PRECI-BAR

Riders

INSTRUCTIONS FOR USE

Rev. 02.2025

EN - English version

CE 0477 MD

ATTACHMENTS FOR DENTAL PROSTHESES

Medical device according to Regulation (EU) 2017/745 - Class IIa

Intended use: Medical devices for prosthetic dentistry for anchoring combined and removable dental prostheses.

Intended users: Medical devices for exclusive use by professional dentist and dental technician.

Patients target group: Adult patients with problems with the chewing system, who require clinical dental treatment to restore functions through the application of combined or removable dental prostheses.

Expected clinical benefit: Restoration of the chewing function and the aesthetics of the chewing system.

Contra-indications: Do not use the devices for purposes other than their intended use. Not to be used on patients who are allergic or intolerant to the materials constituting the devices, in particular for attachments containing Nickel; any allergies should be analyzed during the clinical planning phase. If necessary, subject the patient to an allergy test to verify product tolerability. Do not use the devices continuously; instruct the patient to remove the dental prosthesis for daily cleaning and the night break.

Warnings: Before each use it is necessary to check the integrity of the device; if any parts are detached, oxidized, fractured, broken or showing signs of wear, do not use them.
Dental attachments are DISPOSABLE devices, supplied in NON-STERILE packaging.
Reuse of products marked for single use can compromise their safety, functionality and performance. Single-use products have not been evaluated for their reuse/reprocessing, which carries an increased risk of transmitting infections.
Dental attachments produced with PALLAX (PA) contain cobalt; no information is available regarding safety and efficacy in the treatment of pregnant or breastfeeding women.
If present, cobalt and nickel are indicated on the label (PA: Co 2%, IN: Ni 11%).

Interference: Attachments have not been assessed in terms of safety, heating, migration or compatibility in the magnetic resonance imaging (MRI) environment. The removable prosthesis can instead be removed before the diagnostic investigation without incurring risks and/or interference during MRI investigations.

Maintenance: Instruct patient to use a toothbrush (manual or electric) and a traditional mouthwash for rinsing and daily cleaning of the dental prosthesis. At least an annual check-up by the dentist is recommended. For more information on patient and/or professional maintenance activities, see the document "General maintenance principles" available on download.ckpl.eu.

Cleaning, washing: Proper cleaning is essential for reducing risks and for prevention. To perform these operations correctly, we recommend that you follow the instructions below.

- Dental attachments are supplied clean and washed according to a protocol validated by Nobil Metal.
- It is important that before being used, the dental prostheses are subjected to a cleaning and washing process with a validated method based on the residues of the work carried out by the user.

Disposal: The devices must be disposed of in compliance with relevant legislation in force; if they are used, they must be disposed of in accordance with biological waste disposal legislation in force.

Disclaimer: The dental attachments must be used by specialised personnel who are familiar with the clinical protocols of use and are able to recognise any defects of the devices. The manufacturer denies all liability for direct and/or indirect damages arising from the user's inexperience, any changes made by the user to the original form of the devices, their improper use and/or incorrect storage and treatment.

Notice about serious incidents: If, during use of the devices or in the context of their use, a serious incident should occur, the patient and/or the user must report it to the competent Authority of the Member State where the event occurred and to the manufacturer Nobil Metal SpA, specifying the code and lot number of the concerned product.

Summary of safety and clinical performance: The summary of the safety and clinical performance (SSCP) for the dental attachments can be consulted on the European medical devices database (Eudamed) at the following link: ec.europa.eu/eudamed. The search can be made by means of the basic UDI-DI included in the EU Declaration of Conformity.

Product description: The PRECI-BAR rider system on horizontal bar (Dolder) is suitable for use with root caps, crowns and implants. The bar-mounted rider system is widely used with excellent results in the presence of only two pillars or more in different positions. The system, in addition to giving stability to the prosthesis, allows the patient to get used to it very easily.

Materials: The riders are available in stainless steel (IN), ORAX (OR) and PALLAX (PA) alloys, with Standard or Mini dimensions. The space maintainers (not classified as medical devices) are made of stainless steel for the Mini riders and of brass for the Standard riders.

 Dimensions STANDARD 2.20 mm MINI 1.60 mm	 1100/H/MR/PA 1102/H/MR/PA	 1100/H/MR/OR 1102/H/MR/OR	 1100/H/MR/IN 1102/H/MR/IN

PROCESSING INSTRUCTIONS

Procedure

- Cut the rider as needed (minimum length 9 mm).
- Place the rider on the bar (with dynamic oval profile use the space maintainer).
- Eliminate all undercuts.
- Leave the riders extensions free to allow for activation or deactivation.
- Proceed to the preparation of the acrylic with the desired technique.
- After finishing the curing, remove the space maintainer, clean the rider and activate it.

Bar structures can be prepared with CAD/CAM technology.

Legend of symbols shown on the label			
	Instructions for use in electronic format		Batch number
	CE conformity mark for class IIa and IIb devices		Identifier code
	CE conformity mark for class I devices		Medical device
	Not reusable		Supplied in NON-STERILE packaging
	Attention, read the instructions for use		
	Manufacturer		Distributor
(01) XXXXXXXXX	UDI device identifier (UDI-DI)		Unique Device Identifier

The instructions for use can be consulted on download.ckpl.eu
Technical doubts or additional questions: send an e-mail to info@ckpl.eu

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