

Single use only. Do not resterilize.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Imported by: Dawa Medical LLC

1. Indications for use

The endomina® system, composed of a triangulation platform (endomina® platform) and an instrument for tissue piercing and approximation (TAPES), is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract. The system is to be used on an adult population.

1.1. Contraindications

Contraindications include those specific to the use of an endoscopic suturing system, and any endoscopic procedure, which may include, but not limited to, the following:

- This system is not for use when endoscopic techniques generally are contraindicated.
- This system is not for use with malignant tissue.
- This system is not for use with any malformations from mouth to esophagus (incl. pharynx).

1.2. Warnings

- Do not use a device where the integrity of the sterile packaging has been compromised, if the device appears damaged nor if the device is placed outside a clean zone.
- Only medical professionals who have received the necessary training and possessing sufficient skill and experience in similar or the same techniques should perform endoscopic procedures.
- No TAPES or instrument should be present in endomina® platform during removal from the patient. If said tool is sticking out of the platform, this could lead to laceration or perforation.
- TAPES distal end must always be kept under visual control when the needle is outside the triangulation platform. Not respecting this precaution could lead to dangerous perforations of neighboring organs.
- Do not resterilize or reprocess the endomina® system.
- If the endomina® system is used to oversew foreign objects, such as staples, stents, clips or mesh, it is possible for the needle to become trapped in the foreign body, requiring surgical intervention.
- If one of the anchors becomes detached and falls into a body cavity of the patient, retrieve it.
- The safety and effectiveness of the endomina® system has not been evaluated for specific procedures (e.g., endoscopic sleeve gastropasty, endoscopic mucosal resection) or to close gastric wall defects which may result from resections.

1.3. Precautions

- The system may only be used if purchased from Endo Tools Therapeutics S.A. company or one of its authorized agents.
- The system has not been tested on women who are pregnant, trying to become pregnant or nursing; children; elderly and people with pre-existing conditions that may lead to fragile mucosa.
- In all cases, an endoscopic examination is necessary prior to using the endomina® system in order to detect any malformation of the esophagus or contraindication to endoscopic suturing. Always check that the endomina® platform is not too large for the patient's natural orifice.
- Do not kink endomina® platform channels.
- Do not use the endoscope in full retroversion when endomina® system is fixed on it.
- Use of the system is only recommended when inserted over rigid guidewires.
- Ensure that shoulders are closed and that the arm of the endomina® system is not bent during introduction and removal.
- Verify compatibility of endoscopic instruments and accessories and ensure performance is not compromised.
- If resistance is encountered when inserting a tool, such as TAPES, into the endomina® platform, straighten the arm until the tool can be inserted smoothly and make sure endomina® platform channel radius allows the insertion of the rigid part of the tool. If insertion is not possible, change the tool and/or check that its diameter is small enough for insertion into endomina® platform.
- Always use CO2 insufflation.

1.4. System compatibility

The endomina® platform is only compatible with TAPES device and vice versa.

Nevertheless, tools are needed during the use of the endomina® system including:

- Guidewires: the system is compatible with rigid guidewires for dilators with a maximum diameter of atraumatic tip of 1,9mm, minimum length of 200cm and maximum length not exceeding 450 cm such as Cook medical -SGW-250-SD- Ref G21962.
- Endoscope: the system is compatible with endoscope from 8.5 to 11.0 mm diameter and from 1030 to 1100mm length. Validated endoscope models are: Pentax (EG-2970K, EG-2985K), Olympus 160 Series (GIF-160, GIF-Q165), Olympus 180 series (GIF-H180, GIF-H180J, GIF-H185), Olympus 190 series (GIF-H190, GIF-HQ190), Olympus GIF-EZ1500, Fujinon Eluxeo 700 series (EG-760R, EG-760Z) and Fujinon (EG590WR, EG-600WR)
- Grasping forceps: the system is compatible with grasping forceps with jaw opening of at least 8mm, alligator (= both rat tooth and crocodile), diameter compatible with endoscope i.e. 2.8mm such as Steris endoscopy: Raptor - grasping device
- Monofilament snare: Endoflex monofilament snare 6mm NOE342212M-G or 10 mm NOE342213M-G, 2.8mm diameter
- Loop cutter: single use or reusable loop cutter compatible with the endoscope used such as Olympus reusable loop cutter Ref. 026339 or Olympus single use loop cutter Ref. FS-410.

1.5. Adverse events

Possible complications that may result from using the endomina® system include, but may not be limited to:

- Pharyngitis / sore throat
- Abdominal pain and/or bloating
- Nausea and/or vomiting
- Bleeding
- Hematoma
- Pneumoperitoneum
- Pharyngeal and/or esophageal laceration
- Aspiration
- Acute inflammatory tissue reaction
- Minor peritonitis
- Pharyngeal and/or esophageal and/or gastric perforation
- Wound dehiscence
- Stricture
- Infection / sepsis
- Intra-abdominal (hollow or solid) visceral injury
- Conversion to laparoscopic or open procedure
- Death

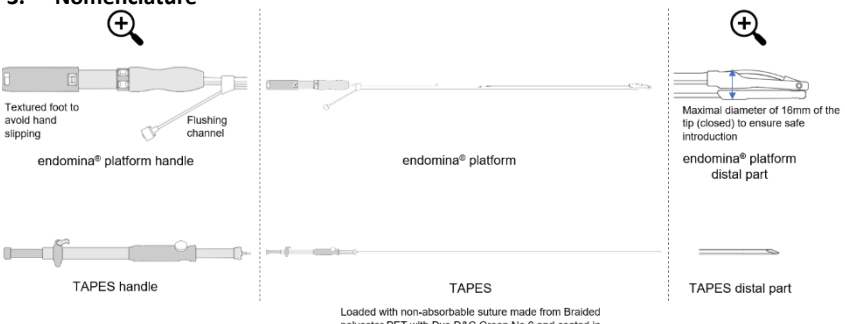
2. Packaged system



Package 1: endomina® platform

Package 2: TAPES device

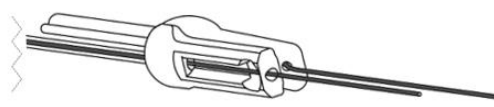
3. Nomenclature



4. Assembly

NOTE: Always keep the handle firmly in the hand to avoid undesired movements. A different colour is used to distinguish the moving parts (blue) and the non-moving parts (grey).

- 4.1. Prepare an endoscope and place two guidewires for dilators in the patient's duodenum or stomach.
- 4.2. Remove endomina® platform and TAPES devices from packaging.
- 4.3. Check that endomina® platform opens and closes by turning the endoscope fixation wheel and checking visually that the shoulders move apart from each other. If they do not move, help the movement by separating them manually. Do not force the movement on the endoscope fixation wheel. If an issue occurs, do not use the endomina® platform and replace with a new one.
- 4.4. Check the action of the arm to detect any issue. If an issue occurs, do not use the endomina® platform and replace with a new one.
- 4.5. Insert endomina® platform (closed) on stiff guidewires.



WARNING: Device can only be inserted in natural orifice (mouth).
CAUTION: Never insert endomina® in the open position.
NOTE: Indicative marking ring at 60cm from the tip of the shoulders.

- 4.6. Insert endoscope into patient.
- 4.7. Open endomina® platform by turning the wheel, and insert the endoscope into endomina® platform.



NOTE: Stronger tactile feedback/resistance when at max expansion. Visual marking on active shoulder to indicate scope position.

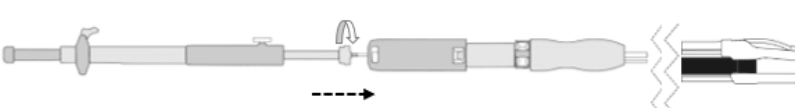
- 4.8. Close endomina® platform around the endoscope by turning the wheel.



WARNING: Ensure endomina® platform is closed on the endoscope.

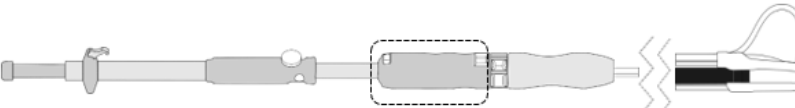
5. Load suturing system

- 5.1. Insert the TAPES device into endomina® platform's channel and turn ¼ to lock it. The endomina® system is formed.



WARNING: The arm of endomina® platform must be straight when introducing the needle.
NOTE: TAPES is provided with handle in position A to ensure the needle is not protruding from the distal end of the system.

- 5.2. While pushing on the handle's pivots, bend endomina® platform's arm all the way by pushing the handle until locked

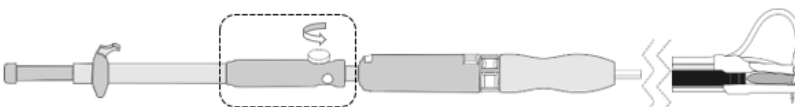


NOTE: Window in the endomina® shoulder to visually check the arm movement. "Click" sound and mechanical block induced by arm pusher pivots when reaching the fully bent position.

- 5.3. Position the system and the scope until target anatomy is located.
CAUTION: Remain aware that endomina® platform's arm takes space in the cavity and can alter manoeuvrability.

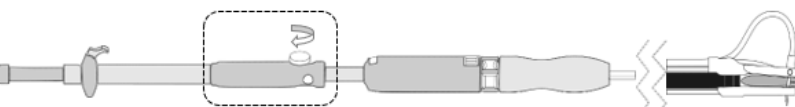
6. Tissue suturing

- 6.1. Grab tissue with forceps and pull the tissue inside endomina® platform. Unlock TAPES position and advance the TAPES needle pusher to pierce the tissue.

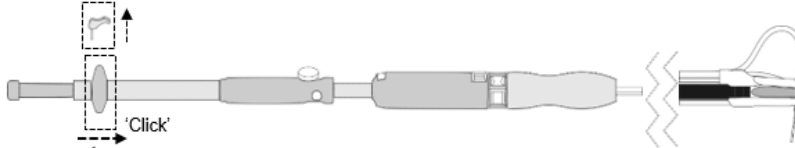


NOTE: Screw cannot detach from the device by design. A-B-C-STOP markings on TAPES handle to indicate position of the needle; advancing the needle is slowed down by design when reaching the STOP, piercing range is limited by design.

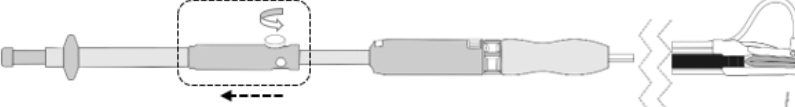
- 6.2. Pull back the needle until only its tip is visible and lock the position.



- 6.3. Release security pin and advance the distal pusher carefully all the way until hearing a "click". Pull back the distal pusher until the distal anchor drops.
CAUTION: The safety pin must only be removed immediately prior to deploying the first anchor.
CAUTION: Do not release the anchor inside endomina® platform's working channel.
CAUTION: After releasing the distal anchor, do not turn the handle as it will release the proximal anchor.



- 6.4. Unlock TAPES position, then unpierce tissue by going back with the needle and releasing some slack out of the needle by going away from the tissue with the whole system.



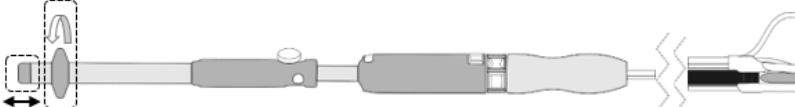
- 6.5. As in step 6.1., grab and pierce the second bite of tissue. Pull back TAPES until only its tip is visible and lock the position.

NOTE: Screw cannot detach from the device by design.



A-B-C-STOP markings on TAPES handle to indicate position of the needle; advancing the needle is slowed down by design when reaching the STOP, piercing range is limited by design.

- 6.6. Turn the distal pusher, then move the proximal pusher back and forth to release proximal anchor.

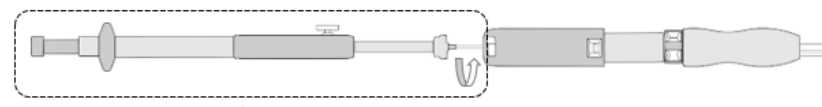


- 6.7. Unlock TAPES position, then unpierce tissue by going back with the needle.



- 6.8. Unbend endomina® platform's arm.

- 6.9. Unlock ¼ turn and remove TAPES device from endomina® platform.



CAUTION: Check the needle tip integrity after removal and ensure that the tip is still attached to TAPES device. If needle tip is missing retrieve it from the patient using sharp foreign body extraction method. Pictures below show the needle configuration acceptability.

- 6.10. Open endomina® platform by turning the wheel to remove the endoscope from endomina® platform.

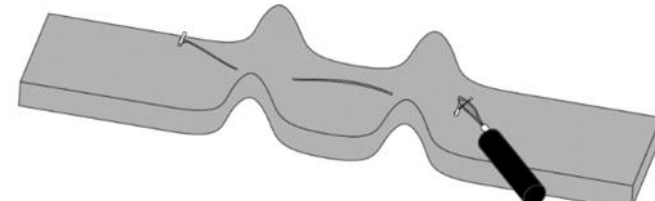


- 6.11. Close endomina® platform under visual control by turning the wheel and hold it at the mouth of the patient.

NOTE: If stitching is complete for this TAPES, proceed to Section 7 to secure and cut the suture. Multiple TAPES can be utilized, refer to Section 8.

7. Securing and cutting suture

- 7.1. With the endoscope, find the distal anchor which contains the prehension knot and catch it with a monofilament snare. Then pull the snare inside the endoscope channel until reaching desired suture tension. When the tissue is approximated, release the knot.



NOTE: When tightening, the user can always stop pulling the snare. This allows moving the endoscope backwards to obtain an overview of the tissue approximation before further tightening if needed.
WARNING: Excessive tension may damage tissue or suture.

- 7.2. Cut the remaining thread with a loop cutter.

WARNING: Leaving excessive suture may lead to patient's complication such as bezoar formation.

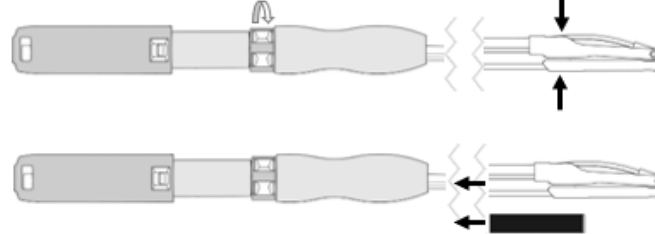
8. Multiples sutures

- 8.1. Repeat steps 6.1 to 7.2 to create multiple tissue approximations. A maximum of 15 TAPES can be used per patient and per procedure.

- 8.2. The endomina® platform can be utilized with multiple sutures (maximum 15 TAPES). Removal of the endomina® and endoscope after tightening is not required if further sutures are to be deployed. To use another suture (TAPES), return to step 5.1 and follow all subsequent steps. If suturing is complete, proceed to Section 9 for removal of the device.
NOTE: If endomina® platform is removed between stitching, ensure that channels are not obstructed.
CAUTION: When multiple tag chains are used, avoid sutures crossing each other.

9. Removal of device

- 9.1. Once suturing is finished, make sure the endoscope is out of endomina® platform and that endomina® platform is properly closed, then remove the device and the scope sequentially under visual control.



10. MRI Safety Information

The implantable part of endomina® system is MR safe.

11. Troubleshooting

Behavior	Resolution
Foreign body obstruction	Try to clear the channel with an atraumatic tool such as a forceps of an appropriate size or a guidewire
Guidewire does not pass at the appropriate designed channel / place	<ol style="list-style-type: none"> Make sure the guidewires used are of the appropriate diameter If not possible change the device
The endomina® platform wheel is broken	<ol style="list-style-type: none"> Try to secure the wheel or the rack If not possible change the device
Arm does not unbend	<ol style="list-style-type: none"> Use 5 french forceps through the needle channel. Once out of endomina® platform, under visual control, open endomina® platform and pull back while keeping it open until the arm unbends. Change endomina® platform.
Misalignment of endomina® platform's shoulders	<ol style="list-style-type: none"> Try to open endomina® platform and realign the system in an axial position (i.e. the scope as straight as possible) If unsuccessful, change the device
Suture movement restricted	<ol style="list-style-type: none"> Release some slack by moving away from the tissue with the whole system.
Insertion of TAPES into endomina® platform is difficult	<ol style="list-style-type: none"> Straighten endomina® platform Go back with the needle a few millimeters and turn it before advancing it again. Repeat several times until it works. If strong resistance remains, take the needle out and try again with some approved lubricant or silicone spray. Check that the anchor is not coming out before putting the needle back in.
Locking of TAPES into endomina® platform is difficult	<ol style="list-style-type: none"> If there is resistance at the end of needle introduction, right before locking it to endomina® platform, usually occurring as a spring-like (elastic) behavior, this likely means that TAPES is impacted in the metallic coil of endomina® platform. Verify that endomina® platform's arm is fully unbent, pull needle out 1-2cm, turn it a little, and fully advance it again. Repeat as necessary. Once TAPES has locked, proceed with the usual procedural steps but check TAPES' needle exit under vision before piercing tissue to make sure that it is not impacted inside endomina® platform.
Anchor is out before insertion of TAPES in endomina® platform	<ol style="list-style-type: none"> Push it back inside with the safety pin.
Difficult piercing	<ol style="list-style-type: none"> Keep pressure on the handle of the needle until it passes. Apply and release pressure with the needle whilst keeping the tissue under tension with the grasper and jiggle a little bit with the scope. If this does not work, retract the needle, make sure that the endomina® is properly aligned and that the needle goes through the window before trying to pierce again. Depending on alignment of the endomina® platform's shoulders, the physician can adapt the position of tissue in endomina®.
First anchor is blocked inside	<ol style="list-style-type: none"> If there is a strong resistance, don't force on the distal pusher. Slightly advance the needle first and then try again.

Behavior	Resolution
	<ul style="list-style-type: none"> ii. If anchor is still blocked, keep pressure on the distal pusher whilst slowly going back and forth a few millimeters with the needle until the anchor comes out. iii. If unsuccessful, unpierce until position A, lock the needle, release the tissue, and straighten the arm. Then, advance the first anchor a few millimeters, bend the arm back and check that the anchor is not protruding from the needle. Proceed with the procedure. iv. If this still does not work, change TAPES.
Distal pusher (wire) is bent	<ul style="list-style-type: none"> i. If the first anchor is out, pull the pusher back to its initial position and proceed to second piercing. ii. If first anchor is not out, don't push on the distal pusher (it won't work); pull it back to its initial position and try to release anchor by slowly advancing the proximal pusher. Stop as soon as anchor is out and put the pusher back into its initial position. iii. If the above does not work, change TAPES.
Distal pusher (wire) is broken	<ul style="list-style-type: none"> i. If first anchor is out, proceed to second piercing. Use surgical forceps to pull on the wire as much as possible before dropping the second anchor. ii. If first anchor was not out, try to release it by advancing the proximal pusher slowly. If it works, retract the proximal pusher and then use surgical forceps to pull back the broken wire from the distal pusher. iii. If the above does not work, change TAPES.
First anchor completely buried in mucosa before second piercing	<ul style="list-style-type: none"> i. Do not release the second anchor. Cut the wire with the loop cutter through the scope and change TAPES.
If ball is blocked in snare	<ul style="list-style-type: none"> i. Play with the snare against the mucosa until it drops. ii. Flush with the scope jet channel (if available). iii. If the ball is still blocked, leave snare open, put some tension on the wire by moving the scope, if necessary up until esophagus or down into duodenum. iv. If ball is still blocked, cut the snare handle, remove the scope and leave snare inside (hold it at the mouth), go back alongside with the scope and cut the wire with adapted tool. Remove the snare and use a new one for the next suture.

12. Table of symbols

Description	Symbol	Description	Symbol
Consult instructions for use		Caution	
Do not reuse		Lot number	
Do not resterilize		Catalog number	
Used by date		Serial number	
Manufacturer		Keep away from sunlight	
Sterilized using ethylene oxide		Keep in dry location	
Store at room temperature (1-30°C / 33.8-86°F)		Distributor	
Single sterile barrier system with protective packaging outside		Importer	
Do not use if package is damaged		Caution: Federal law restricts this device for sale by or on the order of a physician	
Medical Device		MR safe	

13. Disclaimer of warranty and limitation of remedy

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