Patient Information Document
N-PSBTPI-3 — 2022-11
EN

Har-El Pharyngeal Tube

Pharyngeal Salivary Bypass Tube

MR CE 0297

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1 Dear Patient,

You have been given an implant of the type Har-El Pharyngeal 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

2.1 Symbols Glossary

Symbol	Description
	MR safe
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	(EU) Authorized representative in the European Community
	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

Download link for the Patient Information Document:[1)]	www.bosmed.com/pi/n-psbtpi
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):	4063107EST9U
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.

For Australia:

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 you live.

https://www.tga.gov.au/

3 What you must look out for

1. Eat only pureed food. Eat slowly and drink plenty of fluids. This is important so that the food can pass through your Har-El Pharyngeal Tube and does not block your Har-El Pharyngeal Tube.

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: Hoarseness, articulation problems, swallowing difficulties, foreign body sensation
4. 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 Har-El Pharyngeal 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 Har-El Pharyngeal Tube has been reached ([Expected Lifetime, page 3]).

4 Product Description

4.1 General information

- Funnel-shaped proximal end
- Clear / radiopaque (depending on specifications)

For specifications please refer to the implant card.

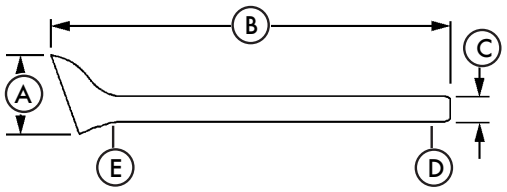

Illustration 1: Har-El Pharyngeal Tube

A	Ø 35 mm
B	183 mm
C	Ø 12 mm
D	Distal end
E	Proximal end; funnel-shaped end for anchoring at the level of the tongue base

4.2 Materials with Potential Patient Contact

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

5 Intended Use

5.1 Intended Purpose

Stent for the cervical esophagus to manage fistulae or strictures.

5.2 Patient Target Group

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

- Adults
- Patients of all genders

5.3 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 Possible Complications and Side Effects

- Impaired motility of the arytenoids, causing hoarse voice
- Foreign body sensation

7 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.

The product is MRI safe.

8 Other Residual Risks

Beyond the listed safety instructions, possible complications and side effects, no further significant residual risks are known.

9 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.