ProUltra® Endo Tips

US

Ultrasonic instruments for use in endodontic therapy

Rx Only
For Dental Use Only

DIRECTIONS FOR USE

1) INDICATIONS FOR USE
ProUltra® Endo tips are ultrasonic instruments for use in endodontic therapy by application of ultrasonic vibration. ProUltra® Endo Tips are used in conjunction with an ultrasonic energy-generating unit to provide the energy for tip oscillation.

2) CONTRAINDICATIONS
None known.

3) WARNINGS
None known.

4) PRECAUTIONS
- The power settings used are ultimately determined by the clinician's experience with ultrasonics and the power needed to safely complete the specific procedure.
- ProUltra® Endo Tips are designed specifically without a water port for increased efficiency, visibility and durability. However, the use of external water is recommended for certain applications, as noted below.
- Indicated power settings are intended for use with the ProUltra Piezo Booster and Satelec P5 ultrasonic units. Settings may not be appropriate for other units. Please refer to the instructions for use of the manufacturer of your ultrasonic unit.
- The tips must be tightened onto the ultrasonic generator handpiece with the enclosed wrench prior to use. Failure to do so will hinder the tip's vibration.
- All endodontic procedures should be performed with sufficient magnification.

5) ADVERSE REACTIONS
None known.

6) STEP-BY-STEP INSTRUCTIONS

Clinical Applications

1) Select the appropriate tip for the procedure, based on the chart below. The specific size endodontic ultrasonic instrument chosen for any specific tooth is based on coronal access, the root anatomy, the procedural application and visibility. ProUltra® Endo Tips number 3 through 5 are used for intracanal obstructions. ProUltra® Endo Tips number 6 through 8 are used for apical.

Tip Selection

Procedure	*Tip No.*	*Use External Water*
Disassembling restorative segments	ProUltra 1 or 2	Optional
Eliminating pulp chamber cores: (amalgams, composites, cements, cast gold)	ProUltra 1 or 2	Optional
Dislodging metal posts	ProUltra 1 or 2	Yes
Removing pulp stones	ProUltra 2 or 3	No
Locating calcified or hidden canals	ProUltra 2 or 3	No
Troughing fins and isthmuses for orifices	ProUltra 2 or 3	No
Removing obturation materials	ProUltra 3, 4, 5, 6, 7 or 8	No
Removing broken instruments	ProUltra 3, 4, 5, 6, 7 or 8	No

2) Choose the appropriate minimum power setting for the tip that is being utilized. (See chart that follows).
3) Increase the power gradually up to the maximum power setting for that tip, as needed maximize clinical performance.
4) The power must be on when engaging dentin.

	Power Setting	
Tip	*Minimum*	*Maximum*
Endo-1	5	13 - 14
Endo-2	5	13 - 14
Endo-3	1	6
Endo-4	1	5
Endo-5	1	4
Endo-6	1	4
Endo-7	1	4
Endo-8	1	4

7) DISINFECTION, CLEANING AND STERILIZATION

Reprocessing Instructions for ProUltra® Endo Tips

I - FOREWORD

Devices that are marked as “sterile” do not require any specific treatment before the first use. For all other devices not labelled “Sterile”, cleaning and sterilization prior first use is required according to section III - STEP-BY-STEP INSTRUCTIONS part 4 to 8 of this DFU.

For those devices that are not labelled “single use”, re-processing of the devices should be carried out as per this DFU. For hygiene and sanitary safety purposes, these instruments must be cleaned and sterilized before each re-use to prevent any contamination.

II - GENERAL RECOMMENDATION

1) Use only a detergent solution, with disinfecting effect, which is approved for its efficacy (VAH/ DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the detergent solution manufacturer. For all metal devices, it is recommended to use anticorrosion disinfecting and cleaning agents.
2) For your own safety, please wear personal protective equipment (gloves, glasses, mask).
3) The user is responsible for the cleaning and sterilization of the product for the first cycle and each further usage as well as for the usage of damaged or dirty devices where applicable after sterilization.
4) It is safest for the practitioner to use our devices only once. Should our devices be reused, we recommend that they should not be used more than 10 times. After each processing they should be carefully inspected before use: the appearance of defects such as deformations (bent, unwound), breakage, corrosion, loss of colour coding or marking, indicate that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.
5) Single use marked devices are not approved for re-use.
6) For the final rinsing step deionised water use is mandatory, whether using an automated washer-disinfector or a manual cleaning method. Tap water is permissible for the other rinsing steps.
7) Avoid device to dry out, prior to, or during pre-disinfection, or cleaning. Dried biological material can be difficult to remove.
8) Use only device appropriated support for reprocessing.
9) Do not use label systems or identification markers directly on the device.

III - STEP-BY-STEP INSTRUCTIONS

	Operation	***Activities***	***Warning and remarks***
1.	Disassembling	- Disassemble the device, if applicable.	
2.	Pre-Disinfection	- Soak all devices immediately after use in a disinfection solution (We recommend the use of Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner at 0.4% for a minimum of 15 minutes). Use a tray made from high density polyethylene or stainless steel. - Brush the device for a minimum of 30 seconds. - Visual inspection under appropriate lighting (min-500 lux), if impurities are still visible continue to brush until complete removal.	- Follow instructions and respect concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on devices). - The pre-disinfection solution should be a specific solution targeted by the supplier for pre-disinfection. It should be used at the dilution specified by the supplier. It should contain, or be combined with a proteolytic enzyme. - The pre-disinfection solution should be aldehyde free (to avoid blood impurities fixation) and without di- or triethanolamines as corrosion inhibitor. Change the pre-disinfection solution regularly i.e. When it becomes soiled, or when efficacy is diminished due to exposure to microbial loads. - Do not use pre-disinfecting solutions containing Phenol or any products, which are not compatible with the devices. - The device must be manually brushed with a soft brush made from either nylon, polypropylene or acrylic.
3.	Rinsing	- Abundant rinsing (at least 1 min) under running water (ambient temperature).	- Use tap water for rinsing. - If a pre-disinfectant solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the cleaning step.

4a.	Automated Cleaning with washer- disinfector	- Place the devices in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices or posts. - Place the devices in the washer-disinfector and execute the defined cycle (Ao value > 3000 or, at least 5 min at 90°C (194°F)). - Use a detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 0.4%).	- Discard any devices with defects (broken, bent,…). - Avoid any contact between instruments or posts when placing in the washer-disinfector use kits, supports or containers. - Follow instructions and concentrations given by the manufacturer of the detergent solution. - Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer. - The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer. - Use only approved washer-disinfector according to EN ISO 15883, maintained and validated regularly. - It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with its DFU The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.
OR			
4b.i	Manual Cleaning assisted by an ultrasonic device	- Place the devices in a kit, support or container (made from stainless steel, polypropylene or titanium) to avoid any contact between devices. - Immerse in the detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 2%), assisted by an ultrasonic device if suitable for at least 15 min.	- No visible impurities should be observed on the devices. - If visible impurities are observed on the devices, the device must be manually brushed with a soft brush (made from either nylon, polypropylene, acrylic) until visible impurities are removed. - Discard any devices with defects (broken, bent, and unwound). - Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution. - It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with the DFU of the detergent solution manufacturer). - The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.
4b.ii	Rinsing	- Abundant rinsing (at least 1 min) under running water (ambient temperature).	- Use deionised water for rinsing. - If the previously used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving.
4b.iii	Drying	- Devices should be thoroughly dried before inspection and packaging.	- Dry with a single use non-woven cloth. - Devices should be dried until visual traces of moisture are eliminated. - Particular attention has to be paid to effectively dry joints or cavities within a device.
5.	Inspection	- If applicable assemble the devices. - Inspect the devices functionality. - Visually inspect devices with naked eye under appropriate lighting (min 500 lux) and sort out those with defects. If impurities are still visible repeat operations from step 4 (automated or manual cleaning).	- Dirty devices must be cleaned again. - Discard devices, which show any defect as described in the General Recommendation above (point 4).
6.	Packaging	- Place the devices independently double-packed in sterilization pouches.	- Device must be double-packaged using paper-plastic pouches for steam sterilization prior sterilization. Ensure that the pouches are suitable for steam sterilization and were validated and manufactured as per ISO 11607 and EN 868-5. - Use an appropriate packaging, moist-heat resistant (141°C, 286°F) and compliant with ISO 11607. - Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers. - For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing. - Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermosealer must be calibrated and qualified. - Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.

7.	Sterilization	- The following sterilization cycles can be used : • 132°C (269.6°F), 4 minutes; • 134°C (273.2°F), 3 minutes; • 134°C (273.2°F), 18 minutes. We recommend a steam sterilization at 134°C / 273.2°F during 18 minutes for the purpose of de-activating potential prions.	- The instruments and posts must be sterilized according to the packaging labelling. - When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded. - Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer. - Use only Pre-Vacuum air Removal steam sterilizer that are matching the requirements of EN 13060 (class B, small sterilizer) and EN 285 (full size sterilizer), with saturated steam. - Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 min. - Respecting the maintenance procedure of the sterilizer is under the responsibility of the the owner and should be performed following the requirements for medical devices sterilization (examples: planning of maintenance, qualification, acceptance criteria of condensate and water as per EN 285, annex 2). - Control the efficiency and acceptance criteria of the sterilization procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters). A special attention should be paid to the packaging integrity if the sterilization cycle 134°C (273.2°F), 18 minutes was used. - Store traceability records and define shelf-life according to packaging manufacturer guidelines. - Shorter sterilization cycles according to local regulations are possible but are not guaranteed to de-activate prions.
8.	Storage	- Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature (typically 15 - 25°C (59 - 77°F)).	- After sterilization, the product should be manipulated with care in order to keep the integrity of the packaging (sterile barrier). - Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date). In case of damage, a complete rework should be performed. - Check the Instructions For Use given by the pouch manufacturer to determine the shelf life of the sterile packaging.

Symbols	EN
	Non-returnable if seal is broken
	Consult instructions for use
	Sterilize before use

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