

ASKINA® DresSil

PRODUCT DATA SHEET



ADMINISTRATIVE INFORMATION

HEAD OFFICE ADDRESS	B. Braun Hospicare Ltd. Colloney, Co. Sligo. Ireland
SBA	Wound Management
SAFETY OFFICER MEDICAL DEVICES	Amelia Cattigan
LAST UPDATE	31/12/2020

DESCRIPTION, COMPOSITION AND PROPERTIES OF THE DEVICE

COMMON NAME (FAMILY)	Silicone foam dressings (561)
TRADE NAME	Askina® DresSil
REFERENCES	5295710, 5291010, 5291510, 5291210, 5292005
GMDN CODE	46854 – Dressing, wound-nonadherent, absorbent
MEDICAL CLASS	II B

DESCRIPTION OF THE DEVICE

Askina® DresSil, is a sterile dressing consisting of:

- a perforated silicone wound contact layer
- a highly absorbent polyurethane foam
- a vapour permeable waterproof outer film

In the presence of exudate, Askina® DresSil helps maintain a moist wound environment conducive to natural healing conditions.

COMPOSITION OF THE DEVICE

Components

- A perforated silicone wound contact layer
- A highly absorbent polyurethane foam
- A vapour permeable waterproof outer film

PROPERTIES OF THE DEVICE	Adhesion to steel	5 - 30 gf/25mm
	Fluid handling	> 125 g/100cm ² /24h
	Wicking	< 60 seconds
	Release from Liner	Physical peel with no residue

KEY DRIVERS & INDICATIONS

KEY DRIVERS	Gentle and secure adherence
	Minimized trauma during dressing changes
	Significant absorption capacity
	Easy to use
	Good conformability on difficult-to-dress areas and skin contours
	Repositionable, can be cut to shape
	Improves patient comfort
	Hypoallergenic

INDICATIONS	Askina® DresSil is indicated for the management of:
	Pressure ulcers
	Venous leg ulcers
	Arterial leg ulcers
	Diabetic foot ulcers
	1st and 2nd degree burns
	Donor sites
	Skin tears
	Difficult to dress areas

STERILIZATION PROCESS: REPORT

STERILE MD: YES/NO	Yes
STERILIZATION METHOD	Ethylene Oxide (EO)

CONSERVATION AND STORAGE CONDITIONS

STORAGE CONDITIONS	[5° - 25°] C
TRANSPORT CONDITIONS	No restrictions
SHELF LIFE	3 years from date of manufacture

SAFETY IN USE

TECHNICAL: MRI, X-RAY DETECTABLE	N/A
ORGANIC	Latex free
BIOCOMPATIBILITY	Doc References n° HOSP 417, HOSP 419, HOSP 498

STANDARDS & REQUIREMENTS

Council Directive 93/42/EEC
ISO 13485
ISO 14971
MEDDEV 2.7/1 rev.4
ISO 10993-1
ISO 10993-5
ISO 10993-7
ISO 10993-10
ISO 11135
ISO 11737-1
ISO 11737-2
ISO 15223-1

RECOMMENDED USE

Yes, presence of IFU n°P1186-00 Revision 06.

Precaution: If signs of infection develop or if the wound deteriorates unexpectedly, contact the proper medical authority. Resume use when normal healing conditions are present. Re-use of single-use devices creates a potential risk to the patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient. Sterile unless pack damaged or opened.

IFU: YES/NO

PRECAUTION OF USE

CONTRAINDICATION

Contraindications: Do not use Askina® DresSil, Askina® DresSil Border, Askina® DresSil Heel or Askina® DresSil Sacrum

- On ulcers resulting from infection, such as tuberculosis, syphilis
- On deep fungal infections
- On third degree burns

If after 4 weeks of Askina® DresSil, Askina® DresSil Border, Askina® DresSil Heel or Askina® DresSil Sacrum treatment, there has been no improvement, then, in line with accepted wound management practice, the original diagnosis and overall therapy should be reassessed.

In the rare event of sensitivity or allergic reaction to the dressing (materials), discontinue use of the dressing.

ADDITIONAL PRODUCT INFORMATION

REUSABLE/SINGLE USE DEVICE

Single patient use.

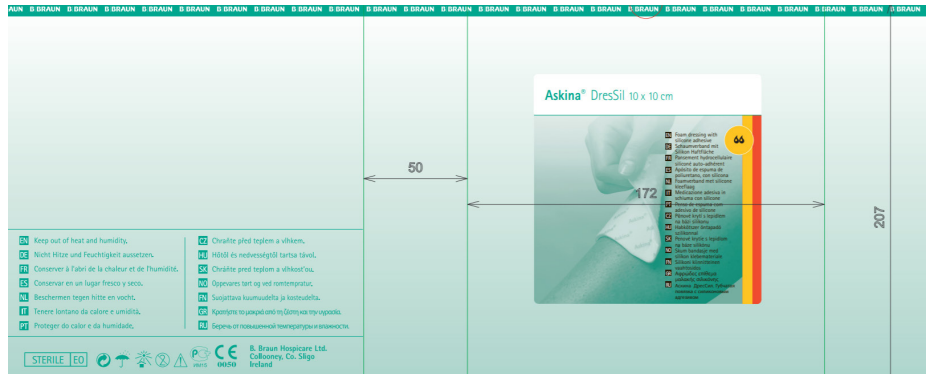
Re-use of single-use devices creates a potential risk to the patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

PACKAGING & REFERENCES

Primary Packaging: Individual single peel pack designated as a microbiological barrier to assure the sterility of the product.

Cardboard Box: Transport box for dispatching.

PACKAGING & PRODUCT LABEL



REFERENCES

Reference	Description	Size	Quantity per box
5295710	Askina® DresSil	5 x 7 cm	10
5291010	Askina® DresSil	10 x 10 cm	10
5291510	Askina® DresSil	15 x 15 cm	10
5291210	Askina® DresSil	10 x 20 cm	10
5292005	Askina® DresSil	20 x 20 cm	5

This document, its contents, including institutional data, information trademarks and logos mentioned herein are the exclusive property of B. Braun.

Any representation and / or reproduction, total or partial, of this document and its contents without the express prior consent of B. Braun, is strictly prohibited and constitutes an infringement of the intellectual property rights of B. Braun.

B. Braun Medical | SAS with a share capital of 31 000 000 € | RCS Nanterre 562050856

www.bbraun.com/wound-management

09/2021