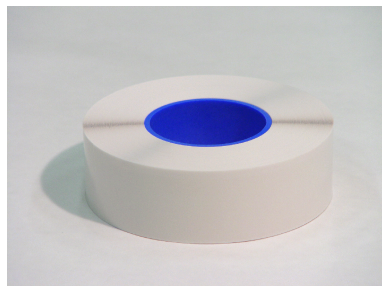


Med/PE175W+™ OR-tape for re-usable drapes

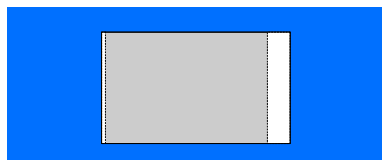


Intended use

The OR-tape Med/PE175W+™ 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/PE175W+™ is a double sided tape consisting of a thin polyester carrier, both sides of which are coated with a uniform polymer adhesive layer. The adhesives are pressure and temperature sensitive and completely soluble on the textile side during the washing process. On the patient side it has a disinfectant-resistant adhesive coating which is not soluble but does not leave any residual on the drape.



Appliance

Med/PE175W+™ 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 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

- During surgery, the tape is unaffected by body fluids and other fluids used during surgery.
- Coated with two special types of adhesive, this tape ensures both maximum performance during surgical procedures, as well as easy 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

- 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/PE175W+™	2,5cm x 100m	010.025100+	8 rolls per case	Sensitive applications (e.g. paediatrics).
Med/PE175W+™	4cm x 100m	010.040100+	25 rolls per case	Standard size for less demanding applications.
Med/PE175W+™	5cm x 100m	010.050100+	20 rolls per case	Standard size for the most common applications.
Med/PE175W+™	10cm x 100m	010.100100+	10 rolls per case	For very demanding applications and U-drapes.

* Custom dimensions are available on request.

Med/PE175W+™ OR-tape for re-usable drapes

Properties	
• Identification color	blue core
• Sterilization	steam sterilization
• Construction ④ Adhesive textile side ③ Carrier ② Adhesive patient side ① Release liner	wash soluble polyester non-wash soluble
• ④ Adhesive textile side (wash soluble) Wash soluble ¹ Resistant to fluids (pH-neutral water and bodily fluids) Resistant to (alcohol containing) disinfectants Coating Peel (FTM1/20min.) Shear (FTM8) Tack (FTM9)	yes yes no 45 g/m ² ± 10% min. 25 Newtons / 25mm min. 240 min. min. 30 Newtons / 25mm
• ③ Carrier Material Thickness	polyester 12 µm ± 0.5 µm
• ② Adhesive patient side (non-wash soluble) Wash soluble Resistant to fluids (pH-neutral water and bodily fluids) Resistant to (alcohol containing) disinfectants Coating Peel (FTM1/20min.) Shear (FTM8) Tack (FTM9) Tested for Cytotoxicity (ISO 10993-5) Tested for Skin Irritation (ISO 10993-10) Tested for Skin Sensitisation (ISO 10993-10)	no yes yes 32 g/m ² ± 10% min. 30 Newtons / 25 mm min. 1.440 min. min. 35 Newtons / 25 mm yes yes yes
• ① Release liner Color Grammage	white 86 - 94 g/m ²
• Dimensions Width (typical; other sizes available upon request) Length (typical; other sizes available upon request)	2,5 - 10 cm 100 m
• Other Core Fingerlifts	polystyrene / blue 1 mm / 6 mm
• 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) 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.	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 The adhesive completely dissolves during a standard washing process with a pH-value > 8. The polyester carrier should be removed after the washing process, before the drying process.