Patient Information Document

NO0087PI-2 — 2021-11

EN

EWS™

Endobronchial Watanabe Spigots

MR CE 0297

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1 Dear Patient,

You have been given an implant of the type EWS. 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
	Patient name
	Implantation date
	Name of facility through which the implantation was performed
	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.

3 What you must look out for

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. Avoid activities that put a lot of strain on the chest or lungs (e.g. sports activities).
3. Contact your doctor if you experience one or more of the following symptoms: Breathing difficulties, shortness of breath, hemoptysis (bloody cough)
4. 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 EWS 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 Device Description

4.1 General

- Radiopaque
- Conical
- Studded exterior

EWS	Ø max. [mm] (without studs)
S	5
M	6
L	7

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
EWS	100% mixture of implant-grade silicone and pharmaceutical barium sulphate	Patient	With every use

5 Intended Use

5.1 Intended Purpose

Occlusion of segmental and subsegmental bronchi during bronchoscopy.

5.2 Indications

- Bleeding of the segmental or subsegmental bronchi
- Pneumothorax

5.3 Contraindications

Bronchial anatomy, which makes a safe placement of the product impossible.

5.4 Patient Target Group

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

- Children and youth
- Adults
- Patients of all genders

5.5 Expected Lifetime

No product-related restrictions.
Duration of treatment at the discretion of the treating physician.
The product, in most cases, will be removed upon healing of the surgical repair.

6 Expected Clinical Benefit

According to the clinical evaluation, the product can be used easily and safely for treatment according to the indications mentioned.

7 Possible Complications and Side Effects

- Migration
- Infection
- Atelectasis
- Dyspnoea
- Fever
- Temporary hemoptysis
- Obstructive pneumonia

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.
Any method for reducing tissue, such as chemotherapy or radiation therapy, can lead to migration.

9 Follow-up measures after removal of the product

The follow-up measures after removal of the product will depend on your underlying disease as well as your general health and shall be at the discretion of your treating physician.

10 Additional Information

Download link for the Patient Information Document:[1)]	www.novatech.fr/pi/no087pi
Summary of Safety and Clinical Performance (SSCP): [1) 2)]	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):	4063108EWSAD

[1)] Updated on an ongoing basis.

[2)] Is only available with the entry into force of the EUDAMED database.

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

For Australia:

ATTENTION: 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/