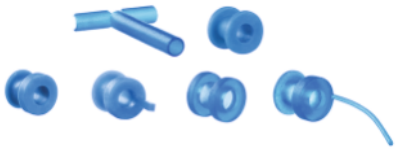
Patient Information Document

80839PI-1 — 2022-08

EN

bess|oto T-Tube
bess|oto Shepard
bess|oto Reuter
bess|oto Donaldson

Tympanic Ventilation Tube



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1 Dear Patient,

You have been given an implant of the type bess|oto T-Tube / Shepard / Reuter / Donaldson. 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

2.1 Symbols Glossary

Symbol	Description
	MR safe
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	Distributor
	Patient name
	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website
	Information on the medical device on the back of the implant card

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.

2.3 Additional Information

Download link for the Patient Information Document:[1)]	www.besspro.eu/pi/pi80839
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):	4063106VETAY
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.

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

3 What you must look out for

⚠ WARNING

- Protect the auditory canal from water penetration.
  Otherwise there is a risk of inflammation / infection of the tympanic cavity.

- Avoid strong fluctuations of the ambient pressure (e.g., diving, taking headers into the water, explosions). Otherwise there is a risk of injury to the tympanic membrane / the ossicles, possibly leading to a sense-of-hearing or vestibular disorder.

1. 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.
2. Contact your doctor if you experience one or more of the following symptoms: Earache, feeling of pressure or itching in the ear, bleeding from the ear, hearing loss
3. Stick to the appointments you make with your treating physician for follow-up examinations and observe their instructions for any necessary follow-up measures.

ATTENTION: Your bess|oto T-Tube / Shepard / Reuter / Donaldson 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.

4 Product Description

4.1 General information

[Specifications, page 4]

4.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Ventilation Tube	Silicone / fluoroplastic [Specifications, page 4]	Patient	With every use

5 Intended Use

5.1 Patient Target Group

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

- Infants and young children
- Children and youth
- Adults
- Patients of all genders

5.2 Expected Lifetime

Expected lifetime: 5 years

ATTENTION: The expected lifetime is the time that the manufacturer expects the product to be safe and perform its function. The actual application duration may deviate from this and is at the discretion of your attending physician.

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

- Skin irritations or allergies
- Formation of granulation tissue
- Inflammation
- Product occlusion
- Premature rejection of the ventilation tube
- Rupture of the tympanic membrane
- Absence of spontaneous rejection of ventilation tube
- Cicatrisation and hyaline degeneration
- Permanent tympanic membrane perforation after the end of the therapy
- Injury to jugular vein bulb
- Injury to ossicular chain (in case the product is inserted in the wrong place)
- Infections, if external bacteria gain access to the tympanic cavity via the ventilation tube
- Tympanic sclerosis

- Cholesteatoma formation due to epithelium entry during paracentesis / tympanic ventilation tube insertion
- Medial dislocation of the tympanic ventilation tube
- Otorrhea

8 Combining with Other Procedures

The product is MRI safe.

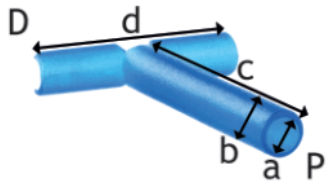
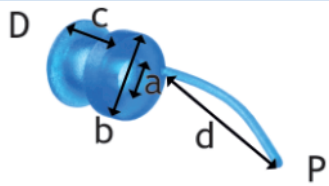
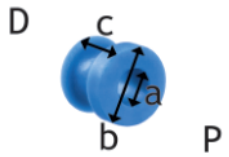
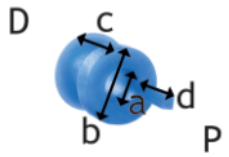
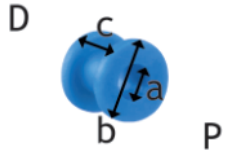
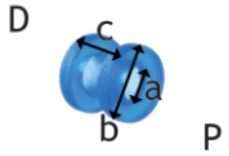
9 Other Residual Risks

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

Follow-up after product removal is at the discretion of your attending physician.

11 Specifications

	REF	Material	a / b / c / d [mm]
bess|oto T-Tube			
	BM 11 1005	Silicone, blue	1,3 / 1,7 / 12 / 8
	BM 11 1006	Silicone, blue	1,3 / 1,7 / 9 / 8
	BM 11 1007	Silicone, blue	1,3 / 1,7 / 7,5 / 8
	BM 11 1008	Silicone, blue	1,3 / 1,7 / 6 / 8
bess|oto Shepard			
	BM 11 1016	Silicone, blue	1,1 / 2,4 / 2,3 / 7,5
	BM 11 1017	Fluoroplastic, blue	1,14 / 2,4 / 2,2 / -
	BM 11 1018	Fluoroplastic, blue	1,14 / 2,4 / 2,2 / 2,7
bess|oto Reuter			
	BM 11 1031	Fluoroplastic, blue	1,14 / 2,6 / 1,65 / -
	BM 11 1033	Fluoroplastic, blue	1,27 / 3,0 / 2,1 / -
bess|oto Donaldson			
	BM 11 1041	Silicone, blue	1,1 / 2,3 / 2,2 / -
D = distal end; P = proximal end			