 <p>TARUN ENTERPRISES Regd. Office: 8/8, Strachy Road, Allahabad-211001, Uttar Pradesh, India Works: Shed No. E 20, NSIC Campus, Mirzapur Road, Naini, Prayagraj-211009, UP, India</p>	TECHNICAL CONSTRUCTION FILE TE/TCF-04	ISSUE NO.: 01 Issue Date: 05.10.20 REVISION NO.: 00 DATE OF REV : Nil
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INTENDED USE

Drapes are used for isolation of the surgical field during surgery, after painting the area with povidone iodine in order to maintain strict asepsis.

MATERIALS USED: SMS 43 Gsm, PE Non Woven Fabric, 1.Double Sided Tape for Collection bag, 2. Aperture Sticker (Incision Film), Nose wire 2.5mm, Double sided Tape

INDICATIONS

- Surgery
- Treatment of Patients for any communicable disease

CONTRAINDICATIONS

- Not to be used in patients with known hypersensitivity to any of the materials used.

INSTRUCTIONS FOR USE


- Open packed pouch carefully.
- Ensure packing intact cleaning before use /wear of these products.
- Respiratory protection for certain particulates, such as mineral wool dust, flour dust, etc., also applies to liquid or non-oily non-harmful volatile gas particles.
- Store it in a cool and dry place.
- The products should not be re-sterilized once used, must inspect and check the product before use.
- Should not be used if the packing is damaged.
- For single use only.Do not reuse
- After use, this products must be disposed –off as per country law of bio-waste rule



WARNING

- For single use only
- Check expiry date prior to use.
- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/ or functional damage to device or packaging.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and country laws and regulations.
- Ensure proper disposal of product and packing after use.
- Use the product immediately after opening the individual packing.
- The product should not be reprocessed.
- The product should be used by a doctor/ Registered practitioner or Paramedic.
- Store in a cool and dry place. Protect from excessive heat or direct sunlight.
- Mishandling or improper transport can cause damage to the products or packaging.

Prepared & Issued By: MR		Checked & Approved By: CEO	
Nikita Jaggi		Tarun Jaggi	

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- The product is non-toxic, sterile and non-pyrogenic if the packaging is intact. Tarun Enterprises, India does not hold any responsibility for any consequences from misuse of the products.

Cautions

- Not to be used for paint, harmful gas, asbestos, sandblasting
- This product does not provide oxygen.
- Cannot be immediately threatened in the concentration of harmful substances to life and health (ID ton concentration the environment can not be used, can not be harmful
- This product cannot be altered or misused.

Tarun Enterprises disclaims any responsibility for possible consequences resulting from improper use.

KNOWN CHARACTERISTIC OF DEVICE IN CASE OF RE-USE.

Since the cleaning/sterility of the device cannot be guaranteed, chances of infection OR disease can transfer

RISK OF REUSE - Reuse of the device may lead to redness, sneezing, dryness, respiratory infection and respiratory distress

Disposal System

Discard the device in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.

Target Age Group

For all age groups.

Storage Condition:

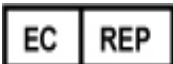
Temperature : 10°C to 40°C
Humidity : 60±5%
Device Life : 05 Years



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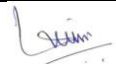
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INSTRUCTION FOR USE**SECTION NO.- 15****Explanation of Symbols:**

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Conformity of European Norm with Notified Body Number		Authorized European Representative		Batch/Lot Number
	Manufacturer		EO Sterile Product/Device		Moisture Limitation
	Don't re-use		Do not re-sterilize		Keep away from sunlight
	Date of Expiry		Temperature Limitation		Pyrogen Free
	Date of Manufacturing		Consult IFU		Caution/Warning (Read instruction before use)
	Do not use if package damaged				

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