Technical Data Sheet

Pagasling® (sterile)

General Product Description/Intended Purpose

Pagasling® sterile, surgical invasive, twisted gauze sponges are manufactured from 100% cotton according to EN 14079. The sponges are made of one piece, without using a ring.
Pagasling is a single-use, sterile, surgical invasive, twisted gauze sponges for short-term treatment of injured skin, body cavities, mucosal membranes, tissues to absorb body fluids (e.g. exudate, blood), to clean wounds, to pack small wounds and/or as carrier material for externals (e.g. ointments, disinfection) on humans used by instructed lay persons and health care professionals. A new device can be applied indefinitely.

Application/Indication

The primary function of the device is to absorb body fluids e.g. exudate, blood. It is also used for wound cleansing and/or the packing of small wounds. The device can be used as carrier material for externals e.g. ointments, disinfection.

Reference Numbers

REF	name	size	Gauze type	pieces per pouch (with two cavities)	pouches per box
4812743	Pagasling (sterile)	Plum (No.3)	20 threads	4 (2+2)	20
4814092	Pagasling (sterile)	Egg (No.4)	20 threads	10 (5+5)	18
4812842	Pagasling (sterile)	Plum (No.3)	20 threads	5 (2+3)	20
4814004	Pagasling (sterile)	Extra (No.5)	20 threads	10 (5+5)	18
4814145	Pagasling (sterile)	Plum (No.3)	20 threads	20 (10+10)	18

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

Not known

Sterile Device
The sterile packaging is in accordance with DIN EN ISO 11607.
Gas sterilization 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	

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.

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Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Pagasling® 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

Pagasling® (sterile)	
property	**value**
Sinking time	< 10 sec
Number of threads	Warp 120 ± 6/100 mm Weft 80 ± 5/100 mm
Area weight	≥ 27 g/m2
Tensile strength dry	Warp ≥ 60 N/50 mm Weft ≥ 35 N/50mm
Optical brighteners	none

Material Characteristics

Gauze
100% chlorine free bleached cotton according EN 14079

Labelling

Lot-No. with 9-digit code
e.g.:

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

Manufacturing date

e.g.:	2019	04	01
	year	month	day

Pagasling® (sterile)

Expiry date

e.g.:	2024	04	01
	year	month	day

Shelf Life: 5 years

Medical Device

MD

Unique Device Indetification (UDI)

UDI

Single Sterile Barrier Symstem

Single sterile barrier system

Latest Date of Revision: 2020-03-30