

ATTACHMENTS LV

LV KON

Frictions for removable dental prosthesis



INSTRUCTIONS FOR USE

Rev. 05.2021

EN - English version

MD

CE



FRICIONS FOR REMOVABLE DENTAL PROSTHESIS

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

Intended use: Medical devices for anchoring 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 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; any allergies should be analyzed during the clinical planning phase. 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.



The frictions for dental prosthesis 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.

Interference: There are no risks and/or interferences during the carrying out of diagnostic investigations (magnetic resonance) on patients with the devices in question. The removable prosthesis can be removed before the diagnostic investigation.

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.

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 frictions for dental prosthesis developed by Nobil Metal 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. Nobil Metal 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 incident: 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.

Product description: LV KON is a telescopic friction system, developed to offer retention for partial, full and implant supported restorations.

LV KON frictions are supplied in various degrees of elasticity and hardness, characterized by a different degree of retention. Each degree of retention was given a specific color to facilitate identification.

The LV KON system also includes the laboratory duplication accessories (no medical devices), necessary for the processing and preparation of the mobile prosthesis.

Materials: The LV KON frictions and the accessory for direct modeling (MD) are made of biomedical grade Polyether block amide Pebax (PBA); the accessory for duplication technique (DS) is made of castable Polystyrene.

FRICTIONS FOR REMOVABLE DENTAL PROSTHESIS					
TYPE		RETENTION	TYPE	RETENTION	
	LV KON 0 WHITE H: 10 mm W: 3 mm T: 1.07 mm	REDUCED		LV KON 3 YELLOW H: 10 mm W: 3.02 mm T: 1.09 mm	MEDIUM
	LV KON 1 BLUE H: 10 mm W: 3,02 mm T: 1.09 mm	REGULAR		LV KON 4 RED H: 10 mm W: 3.04 mm T: 1.15 mm	STRONG
	LV KON 2 GREEN H: 10 mm W: 3,02 mm T: 1.09 mm	NORMAL		LV KON 5 VIOLET H: 10 mm W: 3.04 mm T: 1.15 mm	EXTRA-STRONG
LABORATORY ACCESSORIES					
	LV KON MD WHITE H: 10 mm W: 3 mm T: 1 mm			LV KON DS ORANGE H: 10 mm L: 3 mm S: 1 mm	

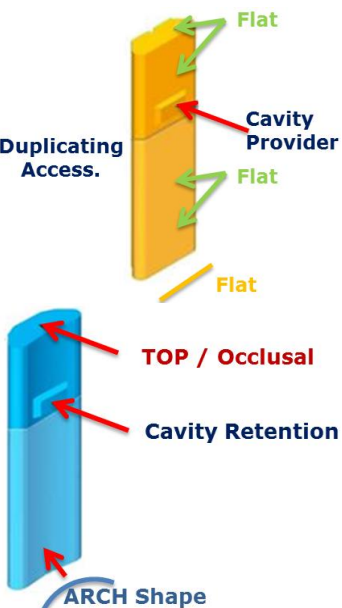
PROCESSING INSTRUCTIONS

To get the best results with LV KON, you should consider where exactly to place the retention strips in order to obtain a maximum of friction surface in opposite positions.

Fixed primary construction

- Determine the path of insertion and wax-up crowns or bars with a 0° - 2° maximum conicity in the area where you want them to be placed.
- A minimum parallel height of 4 mm and 3 mm large is required to obtain an optimal result.
- 2 till 6 friction strips may be incorporated in a complete restoration.

Removable secondary structure












	Direct modeling technique <ul style="list-style-type: none"> ▪ Place the white accessory KN-852-W, with its flat side with against the parallel wall, shorten it and fix it. ▪ The accessory may be shortened till 4 mm. ▪ Use a strong material such as UNDERWAX to include the accessory in the wax-up of the secondary telescopic part. ▪ Remove the white accessory before investing and casting the secondary construction. ▪ The cavity retention should be perfectly reproduced.
	Duplicating technique <ul style="list-style-type: none"> ▪ Place the orange accessory KN-852-O, with its flat side against the parallel wall, shorten if necessary and fix it. ▪ Prepare the model for the duplication with silicone, and poor the refractory model. ▪ Wax-up around the replica of the accessory with 0.3 mm thickness.
	CAD/CAM technique <ul style="list-style-type: none"> ▪ Use only the STL files available on lvattachments.nobilmetal.it

Relining / Rebasing

- Proceed the usual way to take the impression with the retention strips.
- Remove the retention strips from their cavity.
- Fill up the space of the cavities with plaster/silicone and separate before pouring the stone model
- Proceed as usual and, at the end, replace all retention strips



Legend of symbols shown on the label

 lvattachments.nobilmetal.it	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
	Manufacturer		Attention, read the instructions for use
(01) XXXXXXXXX	UDI device identifier (UDI-DI)		Unique Device Identifier



You can find the instructions for use on lvattachment.nobilmetal.it
 Technical doubts or extra questions: send an e-mail to attachments@nobilmetal.it



Nobil-Metal S.p.A.

Strada San Rocco, 28 14018 Villafranca d'Asti - Italy
 Tel. +39 0141 933811 - Fax +39 0141 943840
 E-mail: contact@nobilmetal.it - <http://www.nobilmetal.it>