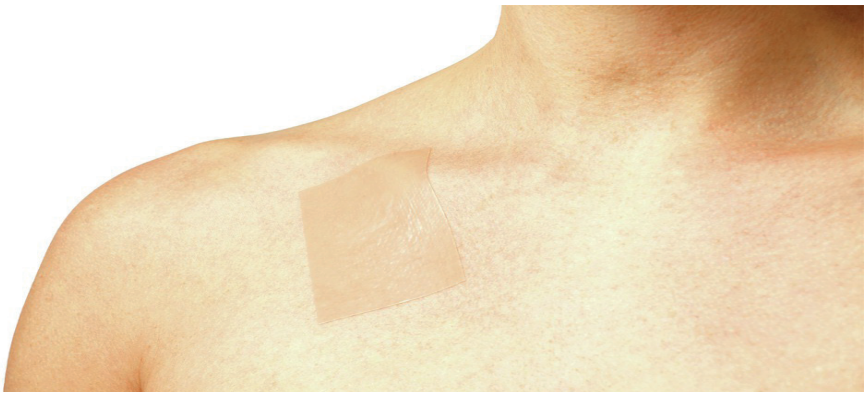
B BRAUN
SHARING EXPERTISE

ASKINA® Scar Repair

TECHNICAL FILE



ADMINISTRATIVE INFORMATION	
HEAD OFFICE ADDRESS	B. Braun Hospicare Ltd. Colloney, Co. Sligo. Ireland
SBA & PRODUCT MANAGER	Wound Management, Louis vanden Schrieck
SAFETY OFFICER MEDICAL DEVICES	Stephan Krause
LAST UPDATE	30/09/2020

DESCRIPTION, COMPOSITION AND PROPERTIES OF THE DEVICE	
COMMON NAME (FAMILY)	Scar Management (566)
TRADE NAME	Askina® Scar Repair
REFERENCES	5695705, 5691805, 5694305, 5691403
GMDN CODE	44898 - Non-sterile scar management dressings, reusable
MEDICAL CLASS	I ns
DESCRIPTION OF THE DEVICE	Askina® Scar Repair is a thin, conformable, reusable non-sterile adherent dressing consisting of a vapour permeable, waterproof outer film and non-woven laminate, a soft silicone skin contact layer which conforms to the wound surface and adheres safely to the skin.
COMPOSITION OF THE DEVICE	Components
	Tan coloured polyurethane film
	Non-woven (PET)
	Silicone gel
	Release liner (LDPE diamond grid)

PROPERTIES OF THE DEVICE	Thickness (without liner)	0,35 ± 0,05 mm
	Adhesive tack	450 – 800 gf

KEY DRIVERS & INDICATIONS	
KEY DRIVERS	Prevents formation of hypertrophic scars
	Prevents formations of keloid scars
	Reduces the size of hypertrophic or keloid scarring
	Waterproof
	Permeable to water vapour
	Self-adherent
	Very comformable and confortable to wear
	Easy to remove
	UV protection
	Can be re-applied uo to 7 times, depending upond residual adhesivity
	Can be used in conjunction with creams and lotions
INDICATIONS	Askina® Scar Repair is indicated for the management of:
	Hypertrophic and keloid scars
	Closed wounds for prevention of hypertrophic or keloid scarring after surgery
	Askina® Scar Repair is indicated for external use only.

STERILIZATION PROCESS: REPORT	
STERILE MD: YES/NO	No
STERILIZATION METHOD	N/A

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

SAFETY IN USE

TECHNICAL: MRI, X-RAY DETECTABLE	N/A
ORGANIC	Latex, DEHP, phthalate free
BIOCOMPATIBILITY	Doc References n° BER-027
STANDARDS & REQUIREMENTS	Council Directive 93/42/EEC
	UNE-EN ISO 13485:2018
	UNE-EN ISO 14971:2012
	UNE EN ISO 14698-1: 2004
	UNE-EN ISO 14644-2:2016
	UNE-EN ISO 1041:2009+A1:2014
	UNE-EN ISO 15223-1:2016
	UNE-EN ISO 10993-1:2018
	MEDDEV 2.7.1. Rev.·4
	ICH Guideline Q1A (R2)
	European Pharmacopeia

RECOMMENDED USE

IFU: YES/NO	Yes, presence of IFU n°P820-1243 Revision 01.
PRECAUTION OF USE	Precaution: Do not stretch the dressing during application as tension can cause skin trauma and may cause the dressing to lift at the corners. To prevent skin irritation and to ensure good adhesion, make sure the skin is clean, free of soap residue and lotion and allowed to dry thoroughly before applying the dressing.
CONTRAINDICATION	Contraindications: If signs of irritation or infection develop or if the scar deteriorates unexpectedly, contact the proper medical authority. Caution if known allergy to silicone exists. The product cannot be used on open or infected wounds.

ADDITIONAL PRODUCT INFORMATION

REUSABLE/SINGLE USE DEVICE	Reusable. Askina® Scar Repair is indicated for external use only.

PACKAGING & REFERENCES

Individual single peel pack. Transport box for dispatching and additional protection against damage during transportation.

PACKAGING & PRODUCT LABEL

REFERENCES

Reference	Description	Size	Quantity per box
5695705	Askina® Scar Repair	5 x 7.5 cm	5
5691805	Askina® Scar Repair	10 x 18 cm	5
5694305	Askina® Scar Repair	4 x 30 cm	5
5691403	Askina® Scar Repair	2 x 14 cm	5