

Lusan[®] gauze swabs (sterile)

General Product Description/Intended Purpose

Lusan[®] gauze swab (sterile) are manufactured from 100% cotton according to EN 14079.

Non-invasive use:

Single-use, sterile gauze swabs are used on humans by lay persons and healthcare professionals as a primary or as a secondary wound dressing, to absorb body fluids, e.g. exudate or blood, on skin, injured skin, or mucosal membranes, as a primary or secondary wound dressing. It can also be used in combination with ointments and compression material such as bandages for up to long term use. A new device can be applied indefinitely.

Invasive use:

Single-use, sterile gauze swabs are used on humans by lay persons and healthcare professionals for short-term use, for the absorption of body fluids, e.g. exudate, or blood on injured skin, natural body cavities and mucosal membranes, also in the context of minor surgeries.

Application/Indication

Gauze swabs achieve absorption of body fluids, e.g. exudate, or blood, due to use of light wide-meshed cotton fabric (gauze). Gauze swabs can be used to clean wounds and as carrier material of externals e.g. disinfection, or ointments. Moreover, the devices can also be used as a mechanical barrier.

The device is fixed on the patient by bandages, tapes or other fixation materials as a primary and/or secondary dressing for wounds.

Reference Numbers

REF	name	[cm ²]	gauze type	number of ply	pieces per pouch	pieces per folding box
2922810	Lusan [®] (sterile)	400 (± 8%)	20 threads	8	5	5
2922820	Lusan [®] (sterile)	400 (± 8%)	20 threads	8	5	10
2922830	Lusan [®] (sterile)	400 (± 8%)	20 threads	8	5	20



Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

Not known

Sterile Device

The sterile packaging is in accordance with DIN EN ISO 11607.

Sterilization with ethylenoxide according to DIN EN ISO 11135 with validated process

Instruction	Symbol acc. to EN ISO 15223-1
Do not use if package is damaged	
Do not resterilize	

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Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Lusan[®] should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

Lusan [®] (sterile)	
property	value
Sinking time	< 10 sec
Number of threads	warp 120 ± 6/100 mm weft 80 ± 5/100 mm
Area weight	≥ 27 g/m ²
Tensile strength dry	warp ≥ 60 N/50 mm weft ≥ 35 N/50 mm
Optical brighteners	none


Material Characteristics

Gauze
100% chlorine free bleached cotton according EN 14079


Labelling

Lot-No. with 9-digit code

e.g.:


	9	999	01	00	1
explanation	[9 = 2019]	[999-000]			
definition	year	serial production order			for internal purposes only

Manufacturing date

e.g.:		2019	04	01
		year	month	day

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Expiry date

e.g.:  2024 04 01
year month day

Shelf Life: 5 years

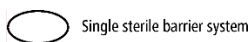
Medical Device



Unique Device Identification (UDI)



Single Sterile Barrier System



Latest Date of Revision: 2020-01-22