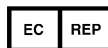


Instructions for Use
N-MTIT -2.0 — 2019-07
EN

Montgomery® Thyroplasty Instrument Set Thyroplasty Instrument Set



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1 About these Instructions for Use

1.1 Symbols Glossary












Symbol	Title/Description of Symbol	Standard Designation Number + Symbol Designation Number
	Caution: Consult Instructions for Use	ISO 15223-1:2016 – 5.4.4
	Do not use if package is damaged	ISO 15223-1:2016 – 5.2.8
	Keep away from direct sunlight	ISO 15223-1:2016 – 5.3.2
	Keep dry	ISO 15223-1:2016 – 5.3.4
	Catalog number	ISO 15223-1:2016 – 5.1.6
	Batch code	ISO 15223-1:2016 – 5.1.5
	Quantity per packaging unit	N/A
	Manufacturer	ISO 15223-1:2016 – 5.1.1
	(EU) Authorized representative in the European Community	ISO 15223-1:2016 – 5.1.2
	(USA) Caution: Federal Law restricts this device to sale by or on the order of a physician.	N/A
	Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling).	N.a.

Table 1: Symbols Glossary

Standard Designation Number	Standard Title
ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Table 2: Titles of Standards used in the Symbols Glossary

1.2 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.

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.

3 Product Codes / REF

3.1 Thyroplasty Instrument Set

REF	Name
MT-200	Thyroplasty Instrument Set
MT-200P	Thyroplasty Instrument Set (Single Procedure Set)

3.2 Thyroplasty Instruments

REF	Name
MT-201	Window Caliper, 7 mm, Female
MT-202	Window Caliper, 9 mm, Male
MT-203	Outline Instrument, Female
MT-204	Outline Instrument, Male

REF	Name
MT-205	Curved Hook, Small
MT-206	Curved Hook, Large
MT-207	Sharp Hook, Small
MT-208	Sharp Hook, Large
MT-209	Duckbill Elevator, 3 mm
MT-210	Duckbill Elevator, 5 mm
MT-211	Chisel Elevator
MT-212	Implant Inserter, Female
MT-213	Implant Inserter, Male

4 Scope of Delivery

The product is non-sterile but clean and ready for sterilization.

4.1 Thyroplasty Instrument Set

- 1 x each thyroplasty instrument [▶Thyroplasty Instruments, page 3]
- 1 x Thyroplasty Instrument Set Tray
- 1 x Product Registration Card (for US use only)

4.2 Thyroplasty Instrument

- 1 x thyroplasty instrument according to specification

5 Intended Use

The *Montgomery Thyroplasty Implant System* is designed as part of a surgical operation, which accomplishes medialization of a paralyzed vocal cord in order to improve voice quality.

6 Indication

- Unilateral vocal cord paralysis

7 Contraindication

There are no known contraindications.

8 Special Patient Groups

Does not apply.

9 Product Description

Part of the *Montgomery Thyroplasty Implant System*.

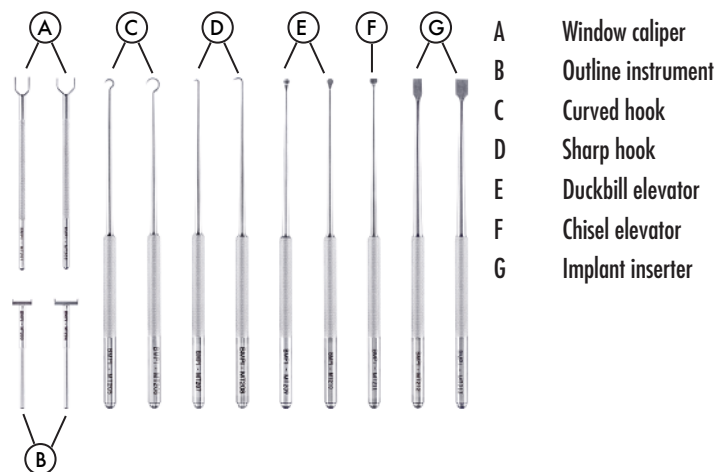


Illustration 1: Instruments

10 Material

- Thyroplasty Instruments: Stainless steel
- Tray: Plastic, metal

11 Lifetime

[▶Limitations on Reprocessing, page 5]

12 Shelf Life and Storage

[▶Limitations on Reprocessing, page 5]

13 Possible Complications and

Please refer to *Instructions for Use: Montgomery Thyroplasty Implant, Montgomery Thyroplasty Measuring Kit (N-MTIS)*.

Side Effects

14 Combining with Other Procedures

Does not apply.

15 Reprocessing

The instructions listed below have been validated by the medical device manufacturer as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions should be properly evaluated for effectiveness and potential adverse consequences.

15.1 Warnings

15.1.1 General information

Does not apply.

15.1.2 Cleaning and Disinfection Agents

Only use agents suitable for cleaning / disinfection of metals.

15.2 Limitations on Reprocessing

Frequent reprocessing has little impact on these instruments. The end of the product lifetime is usually based on wear and tear as well as damage from use.

15.3 Pre-treatment at the Point of Use

Does not apply.

15.4 Preparation for Cleaning

Start:	As soon as possible, but at the latest 30 min after product use
<ol style="list-style-type: none">1. Remove any gross contaminants and residues. To do so, soak a disposable sponge or gauze-pad in water and clean the product with it. Clean areas that are difficult to access with a soft bristle brush.2. Carry out a visual inspection to make sure that the product is free from contaminants and residues. Otherwise repeat cleaning.	

15.5 Automated Cleaning and Disinfection

Not validated for this product.

15.6 Manual Cleaning and Disinfection

Required materials:

- Cleaning agent: MadaClenz-Plus (MADA, Carlstadt, NJ 07072)
- Disinfection agent: MadaCide-I (MADA, Carlstadt, NJ 07072)
- Soft bristle brush
- Distilled water

Make sure that while in the bath the product is well-covered with liquid and that it does not come in touch with any other products.

15.6.1 Manual Cleaning

1. Place the product in the cleaning bath for the prescribed reaction time.
2. Remove the product from the cleaning bath.
3. Rinse the product 2 times in distilled water. Use fresh water each time.

15.6.2 Manual Disinfection

1. Prepare an ultrasonic cleaner with disinfectant / detergent agent solution and submerge the product. Dilution and duration as directed by the manufacturer.
2. Place the product in the disinfection bath for the prescribed reaction time.
3. Clean the product in the ultrasonic bath (42 kHz, 10 min, 20 °C).
4. Remove the product from the disinfection bath.
5. Rinse the product 2 times in distilled water. Use fresh water each time.

15.7 Drying

1. Wipe off any excess water.
2. Place product on a clean surface to dry.

15.8 Inspection and Function Testing

3. Return the instruments to the tray.
1. Inspect the product for dirt. Clean and disinfect contaminated products again.
2. Inspect the products for damage (e.g., damaged surfaces, deformations, other mechanical damage). Separate damaged products.

15.9 Packaging

Does not apply with flash sterilization procedure for immediate use.

Packaging requirements:

- Adequate protection of the product and the sterilization packaging from mechanical damage
- Adequate packaging size (tension-free sealing)
- Suitable for steam sterilization

1. Wrap the tray with instruments in the sterilization packaging.

15.10 Sterilization

Method A

Sterilization procedure:	Gravitation procedure
Minimum temperature:	121 °C
Minimum holding time:	20 min
Minimum drying time:	10 min

Method B

Sterilization procedure:	Gravitation procedure, flash (unwrapped, for immediate use)
Minimum temperature:	132 °C
Minimum holding time:	5 min
Minimum drying time:	10 min

15.11 Storage

After sterilization, store the product dry and dust-free in the sterilization packaging.

15.12 Additional Information

Does not apply.

16 Application Instructions

WARNING

- The product is not sterile. Process the product before first and any further application. This is the only way to ensure the product is germ-free and functional.

Please refer to *Instructions for Use: Montgomery Thyroplasty Implant, Montgomery Thyroplasty Measuring Kit (N-MTIS)*.

17 Instructing the Patient

Does not apply.

18 Aftercare

Does not apply.

19 Maintenance

Does not apply.

20 Disposal

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 re-sterilized 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.bosmed.com> apply in all remaining instances.