

Änderungsnummer / Change Master: C2260

Objektverknüpfungen / Object Links:

JBX 40034195 000 01 LP Detectable Finger Dressing Sterile

JBX 40034207 000 01 Leukoplast Detectable Sterile

Dokumentenstückliste / Document Structure:

Status		Responsible	Date
IE	in Erstellung	DEHNINA	25.11.2020
AF	Freigabeanford.	DEHVEDY	11.12.2020
FR	freigegeben	DEHNIRO	11.12.2020

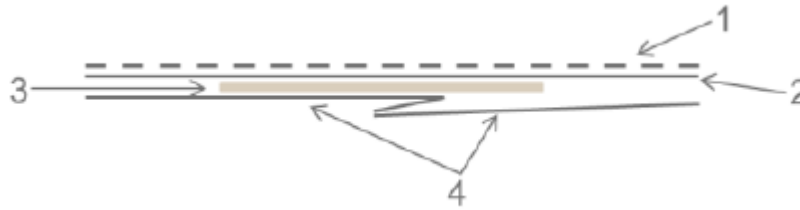
Product Data Sheet

1.0 Name of the product	Leukoplast Detectable Sterile and Leukoplast Detectable Finger Dressing Sterile
2.0 Product description	
2.1 Description	<p>Leukoplast® detectable (sterile) consists of a blue coloured PUR film, which is coated on one side with an acrylic adhesive. A white absorbent wound pad which is detectable is applied centrally on the coated side of the wound dressing. The adhesive mass of Leukoplast® detectable (sterile) is fully covered with two white, one side siliconized release papers. The lower release paper has got a fold which is overlapped by the upper release paper. Leukoplast® detectable (sterile) is cut, sealed into printed paper and packed into folding boxes and sterilised with EO. The wound pad contains metal and X-Ray detectable materials.</p> <p>Leukoplast® detectable (finger dressing sterile) consists of a blue coloured PUR film, which is coated on one side with an acrylic adhesive. A white absorbent wound pad which is detectable is applied centrally on the coated side of the wound dressing. The adhesive mass of Leukoplast® detectable (finger dressing sterile) is fully covered with two white, one side siliconized release papers. The lower release paper has got a fold which is overlapped by the upper release paper. Leukoplast® detectable (finger dressing sterile) is cut, sealed into printed paper and packed into folding boxes and sterilised with EO. The wound pad contains metal and X-Ray detectable materials.</p>
2.2 Intended purpose	Leukoplast® detectable (sterile) and Leukoplast® detectable (finger dressing sterile) is intended for minor wounds like cuts, lacerations, abrasions or as cover of puncture sites after blood withdrawal or vaccination. Especially for situations where dressing needs to be visuable if lost.
2.3 Instructions for use	No: Instructions for use not necessary for class I/Is/IIa products. First aid dressings like the FADs have been used for decades and the usage of these devices are common knowledge.
2.4 Warnings and precautions for use	Do not re-use. Do not use if pouch is damaged.
2.5 Contraindications	No contraindications are known for this device.
2.6 Transport Precautions	not applicable

2.7 Duration of application / Period of use

FADs can be used from one day to several days depending on the status of the wound and the skin condition.

2.9 Composition



Designation (incl. no. in drawing)	Description	% of final product
Backing (1)	Polyurethane with Polystyrene	36
Adhesive (2)	Polyacrylate adhesive	16
Wound Pad (3)	Viscose/Polypropylene/Polyethylene Detectable layer: Aluminium/tungsten	17
Release liner (4)	siliconized paper	31

2.10 Product range

Product	Size	Per folding box	Per shipper	Product code
76453-00000-00	19X120 mm	50	24	76453-00
76453-00001-00	28X72 mm	50	12	76453-01
76453-00002-00	ASS	1	12	76453-02
76453-00003-00	22X72 mm	100	36	76453-03
76453-00004-00	50X72 mm	100	36	76453-04
76453-00005-00	44X50 mm	50	12	76453-05
76453-00006-00	ASS	1	24	76453-06
2.12 Storage conditions		Dry, clean and without exposure to direct sunlight		
2.13 Shelf life/Storage time		5 years		
2.14 Sterilization		sterilized with Ethylene oxid		

3.1 key quality parameters	Characteristic	Method	Target
	Adhesion to steel (final product)	Essity internal	2.0 - 6.5 N/cm

substance	Yes / No	Remark
PVC in product	No	-
Softeners (Phthalates)	No	-
Latex	No	-
Lanolin and lanolin derivates	No	-
Colophony (CAS 8050-09-7, 8052-10-6, 73138-82-6, 73905-20-1) and derivates	No	-
CMR substances	No	-

Packaging / Labelling	Yes / No	remark
PVC in packaging	No	-
Cellulose in packaging, bleech / recycled	Yes	No recycled fiber in primary pack.
Producer responsibility for waste handling	No	-

Sterile products offered in 3-layer concept	No	-
Brown cardboard in distribution packaging	Yes	-
Ruler on the dispensing package	No	-
Visible and recognizable dimensions on dressing materials	Yes	-
Recycled material	Yes	Partly recycled fibers in brown transport box.

History

Version / Date	Page / Item	Description of Change
01/25.11.2020	All	New document