Instructions for Use
N-MSTT-12 — 2022-11
EN

Montgomery® Safe-T-Tube™

Tracheal T-Tube

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Table of Contents

1 About this Document

1.1 Symbols Glossary

Symbol	Title/Description of Symbol	Standard Designation Number + Symbol Designation Number
	Caution: Consult Instructions for Use	ISO 20417: 2021 - ISO 7010-M002
	Do not use if package is damaged	ISO 15223-1: 2021 - 5.2.8
	Keep away from direct sunlight	ISO 15223-1: 2021 - 5.3.2
	Keep dry	ISO 15223-1: 2021 - 5.3.4
	Use-by date	ISO 15223-1: 2021 - 5.1.4
	Sterilized using ethylene oxide	ISO 15223-1: 2021 - 5.2.3
	Do not re-use	ISO 15223-1: 2021 - 5.4.2
	Do not resterilize	ISO 15223-1: 2021 - 5.2.6
	Double sterile barrier system	ISO 15223-1: 2021 - 5.2.12
	MR safe	ASTM F2503- 20 – 7.3.1
	Medical device	ISO 15223-1: 2021 - 5.7.7
	Catalog number	ISO 15223-1: 2021 - 5.1.6
	Batch code	ISO 15223-1: 2021 - 5.1.5
	Unique Device Identification (UDI)	ISO 15223-1: 2021 - 5.7.10
	Quantity per packaging unit	N/A
	Manufacturer	ISO 15223-1: 2021 - 5.1.3
	Date of manufacture	ISO 15223-1: 2021 - 5.1.3
	(EU) Authorized representative in the European Community	ISO 15223-1: 2021 - 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
	Patient name	ISO 15223-1: 2021 - 5.7.3
	Date of implantation	ISO 15223-1: 2021 - 5.7.6
	Name of the implanting healthcare institution / provider	ISO 15223-1: 2021 - 5.7.5
	Patient information website	ISO 15223-1: 2021 - 5.7.4

Table 1: Symbols Glossary

Standard Designation Number	Standard Title
ISO 15223-1: 2021	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
ASTM F2503- 20	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

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.

1.3 Additional Information

Download link for these Instructions for Use:[1)]	www.bosmed.com/ifu/n-mstt
Download link for the Patient Information Document:[1)]	www.bosmed.com/pi/n-msttpi
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):	4063107STTC5
Disclaimer for the availability of the SSCP	The implementation described here applies only with the entry into force of the EUDAMED database.

[1)] Updated on an ongoing basis.

1.4 Safety-related Changes

Document number	Edition date	Changes
N-MSTT- 11	2022-09	Added: WARNING: When using the product Montgomery Safe-T-Tube concomitantly with other implants in the vicinity of the target area: Use great care in planning, product selection, fitting and placement. Also make sure that the products do not touch each other in situ, even if the patient swallows or coughs. WARNING: Always secure the tracheal T-tube using the safety ring of the plug/ring set. WARNING: Do not grasp the product with pointed or sharp instruments (e.g., for placing or removing the product). WARNING: If the upper limb of the tracheal T-tube is blocked (e.g., by a foreign object or by concomitant use of a closed laryngeal stent): Ensure the external limb is free of obstruction and the patient can safely breathe through this airway.
N-MSTT- 12	2022-11	None

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.

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 the user and/or patient is established.

3 Product Codes / REF

3.1 Tracheal T-Tube

Size	REF: Clear / Radiopaque
6 mm	320006 / 32006R
7 mm	320007 / 32007R
8 mm	320008 / 32008R
9 mm	320009 / 32009R

Table 3: Pediatric

	REF: Clear / Radiopaque		
Size	Standard	Thoracic	Extra-long
10 mm	420010 / 42010R	520010 / 52010R	620010 / 62010R
11 mm	420011 / 42011R	520011 / 52011R	620011 / 62011R
12 mm	420012 / 42012R	520012 / 52012R	620012 / 62012R
13 mm	420013 / 42013R	520013 / 52013R	620013 / 62013R
14 mm	420014 / 42014R	520014 / 52014R	620014 / 62014R
15 mm	420015 / 42015R	520015 / 52015R	620015 / 62015R
16 mm	420016 / 42016R	520016 / 52016R	620016 / 62016R

Table 4: Standard / Thoracic / Extra-long

Size	REF: Clear / Radiopaque
8 / 10 mm	721008 / 71008R
10 / 13 mm	721310 / 71310R

Table 5: Tapered

If the required length of the product is known prior to surgery the manufacturer will customize the product as needed. For further information please contact the manufacturer.

3.2 Accessories / Replacement Parts

REF	Name
321066	Plug/Ring Set: 6/7 mm
321086	Plug/Ring Set: 8/9 mm
321106	Plug/Ring Set: 10 mm
321126	Plug/Ring Set: 11 mm
321107	15 mm Adaptor: 10 mm
321127	15 mm Adaptor: 11 - 16 mm

Table 6: Accessories / Replacement Parts

ATTENTION: These parts are non-sterile and sold seperately.

4 Scope of Delivery

- 1 x Tracheal T-Tube
- 2 x plug/ring set
- 1 x Patient Pak ™
  - 1 x Cleaning and Care Instructions (N-STCC)
  - 1 x Plug/Ring Set storage container
- 1 x implant card
- 3 x product label

5 Product Description

5.1 General information

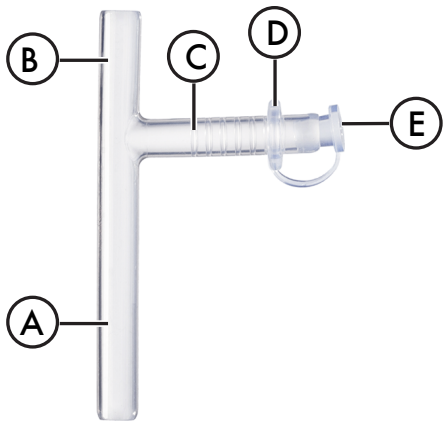


Illustration 1: Montgomery Safe-T-Tube

A	Lower limb (intraluminal), smooth
B	Upper limb (intraluminal), smooth
C	External limb (extraluminal), with ring and groove system
D	Plug/ring set: Safety ring
E	Plug/ring set: Plug

- Clear / radiopaque (depending on specifications)

5.2 Structure and Operation

With its radial force, the product holds the trachea and a tracheostoma open, thus maintaining a tracheal airway, and stabilizes the reconstituted or reconstructed trachea.

5.3 Materials with Potential Patient Contact

The following table lists all materials of the implant with which the user or the patient has contact during use, either for every application ("standard") or in case of a damage to the product ("potentially").

Product (part)	Material	Contact person	Type of contact
Montgomery Safe-T-Tube (clear)	100% implant-grade silicone	Patient	Standard
Montgomery Safe-T-Tube (radiopaque)	100% blend of implant-grade silicone, barium sulphate and titanium dioxide	Patient	Standard

Not made with natural rubber (latex).
No products made with natural rubber (latex) are used in the production process.
ATTENTION: Do not use the product if the patient has known intolerances / allergies to the materials used.

5.4 Other Devices to be Used in Combination with the Device

Aside from the equipment and materials required for placement, the product Montgomery Safe-T-Tube is intended to be used in conjunction with the following products:

- Respiratory accessories

6 Intended use

6.1 Intended Purpose

The product is designed to maintain an adequate tracheal airway, as well as to provide support in the stenotic trachea that has been reconstituted or reconstructed.

6.2 Indications

- Acute laryngotracheal injuries
- Support reconstituted airway
- Support reconstructed airway
- With segmental resection and anastomosis
- With tracheal stenosis when the cervical airway cannot be repaired
- Substitute for the cervical trachea when it cannot be reconstructed

6.3 Contraindications

- Aspiration by the patient

- Positive pressure-assisted respiration

6.4 Patient Target Group

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

- Children and youth
- Adults
- Patients of all genders

6.5 Intended User

6.5.1 Initial Product Placement

The intended user is a physician with experience in treating similar cases with this product or with comparable products or a physician with the following speciality:

- ENT (otorhinolaryngology)
- Thoracic surgery

6.5.2 Cleaning and Care

Patient or caregiver [Instructing the Patient, page 11]

6.6 Expected Lifetime

⚠ WARNING

- Do not use products that have become damaged.
  This is the only way to ensure the product is functional.

Expected lifetime: 6 months
Maximum application duration: 6 months

6.7 Intended Place of Use

6.7.1 Initial Product Placement

- Operating theatre
- Treatment room
- Endoscopic procedure room
- Examination room

6.7.2 Cleaning and Care

- Examination room (outpatient care)
- Domestic environment

7 Expected Clinical Benefit

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

8 Possible Complications and Side Effects

- Granulation tissue formation in the airway with the need of surgical intervention
- Secretion obstruction
- Microbial colonisation
- Infection

9 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.
- With anaesthesia: Use a balloon catheter to occlude the upper end of the product. Make sure that the balloon catheter does not protrude beyond the upper end of the product.
  Otherwise there is no closed system. The supply of your patient is not ensured.

The product is MRI safe.

10 Shelf Life and Storage

For date of expiry, see the product label.
Store the product in unopened original packaging.

11 Processing

⚠ WARNING

- Single use product: Do not process (e.g., 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, processing or resterilization could lead to material degradation.

12 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.
- Only remove the product from storage packaging immediately before use. When the product is removed from the packaging, observe the relevant hygienic regulations.
  Otherwise there are risks to the health of your patient.
- Choose product size according to the anatomic situation. Make sure to provide an adequate airway.
  Otherwise, there may be necrosis / migration / risk of suffocation.
- In case of product modifications, ensure that there are no sharp edges.
  Otherwise there is a risk of injury.
- Do not grasp the T-Tube with pointed or sharp instruments (e.g., for placing or removing the product).
  Otherwise, the T-tube may be damaged and parts of the T-tube may enter the lower airways. There is a risk of patient suffocation.
- Make sure that the upper end of the tracheal T-Tube does not rest on the vocal cord level but at level of the inferior subglottis.
  Otherwise there is the risk of aspirating fluids or food.
- Always secure the tracheal T-tube using the safety ring of the plug/ring set.
  Otherwise the product can get into the lower respiratory tract. Otherwise there is a risk of patient suffocation.
- If the upper limb of the T-tube is blocked (e.g., by a foreign object or by concomitant use of a closed laryngeal stent):
  Ensure the external limb is free of obstruction and that the patient can safely breathe through this airway.
  Otherwise there is a risk of patient suffocation.
- When using the product Montgomery Safe-T-Tube concomitantly with other implants in the vicinity of the target area: Use great care in planning, product selection, fitting and placement. Also make sure that the products do not touch each other in situ, even if the patient swallows or coughs.
  Otherwise there is a risk of patient injury.

ATTENTION: If the use of respiratory accessories is required: Use the 15 mm adaptor (available as an accessory). To do so, insert the smaller end of the 15 mm adaptor into the external limb of the tracheal T-Tube.
Perform intervention under general anaesthesia.
Generelly recommended procedure: [▸Product Placement - through Tracheostoma, page 9]
[▸Product Placement - Endoscopically, page 9]
Procedure recommended for patients with subglottic stenosis: [▸Product Placement - Endoscopically, page 9]

12.1 Required Equipment and Materials

- If the use of respiratory accessories is required: 15 mm adaptor of required size

12.1.1 Placement through Tracheostoma

- 2 x curved hemostat

12.1.2 Endoscopic Placement

- Laryngoscope
- Dilators
- Endoscopic forceps

For placement through a catheter aditionally:

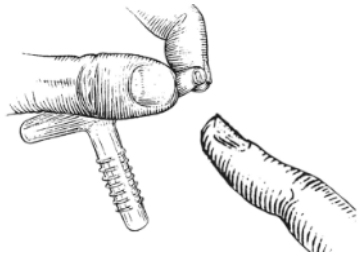
- Small catheter

12.2 Product Preparation

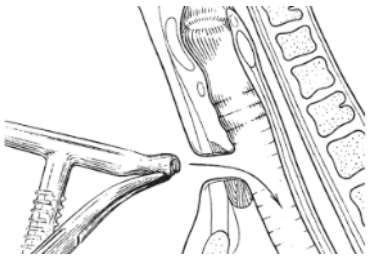
1. Carefully remove the product from the sterile packaging.

12.3 Product Placement - through Tracheostoma

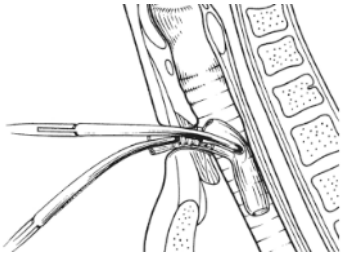
1. Trim the product if needed.
   ATTENTION: Make sure that the upper end of the tracheal T-Tube rests at level of the inferior subglottis and that there are no sharp edges. See safety instructions: [Application Instructions, page 8]



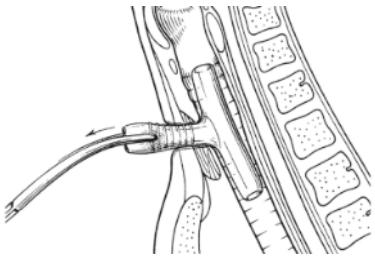
2. Grasp the end of the lower limb with the first hemostat.



3. Insert the grasped end through the tracheostoma into the inferior trachea. Release the first hemostat.



4. Grasp the end of the upper limb with the first hemostat. Grasp the end of the external limb with the second hemostat.
5. Insert the grasped end of the upper limb through the tracheostoma into the superior trachea. Release the first hemostat.



6. Use the second hemostat to pull the tracheal T-Tube into anterior direction until the tracheal T-Tube is in its correct position. Release the second hemostat.

12.4 Product Placement - Endoscopically

12.4.1 Access

1. Expose the larynx using a laryngoscope.
2. Dilate the subglottic stenosis using the dilators.
3. Chose the tracheal T-Tube: The diameter must be slightly smaller than the diameter of the largest dilator that passed the stenosis.
4. Trim the product if needed.
   ATTENTION: Make sure that the upper end of the tracheal T-Tube rests at level of the inferior subglottis and that there are no sharp edges. See safety instructions: [Application Instructions, page 8]

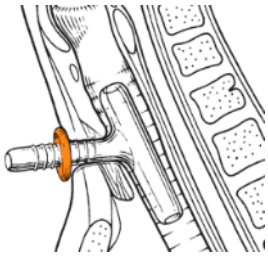
12.4.2 Product Placement Using a Small Catheter

1. Insert the forceps through the laryngoscope.
2. Insert the small catheter through the tracheostoma and grasp it with the forceps.
3. Pull the catheter out of the mouth.
4. Insert the catheter through the external limb first and then through the upper limb of the tracheal T-Tube.
5. Fix the catheter with a ligature at the upper end of the tracheal T-Tube.
6. Insert the tracheal T-Tube into the larynx. Pull the external limb out of the tracheostoma. The lower limb glides into the inferior trachea.
7. Release the ligature. Remove the catheter.

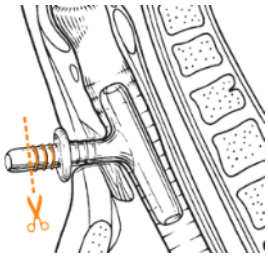
12.4.3 Alternative: Product Placement Using Endoscopic Forceps

1. Use a laryngoscope and endoscopic forceps to insert the tracheal T-Tube through the subglottic region into the inferior trachea.
2. Visualize the external limb of the tracheal T-Tube through the tracheostoma.
3. Grasp the external limb with a hemostat / with forceps and pull it through the tracheostoma.

12.5 Securing the Product



1. Install the safety ring of the plug/ring set on the external limb. If neccessary, cut the safety ring off the plug with the help of scissors. ATTENTION: Advance the safety ring until it rests against the skin. In this way, the safety ring helps to prevent a dislodgement of the tracheal T-Tube in posterior direction.
2. If the smooth portion instead of the portion with the ring and groove system is visible outside the body: Install a second safety ring on the external limb. The first safety ring will work as a spacer, the second safety ring will fix the tracheal T-Tube in place.



3. Shorten the external limb by cutting it with straight scissors or a scalpel blade. ATTENTION: Leave a length of at least 2 rings of the ring and groove system past the safety ring to enable the tracheal T-Tube to be grasped if neccessary.

12.6 Product Removal

1. Grasp the external limb with one hand.
2. Press the fingers of the opposite hand firmly against the skin above and below the tracheostoma.
3. Remove the tracheal T-Tube with a steady and firm pull into anterior direction. If neccessary apply a small vertical incision above and below the tracheostoma.
4. If neccessary: Grasp any parts of the tracheal T-Tube that remain in the trachea with a curved hemostat and remove them.

13 Aftercare

13.1 Configuration of the T-Tube

⚠ WARNING

- If the upper limb of the T-tube is blocked (e.g., by a foreign object or by concomitant use of a closed laryngeal stent): Ensure the external limb is free of obstruction and that the patient can safely breathe through this airway. Otherwise there is a risk of patient suffocation.

Provided the upper limb is free of obstruction and the patient can safely breathe through this airway: Occlude the external limb with the plug.
If the external limb is not closed for a longer period of time: Supply humidified air.

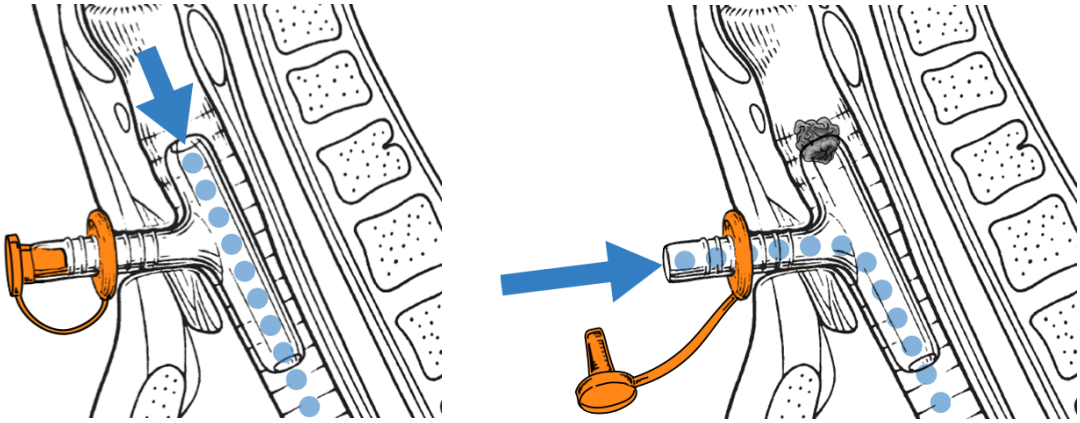


Illustration 2: Left: Upper limb is free, Right: Upper limb is blocked

ATTENTION: As a general rule, the T-tube must be secured with the safety ring. If the T-tube cannot be secured with the safety ring for a short time (e.g. during tracheostoma care): Hold the external limb firmly so that the T-tube does not slip into the trachea.

13.2 Patient Monitoring

Monitor air movement and breath sounds, and evaluate at least once every eight hours.
Monitor the position of the external limb:

- Position changes to anterior: Possibly indicates edema
- Position changes to posterior: Possibly indicates a displacement

14 Instructing the Patient

ATTENTION: Fill out the implant card and give it to the patient.
Prior to being discharged from hospital the patient / a caregiver must be able to perform all procedures according to *Cleaning and Care Instructions* (N-STCC). ATTENTION: Forward *Cleaning and Care Instructions* to the patient.

15 Follow-up measures after removal of the product

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

16 Cleaning and Care

16.1 General

⚠ WARNING

- Always keep the tracheal T-tube clean and free from obstructions.
  Otherwise there is a risk of patient suffocation.
- To be prepared for an emergency removal of the tracheal T-Tube: Always keep a standard tracheal cannula in a size smaller than that of the tracheal T-Tube at hand.
  Otherwise there is a risk of patient suffocation.

Keep at hand during the complete application duration:

- Appropriate standard tracheal cannula
- Curved hemostat, atraumatic

Cleaning and care of the tracheostoma: At the discretion of the treating physician.

16.2 Lavage of the Tracheal T-Tube

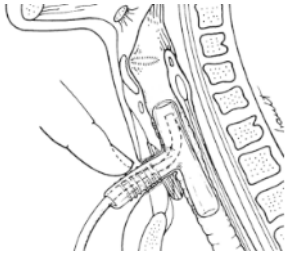
- Frequency: Every 2 hours (with patient awake) / every 4 hours (with patient asleep)

1. Remove the plug.
2. Use a syringe without needle to apply 1 ml saline solution into the external limb.
3. Close the external limb with the plug. Have the patient cough to clear secretions. Suction if neccessary.
4. Repeat with 1 – 3 ml until the tracheal T-Tube has been cleared.

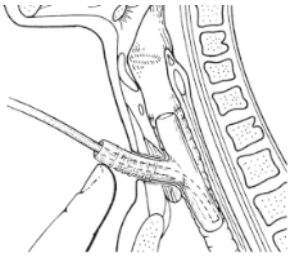
16.3 Suction the Tracheal T-Tube

- Frequency: At the discretion of the treating physician.

ATTENTION: The suction catheter must be small enough to be easily inserted into the external limb.



1. Superior suctioning: Bend the external limb downwards. Insert the suctioning catheter.



2. Inferior suctioning: Bend the external limb upwards. Insert the suctioning catheter.

16.4 Emergency Procedures

16.4.1 With Signs of a Partial Airway Obstruction

1. Remove the obstruction. To do so, lavage and suction the tracheal T-Tube.
   [Lavage of the Tracheal T-Tube, page 11]
   [Suction the Tracheal T-Tube, page 11]

16.4.2 With a Complete Airway Obstruction

1. Remove the tracheal T-Tube. [Product Removal, page 10]
2. Insert the tracheal cannula.
3. If neccessary provide the patient with artificial respiration through the tracheal cannula.

ATTENTION: Always monitor air movement and breath sounds.

17 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.

18 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.bosmed.com apply in all remaining instances.