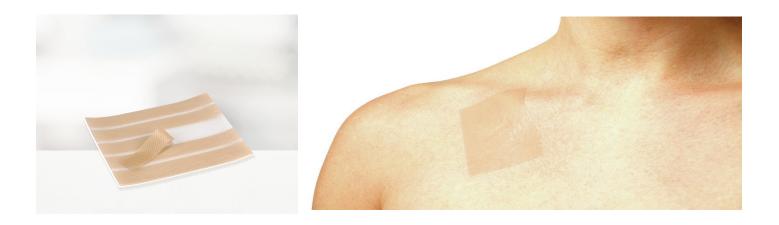


ASKINA[®] Scar Repair TECHNICAL FILE



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 P	ROPERTIES 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	l ns		
DESCRIPTION OF THE DEVICE	Askina [®] Scar Repair is a thin, conformable, reusable non-sterile adherent dressing con- sisting 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.		
	Components Tan coloured polyurethane film		

 COMPOSITION OF THE DEVICE
 Non-woven (PET)

 Silicone gel
 Release liner (LDPE diamond grid)

PROPERTIES OF THE DEVICE	Thickness (without liner)	0,35 ± 0,05 mm		
TRUPERTIES OF THE DEVICE	Adhesive tack	450 – 800 gf		
EY DRIVERS & INDICATIONS				
	Prevents formation of hyp	pertrophic scars		
	Prevents formations of keloid scars			
	Reduces the size of hyper	Reduces the size of hypertrophic or keloid scarring		
	Waterproof			
	Permeable to water vapour			
KEY DRIVERS	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			
	Askina® Scar Repair is inc	licated for the management of:		
	Hypertrophic and keloid scars			
INDICATIONS	Closed wounds for prever	ntion 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
	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
STANDARDS & REQUIREMENTS	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	
	Yes, presence of IFU n°P820-1243 Revision 01.
IFU: YES/NO PRECAUTION OF USE CONTRAINDICATION	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.
	Contraindications: If signs of irritation or infection develop or if the scar deteriorates unexpectedly, contact the proper medical authority. Caution if known allergy to silico- ne 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

BIBRAUN BIBRAUN BIBRAUN BIBRAUN BIBRA Askina® Scar Repair Askina® Scar Repair Askina® Scar Repair en Soft Silicone Dressing for de Weiche Silikon-Auflage es fr icone souple pour des cicatrices it de alicona de alicona Medi Diffuge 2 Lifera 3 Li dicazione al silicone per rattamento delle cicatrici destenser og iller bi nl acht siliconen verband vo itteken behandeling bg ка силиконова превр обработване на рани CEJ[™] ≜ Braun H ©©© ♣ ■ Slop CS ěkké silikonové krytí pro Μαλακό Επίθεμα Σιλικο για Διανείριση Ουλών el **BBRAUN BBRAUN** et side armide hu Askina® Scar Repair Askina® Scar Repair s silikona pārsējs по pl pt c C Hocke Sam c C Ansorat of He cleated C Ac 15 Strips Soft Silicone Dressing for Scar Management de sile v ES Silve ibhegek Mai E23 otija ritu kotija Iza 🖬 Pena CEA B Brau Colloc sk Mäkké silikó **B**BRAUN **B**BRAUN sv Mjukt silikonförband för ärrbehandling Yara İzi Yönetimi İçin Yumusak Silikon Örtü tr <u>A</u> @G ≭ **I** (E 50 13060-00 w P **BBRAUN**fec P ▲ 漆 i 5'0

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

PACKAGING & PRODUCT LABEL

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

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B. Braun Medical | SAS with a share capital of 31 000 000 ${\ensuremath{ \ensuremath{ \in \ensuremath{ \ensure$

www.bbraun.com/wound-management