Patient Information Document

pi40033-1 — 2025-03

EN

bess|folio, unrestricted (> 29 d)

Silicone Sheetings

MR CE 0297

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1 Dear Patient,

You have been given an implant of the type bess|folio, unrestricted (> 29d). For your own safety, please read this Patient Information Document carefully and keep it somewhere safe. If you have any questions about your implant, please contact the physician who treats you.

2 About this Document

2.1 Symbols Glossary

Symbol	Description
	MR safe
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	Distributor
	Patient name
	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website

Table 1: Symbols Glossary

2.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of your general condition or your death.

NOTICE

Product damage or other damage may occur in case of non-compliance.

2.3 Additional Information

Download link for the Patient Information Document:[1)]	https://www.besspro.eu/pi/pi40033
This patient information is based on the following instructions for use:	40033-14 (2025-03)
Disclaimer for the availability of the SSCP	As a general rule: The SSCP will only be made available after the product has been authorised in accordance with REGULATION (EU) 2017/745 (MDR). The implementation described here does not apply until the corresponding module of the Eudamed database comes into force. Until then, the SSCP is available at the following download link: https://www.besspro.eu/sscp/sscp40033
Summary of Safety and Clinical Performance (SSCP): [1)]	https://ec.europa.eu/tools/eudamed To search for the product-specific SSCP, enter the basic UDI-DI of the product.
Basic UDI-DI (device identifier):	4063106FOL8W

[1)] Updated on an ongoing basis.

The catalog number and batch code for your implant can be found on your implant card.

3 What you need to pay attention to

1. Always carry your implant card with you. Show your implant card and this Patient Information Document to your treating physician before undergoing diagnostic or therapeutic procedures.
2. Contact your doctor if you experience one or more of the following symptoms: Itching, pain, hearing loss
3. Stick to the appointments you make with your treating physician for follow-up examinations and observe their instructions for any necessary follow-up measures.

ATTENTION: Your bess|folio, unrestricted (> 29d) must be monitored regularly by your attending physician. Be sure to keep your appointments for these follow-up examinations and follow your physician's advice on the necessary aftercare measures. This is especially true when the intended lifetime of your bess|folio, unrestricted (> 29d) has been reached ([Expected Lifetime, page 3]).

4 Product Description

4.1 General information

Silicone sheetings for customisation. Depending on specification with polyester reinforcement.
[Specifications, page 3]

4.2 Materials with Potential Patient Contact

- Silicone sheetings: 100 % silicone, medical grade, implantable; depending on specification: with white pigments
- Polyester reinforcement (depending on specification): 100% polyester

5 Intended Purpose

5.1 Patient Target Group

The product is suitable for use in the following patient groups:

- Infants and young children
- Children and youth
- Adults
- Patients of all genders

5.2 Expected Lifetime

Expected lifetime of the product: 2 months

6 Possible Complications and Side Effects

The following product-related complications are known:

- Temporary conductive hearing loss (until product removal)
- Itchiness
- Light pain on removal

7 Combining with Other Procedures

The product is MRI safe.

8 Follow-up measures after removal of the product

Follow-up after product removal is at the discretion of your attending physician.

9 Specifications

REF	Dimensions [mm]	Properties
BM 20 3010	0,12 x 150 x 200	Transparent
BM 20 3011	0,12 x 150 x 200	White-transparent
BM 20 3020	0,25 x 150 x 200	Transparent
BM 20 3050	0,50x 150 x 200	Transparent
BM 20 3100	1,00 x 150 x 200	Transparent
BM 20 3150	1,50 x 150 x 200	Transparent
BM 20 3300	3,00 x 150 x 200	Transparent
BM 20 6050	0,50 x 150 x 200	Transparent, polyester-reinforced
BM 20 6100	1,00 x 150 x 200	Transparent, polyester-reinforced

REF	Dimensions [mm]	Properties
BM 20 6150	1,50 x 150 x 200	Transparent, polyester-reinforced

Table 2: bess|folio, unrestricted (>29d)