Patient Information Document

NO0094PI-1 — 2025-04

EN

FOLIOXANE® UNRESTRICTED (> 29 d)

Silicone Sheetings

MR CE 0297

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1 Dear Patient,

You have been given an implant of the type FOLIOXANE UNRESTRICTED (> 29 d). 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)]	www.novatech.fr/pi/no094pi
This patient information is based on the following instructions for use:	NO0094-15 (2025-04)
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: www.novatech.fr/sscp/sscp094
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 FOLIOXANE UNRESTRICTED (> 29 d) 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 FOLIOXANE UNRESTRICTED (> 29 d) 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
- 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

- 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
FU012XS	0,12 x 50 x 50	Transparent
FU025XS	0,25 x 50 x 50	Transparent
FU050XS	0,50 x 50 x 50	Transparent
FU100XS	1,00 x 50 x 50	Transparent
FU012S	0,12 x 70 x 90	Transparent
FU025S	0,25 x 70 x 90	Transparent
FU050S	0,50 x 70 x 90	Transparent
FU075S	0,75 x 70 x 90	Transparent
FU100S	1,00 x 70 x 90	Transparent

REF	Dimensions [mm]	Properties
FU150S	1,50 x 70 x 90	Transparent
FU300S	3,00 x 70 x 90	Transparent
FU050M	0,50 x 90 x 150	Transparent
FU100M	1,00 x 90 x 150	Transparent
FU012L	0,12 x 150 x 200	Transparent
FU025L	0,25 x 150 x 200	Transparent
FU050L	0,50 x 150 x 200	Transparent
FU075L	0,75 x 150 x 200	Transparent
FU100L	1,00 x 150 x 200	Transparent
FU150L	1,50 x 150 x 200	Transparent
FURD050S	0,50 x 70 x 90	Transparent, polyester-reinforced
FURD075S	0,75 x 70 x 90	Transparent, polyester-reinforced
FURD100S	1,00 x 70 x 90	Transparent, polyester-reinforced
FURD075M	0,75 x 90 x 150	Transparent, polyester-reinforced
FURD050L	0,50 x 150 x 200	Transparent, polyester-reinforced
FURD100L	1,00 x 150 x 200	Transparent, polyester-reinforced

Table 2: FOLIOXANE UNRESTRICTED (> 29 d)