Instructions for Use

NO087-9 — 2020-08

EN

EWS™

Endobronchial Watanabe Spigots

NOVATECH SA

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1 About this Document

1.1 Symbols Glossary

Symbol	Description
	Caution: Consult Instructions for Use
	Do not use if package is damaged
	Keep away from direct sunlight
	Keep dry
	Sterilized using hydrogen peroxide
	Do not re-use
	Do not resterilize
	Single sterile barrier system
	MR safe
	Medical device
	Catalog number
	Batch code
	Quantity per packaging unit
	Manufacturer
	Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling).

Table 1: Symbols Glossary

1.2 Terminology

- Distal: From the surgeon's view further away
- Proximal: From the surgeon's view closer

1.3 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

1.4 Additional Information

Download link for these Instructions for Use:	www.novatech.fr/fr/ifu/no087

2 Important Safety Information

⚠ WARNING

- Before using the product, read the Instructions for Use. Adhere to and save the Instructions for Use.
  Otherwise there are risks to the health of your patient.
- Application only by a physician trained in the procedure.
  Otherwise there are risks to the health of your patient.
- Do not disassemble or modify the product.
  Otherwise there are risks to the health of your patient.

3 Product Codes / REF

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4 Scope of Delivery

REF	Quantity EWS	Size EWS
01EWS12A	12	3 x S 6 x M 3 x L
01EWS3S	6	6 x S
01EWS3M	6	6 x M
01EWS3L	6	6 x L

Product sterile, individually packaged, in blister pack.

5 Intended Use

Occlusion of segmental and subsegmental bronchi during bronchoscopy.

6 Indication

- Pneumothorax
- Bleeding of the segmental or subsegmental bronchi

7 Contraindication

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

8 Special Patient Groups

Does not apply.

9 Product Description

- Radiopaque
- Conical
- Studded exterior

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

10 Material

- Silicone (unrestricted)
- Barium sulfate

Not made with natural rubber (latex).
No products made with natural rubber (latex) are used in the production process.

11 Lifetime

No product-related restrictions.
Duration of treatment at the discretion of the treating physician.

12 Shelf Life and Storage

For date of expiry, see the product label.

13 Possible Complications and Side Effects

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

14 Combining with Other Procedures

⚠ WARNING

- Laser therapy, argon plasma therapy, 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.

15 Reprocessing

⚠ WARNING

- Single use product: Do not reprocess (e.g., clean, disinfect, sterilize), resterilize or reuse the product.
  This is the only way to ensure the product is germ-free and functional. Due to the mechanical properties of the product, reprocessing or resterilization could lead to material degradation.

16 Application Instructions

⚠ WARNING

- Do not use the product if the packaging or the product is damaged or expired.
  This is the only way to ensure the product is germ-free and functional.
- Choose product size according to the anatomic situation.
  Otherwise, there may be necrosis or migration.

Ensure the presence of hygienic / sterile conditions needed for the intervention.

16.1 Required Equipment and Materials

- Flexible bronchoscope
- Balloon catheter
- Foreign body forceps

All in sterile condition.

- Fluoroscopic equipment

16.2 Product placement

1. Locate the leakage / bleeding using the balloon catheter.
2. Introduce the foreign body forceps outside the patient into the flexible bronchoscope. The distal end of the foreign body forceps must protrude from the bronchoscope.
3. Hold EWS by its wide flat side so that its angle to the foreign body forceps corresponds to the anatomic alignment of the target bronchus as much as possible.
4. Introduce EWS into the identified bronchus using the bronchoscope.
5. Tightly press EWS into the target bronchus.
6. If several leakages / bleeding are identified: Repeat the procedure with more EWS.
7. Perform an x-ray to determine and document the product position.

16.3 Remove the product

1. Introduce the foreign body forceps through the working channel of the bronchoscope.
2. Grasp the EWS and pull it out together with the foreign body forceps and the bronchoscope.

17 Instructing the Patient

The instruction to the patient must include:

- If symptoms persist, see the treating doctor.
- Avoid activities that put a lot of strain on the chest or lungs (e.g. sports activities)

18 Aftercare

- Follow-ups as indicated by the treating physician.

19 Maintenance

Does not apply.

20 Disposal

⚠ WARNING

- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk.
  Otherwise there is a risk of infection for the user and for third parties.

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

21 Warranty

The reliability of the product's material and design at the time of shipment is guaranteed. The manufacturer does not know either the diagnosis of the patient or the nature of the application and has no influence on the conditions under which the product is used. The storage conditions after delivery of the product are also beyond the manufacturer's area of responsibility.

Due to biological and individual differences, no product is 100% effective under all circumstances.

Therefore, the manufacturer cannot guarantee a positive effect or the absence of negative effects for product application. The medical staff must use the product on the basis of their medical training and experience, and they are responsible for correct application.

The warranty (repair or replacement) applies only if the product is used in accordance with these Instructions for Use (for instruments, particularly with regard to handling, cleaning, sterilization and maintenance); the warranty period starts on the delivery date.

If you have reason to believe that a new product is faulty, please contact the Customer Service in writing immediately and provide as detailed a description as possible of the fault, the REF (product code), and the LOT (batch code) and/or series number. All allegedly defective products must be returned to us for inspection. Instruments have to be completely cleaned and sterilized, appropriate documentation must be enclosed with the return.

If the manufacturer finds that despite all due care the product was defective at the time of delivery, he will repair the product or replace it promptly. If repair or replacement of the product is not possible, the buyer has the right to cancel the purchase or to reduce the payment, but by a maximum of the purchase price amount.

Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, his agents, dealers and suppliers, are excluded unless existing law is contrary to the liability exclusion, e.g. in cases of intent or gross negligence or in the event of physical injury.

All claims based on the consequences of non-compliance with the Instructions for Use, including specified indications, contraindications, warnings, instructions, application, storage and off-label use, as well as the consequences of a combination with third-party products are excluded.

Furthermore, all claims that result from the use of products that have expired, or were used despite the obvious damage to the packaging, or resterilized and/or recycled contrary to the Instructions for Use, are excluded.

No one is allowed to change the above conditions, make further warranty or liability declarations, or guarantee any properties that surpass those specified in the Instructions.

The General Terms and Conditions of the manufacturer, which can be accessed at http://www.novatech.fr/gtc apply in all remaining instances.

22 Additional information

Dutau, Hervé; Palot, Alain; Haas, Andrew; Decamps, Isabelle; Durieux, Olivier (2006): Endobronchial Embolization with a Silicone Spigot as a Temporary Treatment for Massive Hemoptysis. Respiration, 73 (6), 830-832.

Watanabe, Y. et al. (2003): Bronchial Occlusion with Endobronchial Watanabe Spigot. Journal of Bronchology, 10 (4), 264-267.