Information For Use Product Datasheet

STERILE SINGLE USE NONSTICK BIPOLAR FORCEPS WITH CABLE

Reference: **CSUP308U**

Report No.:
TDS.CSUP308U
Issue 01 Date: 02.02.2023

Description:



Length: 10.8cm
Tip: 0.5 mm
Type: Straight Angled
Wire length: 3m
Connection: 2 Pin Rotating Connector

Intended Use:

Electrosurgical bipolar forceps are used in Electrosurgery to cutting and coagulating with accessories and intended to remove tissue and control bleeding by use of low frequency electrical current. Cosil Instruments Company's bipolar forceps are available in a wide variety of designs both (European & American pattern), length and tip sizes to cover a wide range of surgical applications. They are precision crafted from the finest grade stainless steel, silver tips and coated with nylon powder to provide superior control and safety.

Authorized Intended User:

Only skilled medical personnel and personnel trained in this product are permitted to use the bipolar forceps.
The bipolar forceps are intended for open surgery and are used for manipulating and coagulating biological tissue. They are not intended for direct contact with the heart or central circulatory system. The bipolar forceps are connected by an electrosurgical cable to the bipolar output of the electrosurgical generator. They are activated by means of a foot-operated switch. It is recommended that a smoke evacuation system be used.

Indications

All surgical interventions where cutting and hemostasis is required (Cut and Coagulate) Refer to B, BF and CF type of electrosurgical generators while performing operations.

Contraindications

"Bipolar forceps have not been shown to be effective for **tubal sterilization or tubal coagulation** for sterilization procedures and should not be used for these procedures. **pacemakers or implantable cardiac defibrillator (ICD) devices** Though not an absolute contraindication, electrosurgery **in patients with cardiac** is a topic of much debate.

The flow of electrical energy during electrosurgery can interfere with the functioning of these devices. This can lead to skipped beats, firing of a defibrillator, bradycardia, asystole, or reprogramming of a pacemaker. While most modern implantable devices are resistant to external electromagnetic signals, the theoretical risk of interference still exists.
Any use of this instrument for tasks other than for which it is indicated will usually result in a damaged or broken instrument.

Classification:

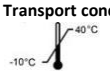
Class: IIb and Rule: 09 according to annexure IX of MDD 93/42/EEC.
All active therapeutic devices intended to administer or exchange energy are in Class IIb (Electrical Energy), Electrosurgical Devices.

Shelf life:

3 years for EO Sterilized ES Bipolar Forceps with/without Cable from the date of manufacturing

Storage, transport & operating conditions:

The bipolar forceps must always be handled with the utmost care during transportation and storage. This applies in particular for fine tips and other sensitive areas.
Transport conditions: Ambient temperature:



Storage conditions:
The specified period of use for the sterile HF electrodes is only valid if stored properly.
Storage conditions for sterile products:

- Dry
- Dustproof/dust content
- Protected from light
- Protected from damage
- Protected against mechanical influences
- Protected from extreme temperature fluctuations
- Separate from non-sterile products
- Clean
- Free from vermin

Atmospheric pressure range: 700 hPA to 1060 hPA

Compatibilities:

These Forceps are compatible with following generators (given they have the corect connector):
Valleylab, Megadyne, Bovie, ERBE, Martin, Tekno, Conmed.

Other:

LATEX FREE: The production material used in products are Latex Free.
Phthalates Free: The production material used in products are Phthalates Free.