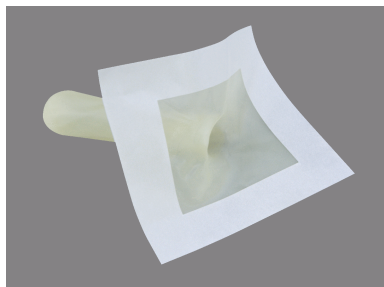


Med/TUR175™ LF inserts for re-usable drapes



Intended use

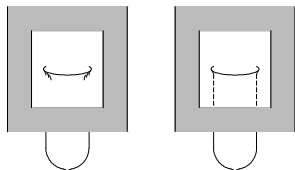
Med/TUR175™ LF inserts are intended to be used for applying re-usable surgical drapes for TUR-surgery (transurethral resection) or surgery of the prostate or the bladder. The inserts can easily be taped over a tailored contour in the drape. This allows protection of the patient and it creates a sterile and hygienic operating environment.

Product description

Med/TUR175™ LF inserts are a latex-free finger sheath provided with 100% wash-soluble adhesive. The finger sheaths are tear-resistant, suitable for steam sterilization and they return to their original state after stretching. During steam sterilization, the adhesive achieves its ultimate adhesive strength, ensuring very strong adhesion between the drape and the insert.

Appliance

Med/TUR175™ LF inserts are applied to re-usable drapes, after which they are steam sterilized and ready for use. After use, the drape is processed in the laundry, during which the insert is removed from the textile. After this process a new insert can be applied to the drapes.



Quality assurance

The inserts are manufactured in accordance with the EN ISO 9001:2008 and EN ISO 13485:2003+AC:2007 standards. This ensures that we deliver products and services that consistently meet customer requirements, guaranteeing full customer satisfaction. All our products have a CE label and comply with the requirements of the Medical Device Directive 2007/47/EC.




Advantages

- Makes it possible to protect the patient with a single drape.
- The inserts are 100% latex-free.
- The inserts are not adversely affected by steam sterilization.
- The adhesive is 100% wash-soluble.
- During steam sterilization, the adhesive achieves its ultimate adhesive strength and ensures a very strong adhesion between the drape and the insert.
- The inserts return to their original state after stretching.
- The inserts are biocompatible.

PRODUCT NAME	DIMENSIONS*	PRODUCT NUMBER	PACKAGING UNIT
Med/TUR175™ E10 LF	10cm x 10cm Tape W = 2cm sheath L= 9cm x W = 3,5cm	120.1010.001	125 pieces per case
Med/TUR175™ E18 LF	18cm x 18cm Tape W = 4cm sheath L= 9cm x W = 3,5cm	120.1818.001	125 pieces per case

*Custom dimensions are available on request.

Med/TUR175™ LF inserts for re-usable drapes

Properties	
• Sterilization	steam sterilization ¹
• Construction ③ Finger sheath ② Adhesive ① Release liner	wash soluble ²
• ③ Finger sheath Material Color Thickness Tested for Cytotoxicity (ISO 10993-5) Tested for Skin Irritation (ISO 10993-10) Tested for Skin Sensitisation (ISO 10993-10)	polyisoprene white 0.3 mm ± 10% yes yes yes
• ② Adhesive Wash soluble ² Peel (FTM1/20min.) Shear (FTM8) Tack (FTM9)	yes min. 25 Newtons / 25mm min. 240 min. min. 30 Newtons / 25mm
• ① Release liner Color Grammage	white 86 - 94 g/m ²
• Fingerlifts	no
• Dimensions Base insert Med/TUR175 E10 LF Base insert Med/TUR175 E18 LF Adhesive Med/TUR175 E10 LF Adhesive Med/TUR175 E18 LF Hole diameter Finger sheath	10 x 10 cm ± 1 mm 18 x 18 cm ± 1 mm 2 cm ± 1 mm 4 cm ± 1 mm oval 3,5 cm x 1 cm ± 10% L = 9 cm x W = 3,5 cm ± 10%
• Latex Latex content of the product	latex free
• Storage Temperature (optimal) (keep away from heat and/or flame) Light (protect from prolonged exposure to bright sunlight and strong U.V. light)  Humidity (avoid damp storage conditions)	15 - 25 °C dark conditions 40 - 70 %
• Reusability	not reusable 
• Directions for use are present in the original packaging 	
• Supported QS/directives EN ISO 9001:2008 (certificate available on request) EN ISO 13485:2003+AC:2007 (certificate available on request) MDD 2007/47/EC, medical device class I (certificate of conformity available on request)	yes yes yes

¹ Use steam sterilization (autoclave) for optimum anchorage to the surgical textile.

² The adhesive completely dissolves during a standard washing process with a pH-value > 8. The latex should be removed after the washing process.