MEDORAH MEDITEK

JAVASTENT® Pseudocyst Stent

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

JAVASTENT® Pseudocyst Stent

Intended Use: JAVASTENT® Pseudocyst Stent is intended for the trans-gastric or trans duodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, with ≥ 70% fluid content that are adherent to the bowel/gastric wall.

Indications for use: JAVASTENT® Pseudocyst Stent are indicated for use in the treatment of the pseudocysts in acute and chronic pancreatitis.

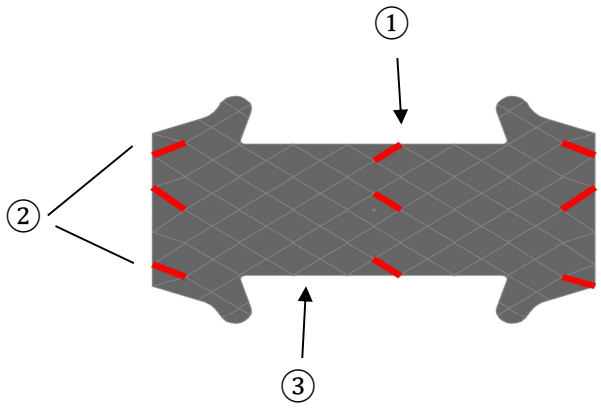
JAVASTENT® Pseudocyst Stent is supplied sterile and for single use only.

Stent Description

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

The JAVASTENT® Pseudocyst Stent is a self-expanding Nitinol tubular mesh prosthesis. The stent is flexible with total 9 radiopaque markers located 3 on both the ends of the stent and 3 at the centre of the stent. The stent has proximal and distal flanges at the ends that aid in preventing migration.

JAVASTENT® Pseudocyst Stent



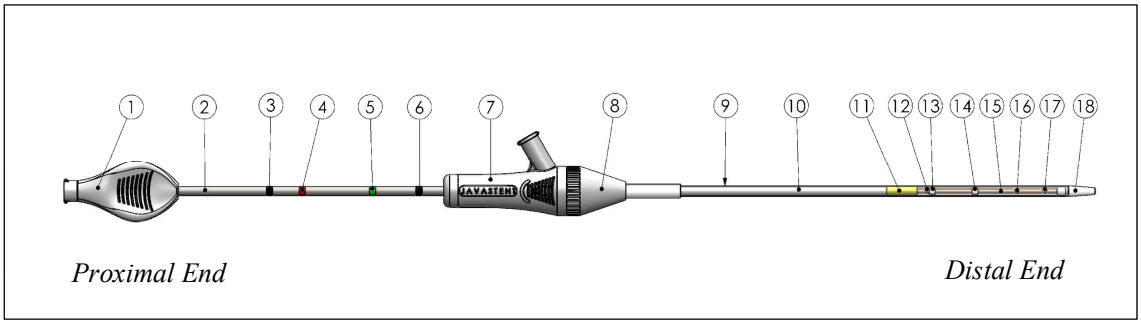
①	Stent
②	Radiopaque Markers
③	Covering Membrane

Delivery device description

COLD Pseudocyst Stent Device

JAVASTENT® Pseudocyst Stent Delivery system consists of a preloaded stent, an outer sheath⑨ with Y-hub connector ⑦, Y-hub connector lower cap⑧, a steel tube ② with a handle ①. There are two black markers ③ ⑥, red marker ④ and Green Marker⑤ present between two black markers. The two black markers ③ ⑥ represent the points of both ends of the preloaded stent and red marker ④ indicates the point of no return

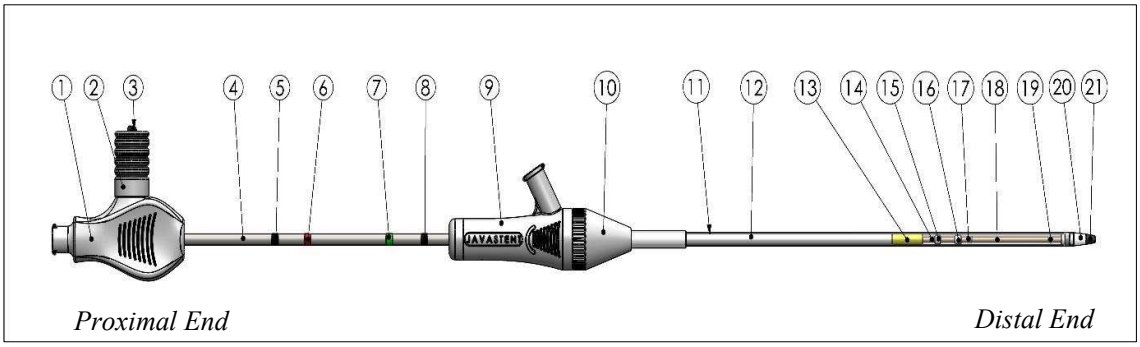
and Green Marker⑤ indicates the deployment of the distal flange. Stent can be re-constrained if the Y-hub connector⑦ of the outer sheath⑨ is not pulled beyond the red marker ④. The delivery system has three radiopaque Inner tube markers ⑫, ⑯ & ⑰ to indicate the positions of stent under fluoroscopy. There is a yellow marker ⑪ located on the distal part of inner sheath⑩ which represents the proximal part of the stent on the 180cm delivery device. The delivery device allows a ≤0.038" guide wire.



①	Handle	⑩	Inner Sheath
②	Steel Tube	⑪	Yellow Marker
③	Proximal Black Marker	⑫	Proximal Radiopaque Inner Tube Marker
④	Red Marker	⑬	Proximal Repositioning Block
⑤	Green Marker	⑭	Distal Repositioning Block
⑥	Distal Black Marker	⑮	Inner Tube
⑦	Y-hub Connector	⑯	Middle Radiopaque Inner Tube Marker
⑧	Y-hub Connector Lower cap	⑰	Distal Radiopaque Inner Tube Marker
⑨	Outer Sheath	⑱	Olive Tips

HOT Pseudocyst Stent Device

JAVASTENT® Stent Delivery system consists of a preloaded stent, an outer sheath⑪ with Y-hub connector ⑨, Y-hub connector lower cap⑩, a cap ②, RF Connector ③ for power supply with a handle ①. There are two black markers⑤ ⑧, red marker ⑥ and Green Marker⑦ present between two black markers. The two black markers ⑤ ⑧ represent the points of both ends of the preloaded stent and red marker ⑥ indicates the point of no return and Green Marker ⑦ indicates the deployment of the distal flange. Stent can be re-constrained if the Y-hub connector ⑨ of the outer sheath is not pulled beyond the red marker ⑥. The delivery system has three radiopaque Inner tube markers ⑭, ⑰& ⑲ to indicate the positions of stent under fluoroscopy. There is a yellow marker ⑬ located on the distal part of inner sheath ⑫ which represents the proximal part of the stent on the 180cm delivery device. The delivery device allows a ≤0.038" guide wire.



①	Handle	⑫	Inner Sheath
②	Cap	⑬	Yellow Marker
③	RF Connector	⑭	Proximal Radiopaque Inner Tube Marker
④	Steel Tube	⑮	Proximal Repositioning Block
⑤	Proximal Black Marker	⑯	Distal Repositioning Block
⑥	Red Marker	⑰	Middle Radiopaque Inner Tube Marker
⑦	Green Marker	⑱	Inner Tube
⑧	Distal Black Marker	⑲	Distal Radiopaque Inner Tube Marker
⑨	Y-hub Connector	⑳	Ceramide Tip
⑩	Y-hub Connector Lower Cap	㉑	Metal Tip
⑪	Outer Sheath		

Contraindications

The JAVASTENT® Pseudocyst Stents are contraindicated for, but are not limited to:

- Hemodynamic instability
- Severe coagulopathy
- All others than indication for use
- Recapturing a stent during its deployment
- Non-inflammatory fluid collections
- Severe Coagulopathy
- Patients for whom endoscopic treatments are contraindicated.
- Multiple sites of obstruction.
- Cystic neoplasms.
- Pseudoaneurysms
- Duplication cysts
- Non-inflammatory fluid collections
- Patients with altered anatomy that precludes the physician's ability to deliver the stent.
- Patients with intervening gastric varices or vessels within a one-centimeter radius of the device needle.

- Patients with any prior true anaphylactic reaction to contrast agents, nitinol (nickel titanium), silicone or any other materials contacting the patient.

Potential Complications

Potential complications associated with the use JAVASTENT® Pseudocyst Stent, but are not limited to:

Procedural Complications

- Stent misplacement
- Inadequate expansion
- Migration
- Bleeding
- Perforation
- Pain

Post stent Placement Complication

- Bleeding
- Pain
- Perforation
- Stent dislocation
- Stent migration
- Vomiting
- Intraperitoneal leakage
- Hematoma
- Fistula
- sepsis
- Stent removal failure
- Stent occlusion
- Fever
- Pancreatitis
- Abscess formation
- Hemorrhage
- Pneumoperitoneum
- Peritonitis
- Inflammation or infection
- Ulceration
- Rupture of intracystic artery

Warnings

- It is uncertain if this device is safe and effective to use in the vascular system.
- Do not use this device for any purpose other than its stated intended use.
- DO NOT use if pouch is opened or damaged.
- Do not attempt to recapture/reload a stent during its deployment.
- The JAVASTENT® Pseudocyst Stent System is supplied sterile and is intended for single use only. DO NOT re-sterilize and/or reuse the device.

- Placement of the JAVASTENT® Pseudocyst Stent should be performed by physicians familiar with endoscopic ultrasonography and who have received training for endoscopic stent placement techniques.
- Do not use this device in any echo-endoscope with a working channel smaller than 3.7 mm.
- This stent must only be used with the delivery system provided.
- Exercise caution and deliberate consideration should precede the use of the device in patients with elevated bleeding times, coagulopathies, or those experiencing radiation colitis or proctitis.
- This stent is designed for short-term implantation. It's important to note that the long-term effectiveness of this stent hasn't been confirmed, so regular monitoring is advised
- During dilation, debridement, irrigation, and cystoscopy procedures through the stent, caution must be exercised to avoid air/fluid leaks and/or stent dislodgement.
- Individuals sensitive to nickel may experience an allergic reaction due to the presence of nickel in this device.

Procedure

For Cold Pseudocyst device:

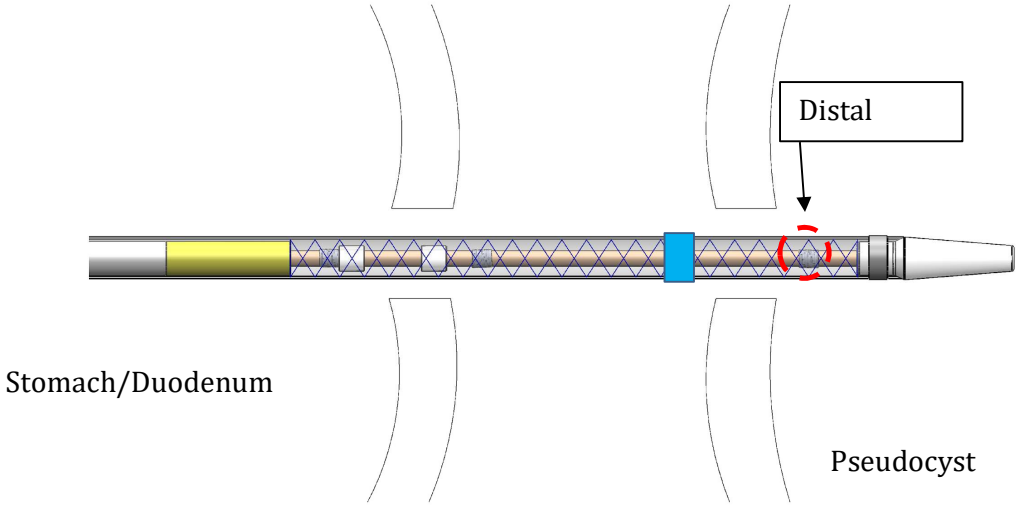
1. The diameter and length of the stent should be determined by the doctor after endoscopic and/or fluoroscopic/ultrasound inspection of the target area.
2. The length and diameter of the stent should be chosen in a way that both walls of the created transmural drainage remain tightly together, thus preventing any migration.
3. Under endoscopic guidance, insert an endoscope (echo endoscope) to the point of lesion. Further, introduce the EUS needle through the working channel of the endoscope. Advance the needle to the lesion site and puncture the lesion.
4. After puncturing, insert the guide wire through the needle and advance it across the lesion. Remove the needle carefully.
5. After needle removal, insert a dilating device such as balloon catheter along the guide wire to the point of lesion and perform dilation.
6. After dilation, remove the balloon carefully.

Refer points 7 to 13

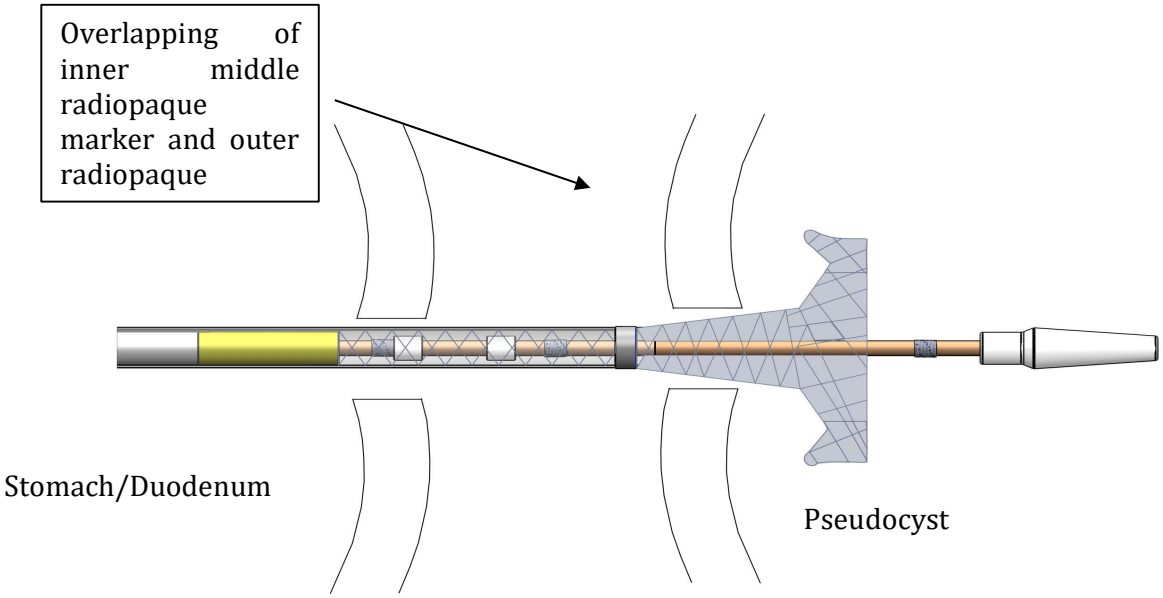
CAUTION: Do not twist the delivery system or employ a stent during the deployment as this may affect positioning and ultimate function of stent.

For Hot Pseudocyst Device

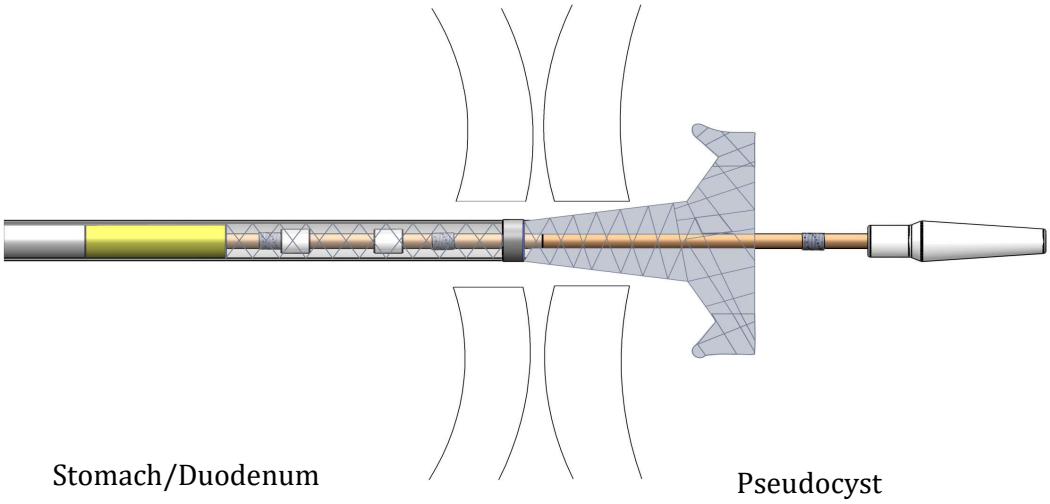
7. Under the fluoroscopic and endoscopic guidance, position the delivery device at the target site.
8. Advance the delivery device to the lesion site and puncture the lesion via current in case of hot Pseudocyst device.
9. Distal inner radiopaque marker should pass through the wall of a pseudocyst.



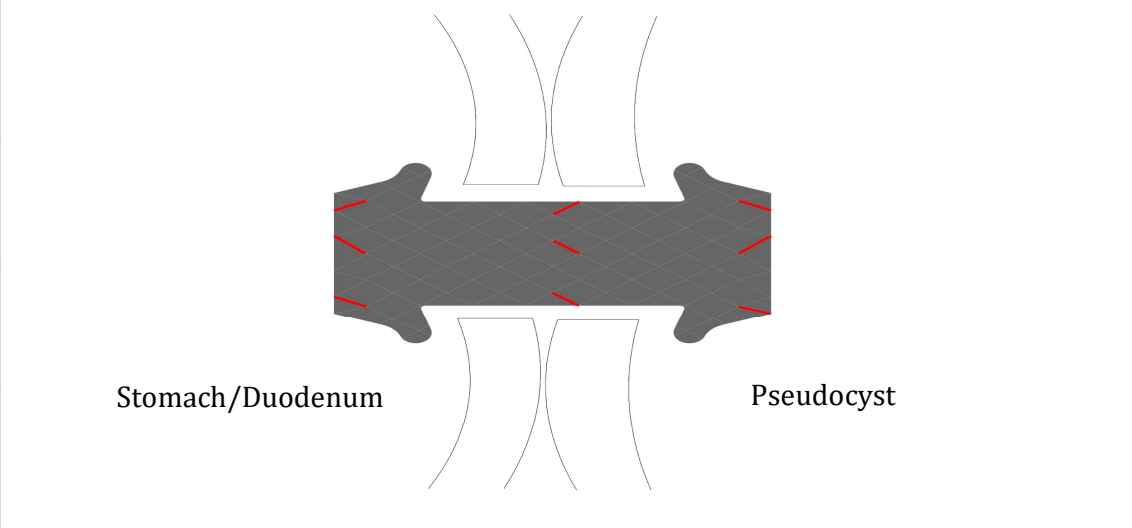
8. To begin stent deployment, immobilize the handle in one hand and grasp the Y-hub connector with the other hand. Gently slide the Y-hub connector back towards the handle.
9. Under EUS and fluoroscopic guidance, verify that distal flange is deployed inside of the target site.
10. Slowly pull back the Y-hub connector until the outer radiopaque marker ⑰ on outer sheath overlaps with the inner middle radiopaque marker ⑫.
11. Check the expansion of the distal flange.



12. Pull back the entire delivery system until the yellow marker ⑪ is visible under endoscopic view.



13. Deploy the proximal flange of the stent under endoscopic guidance while ensuring that the stent connects with both walls together.



CAUTION: Do not push forward or pull backward on the handle with the stent partially deployed. The Y-hub Connector must be securely immobilized. Inadvertent movement of the handle may cause misalignment of the stent and possible damage.

Post Stent Deployment

1. Examine the stent fluoroscopically to confirm expansion.

2. Carefully remove the delivery device, guidewire and endoscope from the patient. If excessive resistance is felt during removal, wait 3~5 minutes to allow further stent

expansion. (Place the inner sheath back into the outer sheath as in the original state prior to removal)

3. Balloon dilation inside the stent can be performed if judged necessary.

Instructions for Removal of JAVASTENT® Pseudocyst Stent:

Use an endoscopic snare to grasp the proximal end of the stent, then gently and carefully remove it.

Change of performance

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

Disposal of a used device

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

Storage

Keep device under normal room temperature and avoid direct sunlight. Follow the first-in-first-out rules and do not use the device out of expiry date.

Explanation of Symbols

	Date of manufacture		Use-by date
	Catalogue Number		Do Not re-use
	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
	Serial Number		

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.

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