ENTire Tonsil Forceps Handpiece

Instructions For Use

ENTire Tonsil Forceps Handpiece Model Number -

ENTire Tonsil Forceps Handpiece	ENTTON01

MD

1. Symbols

REF Catalog number	Manufacturer	Temperature limit	Do not resterilize
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 Community/ European Union
Keep away from sunlight	Type BF applied part complying with IEC 60601-1	CE XXXX CE mark (Medical)	Rx only Caution: Federal law restricts this device to sale by or on the order of a physician

2. Intended Use

The ENTire Tonsil Forceps Handpiece is intended for use as part of the ENTire Medical IRE System and used in conjunction with the IRE Generator for the ablation of soft tissue in Otorhinolaryngology (ENT) surgery, specifically indicated for the reduction of tonsillar tissue in patients with hypertrophic tonsils.

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 IRE Generator. Use 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 anaesthetics or oxidizing gases (such as nitrous oxide (N2O) and pure oxygen) or in close proximity to volatile solvents (such as ether or alcohol).

5. Cautions

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

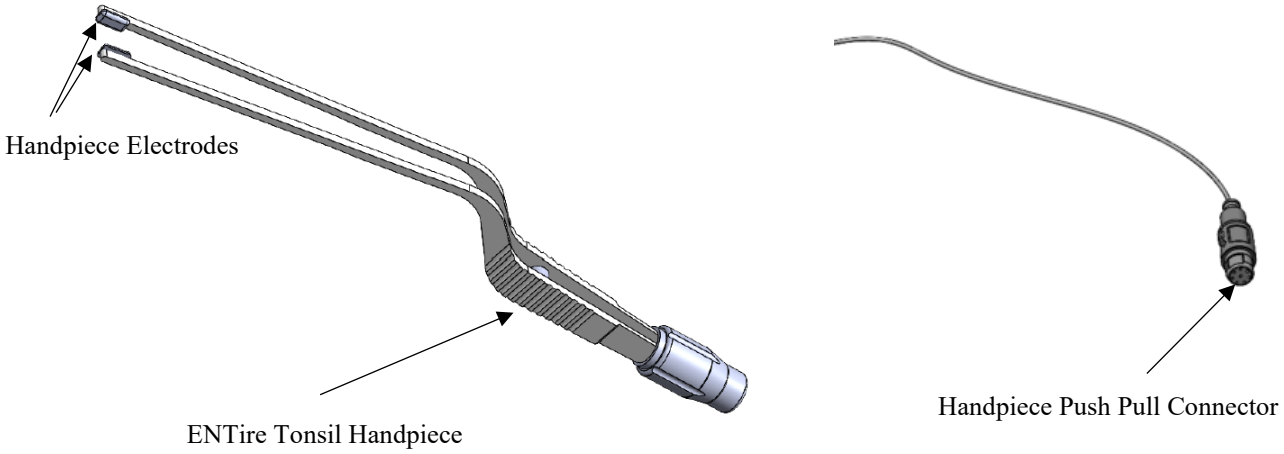
⚠ READ these instructions for use and the generator's User Manual before use (electronic version of the user manual is available by scanning the QR code on the generator label).

⚠ 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 Forceps Handpiece Description

The Handpiece is a sterile single use bipolar electrosurgical device that connects to the ENTire IRE Generator (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 insolated electrodes. The electrodes contact the tonsil from opposite sides to provide a path for energy to pass from the Generator to the tissue. Delivery of energy with the IRE System 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 of the tonsil.
5. Ensure that the check mark on the GUI screen is **green**.
6. Press and release the foot pedal to activate the device.
7. Repeat activation of energy delivery up to six (6) times per site. It is recommended to wait about 4 seconds between applications.
8. As needed, reposition the electrodes and repeat energy delivery to an additional site.
9. The handpiece is a single patient use device.
10. When the treatment has been completed, unplug the handpiece from the Generator.
11. 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 this manual, might lead to patient injury.

10. Environmental Protection

Waste electrical products should not be disposed of with household waste. Please recycle at the appropriate facilities. Check with your local authority for recycling advice or contact your product vendor. The disposal of the IRE System and/or components should be performed according to the WEEE directive 2012/19/EU.

11. Handling and Storage

The ENTire Tonsil Forceps 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 reference the ENTire IRE Generator's User Manual for troubleshooting steps (see User Manual supplied with the generator or see QR code on the Generator label).

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

Note: In the event that any serious incident has occurred in relation to the device this should be immediately reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

ENTire Medical Ltd.
11 Ha'hoshlim St.,
Herzliya, Israel 4672411
Tel: +972.9.9704333
E-Mail: info@ent-ire.com
Website: www.ent-ire.com

EU REP

MedNet EC-REP IIb GmbH
Borkstrasse 10
48163 Münster Germany
Tel: +49 251 32266-64
Fax: +49 251 32266-22
E-mail: contact@mednet-ecrep.com

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0483