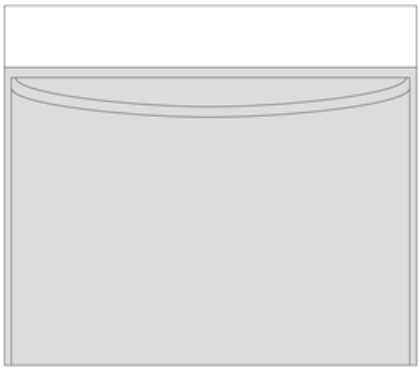
706035
Fluid Collection Pouch

Product details

Size: 40cm x 35cm
Descriptive feature: Adhesive
Color: Transparent
Sterility: Sterile

Images



Delivered items

706035-20

Country of origin: Thailand
Shelf life: 5 years
Sterilization method: Irradiation
Packing information: First packaging layer is a peel-open sterile barrier, paper/plastic. Once opened the sterile barrier cannot be closed again. Second layer is a corrugated board dispenser box. Third layer is a corrugated board transport box.

Packaging level	Pack count	GS1 code
Consumer pack	1	7323190179749
Dispenser box	30	7323190178667

Packaging level	Pack count	GS1 code
Transport box	120	7323190178650
Pallet	5760	7323190178643

Material

Animal tissues:

No

Human blood derivatives:

No

Medicinal substances:

No

Phthalates:

No

Polyvinyl chloride:

No

Product Composition Drape

Product Component	Composition
Main Material	Polyethylene film 80 µm, transparent

Product Performance Drapes, Additional Tests

Characteristics	Test Method	Internal Test Method	Unit	Product Performance Critical Product Area	Product Performance Less Critical Product Area
Absorption	ISO 9073-12	T-1158	g/dm²	N/A	N/A
Flammability	16 CFR 1610.4	N/A	s	Class I, >3.5s	Class I, >3.5s

Technical

Dimension

Dimension text	Dimension value
Outer dimension	40 cm x 35 cm

Disposal instructions

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.

Storage instructions

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.

Classification

Regulation type	MDD Class IS
MDD Classification Rule:	1
CE Certificate Number:	01966
Notified body medical devices/PPE:	BSI (0086)
Intended use MDD:	The product shall manage fluids during surgical interventions

Applied standards: The standards presented below is a selection of the most essential standards that are adhered to.

EN 1041, EN 556-1, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 15223-1, ISO 15223-2, ISO 14001

Removable Label

No

GMDN Code (Global Medical Device Nomenclature)

56731