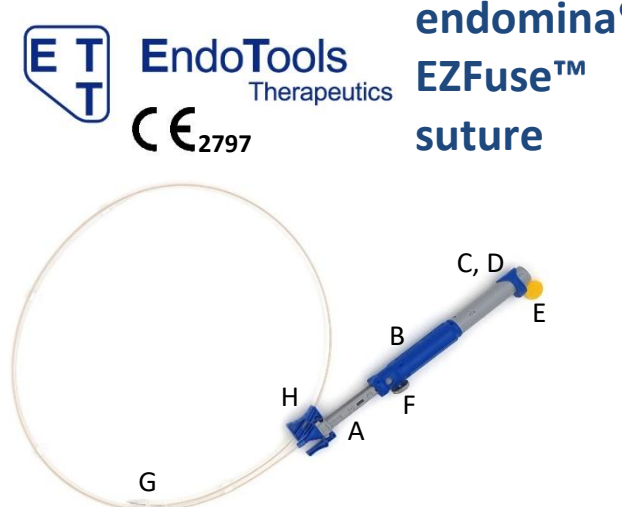




[D-endomina-EZFuse-Suture-EU-IFU--v1--April 2026]

EN – Instructions for use p.1

EN – ENGLISH – Instructions for use

Endoscopic tissue approximation device

Do not use if package is damaged or unintentionally opened.

Terminology and package contents

- A. Fixing handle
- B. Needle pusher
- C. Distal tag pusher
- D. Proximal tag pusher
- E. Safety pin
- F. Brake screw
- G. Needle and tag chain (in the dispenser)
- H. Dispenser attachment

Technical information

Maximum diameter – 1.9 mm

Needle diameter – 1.8 mm

Needle rigid length – 17 mm

Total needle length (excl. handle) – 1 221 mm

Tag diameter – 1.1 mm and 1.2mm

Tag length – 10 mm

Tag material - PEEK

Surgical suture type – EP1.5 (USP 4-0) braided polyester (non-absorbable)

Maximum duration of use – 4 hours

Sterilization by Ethylene oxide (EtO)

Intended use

endomina® EZFuse™ suture is a long-term, single use suturing medical device for endoscopic gastroplasty using a flexible endoscope and a triangulation platform (endomina® v2).

Intended users

The intended users are:

- Nurse(s) trained on the device
 - Nurses in training accompanied by clinical field specialist
 - Endoscopists trained on the device
 - Endoscopists in training accompanied by experienced endoscopist(s)
- All users must understand at least one of the languages in the IFU.

Target patient population

Adults (18 and 65 years) with BMI ≥ 30 kg/m²

Clinical indication

Obesity (restrictive surgery on the stomach)

Clinical benefits of endomina® EZFuse™ suture used in combination with endomina® v2

- Mean excess weight loss (EWL) ≥ 25% at 12 months.
- Improved satiety: >30% volume intake reduction
- More than 50% of patients achieve a total body weight loss (TBWL) of 10% or more at 12 months
- More than 50% of patients experience improvements in quality of life

Performance characteristics of the device

endomina® EZFuse™ suture offers full-thickness tissue approximation made of double plications.

endomina® EZFuse™ suture is easy to use, 5 procedures needed before operator is able to decrease procedure time.

Contraindications

Any contraindication to endoscopy; gastric ulcer; perforations; severe gastritis or any pre-existing conditions that may lead to fragile mucosa; bleeding; oesophagitis; hiatal hernia; women who are pregnant, trying to become pregnant or nursing; children; elderly; addiction (drug or alcohol); bleeding disorders; varices; portal hypertension in the stomach; fibrotic sites; patients taking anti-coagulation therapy.

Warnings

In order to ensure the safe use of endomina® EZFuse™ suture, it is essential to read this paragraph carefully.

- The endomina® EZFuse™ suture is a device for endoscopic gastroplasty. It can only be used through the mouth.
- This document describes the use of endomina® EZFuse™ suture, not the clinical procedures that can be performed with it.
- Before using endomina® EZFuse™ suture make sure that the package is properly sealed and includes all the components shown in the picture and that they are in perfect condition. If any component is missing or damaged, do not use endomina® EZFuse™ suture
- endomina® EZFuse™ suture can only be used by qualified medical staff (an endoscopist or paramedical staff under surveillance by an endoscopist) who has received the necessary training and certification to use it.
- Do not touch needle tip during endomina® EZFuse™ suture removal and disposal : it may be contaminated with potentially infectious substances from the patient.
- endomina® EZFuse™ suture is single-use and cannot be reused: reusing poses a threat of cross contamination between patients. Additionally, reusing device after releasing tags makes device useless.
- endomina® EZFuse™ suture is single-use and cannot be re-sterilized: sterilization process used in hospitals has not been tested and could damage the device.
- Do not use endomina® EZFuse™ suture after expiration date, it could lead to infection or device malfunction (i.e needle detachment).
- If endomina® EZFuse™ suture has been exposed to environmental conditions outside of those specified on the label, do not use endomina® EZFuse™ suture.
- If endomina® EZFuse™ suture is placed outside a clean zone, it cannot be used.
- endomina® EZFuse™ suture can only be used on patients under general anaesthesia.
- endomina® EZFuse™ suture can only be used with endomina® v2 platform. See “Triangulation platform compatibility” for more details.
- If one component of endomina® EZFuse™ suture becomes detached and falls into a body cavity of the patient, retrieve it with endoscopic forceps if it is judged dangerous for the patient’s health.
Note 1: except the needle, components are not radio-opaque.
Note 2: the needle detaching from the device due to a malfunction might lead to perforation of a vital organ or non-vital organ.
- If the triangulation platform does not allow large enough plications to be formed, the suture may not hold.

Precautions

- Patient should be placed in supine position to avoid entrapment of neighboring organs
- Always use CO2 insufflation.
- Never make sudden movements, especially during insertion and removal. This could hurt the patient.
- The needle must not be apparent during the introduction and removal of the triangulation platform. This could hurt the patient.
- endomina® EZFuse™ suture must always be manipulated under visual surveillance when the needle is outside the triangulation platform Not respecting this precaution could lead to dangerous perforations of neighboring organs.
- Always wear appropriate protective clothing, as blood and other tissues carry an infection risk. Suitable protective clothing includes protective goggles, a mask and waterproof clothes and gloves.
- Do not use force to insert endomina® EZFuse™ suture into the triangulation system. If there is resistance, remove it and investigate.
- When multiple tag chains are used, avoid sutures crossing each other.
- Do not insert endomina® EZFuse™ suture into a bent channel. Always introduce endomina® EZFuse™ suture into a channel that is as straight as possible.

- endomina® EZFuse™ suture is a 1,9 mm device. Use it only in a suitable channel (up to 2,3 mm). To use it in a larger channel, use a catheter to avoid guiding issues.
- Always keep the handle firmly in the hand to avoid undesired movements.
- 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.
- A maximum of 15 endomina® EZFuse™ suture can be used per patient and per procedure.
- Always keep at least one additional endomina® EZFuse™ suture in stock before starting a procedure.
- Always have appropriate hemostasis tools available.

Potential harm for the patient

The following harms may occur during or after the use of endomina® EZFuse™ suture:

- Acute inflammatory tissue reaction
- Bleeding requiring hemostasis management during or after the procedure
- Bleeding (stomach, liver, bowel, gallbladder, pancreas, spleen, omentum)
- Cross contamination
- Delayed intervention
- Infection
- Irritation
- Perforation (esophageal and/or stomach)
- Perforation (pharynx, bowel, bladder, spleen, uterus)
- Perforation (heart, lungs, pancreas, liver, aorta)
- Pneumoperitoneum
- Re-intervention might be required
- Sepsis
- Small mucosal tear
- Strong abdominal pain
- Wound dehiscence
- Third party contamination
- User injury

Side effects

Nausea, vomiting, cramps

Procedure

The procedure described here is a checklist for an operation by an experienced user.

1. Check that the endomina® EZFuse™ suture package is not damaged and is perfectly sealed. If any anomaly is detected or if the packaging has been unintentionally opened, do not use endomina® EZFuse™ suture; send it back to Endo Tools Therapeutics.
2. Insert endomina®v2 at the site to be treated.
3. Unpack endomina® EZFuse™ suture and check visually that it is complete and in good condition. Check that the tags are in place and the handle has not been actuated. Remove endomina® EZFuse™ suture from the dispenser by turning the fixing handle. Always hold the needle and the tubing and keep it pointed away from yourself and other people. Do not uncover or unwrap the needle until it is time to use endomina® EZFuse™ suture
4. Check that the needle pusher slides in the fixing handle and check the brake screw. The brake screw can be tightened at any time to lock needle pusher movement.
5. Insert the endomina® EZFuse™ suture into endomina®v2 and turn ¼ to lock it.
6. While pushing on the handle’s plugs, bend endomina®v2 arm all the way by pushing the handle until locked.
7. Fix endomina® EZFuse™ suture TAPES to endomina®v2 with the connector.
8. After the endoscope has been properly assembled to it, actuate endomina®v2 (i.e., bending) to position the endomina® EZFuse™ suture needle correctly.
9. Grab the tissue with the forceps and pull the tissue inside endomina®v2. Unlock endomina® EZFuse™ suture position and advance the endomina® EZFuse™ suture needle pusher to pierce the tissue.
10. Pull back the needle until only its tip is visible and lock the position.
11. 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.
12. 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.
13. As in step 9., grab and pierce the second bite of tissue. Pull back endomina® EZFuse™ suture until only its tip is visible and lock the position.
14. 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’.
15. As in step 12., unlock endomina® EZFuse™ suture position, then unpierce the tissue by going back with the needle.
16. Unbend endomina®v2 arm.
17. Unlock ¼ turn and remove endomina® EZFuse™ suture device from endomina®v2. You may advance the tag pusher to partially cover the needle tip and limit risks of injury.
18. 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.
19. After breakage, keep the forceps closed and remove the remaining thread by taking it out of the endoscope.

End of procedure

1. Check that all the components are present (excluding tags and suture).
2. Dispose of endomina® EZFuse™ suture in the sharp hospital waste bin. Make sure the disposal container is made for disposing of sharp objects and make sure there is enough room in the container for your object to fit. Replace containers when they are two-thirds full or according to hospital rules. If a needle is sticking out of the container, do not push it in with your hands. Call to have the container removed.

Emergency procedure

If endomina® EZFuse suture is stuck in the tissue

1. Actuate the handle to retrieve the needle fully and check that the tag pusher is also retrieved.
2. Assess relationship between blockage and suture release. Release tags or cut the suture with endoscopic scissors or guillotine, if appropriate.
3. Remove any cut or broken parts with foreign body retrievers using standard of care methods. Manage bleeding if necessary

Troubleshooting

Behavior	Resolution
Insertion of endomina® EZFuse suture into endomina® v2 is difficult	<ol style="list-style-type: none">i. Straighten endomina®v2.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® v2 is difficult	<ol style="list-style-type: none">i. If there is resistance at the end of needle introduction, right before locking it to endomina® v2 (spring-like (elastic) behavior), verify that endomina®v2’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® v2	<ol style="list-style-type: none">i. Push it back inside with the traumatic tip of the guidewire.

Behavior	Resolution
Difficult piercing	<ol 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.
	<ol 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.
	<ol 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.
Second tag is blocked inside	<ol style="list-style-type: none">i. If the pusher is bend or broken after the tag has been released, proceed normally to the next stepsii. 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
Pusher is bent or broken	<ol style="list-style-type: none">i. Repeat tissue approximation with a new endomina® EZFuse suture.
Suture cannot be tightened	<ol 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 excess wire with scissors or a loop cutter through the scope.
Suture breakage cannot be achieved after tightening	<ol style="list-style-type: none">i. Retrieve any material that has not been placed according to IFU, using foreign body retrieval methods to prevent obstruction
Foreign body obstruction	

Tag chain removal

In case of necessity, tag chain suture can be cut with a cutting tool between the tags. Tag chain elements should then be removed with a grasper. Dispose of the tag chain in an appropriate trash (for hospital waste)

Storage

endomina® EZFuse™ suture must be stored in its sterile package, in a clean and dry place, away from sun exposure and between 1°C – 30°C temperature.

The sterile package should not be stored underneath other packages that could squash it.

Repairs and modifications

endomina® EZFuse™ suture has no parts that can be repaired by the user. endomina® EZFuse™ suture must not be disassembled, modified or repaired by the user. This could hurt patients or damage other medical devices.

Triangulation platform compatibility

endomina® EZFuse™ suture has been validated with endomina® v2 triangulation platform (endomina® v2)

There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination.

Other endoscopic tools required for the procedure

endomina® EZFuse™ suture can be used with endoscopic tools through the channels of the endoscope. For all tools, test before use.

EN – Triangulation platform compatibility

- [Endo Tools Therapeutics](#) : endomina® v2 - EN – triangulation platform

EN – Other endoscopic tools required

- EN – Crocodile grasping forceps (foreign body retriever)
- EN – All instruments must be compatible with 2.8mm endoscope working channel

EN – Patients are exposed to the following substances and materials, per implant:

- Dichloro benzoic acid: 0,72µg
- 1,4-Benzenedicarboxylic acid, diethyl ester: 7.83µg
- Diphenyl sulfone: 0,37µg
- Nonanal: 0,77µg
- 2-Cyanoethyl acrylate: 0,57µg
- Isophthalic acid, ethyl 3-pentyl ester derivative: 2,66µg
- Pentacosane: 0,66µg
- Hexacosane: 0,95µg
- Heptacosane: 1,26µg
- Aliphatic compound possibly nonacosane: 2,09µg
- Terephthalic acid ester derivative: 2,80µg
- Tri(2-Ethylhexyl) trimellitate: 0,64µg
- Ethylene glycol terephthalate: 0,72µg
- 4-Undecylbenzenesulfonic acid: 0,65µg
- 4-Dodecylbenzenesulfonic acid: 0,38µg
- Stearic acid: 0,63µg
- 2-Naphthalenesulfonic acid: 0,49µg
- 1,1'-Thiobis(2-naphthol): 0,69µg
- 1,4-Di-4-toluidinoanthraquinone: 1,65µg
- Tris(2-ethylhexyl) trimellitate (TOTM): 0,72µg
- Dodecyl sulfate: 0,38µg
- Polyamide (Aminolauric acid 2, cyclic): 0,73µg
- 4-Tridecylbenzenesulfonic acid: 0,46µg
- Palmitic acid: 10,8µg
- Oleic acid: 1,17µg
- Stearic acid: 6,9µg
- Alkylated PET fragment (Terephthalic acid 3, Ethylenediol 3, linear): 1.74µg
- Oxidized Irgafos 168: 4,2 µg
- Bis(4-ethylbenzylidene)sorbitol: 2,7µg
- Polyethyleneterephthalate fragments: 0,66µg

EN – Symbols used

	EN – Consult Instruction for use
	EN – Do not reuse
	EN – Sterile (Ethylene oxide)