

 Electro Surgical Instruments	Sterile & Non-Sterile, Single Patient Use Only		Document #: TFRBI-06-03/01		
	INSTRUCTION FOR USE NEEDLE HOLDERS			Revision #: 01	Doc Date: 10-05-2021
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A needle holder, also called needle driver, is a surgical instrument, similar to a hemostat, used by doctors and surgeons to hold a suturing needle for closing wounds during suturing and surgical procedures. The parts of a simple needle holder are the jaws, the joint and the handles.

INTENDED USE:

Needle Holders are used to hold a suturing needle for closing wounds during the suturing and surgical procedures.

DISPOSABLE PRODUCT:

Check the packing against any damage, pore and tear.

Read carefully expiry date and intended purpose including Sterile Methodology

TESTING AND INSPECTION:

Before use inspect for rust, pits, cracks, pores & dents before use.



WARNING:

- Don't use for second time
- Product material is conductive take away from electric source.
- Don't use without Sterilization
- Don't use wrong instrument. It can be creating problem in operation
- Our instruments are designed for use by competent surgeons, who have a good knowledge of their features and how the instruments should be used. Any other use can compromise the safety of the user and the patient. It is the responsibility of the surgeon to choose the most suitable instrument/size/shape for the surgical technique being performed, based on his experience and expertise. So this product must be used by an expert surgeon/user.

RECOMMENDED CLEANING AND DISINFECT METHOD:

If product is supplied non-disinfected then product should be cleaned/disinfected with a mixture of 70% IPA & 30% Distilled water. Otherwise if products are supplied cleaned/disinfected then there is no need to re-clean or re-disinfect these. Sterilize all instruments before use.

RECOMMENDED STERILIZATION METHOD:

Non-Sterile Instruments can be sterilized by using following methods:

EO Sterilization:

70% CO / 30% ETO

Concentration ETO: 600mg/L

Temperature: 50°C - 55°C

Exposure time: 6hours

Humidity: 60-85% RH minimum

Pressure: 50-60kpa

CONSEQUENCES OF REUSE THE SINGLE USE PRODUCT

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

WARRANTY:

This product is guaranteed to be free from defects in material or workmanship. The warranty is null and void should product damage occur as a result of mishandling or misuse. Care must be taken in the use and reprocessing of this product

SHELF LIFE:

3 years for Non-Sterile Packaging

3 years for Sterile Packaging

OPERATING CONDITIONS:

Follow your operating theater's SOP/Laws (These products are not for use in special temperatures.

STORAGE & TRANSPORT CONDITIONS:

Ambient temperature range: -05°C to +30°C

Relative humidity range: 40% to 70%

Atmospheric pressure range: 700 hPa to 1060 hPa

RECYCLE:

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

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Explanation symbols used on labelling:

- | | | | |
|---|------------------------------------|---|-------------------------|
|  | Consult instructions for use |  | Keep away from sunlight |
|  | For single use only |  | Keep dry |
|  | Do not resterilize |  | Manufacturer |
|  | Do not use if packaging is damaged |  | Batch code |
|  | Used by/expiry date | | |

REF Catalogue No.

STERILE EO Sterilised by ETO (for sterile delivered product only)

EC REP European Union Authorised Representative

MD Medical device

Signature:
Abdul Rehman
(CEO)