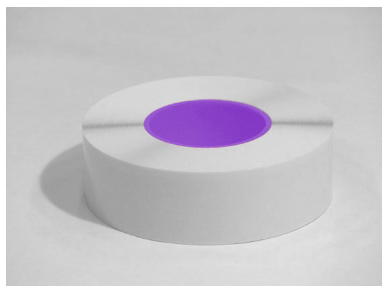


Med/TR300E™ OR-tape for re-usable drapes

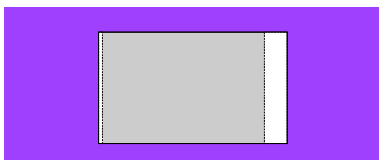


Intended use

The OR-tape *Med/TR300E™* is intended to be used for applying re-usable drapes to the patient's skin in order to create a sterile and hygienic operating environment.

Product description

Med/TR300E™ is a double sided tape consisting of a thin tissue carrier, both sides of which are coated with a uniform polymer 100% wash soluble adhesive layer. The adhesives are pressure and temperature sensitive and completely soluble during the washing process.



Appliance

Med/TR300E™ is applied to the re-usable drape, after which it is steam sterilized and ready for use. After use, the drape is processed in the laundry, during which the tape is 100% removed from the textile. After this process new tape can be applied to the drapes.

Quality assurance

The OR-Tapes 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

- The OR-Tape is 100% wash soluble.
- During surgery, the tape is unaffected by water and body fluids used during surgery.
- This tape ensures both maximum performance during surgical procedures, as well as easy 100% solvability during the washing process in the laundry.
- The OR-Tape can be easily identified by the colour of the synthetic core.
- The bonding strength of the employed adhesives is not adversely affected by sterilization and the tape reaches its ultimate adhesive strength on the textile side after steam sterilization.
- The OR-tape is biocompatible.
- Custom dimensions are available on request.




Recommendations, warnings and precautions

- Only apply the tape to fully dried skin. The adhesive used is less resistant to disinfectants. Improper use of the tape can cause skin irritation.
- Disinfectants containing alcohol also remove the oil from the skin. The tape adheres well to such areas.
- If a disinfectant containing oil or glycerine is being used (mainly for surgery in mucous membrane areas of the skin), or a disinfectant that leaves a film, the adhesion of the tape can be impaired.
- The adhesive strength is highly dependent on the condition of the skin, dryness and any applied disinfectants (and their contents).
- Always remove the tape from the skin (even in the case of healthy skin) in such a way that the skin is not pulled in an upward direction. We recommend removing the drape from the skin carefully in a movement parallel to the skin. This means at an angle of 180 degrees.

PRODUCT NAME	DIMENSIONS*	PRODUCT NUMBER	PACKAGING UNIT	APPLIANCE
Med/TR300E™ (50)	2,5cm x 100m	081.025100	8 rolls per case	Sensitive applications (e.g. paediatrics).
Med/TR300E™ (50)	4cm x 100m	081.040100	25 rolls per case	Standard size for less demanding applications.
Med/TR300E™ (50)	5cm x 100m	081.050100	20 rolls per case	Standard size for the most common applications.
Med/TR300E™ (50)	10cm x 100m	081.100100	10 rolls per case	For very demanding applications and U-drapes.
Med/TR300E™ (50)	15cm x 100m	081.150100	5 rolls per case	For very demanding applications and U-drapes.

* Custom dimensions are available on request.

Med/TR300E™ OR-tape for re-usable drapes

Properties	
• Identification color	purple core
• Sterilization	steam sterilization
• Construction	
④ Adhesive textile side	wash soluble
③ Carrier	tissue
② Adhesive patient side	wash soluble
① Release liner	
• ④ Adhesive textile side (wash soluble)	
Wash soluble ¹	yes
Resistant to fluids (pH-neutral water and bodily fluids)	yes
Resistant to (alcohol containing) disinfectants	no
Coating	45 g/m ² ± 10%
Peel (FTM1/20min.)	min. 25 Newtons / 25 mm
Shear (FTM8)	min. 240 min.
Tack (FTM9)	min. 30 Newtons / 25 mm
• ③ Carrier (100% wash soluble)	
Material	tissue
Thickness	30 - 40 µm
• ② Adhesive patient side (wash soluble)	
100% Wash soluble ¹	yes
Resistant to fluids (pH-neutral water and bodily fluids)	yes
Resistant to (alcohol containing) disinfectants	no
Coating	50 g/m ² ± 10%
Peel (FTM1/20min.)	min. 30 Newtons / 25 mm
Shear (FTM8)	min. 10 min.
Tack (FTM9)	min. 25 Newtons / 25 mm
Tested for Cytotoxicity (ISO 10993-5)	yes
Tested for Skin Irritation (ISO 10993-10)	yes
Tested for Skin Sensitisation (ISO 10993-10)	yes
• ① Release liner	
Color	white
Grammage	86 - 94 g/m ²
• Dimensions	
Width (typical; other sizes available upon request)	2,5 - 10 cm
Length (typical; other sizes available upon request)	100 m
• Other	
Core	polystyrene / purple
Fingerlifts	1 mm / 6 mm
• Latex	
Latex content of the product	latex free
• Storage	
Temperature (optimal) (keep away from heat and/or flame)	15°C - 25°C
Light (protect from prolonged exposure to bright sunlight and strong U.V. light) 	dark conditions
Humidity (avoid damp storage conditions)	40% - 70%
The tape rolls should be laid down flat with the fingerlift sides on one another. The sides without fingerlift should be separated from one another by means of a silicone ring (present in the original packaging).	
Never place the rolls in a vertical position.	
• Reusability	not reusable 
• Directions for use are present in the original packaging 	
• Supported QS/directives	
EN ISO 9001:2008 (certificate available on request)	yes
EN ISO 13485:2003+AC:2007 (certificate available on request)	yes
MDD 2007/47/EC, medical device class I (certificate of conformity available on request)	yes

¹ The adhesive completely dissolves during a standard washing process with a pH-value > 8.