

Instructions for Use

N-MCSV-4 — 2022-04

EN

Montgomery[®] Cannula Speaking Valve

Tracheal Cannula Speaking Valve



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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 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
	Single patient multiple use: The product may be used multiple times (multiple procedures) on a single patient.	ISO 15223-1: 2021 - 5.4.12
	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

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
ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer
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.

NOTICE

Product damage or other damage may occur in case of non-compliance.

1.3 Additional Information

Download link for these Instructions for Use: ¹⁾	www.bosmed.com/IFU/n-mcsv
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¹⁾Updated on an ongoing basis.

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.
- Do not disassemble or modify the product. Otherwise there are risks to the health of your patient.

NOTICE

- Handle the product with utmost care. Otherwise, the product could be damaged.

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

REF	Size
350401	4
350601	6
350801	8
351001	10

4 Scope of Delivery

- 1 x speaking valve
- 1 x storage container
- 1 x Cleaning and Care Instructions (N-MVCC)

5 Product Description

5.1 General information

The one-way valve with a thin silicone diaphragm opens while breathing in and closes during exhalation. That way the valve redirects the air upward through the larynx and allows the patient to articulate.

Triggered by a sudden pressure increase the diaphragm opens outwards. Excess air escapes.

Prevents a displacement of the valve and the tracheal cannula due to coughing.

- For single patient use
- Non sterile

5.2 Structure and Operation

[▶General information, page 4]

5.3 Materials

- Silicone, medical grade

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

For use as a one-way speaking valve on a tracheal cannula, type Montgomery[®].

6 Intended Use

6.1 Intended Purpose

The devices are intended to allow patients with a tracheal cannula to speak without the need for using a finger or thumb to close off the end of the cannula.

6.2 Indications

As with tracheal cannula used.

6.3 Contraindications

- Within the first 48 to 72 hours following the tracheotomy / until surgical secretions have subsided
- Severe laryngeal or tracheal stenosis
- After laryngectomy

6.4 Patient Target Group

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

- 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)
- Pulmonology

6.5.2 Cleaning and Care

Patient or caregiver [▶ Instructing the Patient, page 6]

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: 3 months

6.7 Intended place of use

6.7.1 Initial Product Placement

- 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

- Non-tolerance in some patients
- Dislocation

9 Combining with Other Procedures

The product is MRI safe.

10 Shelf Life and Storage

Store the product in unopened original packaging.

For date of expiry, see the product label.

11 Processing

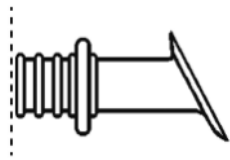
WARNING

- Single patient product: Do not process (e.g., disinfect, sterilize) the product or reuse it for different patients.
Due to the mechanical properties of the product, processing or sterilization could lead to material degradation. If the product is used for different patients, cross-infections are possible.

12 Application Instructions - Initial Product Placement

1. Carefully remove the product from the packaging.

2. If applicable: Pull the plug of the plug/ring-set out of the tracheal cannula.



3. Make sure the tracheal cannula has been trimmed. The tracheal cannula must end flush with one of its rings.



4. Attaching the speaking valve:
Grasp the tracheal cannula. Hold the speaking valve at a slight angle against the tracheal cannula. Push the speaking valve onto the tracheal cannula with a slight twist. When you feel the speaking valve snapping into place it is ready for use.



5. Removing the speaking valve:
Grasp the tracheal cannula with one hand. Twist the speaking valve slightly and remove it from the tracheal cannula.

The manufacturer recommends to have 2 products on hand. This allows one product to be used while the other product is being cleaned.

13 Aftercare

Please refer to *Cleaning and Care Instructions* (N-MVCC).

14 Instructing 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-MVCC). ATTENTION: Forward *Cleaning and Care Instructions* to the patient.

15 Maintaining, Removing, Replacing the Product

Please refer to *Cleaning and Care Instructions* (N-MVCC).

16 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.

17 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.