ENTire Tonsil Forceps Handpiece

Instructions For Use

ENTire Tonsil Handpiece Model Number –

ENTire Tonsil Forceps Handpiece	ENTTON01 F

MD

1. Symbols

REF	Catalog number		Manufacturer		Temperature limit		Do not reserialize
QTY	Quantity		Date of manufacture		Keep dry		Do not re-use
LOT	Batch code		Caution	#	Model number		Double sterile barrier system
	Use-by date		Consult instructions for use	STERILE	Sterilized using steam		Do not use if package is damaged and consult instructions for use
MD	Medical device	UDI	Unique device identifier		Fragile, handle with care	EU REP	Authorized representative in the European Union
	Type BF applied part complying with IEC 60601-1		Keep away from sunlight	Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician		

2. Indications for Use

The ENTire IRE System is indicated for the surgical ablation of soft tissue, specifically for otorhinolaryngology (ENT) indications.

3. Contraindications

- Patients with a pacemaker or similar electro stimulator.
- Patients for whom the anesthesia involves high risk or known or suspected complications for any general or local anesthetic agents
- Epilepsy or other conditions involving convulsions.
- Severe heart disease.
- Pregnancy or breastfeeding.
- Significant systemic illness (e.g., cancer, severe autoimmune disease, neurological disease).

4. Warnings

⚠ ONLY USE the ENTire Tonsil Handpiece with the ENTire Medical IRE System. Use of the handpiece with other systems may result in injury to the patient or operating room personnel.

⚠ DO NOT use a device with damaged insulation or any damage to sterile packaging. Doing so may result in injury to the patient or operating room personnel.

⚠ DO NOT disconnect the handpiece while energy is being delivered. Doing so may result in injury to the patient or operating room personnel.

⚠ DO NOT touch the handpiece electrodes while delivering energy. Doing so could result in injury to the patient or operating room personnel.

⚠ DO NOT continue the procedure if the handpiece or the electrodes are damaged at any point during preparation or use. Doing so may result in injury to the patient or operating room personnel.

⚠ DO NOT re-sterilize or reuse the device. The handpieces are single-use devices. Doing so could result in injury to the patient or operating room personnel.

⚠ DO NOT activate the system when not in contact with the targeted tissue.

⚠ DO NOT use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and pure oxygen) or in close proximity to volatile solvents (such as ether or alcohol).

⚠ **WARNING** Use of the ENTire IRE System shall be performed only by qualified otorhinolaryngology (ENT) physicians who have received hands-on training provided by a company representative. Physicians who have not been trained must not use this device. The first clinical use by each physician shall be attended by a company representative.

5. Cautions

⚠ The IRE System is intended for use by ENT healthcare professionals only.

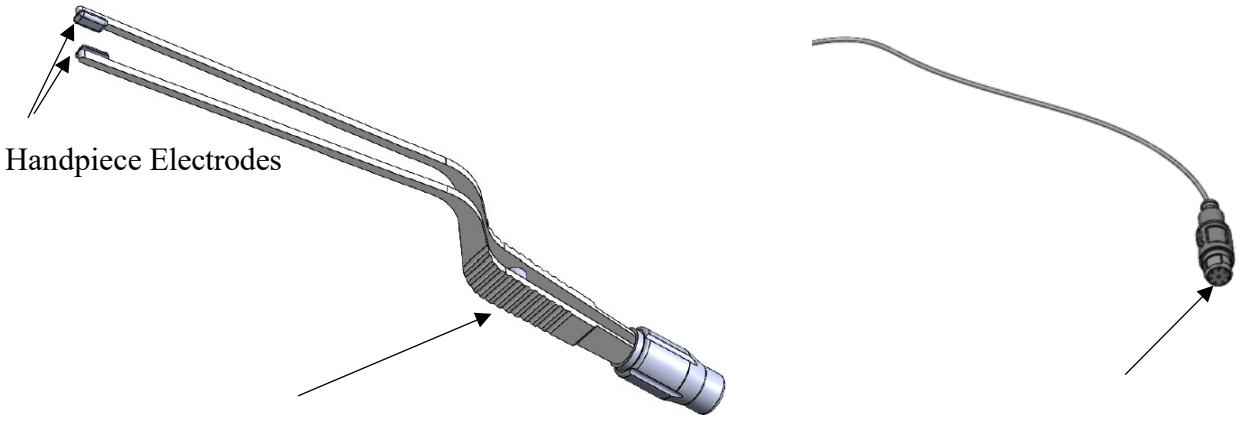
⚠ READ these instructions for use and the generator's User Manual before use (see QR code on the generator label).

⚠ DO NOT use if package is received damaged or open. Doing so may result in injury to the patient or operating room personnel. Contents supplied sterile using steam sterilization.

6. Main Adverse Effects

- Inflammation/ generalized redness in the treated area.
- Swelling.
- Pain or burning sensation.
- Local burns.
- Hematoma.
- Allergic reaction (itching, redness, or rash).
- Scar formation.
- Arrhythmia.
- Reactions to anesthetics.
- Temporary numbness/tingling.
- Severe muscle contraction during procedure.
- Sensory changes at treatment sites.
- Charring.
- Procedural Complication.
- Infection.
- Patients do not receive benefits of therapy.
- Hemorrhage.
- Bleeding (other than bleeding greater than anticipated).
- Injury to anatomical structure.
- Fever.
- Shock.
- Ablative Injury.
- Venous Thrombosis.
- Death.

7. Product Illustration



8. ENTire Tonsil Handpiece Description

The ENTire Tonsil Handpiece is a sterile single use bipolar electrosurgical device that connects to the ENTire Medical IRE System (the "Generator") to allow delivery of pulsed electromagnetic fields to targeted tissue (i.e., the tonsil(s)). The handpiece is covered by an insulating polymer. The distal end of the handpiece consists of two bipolar partially insulated electrodes. The electrodes contact the tissue from opposite sides to provide a path for energy to pass from the Generator to the tissue. Delivery of energy will result in the ablation of treated tissue (through the mechanism of late apoptosis).

9. Instructions for Use

Read this IFU and Generator's User Manual before use.

1. Remove the handpiece from the sterile pouch using the sterile technique, ensuring that the sterile packaging is intact.
2. Connect the handpiece's push pull connector to the Generator, keeping all electrode surfaces in the sterile field.
3. Energy parameters are automatically set once the handpiece is connected to the Generator.
4. Place the handpiece electrodes at desired treatment location.
5. Grasp between the two electrodes and close them until the stopper, ensuring a fixed 5 mm distance. The treatment zone corresponds to the tissue located between the electrodes.
6. Pay attention that the electrodes are in full contact with tissue.
7. The generator will display a green indicator when proper electrode–tissue contact is achieved. If poor contact is detected, the indicator light on the generator near the connection plug will turn red, indicating a non-operational status. The foot pedal will not generate any pulses. In that case, reposition the handpiece on the tissue as needed.
8. When the green indicator is on, press the foot pedal to deliver a pulse sequence (duration less than 1 second). An audible beep will confirm activation.

9. Repeat the application at the same site every 4 seconds, up to six times, or until tissue whitening appears below the electrodes.
10. The handpiece is a single patient use.
11. When the treatment has been completed, unplug the handpiece from the Generator.
12. Dispose of the handpiece in accordance with facility guidelines.

⚠ **WARNING** Failure to follow the limit of the number of applications or operation parameters, as presented in these instructions, might lead to patient injury.

10. Environmental Protection

Electrical waste should be disposed of according to the WEEE directive 2012/19/EU.

11. Handling and Storage

The ENTire Tonsil Handpiece should be stored in a cool, dry place, avoiding exposure to sunlight and extreme temperatures. The lifecycle of each handpiece is 5 years from the date of sterilization. Do not use if this date has passed.

12. For Further Information

Please refer to the ENTire Medical IRE System's User Manual for troubleshooting steps (see QR code on the generator label).

If further information is needed on this product, please contact an ENTire Medical Representative.

Note: If a serious adverse event or device-related malfunction occurs, notify the manufacturer immediately. Adverse events may also be reported to the FDA MedWatch program at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

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