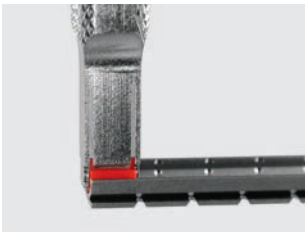
Fig. 32

b) Gold female part

1. Ascertain length of female part (make full use of the maximum length), cut to size and remove flash. No cutting work in the patient's mouth. Wear protective glasses.
2. Grooves can be worked into the retention of the gold female part to provide space for the framework (Figure 33). No cutting work in the patient's mouth. Wear protective glasses.
3. Align the asymmetrical retention of the gold female part depending on aesthetic and functional considerations. Attach and block out female parts (Figure 34).
4. Duplicate model and fabricate individual reinforcing framework (Figure 35).
5. Before incorporating the gold female part, mount the spacer (it will be removed again after incorporation) and block out undercuts in the area of the SFI-Bar® and the implant adapters. **Important:** lamellae must be clear of plastic up to half-way in order to guarantee optimum elastic properties for a long service life. This exposure ensures there is access for activation with suitable auxiliary instruments (Figure 36).

Activation / Deactivation

Use the activator set (Order No. 070 198) for activation by carefully pressing inwards (Figure 37). To deactivate a female part seated too tightly, push the deactivator macro (Order No. 070 201) into the female part (Figure 38) 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.

Fig. 33

Fig. 34

Fig. 35

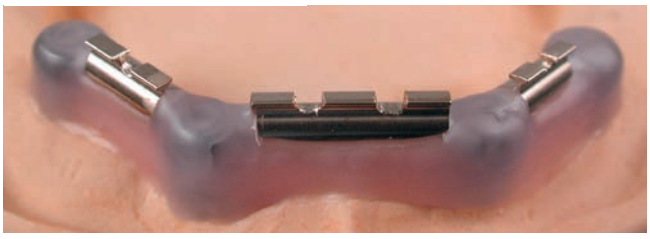

Fig. 36

Fig. 37

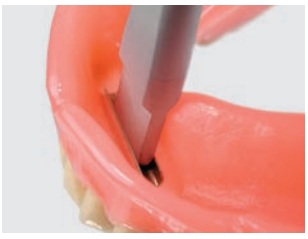

Fig. 38

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