ETHIZIA™ Hemostatic Patch

Optimized device performance quick guide

*Pre-clinical test data are not necessarily indicative of clinical performance.

†Comparison of US indications for use of ETHIZIA™ Hemostatic Patch, EVARREST™ Fibrin Sealant Patch, and TachoSil™.

‡In a clinical trial of open liver surgery, ETHIZIA™ Hemostatic Patch achieved 81% hemostasis at 30 seconds, N=87.

Mechanism of action

ETHIZIA™ is composed of a flexible fibrous gelatin matrix containing a granulate (homogeneous powder) of two synthetic biocompatible polyoxazoline (POx) polymers that, in the presence of water (in an aqueous environment) rapidly link into a hydrogel. The polyoxazoline polymers consist of a POx-ester and POx-amine that result in a hydrogel entrapped within the gelatin matrix adhering to tissue, independent of the coagulation cascade.[1] Upon application and tamponade, the combination of the blood absorbing gelatin fibers and the water soluble polyoxazoline polymers creates a hemostatic mechanical barrier.

Key features

- First and only hemostatic matrix designed to be equally efficacious on both sides*[1-2]
- Only advanced patch approved for use in both open and MIS liver procedures†[3-5]
- Bleeding controlled in 30s‡[6]
- Gelatin-based carrier impregnated patch with POx polymer-based technology[7,8]



ETHIZIA Hemostatic Patch is indicated for use in adult patients with a body weight of ≥25kg as an adjunct to hemostasis in open and minimally invasive surgical procedures on the liver for minimal, mild, or moderate bleeding sites when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

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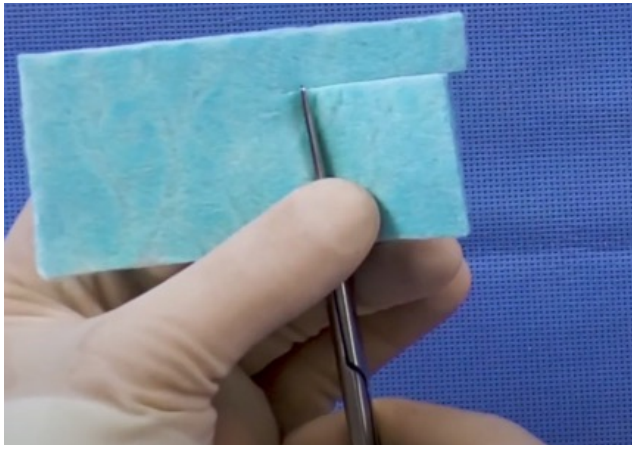
How to use ETHIZIA™ Hemostatic Patch

In open surgery

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.



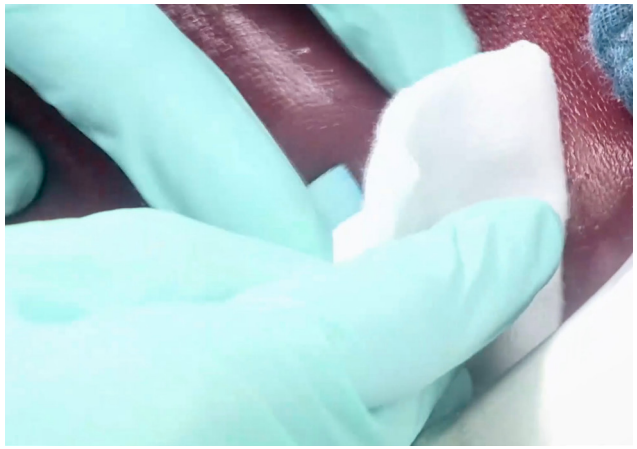
1. **Use dry gloves** to open the outer packaging and present inner, sterile pouch to the sterile field using aseptic technique.



2. If bleeding site is small, patch may be **cut to size.** Ensure scissors are dry.



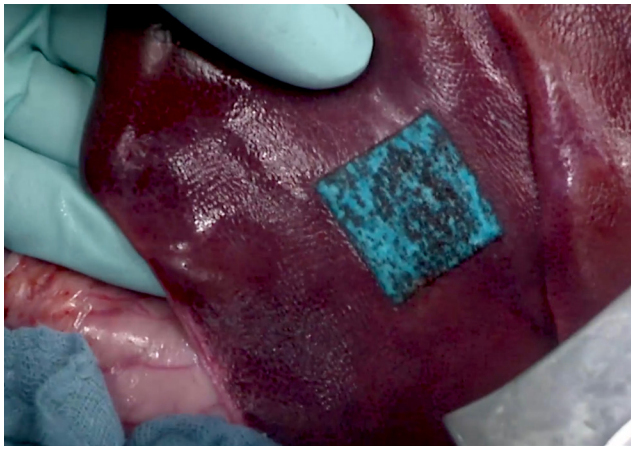
3. Prepare **saline-wetted woven gauze**. Squeeze out excess moisture.



4. **Apply** dry patch to bleeding site with at least **1-cm margins.** Hold in place with **saline-wetted woven gauze,** squeezed of excess moisture.



5. **Immediately apply uniform pressure for 30 seconds** to the entire surface of the patch. Gently remove saline-wetted woven gauze.



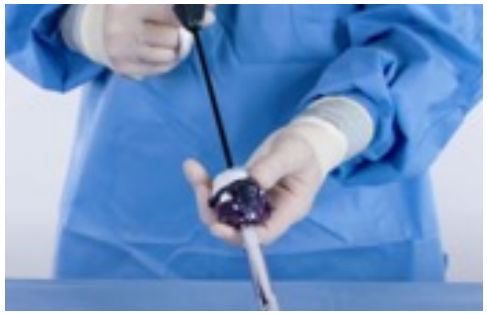
6. If complete hemostasis has not been achieved in 30 seconds, **reapply pressure** with saline-wetted woven gauze or saline-wetted surgical sponge for additional 30 seconds. Additional patches or pieces of patch may be applied.*

*1 full patch for patients between 55-110 lbs, 2 full patches for patients between 110-154 lbs, and 3 full patches for patients between 154 lbs or more

How to use ETHIZIA™ Hemostatic Patch

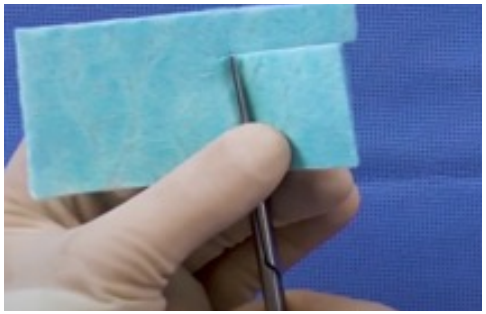
In minimally invasive surgery

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.



1. Select minimum 12mm trocar size.

Dry the trocar, port, and instruments of excess moisture prior to introducing the patch.



2. Full patch may be inserted.

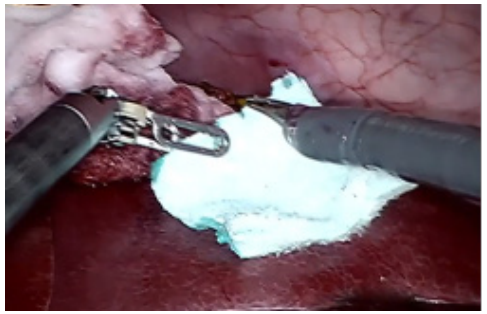
If bleeding site is small, patch may be cut to size. Ensure scissors are dry.



3. **Roll the patch** along the **long axis to reduce the diameter** when introducing it through the trocar.



4. Insert the patch through the trocar with one **continuous motion to minimize exposure** to moisture.



5. **Using one instrument to hold one** side of the patch, use another instrument to unroll The patch.

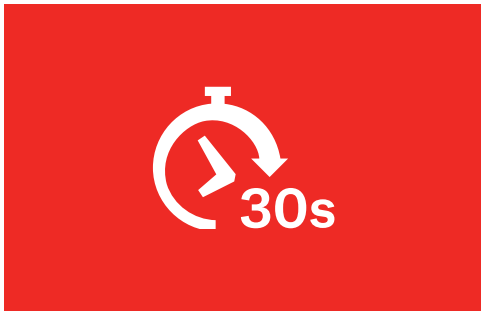


6. **Apply** dry patch to bleeding site with at least **1cm margins**.



7. Place **saline-wetted woven gauze(s)** across the top of the patch and use with multiple MIS tools to **apply uniform pressure for 30 seconds** over the saline-wetted woven gauze.

The saline-wetted woven gauze should already be inside, and **pressure is applied as soon as possible** after unrolling and applying the patch.



8. If complete hemostasis has not been achieved in 30 seconds, **re-apply pressure** with a saline-wetted woven gauze or saline-wetted surgical sponge for an additional 30 seconds.

Additional patches or pieces of patch may be applied.*

***1 full patch for patients between 55-110 lbs, 2 full patches for patients between 110-154 lbs, and 3 full patches for patients between 154 lbs or more**

Easy to use in open and MIS liver procedures*[9]

Malleability and handling**

- ETHIZIA™ Hemostatic Patch is flexible and pliable to be shaped for use in a variety of clinical situations, and on irregular tissue surfaces[10-14]
- Can be stuffed, rolled, pulled apart and trimmed[10-14]
- Can be applied using the “tuft and stuff ”[10-14] technique in open procedures
- Can be rolled and inserted through trocars during MIS procedures[3]
    - Part of one patch or a whole patch is inserted or stuffed into a small cavity, and the remainder of the patch or another patch is laid at over top**



Quick tips for optimized device performance

Things to do[3]

- Store in the provided packaging which includes the drying agent at specified environmental conditions, including storage at acceptable room temperature 5-25°C (41-77°F).
- Observe the expiration date indicated on the outer packaging. Do not use after expiration.
- Use within one hour of opening inner package
- Use dry gloves and surgical instruments (forceps, scissors, trocars) to handle, cut, and apply
- Cut or tear to desired size and shape as needed
- If using tuft and stuff technique, ensure one patch or piece of patch is applied at over top of the stuffed piece/patch.**
- Leave the patch in situ after hemostasis has been achieved
- If complete hemostasis has not been achieved in 30 seconds, reapply pressure with a saline-wetted woven gauze or saline-wetted surgical sponge for an additional 30 seconds
- Use multiple patches if needed (a maximum of 2.1cm²/kg of patient body weight remaining in situ at the end of the operation, or approximately 3 patches in an adult patient of 70kg)

Things to not do[3]

- Use for severe (ie, pulsatile) bleeding
- Use in cardiovascular, neurosurgical, ophthalmic, and urological (if the patch would come in contact with the urinary collection system) procedures because ETHIZIA™ has not been studied in these.
- Hydrate prior to placement
- Replace, reposition, or peel off the patch after application with saline-wetted woven gauze
- Remove the patch at the end of surgery; patch fully resorbed within 4-6 weeks
- Reuse or resterilize

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

*Based on surgeon user satisfaction questionnaire in a clinical trial of laparoscopic and robotic liver and gallbladder procedures, 25 of 25 responses agreed or strongly agreed
**This method was only qualified for bleeding sites which can be easily visualized. The performance of ETHIZIA™ in anticoagulated patients has not been studied.

References: **1.** Roozen EA, Lomme RM, Calon NU, ten Broek RP, van Goor H. Efficacy of a novel polyoxazoline-based hemostatic patch in liver and spleen surgery. World Journal of Emergency Surgery. 2023;18(1). doi:10.1186/s13017-023-00483-x. **2.** Design Verification Completion Report of ETHIZIA™ Hemostatic Sealing Patch. Jan. 27, 2025. Report #101192098. **3.** ETHIZIA™ Hemostatic Patch Instructions for Use. **4.** EVARREST™ Fibrin Sealant Patch Instructions for Use. **5.** TachoSil™ Instructions for Use. **6.** GATT Technologies BV. A Prospective, Multicenter, Randomized, Clinical Investigation Evaluating the Safety and Efficacy of GATT-Patch Versus TachoSil for Hemostasis During Open Liver Surgery. Oct. 3, 2024. DHF-01-SFT-194. **7.** GATT Technologies BV, DHF-01-SFT-201 Clinical Investigation Report, June 2022. **8.** Roozen EA, Lomme RM, Calon NU, ten Broek RP, van Goor H. Efficacy of a novel polyoxazoline-based hemostatic patch in liver and spleen surgery. World Journal of Emergency Surgery. 2023;18(1). doi:10.1186/s13017-023-00483-x. **9.** GATT Technologies BV. A Prospective, Multicenter, Randomized, Clinical Investigation Evaluating GATT-Patch for Hemostasis During Minimally Invasive Liver and Gallbladder Surgery. December, 2025. DHF-01-SP-065. **10.** 5. GATT Technologies BV, DHF-SR-120 Partly heparinized in vivo porcine model ORSI, Nov 2021. **11.** 6. GATT Technologies BV, DHF-SR-142 Partly heparinized in vivo porcine model Radboudumc, Jan 2023. **12.** 7. GATT Technologies BV, DHF-01-SR-152 - GATT-Patch vs Floseal in porcine kidney cavity bleeding, Jan 2022. **13.** 8. Orsi Academy, DHF-01-SR-154 GATT-Patch vs Suturing in a robotic porcine partial nephrectomy model, Feb 22. **14.** 9. GATT Technologies BV, DHF-01-QR-021 Clinical Investigation Report, Feb 2022

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

ETHIZIA Hemostatic Patch Essential Product Information

INDICATIONS

ETHIZIA™ is indicated for use in adult patients with a body weight of ≥25kg as an adjunct to hemostasis in open and minimally invasive surgical procedures on the liver for minimal, mild, or moderate bleeding sites when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

CONTRAINDICATIONS

- ETHIZIA™ is not indicated for use on severe (i.e. pulsatile) bleedings (defined by Surface Bleeding Severity Scale 4-5).
- ETHIZIA™ is not intended for intravascular use. Do not attempt to force ETHIZIA™ into blood vessels and only apply ETHIZIA™ after standard surgical techniques have been used to close the vessel.
- ETHIZIA™ should not be used in infected wounds.
- ETHIZIA™ should not be used in patients with a known hypersensitivity to the component materials, including porcine proteins and FD&C Blue #1.

WARNINGS

- ETHIZIA™ has not been studied in pediatric patients and pregnant or lactating women.
- ETHIZIA™ has not been studied for use during cardiovascular, neurosurgical, ophthalmic, and urological (if the patch would come into contact with the urinary collection system) procedures.
- ETHIZIA™ is not intended to be a substitute for standard surgical technique and/or the proper use of other conventional hemostatic techniques.
- ETHIZIA™ must not be used if applying pressure on the entire surface of the patch would be difficult to achieve. This may result in incomplete hemostasis.
- Care should be taken when using ETHIZIA™ in confined spaces. Product could swell around blood vessels or organs leading to compression or possible organ injury.
- Use the smallest number of patches required to cover and extend the margins of the entire bleeding area by at least 1 cm. Maximum amount for ETHIZIA™ is 150 cm2, calculating to approximately 3 ETHIZIA™, based on a 70 kg patient or 2.1 cm2/kg. The table below includes further information on the maximum amount of ETHIZIA™ when used in patients of different body weights. The safety of higher quantities has not been studied.

Patient body weight (kg)	Maximum amount of ETHIZIA™
25-50 kg	1 ETHIZIA™
50-70 kg	2 ETHIZIA™
≥70 kg	3 ETHIZIA™

- ETHIZIA™ must not be hydrated prior to application. Wetting a patch initiates the formation of a POx hydrogel. Initiating this process prior to application on tissue could lead to decreased hemostatic performance.
- Do not reposition the patch after application with a saline wetted gauze. Once applied with a saline wetted gauze, instant polymer activation will adhere the patch to the tissue and repositioning will risk tearing the patch. Moreover, insufficient patch adhesion upon repositioning will compromise the creation of hemostasis.
- Do not replace or peel off the patch when hemostasis has been achieved. Once hemostasis is achieved through adhesion of ETHIZIA™ to the surface of the tissue to create a physical barrier, attempts at patch manipulation could lead to tissue trauma or rebleeding.
- ETHIZIA™ should be wetted homogeneously after application. Wetting a patch initiates the formation of a POx hydrogel. Implanted dry patch areas may lead to decreased hemostatic performance or adhesions.
- After application of ETHIZIA™, manipulation of the bleeding site and the patch should be minimized.
- ETHIZIA™ may be present on imaging. The patch could potentially obscure underlying structures, present as a possible product encapsulation or mimic pathological conditions on imaging, possibly leading to the need for additional diagnostics or unwarranted intervention.
- ETHIZIA™ is not indicated as a surgical sealant to prevent bile leakage and should not replace meticulous use of standard surgical techniques to prevent bile leakage. The use of surgical drains to mitigate potential complications as a result of bile leakage should be assessed in each specific procedure based on the surgeon's knowledge and specific anatomical and physiologic considerations encountered in surgery.

PRECAUTIONS

- For single use only. Do not re-sterilize. Reuse of single-use devices creates a potential risk of patient infections.
- The performance of ETHIZIA™ for sealing fluid leaks has not been tested.
- The performance of ETHIZIA™ in anticoagulated patients has not been studied.
- Do not use if the product sterile barrier system or its packaging is compromised.
- ETHIZIA™ must be used within 1 hour after opening of the packaging.

ADVERSE REACTIONS

Allergic reactions may occur in the presence of ETHIZIA™ Hemostatic Patch due to hypersensitivity to the component materials, including porcine proteins and FD&C Blue No. 1.

Product swelling may occur around critical structures (e.g. blood vessels, nerves, or organs) leading to compression or possible organ injury.

In the performed clinical investigation on patients undergoing open liver surgery (ClinicalTrails.gov ID NCT04819945), the following events occurred with a possible relationship to the device: hematoma, biloma, and abdominal abscess.

For more information and technical questions, call 1-800-795-0012. For complete information including indications, contraindications, warnings, precautions, and adverse reactions, and directions for use, consult the product instructions for use.

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