MEDORAH MEDITEK

JAVASTENT® Duodenal/Pyloric Stent

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

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Intended Use

JAVASTENT® Duodenal/Pyloric Stent is indicated for use in palliative treatment of the gastroduodenal obstruction caused by intrinsic and/or extrinsic malignant strictures.

Indication for use

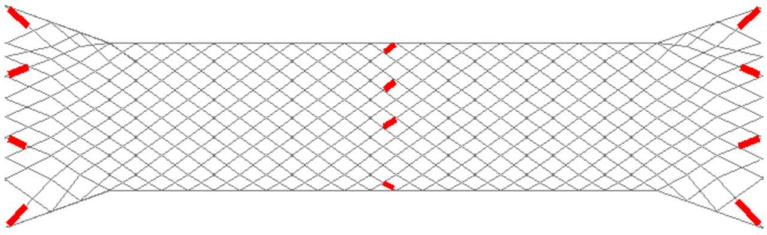
JAVASTENT® Duodenal/Pyloric Stent is indicated for the palliative treatment of pyloric or duodenal strictures caused by malignant tumors.

Stent Description

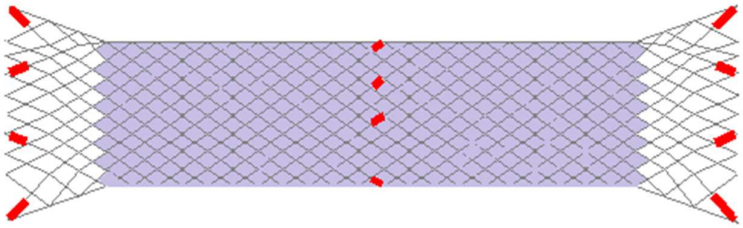
JAVASTENT® Duodenal/Pyloric Stent and delivery system consist of two components: implantable self-expanding metallic stent and over the wire (OTW) delivery device.

The JAVASTENT® Duodenal/Pyloric Stent is a self-expanding Nitinol tubular mesh prosthesis. The stent is flexible with a group of four radiopaque markers located on both ends of the stent and at the centre of the stent. The stent has proximal and distal flares at the ends that aid in preventing migration. JAVASTENT® Duodenal/Pyloric stent is available in uncovered and partially covered models/variants.

JAVASTENT® Duodenal/Pyloric (Uncovered)

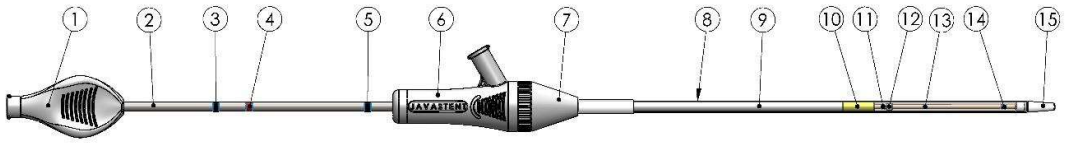


JAVASTENT® Duodenal/Pyloric (Partially Covered)



Delivery device description

JAVASTENT® Duodenal/Pyloric Delivery system consists of a preloaded stent ⑫, an outer sheath ⑧ with Y-hub connector ⑥, and a steel tube ② with a handle ①. There are two black markers ③⑤ and a red marker ④ between two black markers. The two black markers ③ ⑤ represent the points of both ends of the preloaded stent ⑫ and red marker ④ indicates maximum marginal length of repositioning. Stent can be re-constrained if the Y- hub connector ⑥ of the outer sheath ⑧ is not pulled beyond the red marker ④. The delivery system has two radiopaque markers ⑪ & ⑬ to indicate the positions of the stent under fluoroscopy. There is an endoscopic yellow marker ⑩ located on the distal part of inner sheath ⑨, which represents the proximal part of the stent on the 230cm delivery device. The delivery device allows a ≤0.038" guide wire, and its usable length is 230 cm for endoscopic procedures.



①	Handle	⑨	Inner Sheath
②	Steel Tube	⑩	Yellow Endoscopic Marker
③	Proximal Black Marker	⑪	Proximal Radiopaque Marker
④	Red Marker	⑫	Repositioning Block
⑤	Distal Black Marker	⑬	Inner Tube
⑥	Y-hub Connector	⑭	Distal Radiopaque Marker
⑦	Y-hub Connector Lower Cap	⑮	Olive Tip
⑧	Outer Sheath		

Contraindications

The JAVASTENT® Duodenal/Pyloric Stent is contraindicated for, but not limited to:

- Chronically bleeding tumours, if bleeding is active at the time of placement.
- Patient with ascites.
- Strictures that do not allow the passage of guidewires.
- Multiple sites of obstruction.
- Suspected or impending perforation.
- Patients for whom endoscopic treatments are contraindicated.
- Any use other than those specifically mentioned in the indications for use.
- Removal or repositioning of fully deployed uncovered/bare Stents is contraindicated. (See Warnings).

Procedural Complications

- Allergic reaction to contrast/medication
- Aspiration
- Biliary Obstruction
- Cholangitis
- Fever
- Perforation
- Reflux
- Hemorrhage
- Infection

Post Stent Placement Complications

- Allergic reaction to Nickel
- Bowel Impaction
- Foreign Body Sensation
- Inadequate expansion
- Intestinal Perforation
- Nausea/Vomiting
- Pain/Discomfort
- Pancreatitis
- Septicaemia
- Stent Occlusion
- Tumor Ingrowth/Overgrowth
- Ulceration
- Stent Misplacement and/or Migration

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 and clinical applications and risks associated with the procedure is necessary before using the device.

- Contents are supplied STERILE using an ethylene oxide (EO) process. The packaging and the device should be inspected prior to use. Do not use the device if the sterile barrier is damaged.
- The JAVASTENT® Duodenal/Pyloric Stent System is intended for single use only. DO NOT re-sterilize and/or reuse the device. Do not attempt to reload deployed stents onto the delivery system.
- Uncovered/bare stents should not be removed once deployed.
- Do not attempt to recapture/reload the stent once Y-hub connector exceeds beyond the red marker.
- Keep the device at normal room temperature and avoid direct sunlight.
- Do not use the device beyond its use before date.
- Stents 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.

Procedures

Stent Selection

1. Choose a stent with optimum diameter and length after examining the stricture endoscopically and/or fluoroscopically.
2. Measure the diameter of the reference stricture. The stent diameter should be greater than 1mm to 4mm than the largest reference target diameter to achieve secure placement.
3. Choose a stent at least 2 cm to 4 cm longer in full length than stricture length.

Stent Deployment

1. An upper endoscopy or colonoscopy (depending on the distance from anus) is placed at the proximal portion of the lesion.
2. The distal end of the lesion is noted fluoroscopically (by using bony landmarks or opaque clamps).
3. Insert a ≤0.038" guide wire fully across the stricture through the working channel of the endoscope.
4. In the case of a tight stricture, it may be necessary to use a balloon catheter prior to stenting to expand the strictured area.
5. Advance the delivery device carefully over the guide wire until the distal end of the stent passes through the stricture.

6. Deploy the stent by pulling the outer sheath ⑧ slowly while maintaining the position of the steel tube ② by the handle ①.
7. Verify the location of the stricture before deployment. If the stent is not positioned correctly, reload the stent back into the outer sheath ⑧ by pushing it, until it reaches the distal black marker ⑤, and resume the deployment procedure from the beginning. (Refer to **Repositioning Technique**).
8. Remove the delivery device carefully when the stent expansion is confirmed.

Caution

If the tight stricture does not allow the olive tip ⑭ to be pulled back after the deployment, wait a few minutes to allow the stent to fully open and then, remove the delivery device; or reload an inner sheath ⑨ into the outer sheath ⑧ and remove the delivery device.

Deployment

1. Advance the delivery device over the guide wire across the stricture.
2. Immobilize the inner sheath ⑨ by holding the handle ① firmly with one hand, and then, gently start pulling the Y-hub connector ⑥ of outer sheath ⑧ backwards.

Caution

1) When the withdrawal of outer sheath ⑧ is interrupted, stop pulling the Y-hub connector ⑥ and the outer sheath assembly immediately. Reload the stent back into the outer sheath ⑧ and remove the whole delivery device gently to perform the procedure from the beginning.
2) Do not apply excessive force or twist the steel tube ②. If twisting of the delivery device is necessary, hold the Y-hub connector ⑥ of the outer sheath ⑧ and the steel tube ② together to turn the delivery device together.
3) Withdraw the delivery device carefully after the stent placement has been completed.

Repositioning technique

1. Immobilize inner sheath ⑨ by holding firmly by the handle ①.
2. Push the Y-hub connector ⑥ of outer sheath ⑧ gently until the distal black marker ⑤ appears on the stainless-steel tube ② of inner sheath ⑨ to reload the stent. It is recommended to verify this process using a fluoroscope.

Caution

Repositioning is possible only when the Y-hub connector ⑥ of the outer sheath ⑧ is positioned between the red marker ④ and the distal black marker ⑤ on the steel tube ②.

Change of performance

If a 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 of according to the hospital, local and country regulations. Disposal is the responsibility of the user.

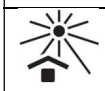
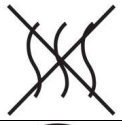
Shelf Life of the product

The typical lifespan of the product is three years from the manufacturing date.

Storage

Store the device under the defined temperature limit and avoid direct sunlight. Follow the first-in-first-out rules and do not use the device beyond its use-by date.

Explanation of symbols

	Date of Manufacture		Use-By date
	Catalogue Number		Do Not Reuse
	Consult Instructions for use		Caution
	Keep away from 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 the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein which are beyond Medorah Meditek Pvt. Ltd. control such as warranties implied to the application of law, sales or specially purpose suitability after handling over, storage, cleaning and sterilisation of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. 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 product other than the replacement of it. Medorah Meditek Pvt. Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other person related to this product.

MEDORAH MEDITEK

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