

DIRECTIONS FOR USE

WARRANTY

Zila, Inc. warrants that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Zila, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the products covered by these Instructions for Use. Insight[®] inserts manufactured by Zila, Inc. are warranted against defects arising from faulty materials or workmanship for one hundred eighty (180) days from the date of purchase. This warranty extends only to the original purchaser. This warranty is subject to the following conditions:

1. Insight[®] inserts must not be subjected to damage, abuse, improper use or improper cleaning, disinfection or sterilization procedures (as determined at the sole discretion of Zila, Inc.).
2. Bending or reshaping the insert, sterilizing it in an improper manner, or using the insert for purposes other than for which it was designed, will void the warranty.
3. There are no warranties, expressed or implied beyond the description on the face hereof. Zila, Inc. neither assumes, nor authorizes any person to assume for it, any other liability for incidental and consequential damages resulting from the use of the insert.

For technical support or questions regarding defective product during the warranty period, please call 800-228-5595. Visit us at www.zila.com.

For sales orders and product information contact:



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CAUTION: This device is for professional use ONLY. Device is not supplied sterile. Sterilize before using for the first time (please refer to the Cleaning/Disinfecting and Sterilization section for proper sterilization and instructions). For infection control, inspect, clean and sterilize before each use thereafter.

Note: When not in use, store Insight® inserts in a clean, dry area with tips protected from damage.

Description of the device

Zila Insight® Ultrasonic Inserts are designed for hygienist, by hygienist for use with magnetostrictive scalers. The Insight® family of magnetostrictive ultrasonic inserts delivers innovative features not found with other ultrasonic inserts. From its tip to its ergonomic grip, the Insight® family of inserts is designed with hygienists in mind. Insight® inserts are available in your choice of tip design and either 25K or 30K operating frequencies.

Indications

Insight® inserts are to be used with magnetostrictive ultrasonic scalers to perform:

- All general supra and subgingival scaling.
- Deplaquing procedures.
- Periodontal debridement.

Contraindications and Warnings

- Inspect and clean ultrasonic inserts prior to first use. For infection control, inspect, clean and sterilize before each use thereafter.
- Insight® inserts should only be used for scaling teeth (cleaning and removing accretions from the tooth surface). Inserts should not be used for any other purpose.

- Not to be used on patients or by clinicians with cardiac pacemakers.
- Not to be used on high-risk infectious patients.
- Not to be used on restorative materials.
- Use the lowest effective power setting. Use of the insert at excessive power settings may damage teeth or roots and could damage the insert. (For power settings, please reference unit power settings).

General Precautions

- Do not attempt to bend or reshape the insert. If dropped, bent or broken, replace the insert. Insert tips which have been bent, broken or altered should not be used.
- Always operate inserts with water flow.
- Always operate inserts with appropriate suction.
- Patients should rinse with an anti-microbial mouth rinse prior to scaling.
- Cold liquid disinfection/sterilization (e.g. glutaraldehyde) and dryheat sterilization are not recommended for Insight® inserts. Sterilization by either of these methods will void the warranty.
- Avoid prolonged contact of the insert with exposed skin or soft tissue. Holding the insert stationary for an extended time may cause damage to teeth or roots.
- Ultrasonic inserts should only be used by personnel trained in their proper use.
- Use of the insert at excessive power settings may damage teeth, roots and insert.

Unit Power Settings

- Insight® IOS inserts should be used with the scaler unit set at a power setting no higher than "medium."
- All other Insight® inserts may be used with the scaler unit set to maximum power.

Storage

- Store insert at room temperature.

Insert Selection

It is recommended that selection of the proper insert be based on one or more of the following:

- Patient's oral condition.
- Type, extent and location of deposits to be removed.
- Root anatomy, considering concavities and furcations.

Basic Instrumentation

1. Select the appropriate insert for the tooth or root to be treated.
2. Fill handpiece with water, wet oring, and use gentle twisting motion to seat insert in handpiece.
3. Use the lowest effective power setting. (Please refer to unit power setting for proper power settings).
4. Adjust the water control until the water flows with a fast drip or mist.
5. Use very light pressure holding the handpiece or insert grip with a pen grasp or modified pen grasp.
6. Position the insert so the point is not directed into the root surface.
7. Using a light, smooth, gentle touch, keep the insert tip in motion at all times using short, controlled, overlapping horizontal, vertical or oblique brush-like strokes. Holding the insert stationary for an extended time may cause damage to teeth or roots.
8. When exploring or evaluating root surfaces, be sure to inactivate the insert.

Cleaning

- Rinse inserts thoroughly to remove gross debris.
- Do not expose Insight® ultrasonic inserts to corrosive chemicals such as chlorides, sulfates, and surface disinfectants.
- If ultrasonic cleaning is desired, fully immerse in a mild ultrasonic cleaning solution for 7 – 10 minutes, or 15 – 20 minutes if the insert is in a cassette.
- Rinse inserts thoroughly after ultrasonic cleaning. (Approx. 30 – 60 seconds for loose inserts and 1 – 1.5 minutes per cassette.)
- Dry ultrasonic inserts completely.

Sterilization

- **Do not use dry-heat sterilization, chemical vapor sterilization or cold liquid sterilants (e.g. glutaraldehyde) with Insight® Ultrasonic Inserts. These methods may cause o-rings to dry out and crack.**
- Sterilize ultrasonic inserts in a cassette or paper pouch in a steam autoclave in gravity/vacuum mood for full cycle: 4 minutes at 135° C.
- Placing pouches in the vertical position inside the sterilization chamber will eliminate weight bearing down on the inserts.
- Allow ultrasonic inserts to dry and cool completely after sterilization cycle for 60 minutes.
- Insight® Ultrasonic Insert should remain in sealed pouch until it is ready to use.