MEDORAH MEDITEK

JAVASTENT® Esophageal Stent

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

JAVASTENT® Esophageal Stent

Intended Use / Indications for use

Intended use- An Esophageal stent is a stent(tube) placed in the esophagus to keep a blocked area open so that patients can swallow soft foods and liquids.

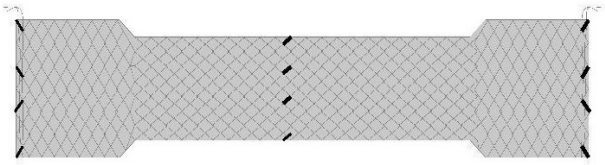
JAVASTENT® Esophageal Stent is used for maintaining the Esophageal luminal patency in malignant and/or benign strictures.

Stent Description

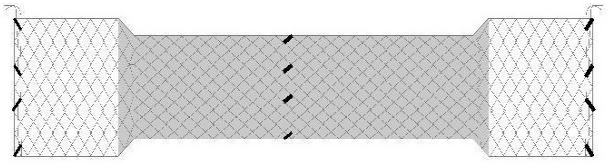
JAVASTENT® Esophageal Stent and delivery system consist of two components: implantable self-expandable metallic stent and over the wire delivery device.

The JAVASTENT® Esophageal Stent is a self-expandable Nitinol tubular mesh prosthesis. The stent has 12 platinum markers in total that are attached within the stent; 4 at the proximal end; 4 at the distal end and 4 at the centre of the flexible esophageal metallic stent. The stent has proximal and distal flares at the ends that aid in preventing migration. Four types of Esophageal stents are available and they are as follows:

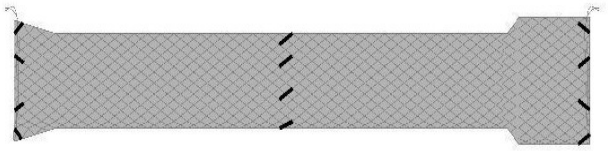
JAVASTENT® Esophageal Fully Covered



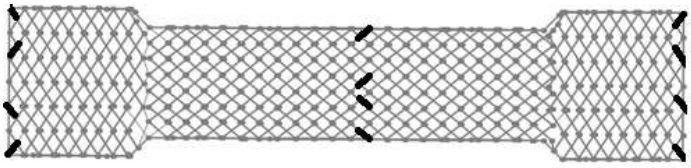
JAVASTENT® Esophageal Partially Covered



JAVASTENT® Esophageal Flare Type

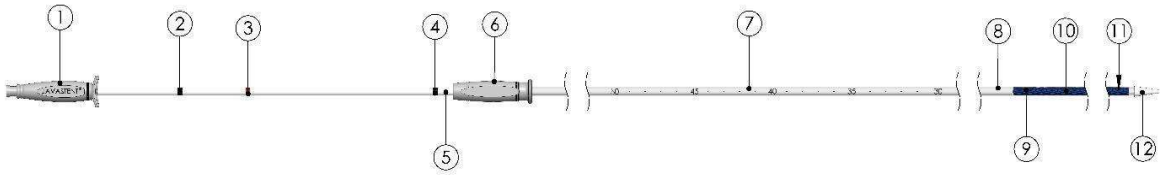


JAVASTENT® Esophageal Uncovered Type



Delivery device description

The delivery device is composed of an outer sheath ⑨, a hub⑥, inner sheath ⑤, olive tip⑫ and a handle①. The proximal part of inner sheath⑤ is reinforced with a stainless-steel tube, and there are two black markers② ④and one red marker ③ between the two black markers. The two black markers② ④represent the ends of the pre-loaded stent, and the red marker ③ indicates the threshold/maximum marginal length for repositioning. The stent can only be re-constrained up to the point of red mark. Additionally, there are centimetre measurement markings ⑦ on the inner sheath ⑤, which is visible through the outer sheath that aids in positioning the delivery device at the stent deployment area.
The delivery device allows a ≤0.038" guide wire. The usable length of the delivery device is 70cm.



①	Handle	⑦	Centimetre Marking
②	Proximal Black Marker	⑧	Radiopaque marker
③	Red marker	⑨	Outer sheath
④	Distal Black Marker	⑩	Inner tube
⑤	Inner sheath	⑪	Stent
⑥	Hub	⑫	Olive tip

Contraindications

The stent is contraindicated for:

- Placement in polyploid lesions.
- Chronically bleeding tumours, if bleeding is active at the time of placement.

- Placement in strictures that cannot be dilated enough and do not allow passage of an endoscope or a delivery system.
- Suspected or impending perforation.
- Removal or repositioning of fully deployed uncovered/bare Stents is contraindicated (See Warnings).
- Recapturing a stent during its deployment is contraindicated.
- Any use other than those outlined under Indications for Use.

Potential Complications

- Esophagitis
- Fever
- Infection
- Edema
- Tumor in / over growth
- Perforation
- Bleeding
- Dysphagia
- Food Bolus Impaction
- Chest pain or retrosternal pain
- Nausea
- Stent migration or misplacement
- Stent break
- Esophageal wall ulceration

Warnings

The entire User's Manual must be read thoroughly before using the device. It must be used by or under the supervision of a physician/s trained in the placement of stents. A detailed knowledge of the techniques, procedures, clinical applications and risks associated with the procedure is necessary before using the device.

- The stent is not intended to be removed and is intended to remain in the body permanently. Attempts to remove stent after placement may cause damage to Esophageal mucosa.
- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged.
- Do not attempt to recapture/reload the stent once the I-shaped hub reaches beyond red marker.
- Fully covered stents can be repositioned immediately after deployment.
- The JAVASTENT® Esophageal Stent System is intended for single use only. **DO NOT** re-sterilize and/or reuse the device.
- Keep the device at normal room temperature and avoid direct sunlight.

- Do not use the device beyond its expiry date.
- Stent must be deployed under fluoroscopic or endoscopic guidance to ensure correct placement.
- Care should be taken while removing the delivery device and guide wire as it can result in stent dislodgement if the stent is not deployed adequately.
- Care should be taken while performing dilation after the stent has been deployed as this may lead to perforation, bleeding, stent dislodgement or migration.
- The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

Procedure

1. Choose the stent with ideal diameter and length based on the length of the stricture measured using an endoscope or fluoroscope.
2. Maintain the delivery device straight outside the body during the deployment procedure.
3. Choose the stent length that is at least 3 cm longer than the actual stricture length. This reduces risk of tumor overgrowth and stent migration.
4. Insert a ≤0.038" guide wire fully across the stricture.
5. Advance the delivery device carefully over the guide wire until the end of the stent is placed at least 2 cm below the tumor.
6. Deploy the stent by immobilizing the handle ① in one hand and by pulling the hub ⑥ of the outer sheath ⑨ slowly towards the handle. Retraction of the outer sheath releases the stent.

Caution

While deploying the stent, do not push or pull the inner sheath. This might lead to stent misplacement or stent misalignment and might lead to patient injuries.

7. Remove the delivery device carefully once the stent is deployed.

Caution

If the olive tip ⑫ gets stuck in the distal part of the stent due to tight anatomies, wait for the stent to fully expand into the lumen or gently move the delivery device back and forth several times and carefully remove the delivery device.

8. Make sure the stent is deployed and secured before removing the delivery device.

Caution

1) When the withdrawal of the outer sheath ⑨ is interrupted, stop pulling the delivery device immediately. Reload the stent back into the outer sheath and remove the whole delivery device gently to perform the procedure from the beginning.
2) Do not apply excessive force and do not twist the inner shaft ⑤. If twisting of the delivery device is necessary, hold both the I-shaped hub of outer sheath ⑨ and the inner shaft ⑤together to turn the delivery device together.

Repositioning technique

1. Immobilize inner sheath ⑤ by holding the handle firmly①.
2. Push the hub of outer sheath ⑨ gently until the distal black marker appears on the inner sheath tube to reload the stent. It is recommended to verify this process using a fluoroscope.

Caution

Repositioning is possible only when the hub of the outer sheath ⑨ is positioned between the red marker ③ and the distal black marker ④ on the inner shaft ⑤.

Post-Procedure Care

- Fluoroscopic or endoscopic examination is performed immediately after the procedure or the following day after the procedure to ensure luminal patency.
- Patients with stent implantation are recommended being on a soft diet to minimize chances of stent obstruction.
- Periodic follow-ups are conducted in the case of symptomatic patients, if required, to ensure there is no stent migration, perforation or obstruction.
- The stent requires about 24 to 48 hours to fully expand. If required, balloon dilatation may be performed while deploying the stent.
- If during follow-ups, stent rupture or stent migration is detected, a new stent or stent-in-stent placement may be recommended.
- After stent implantation, chemotherapy and radiation are not recommended as it increases the risk of stent migration due to tumour shrinkage and/or mucosal bleeding.
- Long-term patency of this device is not currently established. Periodic evaluation is recommended.

Storage
Store the device under defined temperature limit and avoid direct sunlight Follow the First-in, First-out rules and do not use the device beyond its expiry date.

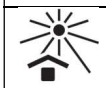
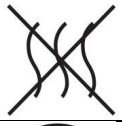
Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

Disposal of a used device

The device used must be disposed off according to the hospital, local and country regulations. Disposal is the responsibility of the user.

Explanation of symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Do Not Reuse
	Consult Instructions for use		Caution
	Keep away from direct sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry
	Do Not Resterilize		Sterilized using Ethylene Oxide

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and

the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

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