

	Sterile & Non-Sterile, Single Patient Use Only	Document #: TFRBI-05-03/01
	INSTRUCTION FOR USE SCALPEL BLADES HANDELS	Revision #: 01 Doc Date: 10-05-2021
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Surgical scalpels consist of two parts, a blade and a handle. The handle is also known as a "B.P. handle".

INTENDED USE:

Scalpel Blades Handles are used to hold scalpel blades. A scalpel is extremely sharp bladed instrument used for surgery and anatomical dissection.

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 use 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 resterilise |  | 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)