



623501 Arm Sleeve



Sterile	Yes
Country Of Origin	Thailand
Sterility barrier quantity Dispenser Box Quantity Transport Box Quantity Pallet Quantity Standard	1 30 180 3240 ISO 10993
Standard	ISO 10993 ISO 14001
Label Of Standard	EN 980 CEE 93/42 ISO 15223
Contains Formaldehyde Contains Collofonium Contains Latex Contains Nickel Contains PVC	No No No No

Composition

Cuffs	A white soft knitted cuff made of 100% polyester.			
Areas	Critical area Less critical area			
Materials				
Body/Sleeve material	Polyethylene film	Polyethylene film		
	40 microns	40 microns		
	Viscose/Polyester nowoven 22 g/m2	Viscose/Polyester nowoven 22 g/m2		

EN Standard

Material code XXVI Patient drapes Base Drape nonwoven comfort High Performance

	Requirement			Drape Performance Less	
Characteristic Resistance to microbial penetratic	Unit	Critical product area	Less critical product area	Critical product area	critical product area
- Dry Resistance to		Not required	≤ 2 Not required	0 6	0 6





microbial penetration - Wet							
Cleanliness -	Log10			NA	NA		
Microbial	(CFU/dm2)	< 2	< 2	(sterile)	(sterile)		
Cleanliness -				NA (plasticNA (plastic			
Particulate matter	IPM	< 3,5	< 3,5	film)	film)		
	Log10 (lint			NA (plasticNA (plastic			
Linting	count)	< 4,0	< 4,0	film)	film)		
Resistance to liqiud							
penetration	cm H2O	≥ 100	≥ 10	>100	>100		
Bursting strength -							
Dry	kPa	≥ 40	≥ 40	74	74		
Bursting strength -							
Wet	kPa	≥ 40	Not required	63	63		
Tensile strength - D	r y N	≥ 20	≥ 20	35	35		
Tensile strength -							
Wet	Ν	≥ 20	Not required	25	25		

- Instruction Intended Use The products are to be used inside or outside the operating theatre, during or in connection with surgical interventions, thereby reducing the risk of bacterial contamination.
- Sterilization Method Irradiation
- MDD Classification Class I Sterile
- CEMark Certificate 01966
- Instruction Storage Mölnlycke Health Care recommends that BARRIER products are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed. Storage facilities for products only protected by the sterility barrier should be kept under conditions where low level of particulate air contamination prevail, so that it would not constitute a risk to the patient when the package is opened and the product is used.
- Instruction Disposal Waste Non-hazardous waste Used BARRIER products and sterility barriers should, in the majority of cases, be classified as non-hazardous waste. They contain high amounts of energy and are well suited for incineration. BARRIER products do not contain any hazardous substances that can leach out if the products are land filled. Transport boxes are designed to fit existing recovery systems. The new BARRIER packaging system complies with the Packaging Waste Directive of the European Union.





Shelf Life

5 years