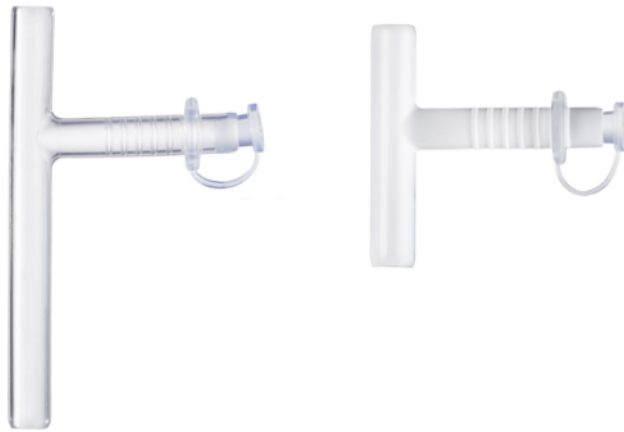


Montgomery Safe-T-Tube

Tracheal T-Tube



Montgomery Safe-T-Tube, Standard
Montgomery Safe-T-Tube, Thoracic



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1 Dear Patient,

You have been given an implant of the type Montgomery Safe-T-Tube. 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

 **New Montgomery Safe-T-Tubes series:
Only accessories REF 361XXX will fit.**

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.

CAUTION

Non-compliance may result in light or moderate injuries or a light or moderate deterioration of your general condition.

2.3 Additional Information

	www.bosmed.com/pi/n-msttnpi
Download link for the Patient Information Document: ¹⁾	
This patient information is based on the following instructions for use:	N-MSTTN-3
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/sscpnmsttn
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

¹⁾ Updated on an ongoing basis. Other language versions are also available there.

For the complete UDI (UDI-PI) please refer to the product label.

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

3 What you need to pay attention to

3.1 General

WARNING

- Always keep the T-tube clean and free from obstructions. Otherwise there is a risk for you to suffocate.
- Do not remove your T-tube! The only exception: An emergency situation in which removal of the T-tube is the sole means to prevent immediate suffocation. Removal of the T-tube poses an immediate risk of suffocation.
- To be prepared for an emergency removal of your T-Tube: Always keep a standard tracheostomy tube in a size smaller than that of your T-Tube at hand. Otherwise there is a risk for you to suffocate.

1. All information on cleaning and caring for your Montgomery Safe-T-Tube can be found at the end of this document. For your own safety, read this information carefully and follow it exactly.
[▶ Cleaning And Care of Your T-Tube, page 5]
In addition, you can find the information in the *Cleaning and Care Instructions* (N-STNCC) that you received from your doctor.
2. 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.
3. Contact your doctor if you experience one or more of the following symptoms: Shortness of breath, fever, bleeding in the throat

ATTENTION: Your Montgomery Safe-T-Tube 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. This is especially true when the intended lifetime of your Montgomery Safe-T-Tube has been reached ([▶ Expected Lifetime, page 4]).

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

3.2 Configuration of the T-Tube - Use of the Plug/Ring Set

WARNING

- If the upper limb of your 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 you can safely breathe through this airway. Otherwise there is a risk for you to suffocate.

Provided the upper limb is free of obstruction and you 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.

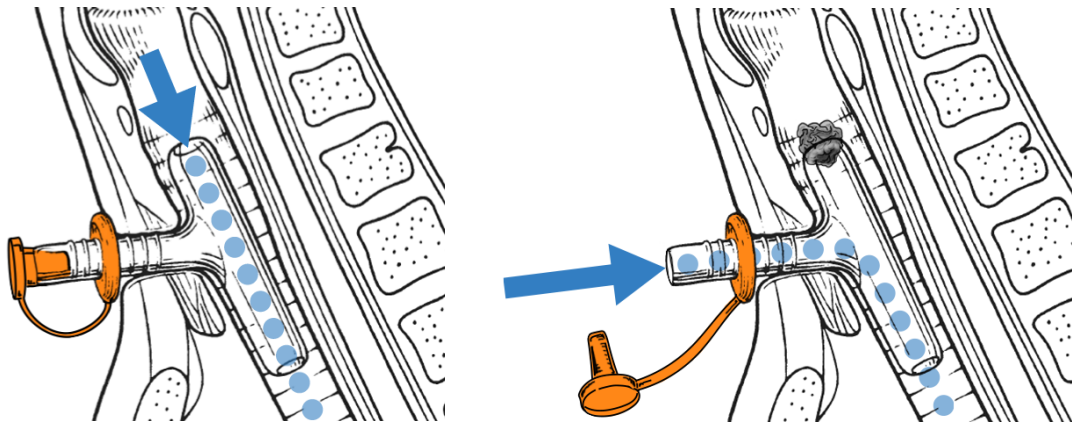
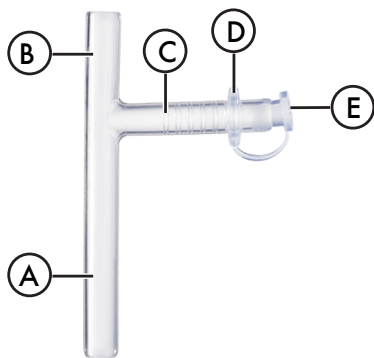


Illustration 1: Left: Upper limb is free, Right: Upper limb is blocked

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.

4 Product Description

4.1 General information



- 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

Illustration 2: Montgomery Safe-T-Tube

- Clear / radiopaque (depending on specifications)

4.2 Materials with Potential Patient Contact

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

5 Intended use

5.1 Patient Target Group

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

- Children and youth
- Adults
- Patients of any gender

5.2 Expected Lifetime

⚠ WARNING

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

Expected lifetime of the product: 6 months

Maximum application duration: 6 months

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

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

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.
- 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.

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

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.

11 Cleaning And Care of Your T-Tube

11.1 Required Equipment and Materials

- Standard tracheostomy tube with obturator, smaller than the T-Tube used
- Isotonic saline solution
- Pipette
- Flexible tracheostomy tube brush with a bristled, nonabrasive distal tip
- Suction unit
- Suction catheter, size: 8 - 12 Ch
- Hemostat

11.2 Lavage

During lavage you squirt saline solution into your T-Tube and then cough to clean the inside of your T-Tube.

Sometimes suctioning is also required to remove excess mucus. [▶ Suctioning, page 5]

1. Take 5 - 10 ml of saline solution with the pipette.
2. Squirt the saline solution into your T-Tube.
CAUTION: Do not inhale while the saline solution is inside your T-Tube.
3. Close your T-Tube with a finger and cough.
4. Repeat if necessary.

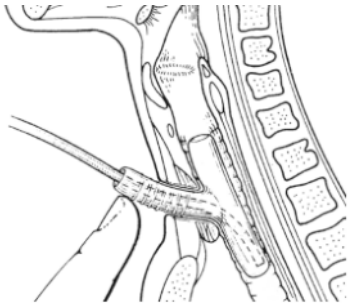
TIP: If your pipette does not have a scale, you can use a teaspoon to determine the amount of saline solution you need: Fill your pipette with the amount of saline solution equivalent to 1 - 2 teaspoons and note the fill level on your pipette.

11.3 Suctioning

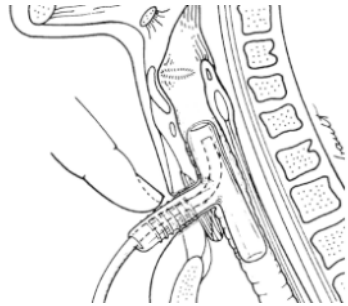
CAUTION

- Do not insert the suction catheter beyond the ends of your T-Tube. Otherwise you might suffer from irritations / coughing.

1. Insert the suction catheter gently into the outer limb of your T-Tube.



2. Gently bend the external limb of your T-Tube up to direct the suction catheter down.
3. Suction the lower limb of your T-Tube.
4. Remove the suction catheter slightly.



5. Gently bend the external limb of your T-Tube down to direct the suction catheter up.
6. Suction the upper limb of your T-Tube.
7. Remove the suction catheter.

TIP: On the tube of the suction catheter, mark how far you have to insert the suction catheter into the upper / lower limb of your T-Tube.

12 Emergency Measures

12.1 Signs for a Blockage of the T-Tube / for Troubled Breathing

- Noise from the T-Tube
- Difficulty of speaking
- Shallow and fast breathing
- Anxiety
- Crowing sounds from the throat
- Change in skin color to pale or blue
- Skin feels cold, but damp to touch

If the patient shows any signs of troubled breathing, act immediately:

12.2 Assessing the Patient's Situation

1. Place the palm of your hand over the T-Tube to assess air movement.
2. Listen for equal breath sounds.
3. If troubled breathing is confirmed or if no air movement can be confirmed: Make an emergency call.
4. After that act depending on the situation:
 - [▶If Troubled Breathing is Confirmed, page 6]
 - [▶If No Breathing Can Be Confirmed, page 6]

12.3 If Troubled Breathing is Confirmed

1. Suction the T-Tube. [▶Suctioning, page 5]
2. Re-assess the patient's breathing.
3. Call the physician to alert him/her of the situation.
4. Upon arrival of the emergency personnel: Inform the emergency personnel that there is a T-Tube in place and show them these instructions.

ATTENTION: In the waiting time, stay with the patient and continue to perform suctioning.

12.4 If No Breathing Can Be Confirmed

⚠ WARNING

- Do not grasp the T-Tube with pointed or sharp instruments to remove it. Otherwise, the T-tube may be damaged and parts of the T-tube may enter the lower airways. There is a risk of suffocation.

If no breathing can be confirmed the T-Tube might be completely blocked. In this case the T-Tube must be removed immediately and be replaced with a smaller size standard tracheostomy tube:

1. Prepare the standard tracheostomy tube and a hemostat.
2. With one hand, grasp the external limb of the T-Tube. At the same time hold the skin above and below the T-Tube with two fingers of the other hand.
3. Remove the T-Tube with a steady, slow pull. If the external limb of the T-Tube tears off: Grasp the remaining portion of the T-Tube with the hemostat and remove it.
4. Insert the standard tracheostomy tube and remove the obturator.
5. If necessary: Suction the airway and ventilate the patient through the standard tracheostomy tube.
6. Upon arrival of the emergency personnel: Inform the emergency personnel that there was a T-Tube in place and show them these instructions.
7. Notify the physician.

13 Specifications

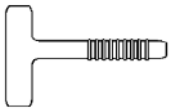
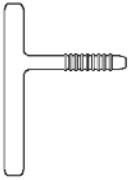


Size ¹⁾	REF: Safe-T-Tube Clear / radiopaque (XXXXXXR)		REF: Compatible accessories	
	Standard	Thoracic	Plug/ring set	15 mm adaptor
				
8 mm	460008 / 460008R	560008 / 560008R	361086	361087
9 mm	460009 / 460009R	560009 / 560009R	361086	361087
10 mm	460010 / 460010R	560010 / 560010R	361106	361107
11 mm	460011 / 460011R	560011 / 560011R	361116	361117
12 mm	460012 / 460012R	560012 / 560012R	361116	361117
13 mm	460013 / 460013R	560013 / 560013R	361126	361127
14 mm	460014 / 460014R	560014 / 560014R	361126	361127
15 mm	460015 / 460015R	560015 / 560015R	361146	361147
16 mm	460016 / 460016R	560016 / 560016R	361146	361147
			Plug/ring set: Silicone 15 mm adaptor: Polypropylene	
¹⁾ Diameter of the intraluminal limb				

Table 2: Safe-T-Tubes, accessories