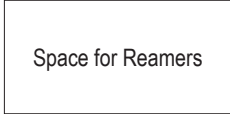


Parmax Reamers

INSTRUCTIONS FOR USE • ENGLISH

BL-6852-00_2024-11-08



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



Refer to the corresponding Parmax Post IFU for further instructions for use.

Material	Stainless Steel.
Intended Use/ Patient Group	Intended to be used as a reaming device, as preparation for an anchorage post.
Intended User	Dentist.
Contraindications	If patients are known to be allergic to any of the materials. Reamers contain nickel.
Safe disposal	The reamers can be used until regarded dull as determined by the Dentist. Dull reamers shall be disinfected then the device can be disposed of in normal metal waste in the clinic, according to local regulations.
Clinical Benefit & Performance Characteristic	Parmax Reamers are part of the endodontic treatment. They allow for sizing and shaping of endodontically treated root canals prior to prosthodontic post treatment.

CAUTIONS

- Sharp – handle with care.
- Extreme care shall be observed to prevent accidental swallowing or aspiration.
- Preventive practices (rubber dam, floss ties or throat pack) should always be utilized. If such an accident occurs, immediately contact a physician.
- 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.

Precautions

- In patients with known allergy to materials: Reamers contain nickel.
- Use medical gloves when handling the device.
- Safe handling of sharps reduces risk of infection and cross-contamination.
- Ensure that the reamer is securely seated in the handpiece by gently pulling it prior to use.
- Reamers are designed to be used in standard contra-angles, at low speed not exceeding 10,000RPM, in sequential size order until the desired preparation has been achieved.
- Limitations on use: discard when dull or bent.

REPROCESSING INSTRUCTIONS IN ACCORDANCE WITH ISO 17664-1:2021

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 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.

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.
















Any serious incident that occurs in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



Parmax Classic Reamers

PRA-1/3FP	PRB-1/3FP
PRA-2/3FP	PRB-2/3FP
PRA-3/3FP	PRB-3/3FP
PRA-4/3FP	PRB-4/3FP
PRA-5/3FP	PRB-5/3FP
PRA-6/3FP	PRB-6/3FP

SYMBOLS GLOSSARY

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