Patient Information Document

N-ACSPI-1 — 2024-04

EN

LACS

Laryngeal Anterior Commissure Stent

MR CE 0297

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1 Dear Patient,

You have been given an implant of the type LACS. 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
	(EU) Authorized representative in the European Community
	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.

2.3 Additional Information

Download link for the Patient Information Document:[1)]	www.bosmed.com/pi/nacspi
This patient information is based on the following instructions for use:	N-ACS-11, 2024-04
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):	4063107LAK8P
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.bosmed.com/sscp/sscpnacs

[1)] Updated on an ongoing basis.

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

For Australia: In case that any serious incident has occurred in relation to the device the incident should be reported to the manufacturer and to the competent authority of the Member State in which you live. https://www.tga.gov.au/

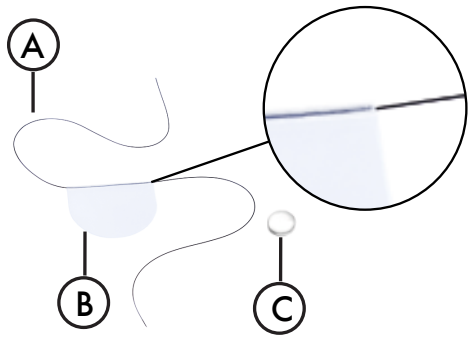
3 What you need to pay attention to

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: Pain at the suture site, sore throat, breathing difficulties, difficulty swallowing
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 LACS 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 LACS has been reached ([Expected Lifetime, page 3]).

4 Product Description

4.1 General information



A	Non-absorbable nylon monofilament suture thread 3.5 M (0 USP)
B	Silicon stent, 0.4 mm thick
C	Suture button

Illustration 1: LACS

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Stent	100% implant-grade silicone	Patient	With every use
Thread	100% nylon	Patient	With every use
Suture button	100 % silicone	Patient	With every use

5 Intended Use

5.1 Intended Purpose

Prevention and treatment of laryngeal glottic synechia (anterior glottic stenosis).

5.2 Patient Target Group

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

- Children and youth
- Adults
- Patients of all genders

5.3 Expected Lifetime

Expected lifetime of the product: 4 weeks
Maximum application duration: 4 weeks

6 Expected Clinical Benefit

According to the clinical evaluation, the product can be used safely and effectively for treatment according to the intended purpose mentioned.

7 Possible Complications and Side Effects

Possible intervention-related complications and side effects:

- Formation of granulation tissue
- Restenosis after removal of the device
- Laryngeal granuloma around the suture

- Skin inflammation at the suture
- Difficulties during surgery because of ossified thyroid cartilage

8 Combining with Other Procedures

⚠ WARNING

- Laser therapy, argon plasma coagulation, high-frequency surgery, and other procedures, the effect of which is due to heat:
  Do not use those methods directly on the product.
  Otherwise, injury to the tissue and product damage are possible.

The product is MRI safe.

9 Follow-up measures after removal of the product

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

10 Other Residual Risks

Beyond the listed safety instructions, possible complications and side effects, no further significant residual risks are known.