

## DIRECTIONS FOR USE

**DENTSPLY**  
TULSA DENTAL  
SPECIALTIES

# ProUltra<sup>®</sup> PIEZOFLOW<sup>™</sup>

## ULTRASONIC IRRIGATION NEEDLE

Manufactured by:

**DENTSPLY Tulsa Dental Specialties**

DENTSPLY International, Inc.

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Johnson City, TN 37604

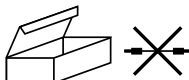
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Manufactured in U.S.A.

U.S. and foreign patents pending.



**Non-Returnable If Opened**

**For Dental Use Only**

**Rx only**



**Do Not Reuse**

### 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<sup>®</sup> PiezoFlow<sup>™</sup> Ultrasonic Irrigation Needles are for use in non-surgical root canal irrigation by application of ultrasonic vibration. The PiezoFlow<sup>™</sup> 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<sup>®</sup> 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.

## DIRECTIONS FOR USE

### 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, facemasks, 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.
- 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 (SKU# PIEZOFLOWAP): 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.

### 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.