Patient Information Document
N-MTISPI-4 — 2025-02
EN

Montgomery® Thyroplasty Implant

Thyroplasty Implant

MR CE 0297

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1 Dear Patient,

You have been given an implant of the type Montgomery Thyroplasty Implant. 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
	Importer
	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/n-mtispi
This patient information is based on the following instructions for use:	N-MTIS-11
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/sscpnmtis
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):	4063107THYBG

[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

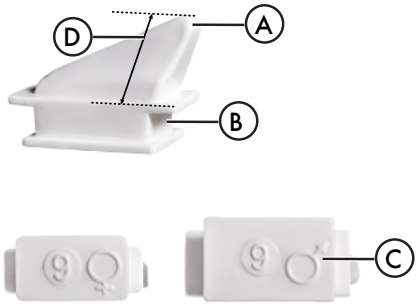
1. Always carry your implant card with you. Show your implant card and this Patient Information Document to your treating physician before undergoing diagnostic or therapeutic procedures.
2. Contact your doctor if you experience one or more of the following symptoms: Difficulties with voice formation / articulation, pain and bleeding in the throat, breathing difficulties, swallowing difficulties, foreign body sensation

ATTENTION: Your implant 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.

4 Product Description

4.1 General information

Part of the *Montgomery Thyroplasty Implant System*.



A	Tip
B	Notch
C	Base with indication of gender and size (= distance D in mm)
D	Reference for size indication

Illustration 1: Montgomery Thyroplasty Implant

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Montgomery Thyroplasty Implant (radiopaque)	100% blend of implant-grade silicone, barium sulphate and titanium dioxide	Patient	With every use

5 Intended Use

5.1 Intended Purpose

The product Montgomery Thyroplasty Implant System is designed for a surgical operation, which accomplishes medialization of an unilaterally paralyzed vocal cord in order to improve voice quality.

5.2 Patient Target Group

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

- Adults
- Patients of all genders

5.3 Expected Lifetime

No product-related restrictions.
Regular check-ups are needed.

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

- Failure to obtain satisfactory phonation, sometimes resulting in a second procedure to replace the implant with an implant of a different size
- Difficulty to stabilize the implant as intended in the thyroplasty window
- Laryngeal edema / intra-laryngeal bleeding that could interfere with the laryngeal airway
- Laryngeal dyspnea
- Tracheal obstruction
- Late postoperative problems such as keloid scar, edema of the paralyzed true vocal cord, and granuloma of the contralateral mobile arytenoid 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 Other Residual Risks

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

10 Follow-up measures after removal of the product

If the product is removed again, follow-up is at the discretion of your treating physician.