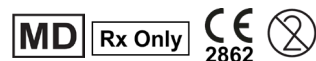


Parmax Posts System

INSTRUCTIONS FOR USE

ENGLISH



BL-6581-05_2022-09-30

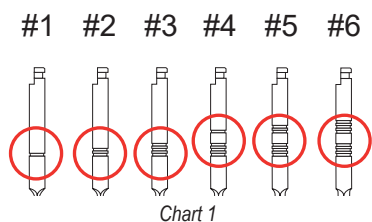
This IFU is available for download on our website www.parmax.se/ifu in the following languages:



These instructions inform the user about the recommended procedures when using the Parmax Posts System. They are intended for use by clinicians with basic training in dentistry. 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.

Parmax Posts System consists of reamers and specially fitted posts in different sizes and materials. The posts are cemented temporarily or permanently in the prepared root canal. The system is to be used by trained dental personnel only.

Parmax Classic 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 Parmax posts. The Reamers are available in various lengths, and in six different diameters, #1-6. Actual diameter is shown with corresponding number of grooves on the shank.



The reamers 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. The threading allows safe re-access to the canal and ease of retrieval, if the need arises. The threading also provides more surface area for better retention and allows excess cement a path to vent out.

Materials	Gold Plated Brass [PG- series] or Titanium [PT- series] Accessories: Reamers: Stainless Steel Keys: Brass
Intended Purpose	Prefabricated dental posts for retention of core materials in endodontically treated teeth.
Intended User	Licensed Dentist.
Patient Population Group	Patients with permanent teeth that are endodontically treated and have extensive coronal damage.
Expected Clinical Benefit	Parmax Posts have retention properties with all standard restorative materials and suit a wide array of indications and requirements. They provide reliable and proven results.
Performance Characteristics	Parmax Posts and reamers are a state-of-the art post system for retention of core materials in endodontically treated teeth with an expandable head.
Contraindications and/or Limitations	Patients suffering from bruxism or suspected bruxism, those with deep overbites, and those with insufficient crown to root ratio. In patients with known allergy to material of the post: Stainless Steel Reamers contain nickel.
Safe Disposal	Posts, dull reamers and keys shall be disinfected then the devices can be disposed of in normal metal waste in the clinic, according to local regulations.

PRECAUTIONS:

- Parmax Posts are delivered non-sterile and shall be disinfected prior to use.
- Parmax posts are intended for single use to avoid risk of infectious cross contamination; chemically disinfect the dental post before use.
- Parmax accessories, including reamers and keys, are delivered factory clean and after removing their wrappings they shall be cleansed and sterilized before use according to disinfection and sterilization instructions for an aseptic procedure.
- All other instrumentation used in this clinical procedure shall be autoclaved with steam sterilization prior to use. The facility should validate its own autoclave steam sterilization machine in accordance with a recognized standard.
- When utilizing the Parmax dispenser, ensure compartment is empty before refilling, to avoid mixing batches, and take note of the new LOT number.
- Parmax posts are non-engaging; they are designed for passive cementation in root canals to prevent risk of root fracture.

CAUTIONS:

- Extreme care must be observed to prevent accidental swallowing or aspiration of endodontic posts or other related small accessory components used in this procedure.
- Preventive practices (rubber dam, floss ties or throat pack) should always be utilized. If such an accident occurs, immediately contact a physician.
- Damaged posts should be discarded.
- Keys contain lead >0.1% w/w.

PRE-USE INSTRUCTIONS FOR POSTS

Posts are single use items; disinfect with 70% Ethanol, 10 minutes soaking followed by air-drying.

How to Use

After endodontic therapy, root-filling material is removed to the predetermined depth with a 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 shall include at least 1.5 mm ferrule of sound tooth structure around the circumference of the preparation. The preparation is commenced by using the Classic [PRA or PRB series] Reamers with a low-speed contra-angle handpiece in sequential order until the desired preparation has been achieved (Fig. 2).

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 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. The prepared root canal shall be thoroughly cleansed and dried prior to cementation of the post (Fig. 3-4).

Cementing

Use the dental cement of choice according to the manufacturer's instructions. The cement is applied on the threaded portion of the post and in the opening of the prepared root canal to coat the wall (Fig. 5). Use an instrument of choice (i.e.: locking tweezer) to slowly insert the post to full depth allowing excess cement to vent (Fig. 6). Avoid active installation by rotating gently back and forth until a slight resistance is met and the post is seated correctly. Radiographic verification is recommended.

NOTE: The Hollow Key may be utilized to rotate the post passively, further spreading cement and eliminating hydraulic pressure. When the cement is completely set, the head of the PG and PT- series posts can be widened by the Cross Key for extra retention of the core material. After the cement has set, remove any excess before completing core preparation (Fig. 7) and fabricating final restoration (Fig. 8).

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

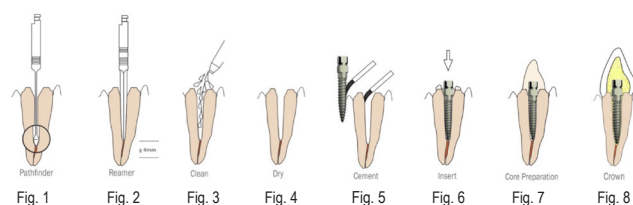


Chart 2

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.

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

STARTER KITS	PG-series	PT-series
60 posts	735011489PG-6036	735008149PTI-60FK
240 posts	735011489PG-240WX	
REFILLS	735011489PG-XAJ	735008149PTI-PFR

REAMERS REPROCESSING INSTRUCTIONS IN ACCORDANCE WITH ISO 17664-1:2021

CAUTIONS:

- 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 I or better, according to ISO 8573-1:2010).
6. Inspect cleanliness. If debris remains after cleaning, repeat from step1.

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.

CLEANING AND DISINFECTION: AUTOMATED

Equipment: Washer-disinfector (validated according to EN ISO 15883-1:2006/ Amd 1:2014).

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 868-5:2018:2018.

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 13060:2014/Amd 1:2018, EN 285:2015/Amd 1:2021, EN 17664-1:2021).

Instructions: Run minimal cycle: Steam temperature/pressure: minimum 134°C (273°F) / 3.06 bar (27 psi). Steam exposure time: minimum 3 min. Vacuum drying: minimum 6 min.


Storage

Follow the instructions provided by the manufacturer of the sterilization pouch regarding the storage conditions and expiration date of the sterilized device.

SYMBOLS GLOSSARY

	Catalog number		Caution		CE marking
	Contains hazardous substances		Consult instructions for use or consult electronic instructions for use		Date of manufacture
	Do not re-use		Washer-disinfector for thermal disinfection		Lot number
	Manufacturer		Medical device		Medical prescription only
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified		Ultrasonic bath		Unique device identification



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