

## Instructions for Use – ENGLISH

### Hensler Premier Disposable Bayonetted Electrocautery Bipolar Forceps

#### **Caution**

Federal law restricts this device to sale by or on the order of a physician.

#### **Caution**

Please read all information contained in this insert. Incorrect handling and care as well as misuse can lead to premature wear of surgical instruments or to risks for patient and user.

#### **Indications for Use**

The Hensler Surgical Single-Use bipolar Forceps are designed to grasp, dissect and coagulate selected tissue.

They must be connected to the bipolar output of an electro-surgical generator using a suitable bipolar cable and must only be used with parameters for bipolar coagulation.

Do not exceed a maximum output of the generator of 600 V<sub>p</sub>.

#### **Contraindications**

Contraindications for the use of electro-surgical instruments are given when the physician's judgement would find their use contrary to the best interest of the patient.

The Hensler Surgical Products Bipolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for this purpose.

#### **Suitable cables:**

Bipolar cables with flat plug

Bipolar cables with 2-pin-plug

#### **Attention:**

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

#### **Use and safety instructions:**

- The inspection, use and handling of electro-surgical devices is the responsibility of the user.
- All instruments must be thoroughly cleaned, disinfected, and sterilized before initial use.
- It is very important to check each surgical instrument for visible damage and wear, such as cracks, breaks or insulation defects before each use. In particular, areas such as blades, tips, notches, locking and blocking devices as well as all mobile parts, insulations have to be checked carefully.
- Never use damaged instruments.
- Never use the instruments in the presence of flammable or explosive substances.
- The instrument must not be laid down on the patient.
- Coagulation should only be performed if the contact surfaces are visible. Do not touch any other metallic instrument during coagulation.

#### **Reprocessing:**

The Hensler Surgical bipolar forceps are NOT to be reprocessed after the Hensler single-use bipolar has been sterilized and used on a patient. Hensler NON-stick disposable NON-sterile bipolars are designed for one-time use only. Reprocessing should never occur. Once the device has been opened after sterilization at the end user facility or hospital, it cannot be re-used.

#### **Non-Stick Bipolar Forceps:**

The polished tips are made of precious metal (silver).

#### **Sterilization:**

Sterilization of the products with fractional pre-vacuum procedure (in accordance with ISO 17665) in consideration of the respective national requirements.

- 3 pre-vacuum phases, pressure at least 60mbar
- Heating up to a sterilization temperature of min. 132°C and max. 137°C
- Shortest exposure time: 3 min.
- Drying time: at least 10 min.

#### **Storage:**

Hensler Surgical Forceps are to be stored in a dry, clean and dust-free area at moderate temperatures between 5°C to 40°C.

#### **Repairs:**

! Never attempt to perform repairs by yourself. For any question on these matters, please contact Hensler Surgical Products, LLC.

#### **Handling:**

During use, all surgical instruments should be handled with maximum care.

This applies particularly to blades, fine tips and other sensitive areas

#### **Warranty**

Hensler Surgical Forceps are exclusively made in Germany. All our products are designed and manufactured to comply with maximum quality requirements. We disclaim any liability for products which, compared to the original product, have been modified, misused or handled or used in an inexperienced way.

#### **Manufacturer For:**

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