DIRECTIONS FOR USE

Manufactured by:
DENTSPLY Tulsa Dental Specialties
DENTSPLY International, Inc.
608 Rolling Hills Drive
Johnson City, TN 37604
1-800-662-1202
1-800-597-2779 (fax)
www.tulsadentalspecialties.com

Manufactured in U.S.A.
U.S. and foreign patents pending.

CAUTION:
• U.S. Federal law restricts this material to the sale by, or on the order of a dentist.

INDICATIONS FOR USE:
• Irrigation during root canal therapy
• Debridement of the root canal during root canal therapy

ProUltra® PiezoFlow™ Ultrasonic Irrigation Needles are for use in non-surgical root canal irrigation by application of ultrasonic vibration. The PiezoFlow™ irrigation needles are used in conjunction with a piezo-electric ultrasonic energy-generating unit to provide the energy for tip oscillation. A syringe or other irrigation source is attached to the Luer-lock connection on the ultrasonic needle. Removal of irrigant is through the operatory vacuum source. Syringes, extension tube-sets, and wrenches are available separately (SKU#: PIEZOFLOWAP). Compatible irrigants include sodium hypochlorite (up to 6%), EDTA (up to 17%), Chlorhexidine (up to 2%) and BioPure® MTAD however working times may vary.

CONTRAINDICATIONS:
• Not for use in roots that have immature apices
• Not for use in roots with open/perforated apices
• Not for use with chloroform

WARNINGS:
• Do not operate ultrasonic irrigation needle in the canal without flowing irrigant; overheating of the surrounding root canal anatomy may result.
• Cease flow of irrigant before removing needle from canal or changing canals.
• Do not re-use; patient cross-contamination may occur.
• Do not re-use; re-use of the tip will lead to crystallization of the irrigant; occluding the needle and increasing the risk of unintentional exposure to irrigants. Do not apply excessive force on the syringe.
• Do not over-insert tip into the canal structure; binding can lead to excessive pressure and irrigant extrusion may occur.
• Working times given in this directions-for-use are for NaOCl. Working times for other irrigants may vary.
**ADVERSE REACTIONS:**
None known.

**PRECAUTIONS:**
- The Ultrasonic Irrigation Needle is intended for use only in fully instrumented root canals and prior to obturation.
- Do not autoclave or chemclave; autoclave temperatures and chemicals may damage the ultrasonic irrigation needle.
- Do not operate ultrasonic irrigation needle without flowing irrigant or damage to the ultrasonic irrigation needle may occur.
- Smaller syringes can generate higher pressures on the tubing connections. A 20 ml syringe is the minimum size recommended.
- Do not express irrigant or activate ultrasonic device if needle does not fit loosely in the canal.
- Do not apply excessive force on the syringe.
- Do not bend or cut the ultrasonic irrigation needle.
- Do not use if the tip becomes occluded, bent or obstructed.
- The ultrasonic irrigation needle may not be compatible with all ultrasonic units. A 3 mm x .6 thread is specified. The outside diameter of the threaded hub is approximately 5.8 mm.
- Operation of the ultrasonic booster above the recommended settings may cause damage to the ultrasonic irrigation needle.
- For the use of ultrasonic units, please refer to the instructions for use from the manufacturer.
- For optimal use of the ProUltra® PiezoFlow™ ultrasonic irrigation needles, use the recommended booster settings and flow rate (See Step-By-Step Instructions).
- A mechanical syringe pump, a peristaltic pump or a syringe dispensing gun may be used to help deliver the irrigant. Adjust/maintain the flow rate to 15 ml per minute.
- The tips must be gently tightened onto the ultrasonic generator handpiece with the ProUltra® Wrench prior to use. Failure to do so will hinder the tip's vibration.
- Protective equipment including gloves, faceshields, and protective bibs should be used.
- Do not use this product if the tooth is not properly isolated with a dental dam and protective equipment. Gloves and face-shields should be used.
- All root canal procedures should be performed with sufficient visibility.

**STEP-BY-STEP INSTRUCTIONS:**
- Use an orifice shaping instrument such as an EndoAccess™ Kit Pulp shaper bur, or a ProTaper® SX or S1 file as necessary to ensure the 0.5 mm diameter Ultrasonic Irrigation Needle has sufficient space to enter the root canal along the straight line access.
- Gently remove the ProUltra® PiezoFlow™ Ultrasonic Irrigation Needle by peeling the backing from the packaging where indicated.

**Wipe Ultrasonic Irrigation Needle and tubing with 70% isopropyl alcohol.**
- **Attach Ultrasonic Irrigation Needle to the ultrasonic handpiece using a ProUltra® Wrench.** Do not over tighten.
- **Attach a 20 ml - 60 ml syringe full of desired irrigant to the Luer-lock connection on the ultrasonic irrigation needle.** If additional tube length is desired, medical grade extension tubing (female to male) can be used.
- **After completing canal preparation, trial-fit the needle into the canal and determine the length at which the needle begins to bind against the canal walls.** Pull the needle back approximately 1 mm and set the silicon stopper to this depth. **Note:** This depth should not be greater than 75% of the working length established for instrumentation. **The needle should not be taken to the apex of the canal.**
- **Place the inactive needle into the canal and begin the delivery of the desired irrigant.** Priming volume may vary depending on the length of the tubing used.
- **Once irrigant fills the canal,** activate the ultrasonic unit. The ProUltra® Piezo Booster should be set to a power level of 5.
- **Maintain a continuous irrigation flow of 15 ml per minute for one minute per canal when using NaOCl.**
- **Gently move the active ultrasonic tip up and down following a consistent straight line path from the canal entrance to your stopper setting.** Be careful to not bind the tip.
- **While irrigating,** use high-volume suction at the access opening to recover used irrigant & debris.
- **Once irrigation is complete stop the flow of irrigant.**
- **Remove the single-patient-use-needle with the ProUltra® Wrench and dispose of in a designated “sharps” container.** Extension tubing and syringe should be disposed of properly.

**STERILIZATION:**
ProUltra® PiezoFlow™ Ultrasonic Irrigation Needles are intended for single-patient use and should not be sterilized. Gently wipe down with 70% isopropyl alcohol only prior to use. Do not autoclave. High autoclave temperatures may damage the ultrasonic irrigation needles.

**OPTIONAL SET-UP AND ACCESSORIES:**
- **Syringe pump:** A mechanical syringe pump, a peristaltic pump or a syringe dispensing gun may be used to help deliver the irrigant. Adjust the flow rate to 15/ml minute
- **Starter Kit (SKUF PIEZOLOWAP):** A starter kit is available from Tulsa Dental Specialties that includes the following components: a 20 ml syringe, 3 feet of extension tubing with Luer Lock connections and a pinch clamp, tubing retainers to secure the tubing to the ultrasonic handpiece and a ProUltra® ultrasonic wrench.