

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® EZFuse system is intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract.

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 endomina® EZFuse suture 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.
- The endomina® EZFuse suture 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 neighbouring organs.
- Do not resterilize or reprocess the endomina® EZFuse system.
- If the endomina® EZFuse system is used to oversaw 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 tags becomes detached and falls into a body cavity of the patient, retrieve it.
- The safety and effectiveness of the endomina® EZFuse 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® EZFuse 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 the channels or the needle of the endomina® EZFuse system.
- Do not use the endoscope in full retroversion when endomina® EZFuse 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® EZFuse 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 endomina® EZFuse suture, into the endomina® platform, straighten the arm until the tool can be inserted smoothly and make sure endomina®'s 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.
- Patient should be placed in supine position to avoid entrapment of neighbouring organs.

1.4. System compatibility

The endomina® EZFuse suture is only compatible with the endomina® platform. Nevertheless, tools are needed during the use of the endomina® EZFuse 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, Pentax EG-2985K, Olympus GIF-H160, Olympus GIF-Q160, Olympus GIF-Q165, Olympus 180 series (GIF-H180, GIF-H180J), Olympus GIF-H185, Olympus 190 series (GIF-H190, GIF-HQ190), Olympus GIF-EZ1500, Olympus GIF 1100, Fujifilm EG-590WR, Fujifilm EG-600WR, and Fujifilm Eluxeo 700 series (EG-760R, EG-760Z).
- Grasping forceps: the system is compatible with grasping forceps with a jaw opening of at least 8mm, with crocodile/pelican features or both alligator feature and rat tooth, diameter compatible with endoscope (i.e. 2.8mm) such as Nexgen Therapeutics: Disposable Grasping Forceps with Pelican Teeth.

1.5. Adverse events

Possible complications that may result from using the endomina® EZFuse 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 device

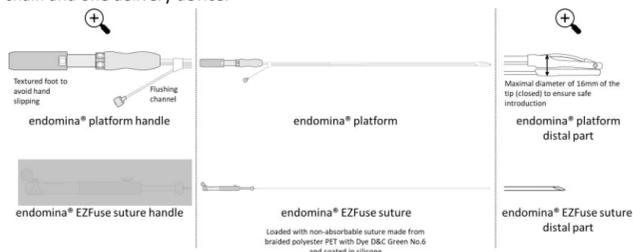
Package 2: endomina® EZFuse suture device

3. Nomenclature

The endomina® EZFuse system is composed of endomina® platform and endomina® EZFuse suture.

The endomina® platform is a short-term, single-use platform providing additional therapeutic channels for a flexible endoscope to be used in surgical endoscopy in the stomach consisting of a bracket or "shoulder" that closes around the endoscope, a tubing system and a handle.

The endomina® EZFuse suture is a single-use device composed of two parts: one suture chain and one delivery device.



The suture chain includes two tags made from a high-performance polymer (PEEK) and a green braided polyester non-absorbable suture. The two tags are threaded over the suture and are similar but one includes a second hole and a one-way knot. Pulling on the suture allows to tighten the chain, which cannot come back. It also includes an integrated cut-point allowing to easily cut the suture after tightening. To that end, the suture includes a large knot for prehension.

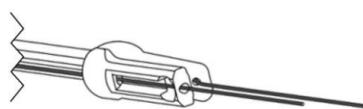


The delivery system is composed of a pusher at the level of the handle allowing to release the suture chain during a procedure.

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).

- Prepare an endoscope and place two guidewires for dilators in the patient's duodenum or stomach.
- Remove endomina® platform and endomina® EZFuse suture devices from packaging.
- 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.
- 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.
- Insert endomina® platform (closed) on stiff guidewires.

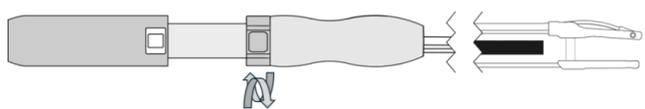


WARNING: Device can only be inserted in natural orifice (mouth).

CAUTION: Never insert endomina® in the open position.

NOTE: Indicative marking ring at 60cm from the tip of the shoulders.

- Insert endoscope into patient. Remove guidewires under visual control.



- 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.

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

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

5. Load suturing system

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

WARNING: The arm of endomina® platform must be straight when introducing the needle.

NOTE: endomina® EZFuse suture is provided with handle in position A to ensure the needle is not protruding from the distal end of the system.

- While pushing on the handle's plugs, bend endomina® platform's arm all the way



by pushing the handle until locked.

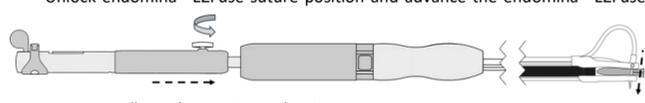
NOTE: A window is present in the endomina® shoulder to visually check the arm movement. "Click" sound and mechanical block induced by arm pusher pivots when reaching the fully bent position.

- 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

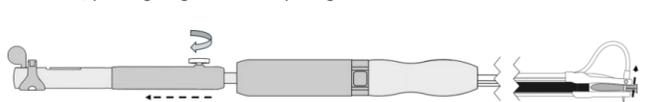
NOTE: endomina® EZFuse suture handle includes a maze guiding the pusher allowing to deliver proximal and distal tags.

- Grab the tissue with the forceps and pull the tissue inside endomina® platform. Unlock endomina® EZFuse suture position and advance the endomina® EZFuse



suture needle pusher to pierce the tissue.

NOTE: Screw cannot detach from the device by design. A-B-C-STOP markings on endomina® EZFuse suture 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.



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

- Remove the safety pin and release the distal tag using the tag pusher. Advance it until the imprinted '2' on the tag pusher to release the distal tag. Pull back the tag pusher until the junction with the imprinted '3'. Visually make sure that the distal



tag has been released and has dropped out of the needle.

CAUTION: The safety pin must only be removed immediately prior to deploying the first tag. CAUTION: Do not release the tag inside endomina® platform's working channel. CAUTION: After releasing the distal tag, do not turn the tag pusher as it could release the proximal tag. NOTE: "Click" sound indicates that the pusher has been appropriately pushed forward to release the tag.

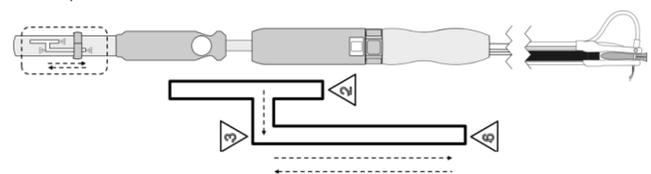
- Unlock endomina® EZFuse suture position, then unpierce tissue by going back with the needle and releasing some slack out of the needle by going away from the tissue with the whole system.

- As in step 6.1, grab and pierce the second bite of tissue. Pull back endomina® EZFuse suture 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 endomina® EZFuse suture 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.

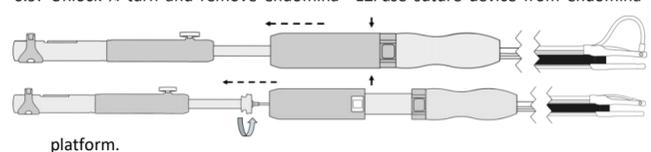
- Release the proximal tag using the tag pusher. Turn the pusher into the parallel track and advance the pusher until the imprinted '6'. Check that the entire suture has been released, including the prehension knot. Make back and forth movements with the tag pusher if necessary. Pull back the tag pusher until the imprinted '3'.



- As in 6.4, unlock endomina® EZFuse suture position, then unpierce the tissue by going back with the needle.

- Unbend endomina® platform's arm.

- Unlock ¼ turn and remove endomina® EZFuse suture device from endomina®



platform.

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



- Open endomina® platform by turning the wheel (as in 4.7) and remove the endoscope from endomina® platform.

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

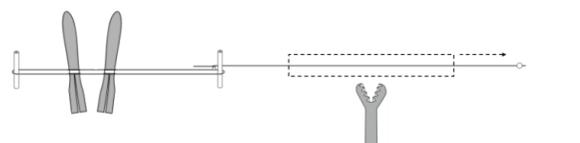
NOTE: If stitching is complete for this endomina® EZFuse suture, proceed to Section 7 to secure and cut the suture. Multiple endomina® EZFuse sutures can be utilized, refer to Section 8.

7. Securing and breaking suture

- With the endoscope, find the prehension portion of the suture between the proximal tag and the prehension knot. With the help of a forceps, grab the prehension portion and pull on it with the forceps inside the endoscope channel to tighten the suture. Continue pulling with the forceps on the suture until breakage of the prehension portion.



CAUTION: Do not catch the prehension knot directly in the forceps jaws as it may damage it and jeopardize tightening. Grab a free portion of suture sufficiently away from the prehension knot.



NOTE: Proper tightening requires the suture to be in tension with the endoscope starting away from the tissue and the tag to be pushed progressively towards the tissue by the endoscope moving forward. When tightening, the user can always stop pulling the forceps. This allows moving the endoscope backwards to obtain an overview of the tissue approximation before further tightening if needed.

- After breakage, keep the forceps closed and remove the remaining thread by taking it out of the endoscope.

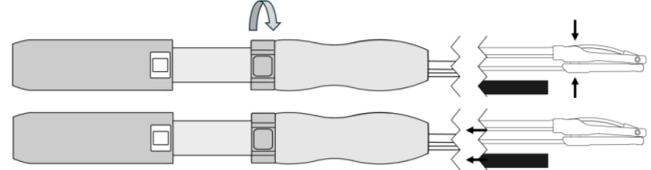
WARNING: Leaving excessive suture may lead to patient's complication such as bezoar formation.

8. Multiple sutures

- Repeat steps 4.7 to 7.2 to create multiple tissue approximations. Safe use of a maximum of 8 sutures was evaluated in porcine colon and stomach; safe use of a maximum of 3 sutures was evaluated in porcine esophagus and duodenum.
- The endomina® platform can be utilized with multiple sutures (Safe use of a maximum of 8 sutures was evaluated in porcine colon and stomach; safe use of a maximum of 3 sutures was evaluated in porcine esophagus and duodenum). Removal of the endomina® and endoscope after tightening is not required if further sutures are to be deployed. To use another suture (endomina® EZFuse suture), return to step 4.7 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 sutures, ensure that channels are not obstructed. CAUTION: When multiple tag chains are used, avoid sutures crossing each other.

9. Removal of device

- 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 endoscope sequentially under visual control.

10. MRI Safety Information

The implantable part of endomina® EZFuse system is MR safe.

11. Troubleshooting

Behavior	Resolution
Guidewire passage issues during introduction of endomina®	<ol style="list-style-type: none"> If a guidewire is blocked inside the endomina® and cannot be retrieved, the endomina should be removed following section 9. Once removed, check that the atraumatic tip of the guidewire is small enough to pass the shoulders (see section 4.5) and check that the guidewires are not kinked then try again If conditions in ii are not met, use different guidewires following the same precautions before insertion into the patient
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 forceps and pull back while keeping it open until the arm unbends. Change endomina® platform.

Behavior	Resolution
Misalignment of endomina® platform's shoulders	<ul style="list-style-type: none"> i. Open endomina® platform and realign the system in an axial position (i.e. the scope as straight as possible). ii. If unsuccessful, open endomina® platform again and slightly push the scope forward, then close again. iii. If unsuccessful, change the device.
Suture movement restricted	<ul style="list-style-type: none"> i. Release some slack by moving away from the tissue with the whole system.
Insertion of endomina® EZFuse suture into endomina® platform is difficult	<ul style="list-style-type: none"> i. Straighten endomina® platform. ii. Go back with the needle a few millimeters and turn it before advancing it again. Repeat several times until it works. iii. If strong resistance remains, take the needle out and try again with some approved lubricant or silicone spray. Check that the tag is not coming out before putting the needle back in.
Locking of endomina® EZFuse suture into endomina® platform is difficult	<ul style="list-style-type: none"> i. If there is resistance at the end of needle introduction, right before locking it to endomina® platform (spring-like (elastic) behavior), 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. ii. Once endomina® EZFuse suture has locked, proceed with the usual procedural steps but check endomina® EZFuse suture' needle exit under vision before piercing tissue to make sure that it is not impacted inside endomina® platform.
Tag is out before insertion of endomina® EZFuse suture in endomina® platform	<ul style="list-style-type: none"> i. Push it back inside with the traumatic tip of the guidewire.
Difficult piercing	<ul style="list-style-type: none"> i. 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. ii. If this does not work, retract the needle, make sure that the endomina® platform 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® platform.
First tag is blocked inside	<ul style="list-style-type: none"> i. If there is a strong resistance, don't force on the tag pusher. Slightly advance the needle first and then try again. ii. If the tag is still blocked, keep pressure on the tag pusher whilst slowly going back and forth a few millimeters with the needle until the tag comes out. iii. If unsuccessful, unpierce until position A, lock the needle, release the tissue, and straighten the arm. Then, advance the first tag a few millimeters, bend the arm back and check that the tag is not protruding from the needle. Proceed with the procedure. iv. If this still does not work, change endomina® EZFuse suture.
Second tag is blocked inside	<ul style="list-style-type: none"> i. If the first tag is out, pull the pusher back to its initial position, cut the suture with a scissors or a loop cutter through the scope and change endomina® EZFuse suture.
Pusher is bend or broken	<ul style="list-style-type: none"> ii. If the pusher is bend or broken after the tag has been released, proceed normally to the next steps iii. If the anchor could not be released prior issue, change device following troubleshooting "first tag is blocked inside" or "second tag is blocked inside" depending on the configuration that is appropriate
Suture cannot be tightened	<ul style="list-style-type: none"> i. Repeat tissue approximation with a new endomina® EZFuse suture.
Suture breakage cannot be achieved after tightening	<ul style="list-style-type: none"> i. Do not put excessive tension on the suture. If the suture does not break after multiple tries, release the forceps, cut the wire with scissors or a loop cutter through the scope.
Foreign body obstruction	<ul style="list-style-type: none"> ii. Retrieve any material that has not been placed according to IFU, using foreign body retrieval methods to prevent obstruction

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12. Table of symbols

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

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