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ETHIZIA™
Hemostatic Patch

[English]

[English Text]

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Instructions for use

ETHIZIA™
Hemostatic Patch

DESCRIPTION

ETHIZIA™ Hemostatic Patch (ETHIZIA) is a sterile, resorbable hemostatic patch that should be applied on a visible bleeding site. It presents as a blue, soft, flexible, porcine gelatin (1 ± 0.2 grams per ETHIZIA) fiber-based gelatin carrier impregnated with NHS-POx / NU-POx granulate (1 ± 0.2 grams per ETHIZIA). Blue color (202 – 686 µg per ETHIZIA) is an aid to visualize ETHIZIA when applied onto a bleeding location. ETHIZIA measures 10 by 5 cm and can be applied on both sides. As ETHIZIA is a homogeneously impregnated fibrous material, it is also suited to being torn into smaller pieces for application on irregularly shaped structures and areas that are difficult to access.

The product is not removed at the end of surgery but is resorbed in 4-6 weeks.

Degradation of ETHIZIA depends upon several factors including the amount used, the anatomical location, and degree of saturation with blood or other fluids. For the maximum amount of patches permitted see Table 2 in the Warnings section.

TABLE 1. ETHIZIA SPECIFICATIONS

PARAMETER	SPECIFICATION
Appearance	Fibrous, coherent patch, homogeneously colored (blue)
Shape	Rectangular
Dimensions	Length: 100 ± 5 mm
	Width: 50 ± 5 mm
	Thickness: 5 ± 3 mm
Weight	1.6 – 2.5 g
Composition	Porcine gelatin (1 ± 0.2 grams per ETHIZIA)
	NHS POx/NU-POx granulate (1 ± 0.2 grams per ETHIZIA)

	FD&C Blue No. 1 (202 – 686 µg per ETHIZIA)
Ratio Blue NHS-POx/NU-POx	Blue NHS-POx/NU-POx (75:25 (w/w) to 85:15 (w/w))
Loading (% of granulates in final finished device)	36-61%
Sterility assurance level (SAL)	10^{-6}

INDICATIONS FOR USE

ETHIZIA Hemostatic Patch is indicated for use in adult patients with a body weight of ≥25 kg 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 minimum number of patches required to cover and extend the margins of the entire bleeding area by at least 1 cm.

A maximum of 3 (150 cm^2) ETHIZIA patches are permitted for a ≥ 70 kg patient or 2.1 cm^2/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.

TABLE 2. ETHIZIA MAXIMUM AMOUNT LIMIT PER KG OF BODY WEIGHT	
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 saline-wetted woven gauze. Once applied with saline-wetted woven gauze(s), 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.

ETHIZIA should be kept dry as it is presented to the surgical site. Contact with wet instruments or other wet materials may result in sticking to surfaces other than the intended target tissue.

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.

PREPARATIONS

Circulating Nurse *(non-sterile):*
Open the outer non-sterile packaging and remove the inner pouch.

Visually inspect all packaging for damage including a careful inspection of all sterile barrier systems for breaches in package integrity immediately prior to use.

Do not use if the product sterile barrier system or its packaging is compromised.

Present the sterile contents (i.e. clamshell) to the sterile field using aseptic technique.

ADMINISTRATION

ETHIZIA is intended to be used by physicians performing open and minimally invasive surgical procedures when adequate pressure across the entire patch can be achieved following application.

Dry gloves and surgical instruments (forceps, scissors, trocars) should be used to handle, cut and apply ETHIZIA. When applying ETHIZIA, minimize contact with wet or bloody surgical instruments or gloves as the device may adhere to other surfaces.

ETHIZIA may be used in combination with electrocautery devices used for general surgery.

ETHIZIA must not be hydrated prior to placement.

ETHIZIA may be cut to the desired size and shape. Select the appropriate size of ETHIZIA so that it overlaps the margins of the bleeding surface by at least 1 cm.

Multiple (pieces of) patches may be used, up to the maximum of 2.1 cm^2/kg body weight, calculating to **1 full ETHIZIA for patients of 25-50 kg, 2 full ETHIZIA for patients 50-70 kg, and 3 full ETHIZIA for patients ≥70 kg**. See table 2 in the Warnings section.

ETHIZIA may be applied to, or (partially) overlap, a previously applied (piece of) patch (“patch on patch”).

The entire ETHIZIA patch must be covered homogeneously with saline-wetted gauze(s) after application over the bleeding site.

Leave ETHIZIA in situ after hemostasis has been achieved. Do not try to forcefully remove the patch.

Do not remove ETHIZIA at the end of the surgery. Excess ETHIZIA material may be removed carefully, at the discretion of the surgeon.

METHOD OF APPLICATION

Apply ETHIZIA dry to the bleeding site with at least 1cm margins and immediately hold in place with saline-wetted woven gauze(s) and uniform pressure over the entire patch surface for 30 seconds. Gently remove the wet woven gauze(s) from the patch. If complete hemostasis has not been achieved in 30 seconds, re-apply pressure with saline-wetted woven gauze(s) or surgical sponge(s) for an additional 30 seconds.

- If hemostasis is not complete with a single patch and blood comes through the patch, apply a new (piece of) ETHIZIA on the bleeding site with a 1 cm overlap with tissue or previously placed ETHIZIA on all sides (“patch-on-patch”). Apply according to the steps above.

- If hemostasis is not complete because ETHIZIA is not adherent to the underlying tissue, with or without hematoma formation underneath, remove the non-adherent part and apply a new (piece of) ETHIZIA on the bleeding site with a 1 cm overlap with tissue or previously placed ETHIZIA on all sides ("patch-on-patch"). Apply according to the steps above.
- Repeat the above steps as necessary, with a maximum of 2.1 cm^2/kg of patient body weight covered by ETHIZIA and remaining in-situ at the end of the operation (approximately 3 patches in an adult patient of ≥70 kg). See Table 2 in the Warnings section.

SPECIFICALLY FOR MINIMALLY INVASIVE USE

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.

1. Select minimum 12mm trocar size.

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

KEEP PATCH DRY BEFORE APPLICATION

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

4. Roll the patch along the long axis to reduce the diameter when introducing it through the trocar. *(Figure A)*

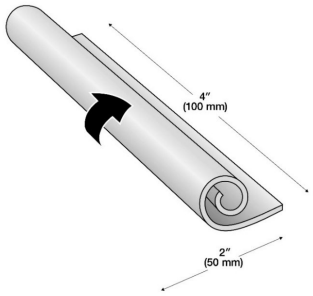


Figure A

5. Insert the patch through the dry trocar with one continuous motion to minimize exposure to moisture. *(Figure B)*

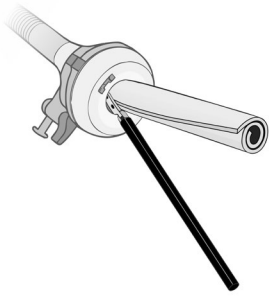


Figure B

6. Using one instrument to hold one side of the patch, use another instrument to unroll the patch.

7. Apply dry patch to bleeding site with at least 1cm margins. (*Figure C)*

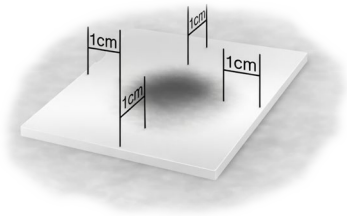


Figure C

8. The saline-wetted woven gauze(s) should be ready to apply over the entire patch as soon as possible after unrolling and applying it to the target bleeding site.
9. The saline-wetted woven gauze(s) should be sufficient in size to cover and moisten the entire patch.

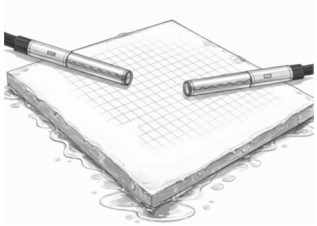


Figure D

10. Place saline-wetted woven gauze(s) across the top of the entire patch and use multiple MIS tools to apply uniform pressure for 30 seconds over the saline-wetted woven gauze(s). (*Figure D)*
11. If complete hemostasis has not been achieved in 30 seconds, re-apply pressure with saline-wetted woven gauze(s) or saline-wetted surgical sponge(s) for an additional 30 seconds. Additional patches or pieces of patch may be applied.

SHELF LIFE, STORAGE AND DISPOSAL

ETHIZIA must be stored in the provided packaging which includes the drying agent and at specified environmental conditions, including storage at acceptable room temperature of 5-25°C (41-77°F).

Observe the expiration date indicated on the outer packaging. Do not use after expiration.

ETHIZIA and packaging may be disposed of as general surgical waste in accordance with local regulations.

CLINICAL EXPERIENCE

A Prospective, Multicenter, Single-arm, Clinical Investigation Evaluating the Safety and Performance of ETHIZIA for Hemostasis during Open Liver Surgery (NCT04819945)

Patients: 47 patients undergoing elective open liver surgery were treated with ETHIZIA for minimal, mild, or moderate bleeding (i.e. Surface Bleeding Severity Scale 1-3).

Effectiveness: Among 47 patients and 63 target bleeding sites, hemostasis was achieved in 30 seconds in 82.7% (N=52/63), in 60 seconds in 93.7% (N=59/63), and in 3 minutes in 96.8% (N=61/63) of bleeding sites. As compared with a literature-derived performance goal of 65.4%, ETHIZIA demonstrated to be non-inferior to a range of approved hemostatic agents in achieving

hemostasis within 3 minutes.

Safety: There were 44 adverse events in total in the 28 of 47 (59.6%) subjects with adverse events. Most patients experienced gastrointestinal disorders (N=5/47; 10.6%), hepatobiliary disorders (N=15/47; 31.9%), infections and infestations (N=8/47, 17.0%), and/or events related to injury and procedural complications (N=4/47; 8.5%). There were 3/44 (6.8%) severe adverse events, which were ascites, hepatic failure, and an abdominal abscess. The majority of events, 36/44 (81.8%) in total, were related to the procedure. Three of the 44 events (6.8%) were also related to the device and were a biloma, an abdominal abscess, and a post-procedural hematoma. All of these events were considered to be possibly related to the device; there were no events that were probably related to the device or with a causal relationship with the device.

A Prospective, Multicenter, Randomized Clinical Investigation Evaluating the Safety and Performance of ETHIZIA versus TachoSil for Hemostasis during Open Liver Surgery (NCT 05385952)

Patients: 131 patients undergoing elective open liver surgery were randomized 2:1 to either ETHIZIA or to the control group TachoSil® Fibrin Sealant Patch* (TachoSil). In total, 87 patients were treated with ETHIZIA for minimal, mild, or moderate bleeding (i.e. Surface Bleeding Severity Scale 1-3). There were 44 patients randomized to TachoSil and 43 received the treatment.

Effectiveness: The primary endpoint of hemostasis at 3 minutes without rebleeding at the 10-minute time point was 93.1% (N=81/87) for ETHIZIA and 76.7% (N=33/43) for TachoSil. This data demonstrates that ETHIZIA is non-inferior to the control group TachoSil ($p<0.0001$). Upon achieving non-inferiority, sequential hypothesis testing demonstrates that ETHIZIA is superior to the control group, TachoSil ($p=0.0038$). Among the 87 patients there were 139 target bleeding sites treated with ETHIZIA and hemostasis was achieved in 30 seconds in 81.3% (N=113/139), in 60 seconds in 92.1% (N=128/139), and in 3 minutes in 95.7% (N=133/139) of bleeding sites, with the median time to hemostasis being significantly shorter for ETHIZIA (30 seconds) versus TachoSil (180 seconds) ($p<0.0001$).

Safety: There were 326 total adverse events in 97 of the 130 (74.6%) subjects. During the study 75.9% (N=66/87) of patients in the ETHIZIA group experienced an adverse event and 72.1% (N=31/43) in the TachoSil group. There were 47 patients with serious adverse events in total, 42.5% (N=37/87) of patients in the ETHIZIA group experienced a serious adverse event and 23.3% (N=10/43) in the TachoSil group. Most patients with serious adverse events in both groups experienced gastrointestinal disorders (N=20/130; 15.4%), events related to injury and procedural complications (N=17/130; 13.1%), infections and infestations (N=9/130; 6.9%), and cardiac disorders (N=6/130; 4.6%). Of the 326 total adverse events, 8/87 (9.2%) of patients experienced events related to ETHIZIA and these were intra-abdominal fluid collection in 4/87 (4.6%) followed by post procedural bile leak in 2/87 (2.3%) and abdominal pain, intraoperative hepatic hemorrhage, hematoma, and pyrexia in 1/87 each (1.1% of subjects each) and 9/43 (20.9%) of patients experienced events related to TachoSil and these were intraoperative hepatic hemorrhage in 6/43 (14.0%) followed by abdominal pain, post procedural bile leak, hematoma, and bacteremia in 1/43 each (2.3% of subjects each). All of these events were considered to be possibly related to the device per investigator; there were no events that had a causal relationship with the device.

Long-term Observational Follow-up: A 5-year observational follow-up for patients who underwent liver resection for cancer is ongoing. The clinical data from this follow-up will include cancer recurrence, cancer-free survival and overall cancer survival.

A Prospective, Multicenter, Randomized Clinical Investigation Evaluating the Safety and Performance of ETHIZIA™ for Hemostasis during Minimally Invasive Liver and Gallbladder Surgery (NCT 05900037)

Patients: 53 patients undergoing elective, minimally invasive (robotic and laparoscopic) liver or gallbladder surgery were randomized and treated 1:1 to either ETHIZIA™ or SURGICEL® Original. In total, 25 patients were treated with ETHIZIA and 28 treated with SURGICEL Original for minimal, mild, or moderate bleeding (i.e. Surface Bleeding Severity Scale 1-3).

Effectiveness: The primary endpoint of delivery and adherence of the agent to the target bleeding site and achievement of hemostasis within 7 minutes from introduction of the first patch through the trocar without rebleeding at the 10-minute timepoint was 100.0% (25/25) for ETHIZIA and 82.0% (23/28) for SURGICEL Original. Among the 25 ETHIZIA patients, there were 35 target bleeding sites treated, and hemostasis was achieved in 30 seconds from initiating pressure in 77.1% (27/35), in 60 seconds in 85.7% (30/35), and in 3 minutes in 91.4% of bleeding sites. The median time to hemostasis from initiating pressure was 30 seconds for both ETHIZIA and SURGICEL Original.

Safety: There were 73 total adverse events in 30 of the 53 (56.6%) patients. During the study, 60.0% (N=15/25) of patients in the ETHIZIA group experienced an adverse event and 53.6% (N=15/28) in the SURGICEL Original group. There were 6 patients with serious adverse events in total; 16.0% (N=4/25) of patients in the ETHIZIA group experienced a serious adverse event and 7.1% (N=2/28) in the SURGICEL Original group. Overall, serious adverse events occurred most frequently in the vascular disorder system class (N=3/53; 5.7%), gastrointestinal disorders (N=2/53; 3.8%) and respiratory, thoracic and mediastinal disorders (N=2/53; 3.8%). All serious adverse events in both groups were single occurrences. Of the 73 total adverse events, 1/25 (4.0%) patients experienced an event related to ETHIZIA (application site hemorrhage; 1/25; 4.0%), and 4/28 (14.3%) patients in the SURGICEL Original group (application site hemorrhage; 4/28; 14.3%) per Investigator assessment. In the ETHIZIA treatment group, the event of application site hemorrhage was considered causally related to ETHIZIA by the Investigator. In the SURGICEL Original treatment group, 2 of the application site hemorrhage events were considered probably related and 2 considered causally related to SURGICEL Original by the Investigator.

* Trademarks and brand names listed are the property of their respective owners.



Medical Device



Sterilized using irradiation


Temperature limit


Manufacturer


Packaging unit


Use-by date



Batch code



Date of manufacture



Do not use if package is damaged and consult instructions for use



Keep away from heat



Do not re-use



Consult instructions for use or consult electronic instructions for use



Do not resterilize



Single sterile barrier system with protective packaging inside



Keep dry



Unique Device Identifier



Contains biological material of animal origin



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



Catalogue number



Caution



MR Safe

[Back Cover]

Ethicon, Inc.
1000 Route 202
Raritan, NJ 08869 USA
1-877-ETHICON
1-513-337-6928

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