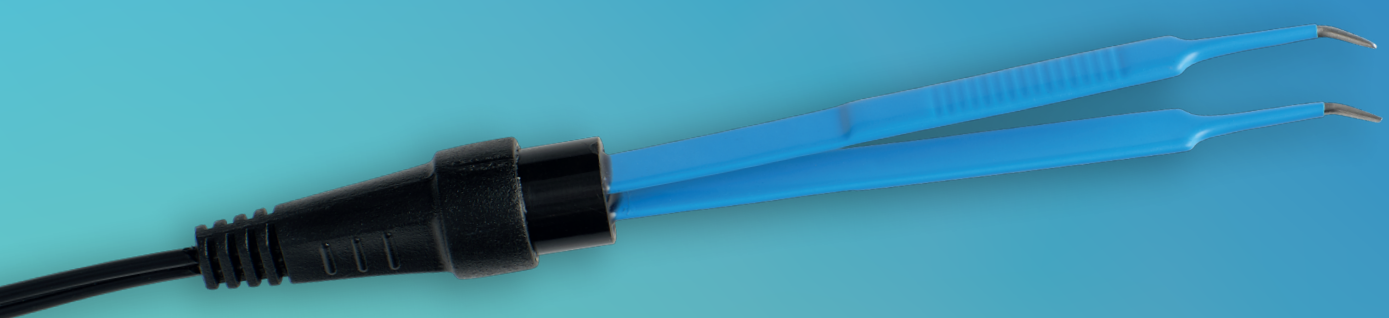
Medical Devices

Toffeln®

Mytera
Single Use Bipolar Forceps

Instructions for Use



Healthcare Ready at toffeln.com

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Sterilization

Non-Sterile Instruments can be sterilized using the following methods.

ETO Sterilization

- **Gas Ratio:** Ethylene oxide/Carbon dioxide Mixture 30/70
- **Concentration ETO:** 600 mg/l
- **Temperature:** 51°C to 55°C
- **Exposure time:** 6 hours
- **Humidity:** 50 to 80 %

Electrical Performance

Forceps:

- **Rated Accessory Voltage:** 1884 V
- **Withstand Peak Voltage:** 2260.88 V
- **Breakdown Peak Voltage Handle Breakdown Voltage:** 5393.54 V
- **Forceps Breakdown Voltage:** 4600

Cable:

201.8.8.3.103 HF Dielectric Strength Withstand:

- **Rated Accessory Voltage:** 3584.51 V
- **Withstand Peak Voltage:** 4301.42 V
- **Breakdown Peak Voltage:** 5221.1 V

Attention

Please read all information contained in this document.

Incorrect handling and misuse can lead to malfunction of surgical instruments as well as injury to the user and/ or patient.

Instruments for electrosurgery should be used only by persons who have been specially trained in the use of such instruments.

Intended use

An electrosurgical bipolar forceps is used in electro surgeries like Parotidectomy, hemorrhoidectomy, Abdominal Hysterectomy, tracheostomy and appendectomy for cutting and coagulation with bipolar cable attached to diathermy generator/radiofrequency generator and intended to remove tissue and control bleeding by use of high-frequency electrical current.

Compatibilities

Generators: Valleylab, Conmed, Megadyne, boviemed, dremed and all others are similar with above mentioned brands up to 1500 peak voltages.

Contraindications

Do not use the bipolar forceps if, in the opinion of a concerned medical practitioner/Surgeon or according to the current professional literature, such use would cause endangerment of the patient, for example due to the general condition of the patient, or if other contradictions are present.

Incidents which have been reported in connection with the use of bipolar systems

Unintended activation with resulting tissue injury on the wrong spot and/ or damage to the equipment.

Alternating current paths leading to burns on spots where the patient or user comes into contact with components without insulation.

Sparks have caused explosions in the proximity of inflammable gases, perforation of organs, sudden severe bleedings.

Use and safety instructions

The non-observance of safety instructions may lead to injuries, malfunctions or other unexpected incidents.

- If the product is supplied in sterilized form, then it is ready to use otherwise before use, all instruments have to be completely cleaned, disinfected and sterilized and their functioning has to be checked.
- Ensure that the insulated parts do not come in contact with hard, pointed or heavy objects during preparation, as such objects may damage the insulation and render the device unusable.
- It is very important to check each surgical instrument for visible damage and wear, such as cracks, breaks or insulation defects before use. In particular areas, such as blades, tips, notches and insulations have to be checked carefully.
- Never use damaged instruments.

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- Non-Stick forceps tips may not be cleaned with metallic brushes, abrasive substances, or other media or tools which may damage the surface of the instrument. Damp swabs or similar should be used to clean the tip area.
- Never use the instruments in the presence of flammable or explosive substances.
- The instrument may not be laid down on the patient.
- Coagulation should only be performed if the contact surfaces are visible and ensure a good contact to the tissue selected for coagulation.
- Do not touch any other metallic instruments, trocar sleeves, optics or things like that during use.
- Observe the use and safety instructions of the manufacturer of the high-frequency diathermy generator/radiofrequency generator.

Handling

During transport, cleaning, care, sterilization and storage, all electrosurgical instruments should be handled with maximum care.

Reprocessing

As the product is "Single Use" therefore it cannot be reprocessed or reused. Product shelf life is defined as following:

- 3 years for Sterilized Bipolar Forceps
- 2 years for Non-Sterilized Bipolar Forceps

Consequences of reuse

Reuse of single use instruments can cause cross contamination. It contains the risk of biological and chemical hazards. Re-sterilization of used instruments can cause the deterioration of any of the materials of the instruments as well.

Storage, transport and operating conditions

- Store instruments in a dry, clean and dust-free area
- Ambient temperature range: -05°C to 30°C
- Relative humidity range: 35% to 68%
- Atmospheric pressure range: 700 hPA to 1060 hPA

Cleaning and disinfect

If the product is supplied non-sterile and non-disinfected then it Ambient temperature range: -05°C to 30°C

Relative humidity range: 35% to 68%

Atmospheric pressure range: 700 hPA to 1060 hPA

Cleaned/disinfected before sterilization. Clean/disinfect the product with mixture of 70% IPA & 30% Distilled water or 100% Ethanol. Inspect each instrument carefully. Special attention must be paid to tip ends and other highly inaccessible areas. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc. Do not use damaged instruments. Disinfected instrument shall be immediately seal packed in sterilization pouch under cleanroom facility to avoid any kind of contamination. Sterilize all instruments before surgery.

Sterile packing compliance

Our sterilization packing complies with ISO 11607 and EN 868 standards.

Sterile pouch inspection

Prior to use the ETO Sterilized single use instruments follow the below instructions:

Use only sterile products packed in sterile pouch. Check the chemical indicator's colour on the pouch that indicates the sterilization process. It shall be changed after sterilization as mentioned on the sterile pouch (After ETO Sterilization the blue/red colour changes into yellow, green or brown). Do not use the instruments found with damaged, tear/break wet or opened seal pouch.

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Preparation for use (instruments with and without fixed cable)

I. If the instrument is supplied without pre-attached/ fixed cable then open the sterile instrument pouch and attach the Bipolar forceps with bipolar cables compatible connector for forceps end as per European or US 2 pin connection patterns and then plug the cable's other end with diathermy generator/radio frequency generator's bipolar compatible socket.

II. If the instrument is supplied with pre-attached/fixed cable then simply open the sterile packed instrument and plug in diathermy generator/radiofrequency generator's bipolar compatible socket.

III. Turn the generator "ON" and make the necessary settings as surgeon require for their use in different kind of surgeries.

IV. Perform connectivity and function test.

V. If bipolar forceps are with irrigation, check irrigation pipe of the instrument for clearance of the passage before using on patient.

Returned goods policy

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by the factory. Products will not be accepted for replacement if they have been used for second time.

Recycling

When reprocessing medical devices please follow your local government Health & Safety procedures.

Warranty

The factory supplies tested and faultless products to the customers. All products are designed and manufactured to comply with maximum quality requirements. We refuse any liability for products which, compared to the original product, have been modified, misused or handled or used in an inexpert way.

Explanation of symbols used on labels

Date of manufacturing	Temperature limit	Does not contain latex
Manufacturing	Keep dry	Do not resterilize
REF Catalogue number	Do not reuse	Nonsterile
LOT Batch code	Do not use if packaging is damaged	MD Medical device
Use-by date/expiry date	Keep out of sunlight	EC REP Authorised European representative
Consult instructions for use	STERILE EO Sterilized using Ethylene Oxide	UKRP UK responsible person

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