Parmax Paralight

INSTRUCTIONS FOR USE

MD Rx Only CE 2862

ENGLISH

This IFU is available for download on our website: www.parmax.se/ifu.

These instructions inform the user about the recommended procedures when using **Parmax Paralight Posts**. They are intended for use by clinicians with a basic level of restorative dentistry and endodontic training. It is the responsibility of the clinician to stay informed, educated and trained. The printed guidelines, including Precautions and Notes, are to be regarded as additions to accepted clinical procedures and protocols.
Paralight post system consist of reamers and specially fitted posts in different sizes. The posts are placed temporarily or permanently in the prepared root canal. The anatomically shaped reamers and posts correspond to the natural morphology of the root canal.
Parmax Reamers are designed to be used in standard contra angle handpieces, at low speed, not exceeding 10,000 rpm. The shape of the reamers corresponds to the shape of the Paralight Posts. The Reamers are available in various lengths, and in four different diameters, #3-6. Actual diameter is shown with corresponding number of grooves on the shank (see Chart 1). The reamer system is size matched to ensure passive seating, when utilizing a size 3 post with a size 3 reamer there is no engagement of the canal walls. This prevents tension build-up and risk of root fractures.

Material:	*Post:* Transparent glass fiber/epoxy solid rod. *Accessories* *Reamers*: Stainless Steel. *Depth Stop*: PVC-compound.
Intended Purpose:	Prefabricated fiberglass anchorage posts for retention of core materials in endodontically treated teeth.
Intended User:	Licensed Dentist.
Patient Population Group:	Patients with permanent teeth that are root filled and have extensive coronal damage.
Expected Clinical Benefit:	Paralight posts have retention properties with all standard restorative resin materials and suit a wide array of indications and requirements. They provide more esthetic results as compared to metal posts, with reliable and proven results.
Performance Characteristics:	Paralight posts and reamers are a state-of-the-art post system for retention of core materials in endodontically treated teeth with improved mechanical adhesion via a roughened surface. Paralight posts transmit light, allowing for complete polymerization of composite inside the canals and reflect natural hues for improved esthetics.
Contra-indications:	Patients suffering from bruxism or suspected bruxism, those with deep overbites, and those with insufficient crown to root ratio. Patients with known allergy to materials: reamers contain nickel.
Safe Disposal:	Posts and depth stops shall be disinfected, then the devices can be disposed of in normal waste in the clinic, according to local regulations. Dull reamers shall be disinfected, then the device can be disposed of in normal metal waste in the clinic, according to local regulations.

PRECAUTIONS:
• Delivered nonsterile and should be disinfected prior to use.
• Posts are intended for single use to avoid risk of infectious cross contamination.
• Reamers are delivered factory clean and should be cleansed and sterilized before use according to provided disinfection and sterilization instructions for an aseptic procedure.
• All other instrumentation used in the clinical procedure should be autoclaved with steam sterilization prior to use. The facility should validate its own autoclave steam sterilization machine in accordance with a recognized standard.

⚠ **CAUTION:**
• Extreme care should be observed to prevent accidental swallowing or aspiration of endodontic posts or other related components used in this procedure. Preventive practices (rubber dam, floss ties or throat pack) should always be utilized. If such an accident should occur, immediately contact a physician.
• Damaged posts should be discarded.
• Posts are designed for passive placement in root canals to prevent risk of root fracture.

PRE-USE INSTRUCTION FOR POSTS
Posts are single use items; disinfect them with alcohol and air dry before use.

REAMERS REPROCESSING INSTRUCTIONS
Reprocessing instructions in accordance with ISO 17664-1.

Caution:	Only use chemicals suitable for stainless steel. Reamers are delivered factory clean and after removing their wrappings they shall be cleansed, disinfected and sterilized before first use and between uses according to the instructions below.
Limitations on Reprocessing:	Reamers are intended for re-use and are delivered factory clean. The devices should be cleansed and sterilized before use according to provided disinfection and sterilization instructions for an aseptic procedure. Discard reamers when dull or damaged.
Initial Treatment at the Point of Use:	Instruction: Wipe off the devices after use to prevent soil and debris to dry onto the instrument. Perform cleaning as soon as possible after use. Do not exceed 2 hours.

CLEANING: MANUAL & ULTRASONIC BATH

Equipment:	Soft bristle brushes of various sizes and ultrasonic bath.	
Detergent:	Follow the agent manufacturers recommendations for concentration and temperature. Manual: Enzymatic or low-alkaline (pH ≤8) detergent suitable for manual cleaning. Ultrasonic bath: Enzymatic or low-alkaline detergent with minimal foaming characteristics.	
Water quality:	Minimum drinking water quality should be used for manual cleaning and distilled or de-mineralized water for ultrasonic bath and final rinse.	
Instructions:	1. Immerse instruments/disassembled parts in freshly prepared cleaning solution as per manufacturer's instructions although maximum 40°C. Clean mechanically with a brush, working beneath the liquid level, until visibly clean. 2. Rinse thoroughly 3. Clean in an ultrasonic bath for a minimum of 5 minutes at maximum 60°C, using a frequency of 35-45 KHz and power min.150 W. 4. Rinse thoroughly for min. 30 seconds. 5. Carefully dry instruments with lint free wipes or clean compressed air (Class 1 or better, according to ISO 8573-1:2010). 6. Inspect cleanliness. If debris remains after cleaning, repeat from step 1.	
Disinfection: **Manual**	Detergent:	Immerse into disinfection solution suitable for stainless steel. Follow the manufacturer's instruction of disinfection solution for concentration and time. Validation performed with 70% Ethanol; 10 minutes soaking followed by air drying in safety cabinet.
Cleaning and disinfection: Automated	Equipment:	Washer-disinfector (validated according to EN ISO15883).
	Detergent:	Enzymatic or low alkaline, suited for medical devices.
	Rinsing agent:	Non-corrosive, neutral rinsing agent, suited for medical devices. Follow agent manufacturer's instructions regarding concentration and temperature.
	Water quality:	Minimum drinking water quality should be used for cleaning and distilled or de-mineralized water for final rinse/disinfection.
	Instructions:	1. Load the instruments/disassembled parts in the washer disinfector. Use a suitable instrument tray. 2. Run program suited for medical devices. Validation performed with following parameters: - Pre-wash in cold water, 2 x 2 min. - Main wash with detergent at minimum 55°C, 10 min. - Rinse in warm water, 2 x 1 min. - Final rinse/disinfection in de-mineralized water at 90°C, minimum 1 min. - Drying at 110° C, minimum 15 min. 3. When unloading, control that the instruments are clean. If necessary, repeat from step 1 or use manual cleaning.
Inspection and Maintenance:	The reamers should be replaced when their functioning and/or performance is affected. Visually inspect the devices after each use. Discard when dull or damaged.	
Packaging for Sterilization:	Equipment:	Standard packaging pouch. Sterile goods packing according to EN 868-5.
	Instructions:	1) Place in individual sterilization pouches. 2) Check that the bag is not stretched. 3) Check correct sealing. Place pouches plastic towards plastic and paper towards paper.
Sterilization:	Caution:	The instrument must be cleaned and disinfected before sterilization.
	Equipment:	Steam autoclave (validated according to EN 13060, EN 285, EN 17664).
	Instructions:	Run minimal cycle: Steam temperature/pressure: Mininum 134°C (273°F) / 3.06 bar (27 psi). Steam exposure time: minimum 3 min. Vacuum drying: minimum 6 min.
Storage	After sterilization, place labeled and sealed sterilization pouch in a dry and dark place. Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.	

How to Use:
After endodontic therapy, root-filling material is removed to the predetermined depth with a Pathfinder, Gates-Glidden drill, peeso reamer and/or hot instrument (Fig.1). A minimum 4 mm of the root-filling material should remain apically. Radiographic verification is recommended.
The preparation should include at least 1.5 mm ferrule of sound tooth structure around the circumference of the preparation.
The preparation is commenced by using the Paralight Reamers [PLR series].

Choosing Post Dimension:
The appropriate size post is a combination of the diameter of the reamer, the length of the canal, and the height of the crown. The sleeve on the post is color coded to correspond with the post's diameter. The grooves on the shaft of the reamer correspond with the reamer's diameter (see Chart 1).
The size number of the post coincides with the last used reamer and the length should be as long as possible without the post head interfering with shape, function, and esthetic properties of the finished restoration.
The fit in the root canal is confirmed without rotating the post and the colored sleeve is moved to the intended post height. The excess is cut with a water-cooled diamond instrument and the post are disinfected with alcohol & air-dried (Fig.4). The prepared root canal shall be acid etched then thoroughly cleansed and dried with paper points prior to placement of the post (Fig.5).

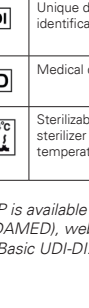
Core Build-up:
Use a flowable dental composite of choice according to the manufacturer's instructions. The bonding agent is applied to the post and in the opening of the prepared root canal to coat the wall (Fig.6). Light-cure composite is introduced into the canal (Fig.7). Dual-cure resin is recommended in canals deeper than 10mm. Use an instrument of choice (i.e.: locking tweezer) to slowly insert the post to full depth allowing excess composite to vent (Fig.8). The light cure is placed directly over the Paralight post supporting it in place (Fig.9). Light cure for 1-2 minutes depending on volume and depth. The core can now be prepared for the final aesthetic restoration (Fig.10).

Post-Op:
Provide the patients with post operative instructions on hygiene and maintenance. In the event of any malfunction, patients should contact their dental provider.

Parmax conforms to the vigilance system according to EU requirements. In the event of serious incident in relation to the device, events shall be reported to Parmax and the competent authority of the Member State in which the provider and/or patient is established without delay.

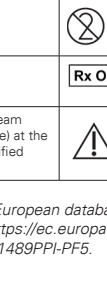
	#	L	Ø		
XS	3	15	1.3		
S	4	15	1.45		
M	5	17	1.6		
L	6	19	1.75		

Chart 1



Pathfinder

Fig.1



Parmax Conical Reamer

Fig.2

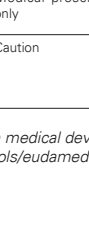


Fig.3

Diamond Alcohol Dry

Fig.4

Etch H2O Dry

Fig.5

Bonding Agent

Fig.6

Flowable Resin

Fig.7

Post Cementation

Fig.8

Final Post & Core Restoration

Fig.9 Fig.10

CE	CE marking		Manufacturer
	Consult instructions for use		Date of manufacture
	Ultrasonic bath	LOT	Lot number
	Washer-disinfector for thermal disinfection	REF	Catalog number
UDI	Unique device identification		Do not re-use
MD	Medical device	Rx Only	Medical prescription only
134°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified		Caution

SSCP is available in the European database on medical devices (EUDAMED), website: https://ec.europa.eu/tools/eudamed by this Basic UDI-DI: 735011489PPI-PF5.

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