Instructions for Use

LIQUIFIX FIX8™ Laparoscopic Hernia Mesh Fixation Device

Single use Device

Contents

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

Read all directions, precautions and warnings prior to use.

These instructions for use provide directions for the proper use of the Advanced Medical Solutions Limited LIQUIFIX FIX8™ Laparoscopic Hernia Mesh Fixation device. They are not intended to be a comprehensive instruction manual for the performance of a laparoscopic surgical procedure. Surgeons should be fully proficient in minimally-invasive/laparoscopic hernia repair surgical techniques, prior to the use of the device,

Device Description

The LIQUIFIX FIX8™ device is designed to fix mesh to soft tissue for hernia repair using n-butyl-2-cyanoacrylate adhesive. The LIQUIFIX FIX8™ Laparoscopic Hernia Mesh Fixation Device is intended to be used with polypropylene or polyester mesh to affix the mesh to the underlying tissue and for tissue-to-tissue approximation of the peritoneum.
LIQUIFIX FIX8™ is comprised of:

a) n-butyl-2-cyanoacrylate adhesive monomer and D&C Violet No.2 dye, in liquid form, supplied in a thin-walled, sealed glass vial; and,
b) a surgically invasive, laparoscopic 5mm diameter cannula, with a handle at the proximal end incorporating a loading chamber, filter, piston chamber and trigger. The distal tip of the device is open to allow the adhesive to be dispensed from it.

The device is designed to be introduced and used through a 5 mm diameter laparoscopic port sleeve. A larger diameter sleeve will require the use of a converter.
Both the cyanoacrylate adhesive in the glass vial and the surgically invasive delivery device are supplied sterile, for single use only.
The implanted material contains ≥99.5% n-butyl-2-cyanoacrylate adhesive. Other notable substances include butylated hydroxyanisole, n-butyl cyanoacetate and formaldehyde, which in summation are ≤0.8%.

Principle of Operation

The glass vial containing the liquid cyanoacrylate adhesive monomer comes preloaded into, and is subsequently broken in, a loading chamber in the handle of the delivery instrument. The adhesive is drawn through a filter into a piston chamber in the delivery instrument handle. After priming, each press of the trigger on the handle of the delivery instrument dispenses 12.5 mg of adhesive from the distal tip of the cannula. A single device contains sufficient adhesive for at least 40 individual applications of the adhesive. The gauge on the side of the delivery instrument gives an indication of the amount of adhesive delivered and the approximate amount remaining.

Mechanism of Action

When applied to the proximal surface of the hernia mesh, the liquid adhesive monomer permeates through the perforations in the mesh to the surface of the underlying tissue, where it polymerizes on contact with moisture on the tissue surface. This process of chemical polymerization fixes the mesh to the surface of the tissue at the site of adhesive contact, maintaining the mesh in position while it is incorporated into the abdominal wall through the normal process of tissue fibrosis. Polymerization occurs as the adhesive comes into contact with moisture. The adhesive bond forms by the polymerization happening between the two overlapped sections of peritoneum tissue and adhering the two surfaces together. The adhesive completes its polymerization reaction within approximately 10 seconds. Once completely set, the adhesive no longer possesses adhesive properties such that tissues or surgical instruments may be placed in contact with it without risk of unwanted adhesion.

Indications for Use

The LIQUIFIX FIX8™ device is intended for use in laparoscopic surgical repair of groin (femoral and inguinal) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall and the approximation of the peritoneum.

Contraindications

- The device is not intended for use when prosthetic material fixation is contraindicated.
- Do not use on patients with a hypersensitivity to cyanoacrylate adhesives, formaldehyde or D&C Violet No. 2 dye.
- Do not use for the fixation of meshes constructed with polytetrafluoroethylene (PTFE) or materials other than polypropylene or polyester.
- Do not use device for closure or fixation of cerebral tissues, blood vessels or peripheral nerves.

Warnings

- The use of LIQUIFIX FIX8™ is limited to those healthcare providers who are qualified to perform laparoscopic hernia repairs. A thorough understanding of the operating principles, risks versus benefits, and hazards involved in utilizing an endoscopic approach is necessary to avoid possible hazards to the user and/or patient. It is recommended that any healthcare provider who intends to use LIQUIFIX FIX8™ read the instructions for use in full, including directions, precautions and warnings.
- This device is provided sterile and is intended for use in a single patient. Do not reuse, reprocess, clean, disinfect or re-sterilize this device as this may compromise the sterility and performance of the device.
- Ensure the device is properly activated and primed before use according to the instructions in the Directions for Use section.
- This device does not contain any user-serviceable parts. Do not attempt to repair or dismantle the device. If at any point the device appears to be damaged or not functioning correctly, check for tip blockage and that the device is able to deliver adhesive anchors after multiple trigger pulls, otherwise discard and replace it with another device.
- Do not dilute or mix the adhesive with other substances.
- Accidental bonding of unwanted tissue may occur due to misapplication of adhesive. Separation of tissues after accidental bonding should only be performed if deemed necessary. Tissues should be separated slowly and carefully with surgical graspers using a peeling motion.
- If adhesive becomes bonded to an unwanted area, removal is possible after complete polymerization (60 seconds) by slowly and carefully peeling the polymerized adhesive from the tissue with surgical graspers. In vivo animal testing was performed to support this practice.
- Upon adhesive removal, if there is resistance upon peeling, residual adhesive should be left to prevent potential injury.
- There is no pre-clinical or clinical data to support use with absorbable meshes in the United States.
- Mesh woven from uncoated polyester or polypropylene fibers were evaluated in the United States Clinical study; coated meshes have not been studied.
- Do not use or apply LIQUIFIX FIX8™ to plug mesh in the retroperitoneum.

Precautions

- The fixation method for any prosthetic device should be determined on the basis of accepted surgical techniques, procedural requirements, and the instruction for use of the prosthetic mesh.
- Ensure the mesh is held in contact with the underlying tissue for approximately 10 seconds during each application of the adhesive to allow for polymerization. Polymerization may take longer than 10 seconds depending on the moisture in the environment.
- The viscosity of the adhesive is only slightly greater than that of water, so adhesive should be applied very carefully to prevent it spreading to unwanted areas.
- The adhesive should always be applied in minimal amounts, i.e. avoid multiple applications of adhesive in any given location. A second application of adhesive can be applied over the first only after full polymerization.
- The application of an excessive amount of adhesive in a single location prolongs polymerization and may prevent adherence. After polymerization, any excess adhesive may lead to detachment of the adhesive film and/or give rise to the formation of small fragments of polymerized adhesive.

- The LIQUIFIX FIX8™ device is designed to fix mesh to soft tissue for hernia repair. Whilst the adhesive will readily adhere to most tissues, the adhesive is not intended to be used directly on exposed bone as the safety and effectiveness have not been established to support this practice.
- The adhesive may not perform as intended if it is being applied to unsuitable locations such as fatty tissues.
- Care should be taken to avoid unwanted contact between surgical instruments and the adhesive during polymerization. Polymerized adhesive can be removed from metal instruments with acetone.
- If the tip of the device comes into contact with excessively wet (e.g. bloody) tissues the likelihood of tip blockage may increase. This can be mitigated through prior use of a sterile gauze swab, to dry the field before applying the adhesive. If the tip becomes blocked, the blockage can be removed by wiping the tip with dry sterile gauze or by using a sterile narrow object (e.g. needle).
- During the hernia repair procedure, care should be taken to ensure that the quality of the hernia repair is not adversely affected when performing other surgical procedures at the same time (which may involve repositioning of the patient).
- LIQUIFIX FIX8™ adhesive is not intended to be used on top of other fixatives such as sutures or tacks.
- At high angles of tip elevation, there is a chance of interrupted glue delivery. Multiple trigger pulls may be required until an adhesive anchor is expressed.
- If the peritoneum is thick, heavy, or under excess tension, approximation may be aided by reduction in pneumoperitoneum pressure or repositioning of the patient.

Potential Adverse Effects of the Device on Health

As with the majority of implanted devices, adverse reactions associated with the use of this device may include transient local irritation at the implant site and a transitory inflammatory foreign body response. Advanced Medical Solutions has determined the potential adverse effects (e.g. complications) listed below may be associated with the use of the LIQUIFIX FIX8™ device. These potential adverse events include, but are not limited to, the following:

- Toxic reaction
- Allergic reaction

Observed Adverse Events

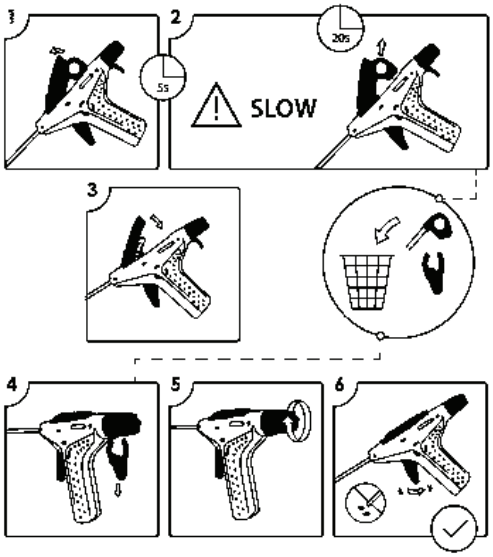
Clinical studies of LIQUIFIX FIX8™ Laparoscopic Hernia Mesh Fixation device have been conducted inside and outside the United States. Possibly device related adverse events observed during the US pivotal study have been described below; a number of these adverse events were possibly device related and possibly/definitely related to the procedure. In addition, adverse events observed during the LIQUIFIX FIX8™ European clinical studies, but not necessarily related to the device itself, included the following:

- Chronic Pain
- Hernia Recurrence
- Urinary Retention
- Minor Surgical Emphysema
- Seroma
- Port Site Hernia
- Port Site Hemorrhage
- Hematoma
- Swelling
- Neuralgia / Hypoaesthesia
- Groin / Testicular pain
- Intestinal obstruction
- Genital hemorrhage
- Spermatic Cord Inflammation
- Orchitis
- Lymphadenitis
- Mesh infection
- Inadvertent enterotomy

- Intra peritoneal bleeding
- Post-operative ileus
- Urinary bladder injury

Directions for Use

Priming the device for use



The device must be properly activated and primed to ensure that it operates correctly.

1) Remove the device from its packaging. Hold the device with the handle vertical and the distal tip of the cannula tilted downwards. Lift the blue lid firmly upward until a cracking sound of the glass ampoule breaking inside the lid is heard.
2) Wait for 5 seconds, then, with the tip pointing downwards and the handle held vertically, slowly pull out red tab no. 2, observing that the adhesive is being drawn into the transparent barrel. This should take approximately 20 seconds. At the end of piston travel, gently disengage the red tab and dispose of.

Warning: A fast transfer stage could result in excessive air being drawn into the dispensing chamber.

3) Gently close the blue lid until it is completely aligned with the body and an audible click is heard.
4) Remove red pull tab no. 4 and dispose of.
5) Rotate the blue knob clockwise approximately 320° until the blue dispenser trigger alongside the handle is released. Care should be taken to avoid impeding the release of the trigger. The distal tip should be directed into the packing tray well no. 6 before the blue knob is rotated.
6) With the cannula tip placed into packing tray well no. 6, prime the device by actuating the trigger until a droplet of adhesive freely emerges. Wipe any excess adhesive from the tip of the cannula onto the inside of the packing tray or on a sterile wipe. The device is now ready for surgical use.

Using the device for hernia repair

- A suggested pressure for pneumoperitoneum is 15mmHg.
- A suggested orientation for the patient is that they are tilted into a head down position
- Fixation can be achieved with LIQUIFIX FIX8™ Laparoscopic exclusively or in conjunction with other fixation methods.

- Mesh fixation can be achieved by applying adhesive anchors in discrete locations across the mesh. As the adhesive is non-invasive and does not penetrate through the tissue, the adhesive can be applied at any location on the mesh.
- To prepare the site for mesh fixation, excess moisture of the surgical field can be reduced by wiping with a sterile swab.
- To deploy a single adhesive anchor, hold the tip of the cannula against the mesh surface and depress trigger and release once. Adhesive should be visualized upon release of the trigger.
- The mesh should be held in contact with the tissue for up to 10 seconds until adhesive has polymerized, as indicated by a change in opacity.
- For porous mesh, the adhesive can be applied to the proximal surface of the mesh, as the liquid adhesive monomer can permeate through the pores in the mesh to the surface of the underlying tissue. Ensure the mesh is positioned with minimal overlapping or folding so that adhesive can easily pass through the mesh pores.

Using the device for peritoneal closure

- To reduce tension on the peritoneum, the intra-abdominal pressure should be decreased. A suggested pressure for pneumoperitoneum is 8mmHg.
- Gravity can also be used to reduce tension on the peritoneum by placing the patient into specific orientations. The patient can be levelled or put into a head up position.
- If the internal side of the lower peritoneal flap is notably fatty, it is possible to invert the lower peritoneal flap to avoid applying glue to the fatty areas.
- Excessive moisture may be removed from the peritoneum by use of a sterile swab. The position of the first adhesive anchor should be located in the area under least tension.
- Peritoneal closure can be achieved by dispensing a drop of adhesive to the upper peritoneal flap, before lifting and holding the lower peritoneal flap onto the adhesive until the adhesive is able to hold the lower peritoneal flap. Continue drop by drop until closure of the peritoneum is complete.
- Upon complete fixation of the peritoneum, the pneumoperitoneum should be evacuated and then re-inflated to check the continuity of the peritoneal closure.

Disposal

After use, dispose of the device according to local procedures and guidelines.

Storage

This device should always be stored in its original packaging.
Store only at temperatures between 5°C (41°F) and 25°C (77°F), away from moisture, direct heat and direct light.
Do not use the device after the expiration date shown on the blister pack.

Sterility

This device is packaged for single patient use and is sterilized by electron beam irradiation and ethylene oxide gas with a sterility assurance level (SAL) of 10^{-6}.
Do not re-sterilize.
Do not use if package is open or damaged.

Magnetic Resonance Safety Information

LIQUIFIX FIX8™ adhesive is MR Safe.

Device-related incidents

If a serious incident occurs in relation to the use of the device this should be reported to the manufacturer. The manufacturer should be contacted through the following email address: plymouth.complaints@admedsol.com

Patient Information

Patient Information may be found at https://na.liquiband.com/

Clinical Study Summary

The safety and effectiveness of LIQUIFIX FIX8™ is derived from one US pivotal study and several clinical studies performed outside-US. The US pivotal study has been summarized below.

Study Design: A prospective randomized, controlled, single blinded, parallel-group IDE non-inferiority study was conducted to evaluate the clinical performance and safety of LIQUIFIX FIX8™ versus control for hernia mesh fixation and peritoneal closure in groin hernia repair. Two hundred and eighty-four (284) patients from five investigational sites across the USA were enrolled in the study. 186 patients underwent Transabdominal preperitoneal repairs (TAPP) and 98 patients underwent Totally Extraperitoneal repairs (TEP) equally divided into the two experimental groups for each surgical approach.

The primary endpoint of reduction in pain is evaluated at the 6-month visit and measures the reduction of recorded Visual Analog Scale (VAS) since baseline (worst pain experienced within 1 month of screening visit). The secondary endpoints of mesh fixation and peritoneal closure (TAPP repairs only) is assessed at time of surgery. Following discharge, study subjects entered the follow-up period consisting of in-clinic and remote visits to assess the secondary endpoints of pain, quality of life as well as the incidence of hernia recurrence and adverse events. Follow-up visits were performed at discharge and then post-operatively at week 1, week 2, month 1, month 3, month 6, month 9 and month 12.

The secondary endpoints assessed were:

- To evaluate the incidence of hernia recurrence in patients following laparoscopic (Totally Extraperitoneal (TEP) and TAPP) hernia repair using LIQUIFIX FIX8™ or control device.
- To compare the use of LIQUIFIX FIX8™ to control device for mesh fixation at time of surgery
- To compare the use of LIQUIFIX FIX8™ to control devices for the approximation of the peritoneum (TAPP repairs only) at time of surgery.
- To evaluate the quality of life experienced by subjects following groin hernia repair by LIQUIFIX FIX8™ or control as measured by the Carolina Comfort Scale (CCS) at baseline (prior to surgery), and at 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months following surgery.
- To compare levels of pain experienced following laparoscopic (TEP and TAPP) groin hernia repair by LIQUIFIX FIX8™ or control device, as measured by VAS at discharge, and at 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months following surgery.
- To evaluate the safety of LIQUIFIX FIX8™ and control device for groin hernia repair by comparing incidence of adverse events in patients post laparoscopic groin hernia repair.

Subject Demographics: A total of 284 subjects were treated in a 1:1 ratio with 142 subjects randomized to LIQUIFIX FIX8™ and 142 to control. Subject demographics and baseline characteristics were well matched between arms. The results are based on the completers for both the PP and ITT population.

Table 1: Demographics (ITT set)

	LIQUIFIX FIX8™ (N = 142)	AbsorbaTack™ (N = 142)	All Subjects (N = 284)
Mean ± SD	59.41 ± 13.696	58.47 ± 14.411	58.94 ± 14.041
Median	61.00	59.00	60.00
Min, Max	22.0, 85.0	26.0, 89.0	22.0, 89.0
Race			
American Indian or Alaska Native	0.0% (0 / 142)	0.0% (0 / 141)	0.0% (0 / 283)
Asian	0.7% (1 / 142)	2.1% (3 / 141)	1.4% (4 / 283)
Black or African American	9.2% (13 / 142)	11.3% (16 / 141)	10.2% (29 / 283)

Table 1: Demographics (ITT set)

More than One Race	0.0% (0 / 142)	0.7% (1 / 141)	0.4% (1 / 283)
Native Hawaiian or Other Pacific Islander	0.0% (0 / 142)	0.0% (0 / 141)	0.0% (0 / 283)
White	90.1% (128 / 142)	85.8% (121 / 141)	88.0% (249 / 283)
Ethnicity			
Hispanic or Latino	2.8% (4 / 142)	2.8% (4 / 142)	2.8% (8 / 284)
Not Hispanic or Latino	97.2% (138 / 142)	97.2% (138 / 142)	97.2% (276 / 284)

Primary Effectiveness Endpoint Results

Change in VAS from baseline to 6 months post-hernia repair

Subjects were considered enrolled in the study once they were randomized. All randomized subjects are included in the intent-to-treat (ITT) population and analyzed according to the treatment to which they were randomized. Additional supportive analyses were performed on the per-protocol (PP) population. The PP population included all subjects treated as randomized who do not have major inclusion/exclusion violations. Of the 284 patients randomized, the analysis of key (primary) effectiveness was based on 131/131 subjects in the LIQUIFIX FIX8™ treatment arm and 130/133 evaluable patients in the Control arm (in the PP completers dataset) and 269/284 patients (in the ITT completers dataset). The results are based on the 6-month follow-up completers for both the PP and ITT population.

The mean change in VAS pain score as measured from 6 months compared to baseline (worst pain experienced within 1 month of screening visit) for LIQUIFIX FIX8™ was -4.9 ± 2.5 and the control was -5.1 ± 2.3 for both the PP and ITT completers. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the upper limits of the two-sided 95% CI based on PP and ITT completers for the difference in the mean change in VAS pain score as measured from 6 months compared to baseline were less than the pre-defined non-inferiority margin set at 0.9. The missing data rate for primary effectiveness endpoint was 1.14% (3 Subjects) for the PP population and 5.28% (15 Subjects) for the ITT population.

Table 2.1: Primary Effectiveness Endpoint: Change in VAS from baseline[1] to 6 months post hernia repair in subjects requiring laparoscopic TEP and TAPP hernia repair (PP set)

	LIQUIFIX FIX8™ (N = 131)	AbsorbaTack™ (N = 133)	Difference[2]	p-value[3]	Non-inferior (Yes/No)[4]
n	131	130			Yes
Mean ± SD	-4.9 ± 2.5	-5.1 ± 2.3			
Median	-4.7	-5.0			
Min, Max	-10.0, 2.0	-10.0, -0.5			
Least Squares Mean			0.22	0.011	
95% CI			-0.36, 0.80		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

1 Worst pain experienced within 1 month of screening visit

[2] LIQUIFIX FIX8™ - AbsorbaTack™

[3] One-sided p-value (Difference < 0.9), based on general linear model for treatment arm adjusted for laparoscopic repair technique with non-inferiority margin of 0.9

[4] Indicated by p-value < 0.025

Table 2.2: Primary Effectiveness Endpoint: Change in VAS from baseline[1] to 6 months post hernia repair in subjects requiring laparoscopic TEP and TAPP hernia repair (ITT set)

	LIQUIFIX FIX8™ (N = 142)	AbsorbaTack™ (N = 142)	Difference[2]	p-value[3]	Non-inferior (Yes/No)[4]
n Mean ± SD Median Min, Max	136 -4.9 ± 2.5 -4.5 -10.0, 2.0	133 -5.1 ± 2.3 -5.0 -10.0, -0.5			Yes
Least Squares Mean			0.25	0.013	
95% CI			-0.33, 0.82		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] Worst pain experienced within 1 month of screening visit

[2] LIQUIFIX FIX8™ - AbsorbaTack™

[3] One-sided p-value (Difference < 0.9), based on general linear model for treatment arm adjusted for laparoscopic repair technique with non-inferiority margin of 0.9

[4] Indicated by p-value < 0.025

Hypothesis Tested Secondary Effectiveness Endpoint Results

Hernia Recurrence at 6 months

A total of three hernia recurrences were recorded in the clinical study; one for LIQUIFIX FIX8™ and two for Control. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the upper limits of the two-sided 95% CI based on PP and ITT completers for the difference in hernia recurrence as measured from 6 months were less than the pre-defined non-inferiority margin set at 10%. The missing data rate for secondary effectiveness endpoint hernia recurrence was 0.38% (1 Subject) for the PP population and 1.06% (3 Subjects) for the ITT population.

Table 3.1: Secondary Effectiveness Endpoint 1: Hernia recurrence rate at 6 months in subjects following TEP and TAPP groin hernia (PP set)

	LIQUIFIX FIX8™ (N = 131 Subjects)	AbsorbaTack™ (N = 133 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	0.8% (1/131)	1.5% (2/132)	-0.8%	<0.001	Yes
95% CI	0.0%, 2.3%	0.0%, 3.6%	-3.3%, 1.8%		

Note: Denominator includes subjects with hernia recurrence by visit or follow up through the visit window open date.

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin

[3] Indicated by Upper CI Limit < 10%

Table 3.2: Secondary Effectiveness Endpoint 1: Hernia recurrence rate at 6 months in subjects following TEP and TAPP groin hernia repair (ITT set)

	LIQUIFIX FIX8™ (N = 142 Subjects)	AbsorbaTack™ (N = 142 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	0.7% (1/141)	1.4% (2/140)	-0.7%	<0.001	Yes

Table 3.2: Secondary Effectiveness Endpoint 1: Hernia recurrence rate at 6 months in subjects following TEP and TAPP groin hernia repair (ITT set)

	LIQUIFIX FIX8™ (N = 142 Subjects)	AbsorbaTack™ (N = 142 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
95% CI	0.0%, 2.1%	0.0%, 3.4%	-3.1%, 1.7%		

Note: Denominator includes subjects with hernia recurrence by visit or follow-up through the visit window open date.

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin

[3] Indicated by Upper CI Limit < 10%

Recurrence rates up to 12-month follow-up have been presented in Table 3.3 below. There were no additional occurrences of recurrence after 6-month follow-up.

Table 3.3: Secondary endpoint: Hernia Recurrence rate[1] at 2 weeks, 3 months, 6 months, 9 months, and 12 months in subjects following TEP and TAPP groin hernia repair (ITT set)

Visit	LIQUIFIX FIX8™ (N = 142)	AbsorbaTack™ (N = 142)
2 weeks	0.0% (0/142)	0.0% (0/141)
3 months	0.7% (1/142)	0.7% (1/141)
6 months	0.7% (1/141)	1.4% (2/140)
9 months	0.7% (1/139)	1.4% (2/138)
12 months	0.8% (1/133)	1.5% (2/135)

[1] Rates are cumulative. Subjects having hernia recurrence at earlier timepoints are carried forward to later dates. Denominator includes subjects with hernia recurrence by visit, confirmed visit attendance, and/or follow-up through the visit window open date.

Hernia Mesh Fixation at time of surgery

Both arms (Treatment and Control) achieved 100% successful mesh fixation at time of surgery. Unsuccessful mesh fixation is defined as requiring the use of an alternative fixation device or additional procedure to achieve adequate fixation. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the lower limits of the two-sided 95% CI based on PP and ITT completers for the difference in hernia mesh fixation at time of surgery were greater than the pre-defined non-inferiority margin set at -10%.

Table 4.1: Secondary effectiveness endpoint 2: Rate of successful hernia mesh fixation in subjects undergoing TEP and TAPP laparoscopic groin hernia repair (PP set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 180 Hernias N = 131 Subjects)	AbsorbaTack™ (N = 193 Hernias N = 133 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	100.0% (131/131)	100.0% (133/133)	-0.0%	<0.001	Yes
95% CI	100.0%, 100.0%	100.0%, 100.0%	-0.1%, 0.1%		

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin. 0.001 added to zero-cells to calculate CI and p-value.

[3] Indicated by Lower CI Limit > -10%

Table 4.2: Secondary effectiveness endpoint 2: Rate of successful hernia mesh fixation in subjects undergoing TEP and TAPP laparoscopic groin hernia repair (ITT set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 195 Hernias N = 142 Subjects)	AbsorbaTack™ (N = 204 Hernias N = 142 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	100.0% (142/142)	100.0% (142/142)	0.0%	<0.001	Yes
95% CI	100.0%, 100.0%	100.0%, 100.0%	-0.1%, 0.1%		

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin. 0.001 added to zero-cells to calculate CI and p-value.

[3] Indicated by Lower CI Limit > -10%

Peritoneal Closure at time of surgery (TAPP repairs only)

Unsuccessful peritoneal closure is defined as requiring the use of an alternative fixation device or additional procedure to achieve adequate fixation. The participating Investigators in the Control arm in the study were able to use AbsorbaTack™, sutures or staples for closure of the peritoneum. LIQUIFIX FIX8™ achieved an 88.4% peritoneal closure success rate in comparison to the Control arms 90.5% when assessed at the Subject Level. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the lower limits of the two-sided 95% CI based on PP and ITT completers for the difference in peritoneal closure at time of surgery were greater than the pre-defined non-inferiority margin set at -15%.

Table 5.1: Secondary effectiveness endpoint 3: Rate of successful peritoneal closure in subjects undergoing laparoscopic TAPP hernia repair (PP set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 108 Hernias N = 86 Subjects)	AbsorbaTack™ (N = 112 Hernias N = 84 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	88.4% (76/86)	90.5% (76/84)	-2.1%	0.006	Yes
95% CI	81.6%, 95.1%	84.2%, 96.8%	-11.4%, 7.1%		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 15% margin

[3] Indicated by Lower CI Limit > -15%

Table 5.2: Secondary effectiveness endpoint 3: Rate of successful peritoneal closure in subjects undergoing laparoscopic TAPP hernia repair (ITT set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 117 Hernias N = 94 Subjects)	AbsorbaTack™ (N = 122 Hernias N = 92 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	87.2% (82/94)	91.3% (84/92)	-4.1%	0.012	Yes
95% CI	80.5%, 94.0%	85.5%, 97.1%	-13.0%, 4.8%		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 15% margin

[3] Indicated by Lower CI Limit > -15%

Ancillary Secondary Effectiveness Endpoints

Quality of Life (Carolina Comfort Scale)

Quality of Life was assessed at each post-operative follow-up visit using a Carolina Comfort Scale questionnaire which assessed pain, sensation of mesh and movement limitations over various activities. A scale of 0 (No symptoms) to 5 (Disabling symptoms) is used to record subject Quality of Life. The accumulative total score can range from 0 to 115 with the higher the score the lower the health-related quality of life. Numerical improvement was observed for comparison of QOL at 12-month post-operative versus 1- week post-surgery, with a mean change of -15.6 ± 16.0 for LIQUIFIX FIX8™ and -15.3 ± 16.1 for control.

Table 6: Secondary endpoint: Carolinas Comfort Scale (CCS) Questionnaire Total Score at 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months (ITT set)

	LiquiBand FIX8 (N = 142)		AbsorbaTack (N = 142)	
	Total Score n Mean ± SD Median (p25, p75) Min, Max	Change from 1 week n Mean ± SD Median (p25, p75) Min, Max	Total Score n Mean ± SD Median (p25, p75) Min, Max	Change from 1 week n Mean ± SD Median (p25, p75) Min, Max
1 week	129 16.1 ± 15.7 12.0 (5.0, 22.0) 0.0, 83.0	N/A	129 16.9 ± 16.6 13.0 (5.0, 24.0) 0.0, 80.0	N/A
2 weeks	136 8.6 ± 13.2 3.0 (0.0, 11.5) 0.0, 64.0	126 -7.7 ± 12.4 -5.0 (-13.0, 0.0) -55.0, 26.0	137 10.2 ± 15.2 4.0 (1.0, 12.0) 0.0, 77.0	128 -7.0 ± 13.2 -5.0 (-11.0, -1.0) -61.0, 47.0
1 month	136 4.8 ± 8.2 2.0 (0.0, 6.0) 0.0, 53.0	125 -12.4 ± 12.6 -9.0 (-18.0, -3.0) -55.0, 12.0	134 5.2 ± 10.5 1.0 (0.0, 5.0) 0.0, 82.0	124 -12.2 ± 14.6 -9.0 (-17.5, -3.0) -75.0, 41.0
3 months	137 2.0 ± 7.6 0.0 (0.0, 1.0) 0.0, 75.0	124 -14.6 ± 16.9 -11.0 (-20.5, -4.0) -83.0, 47.0	126 2.7 ± 8.5 0.0 (0.0, 2.0) 0.0, 69.0	117 -14.4 ± 15.9 -10.0 (-21.0, -3.0) -79.0, 28.0
6 months	136 1.2 ± 3.8 0.0 (0.0, 0.0) 0.0, 24.0	123 -15.1 ± 16.0 -12.0 (-22.0, -3.0) -83.0, 15.0	133 1.8 ± 4.4 0.0 (0.0, 1.0) 0.0, 35.0	122 -15.3 ± 16.7 -11.0 (-23.0, -4.0) -80.0, 24.0
9 months	133 0.9 ± 3.1 0.0 (0.0, 0.0) 0.0, 29.0	123 -15.6 ± 16.3 -12.0 (-24.0, -4.0) -83.0, 24.0	130 1.4 ± 3.8 0.0 (0.0, 1.0) 0.0, 27.0	120 -15.7 ± 16.5 -11.0 (-22.0, -4.5) -80.0, 14.0

Table 6: Secondary endpoint: Carolinas Comfort Scale (CCS) Questionnaire Total Score at 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months (ITT set)

	LiquiBand FIX8 (N = 142)		AbsorbaTack (N = 142)	
	Total Score n Mean ± SD Median (p25, p75) Min, Max	Change from 1 week n Mean ± SD Median (p25, p75) Min, Max	Total Score n Mean ± SD Median (p25, p75) Min, Max	Change from 1 week n Mean ± SD Median (p25, p75) Min, Max
12 months	131 0.5 ± 1.5 0.0 (0.0, 0.0) 0.0, 11.0	120 -15.6 ± 16.0 -11.0 (-23.0, -4.5) -83.0, 6.0	133 0.8 ± 3.5 0.0 (0.0, 0.0) 0.0, 34.0	122 -15.3 ± 16.1 -11.0 (-22.0, -4.0) -80.0, 23.0
If more than 2 patient responses within a domain were missing, then the summary score is set to missing. Otherwise mean imputation is used for missing responses. Score unable to be calculated prior to surgery because patient has not had hernia repair.				

Pain (VAS)

Pain was assessed at each post-operative follow-up visit using a VAS scale tool. The results of the primary effectiveness endpoint of change in VAS pain at 6 month from baseline is described above. Numerical reduction was observed in the results from the 12 month follow-up period, with LIQUIFIX FIX8™ mean change of -3.6 ± 2.9 (N=132) and Control -3.5 ± 3.1 (N=133) in the ITT completers.

Table 7: Secondary endpoint: VAS at pre-surgery, discharge, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months, and 12 months (ITT set)

	LiquiBand FIX8 (N = 142)		AbsorbaTack (N = 142)	
	VAS n Mean ± SD Median (p25, p75) Min, Max	VAS Change from Pre-Surgery n Mean ± SD Median (p25, p75) Min, Max	VAS n Mean ± SD Median (p25, p75) Min, Max	VAS Change from Pre-Surgery n Mean ± SD Median (p25, p75) Min, Max
Pre-surgery	142 3.8 ± 2.9 3.3 (1.5, 6.0) 0.0, 10.0	N/A	142 3.8 ± 3.0 3.0 (1.0, 6.5) 0.0, 10.0	N/A
Discharge	142 3.5 ± 2.1 3.5 (2.0, 5.0) 0.0, 10.0	142 -0.3 ± 3.4 0.0 (-3.0, 2.0) -8.2, 6.5	142 3.7 ± 1.9 4.0 (2.0, 5.0) 0.0, 10.0	142 -0.1 ± 3.5 0.0 (-3.0, 2.9) -8.0, 7.0
1 week	139 2.3 ± 1.9 2.0 (1.0, 3.5) 0.0, 9.0	139 -1.5 ± 2.8 -1.0 (-3.9, 0.5) -10.0, 4.0	140 2.3 ± 1.9 2.0 (1.0, 3.5) 0.0, 7.0	140 -1.5 ± 3.1 -1.0 (-3.3, 1.0) -10.0, 7.0

Table 7: Secondary endpoint: VAS at pre-surgery, discharge, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months, and 12 months (ITT set)

	LiquiBand FIX8 (N = 142)		AbsorbaTack (N = 142)	
	VAS n Mean ± SD Median (p25, p75) Min, Max	VAS Change from Pre-Surgery n Mean ± SD Median (p25, p75) Min, Max	VAS n Mean ± SD Median (p25, p75) Min, Max	VAS Change from Pre-Surgery n Mean ± SD Median (p25, p75) Min, Max
2 weeks	141 1.0 ± 1.4 0.5 (0.0, 1.5) 0.0, 8.0	141 -2.8 ± 2.8 -2.0 (-4.9, -0.9) -10.0, 2.1	141 1.1 ± 1.3 1.0 (0.0, 2.0) 0.0, 6.0	141 -2.7 ± 2.9 -2.0 (-5.0, -0.5) -9.5, 4.0
1 month	138 0.6 ± 1.0 0.0 (0.0, 1.0) 0.0, 5.0	138 -3.2 ± 2.8 -2.8 (-5.1, -0.9) -10.0, 1.0	137 0.7 ± 1.2 0.0 (0.0, 1.0) 0.0, 7.0	137 -3.1 ± 3.1 -2.5 (-5.5, -1.0) -10.0, 6.5
3 months	138 0.2 ± 0.7 0.0 (0.0, 0.0) 0.0, 5.2	138 -3.6 ± 2.9 -3.0 (-6.0, -1.0) -10.0, 1.0	129 0.4 ± 0.9 0.0 (0.0, 0.0) 0.0, 7.0	129 -3.4 ± 3.1 -2.1 (-6.0, -1.0) -10.0, 3.0
6 months	136 0.2 ± 0.8 0.0 (0.0, 0.0) 0.0, 6.0	136 -3.6 ± 3.0 -3.0 (-6.0, -1.0) -10.0, 3.0	133 0.3 ± 0.7 0.0 (0.0, 0.0) 0.0, 4.0	133 -3.5 ± 3.1 -3.0 (-6.0, -1.0) -10.0, 2.0
9 months	133 0.1 ± 0.3 0.0 (0.0, 0.0) 0.0, 2.0	133 -3.7 ± 2.9 -3.0 (-6.0, -1.4) -10.0, 1.0	131 0.2 ± 0.6 0.0 (0.0, 0.0) 0.0, 3.5	131 -3.5 ± 3.0 -3.0 (-6.0, -1.0) -10.0, 1.0
12 months	132 0.1 ± 0.4 0.0 (0.0, 0.0) 0.0, 3.0	132 -3.6 ± 2.9 -3.0 (-6.0, -1.0) -10.0, 0.0	133 0.1 ± 0.6 0.0 (0.0, 0.0) 0.0, 6.0	133 -3.5 ± 3.1 -3.0 (-6.0, -1.0) -10.0, 6.0

Safety / Adverse Events

A total of 271 adverse events (AEs) have been reported in the clinical study across the two treatment arms. The incidence of device-related AEs by subject were comparable in the treatment (34 subjects; 23.9%) and control (43 subjects; 30.3%) groups. Out of these, 18 patients (6 Treatment, 12 Control) had more than one possibly device related AE. In terms of Serious AEs (SAEs), the incidence of possibly device-related adverse events were comparable between the treatment and control groups with 5 events in 5 (3.5%) subjects of device related SAEs in the treatment group compared to 4 events in 4 (2.8%) subjects in the control group. The events in the LIQUIFIX FIX8™ group included two neuralgias, one recurrent hernia, one mesh infection and one small bowel obstruction. The control group possible device related adverse events included two hematoma which required further intervention, and two recurrent hernias. No single patient had more than one possibly device-related serious AE.

Table 8: AEs - Device and/or Procedure Related (ITT set)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)	
# Serious Adverse Events (ITT)	N=11		N=16	
Total related to study device[2]	3.5% (5/142)	5	2.8% (4/142)	4
Total related to study procedure[2]	6.3% (9/142)	9	7.0% (10/142)	10
# Adverse Events (ITT)	N= 114		N=157	
Total related to study device[2]	23.9% (34/142)	41	30.3% (43/142)	55
Total related to study procedure[2]	35.9% (51/142)	76	43.0% (61/142)	107
[2]Related includes possibly and definitely related.				

Serious possibly device-related adverse events observed in the clinical study included Neuralgia, hernia recurrence, mesh infection and intestinal obstruction. A summary of serious adverse events adjudicated by an independent Clinical Events Committee (CEC) as related to the device or procedure can be found in Table 9. The percentage of Subjects with serious device and/or procedure related adverse events is similar across the ITT (6.7%) and PP (6.8%) population.

Table 9: Serious AEs - Device and/or Procedure Related[1] (ITT set)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Atrial fibrillation	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Hematoma	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Inguinal hernia	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Neuralgia	2	2 (1.4%)	0	0 (0.0%)	2	2 (0.7%)
Dizziness	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Hernia	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Incisional hernia	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Intestinal obstruction	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Medical device site infection	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Procedural pain	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Tooth abscess	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Urethral injury	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Urinary retention	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urinary tract injury	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Vomiting	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Total	9	9 (6.3%)	10	10 (7.0%)	19	19 (6.7%)

[1]Related includes possibly and definitely related.

[2]MedDRA Preferred Term

The majority of non-serious device and/or procedure related adverse events were seroma formation. Overall, there were 47 events related to seroma in 44 (15.5%) subjects. All cases were mild in severity and none were considered only

related to the device in both groups. Other notable frequent non-serious AEs were groin pain with 16 events (16 subjects; 5.6%) and urinary retention with 10 events (10; 3.5%). Possibly Related non-serious AEs were comparable between groups with the following notable differences: the incidence of seroma (13.4% Treatment, 17.6% Control) and groin pain (2.8% Treatment, 8.5% Control) was lower in the treatment group. A summary of non-serious adverse events adjudicated by the CEC as possibly or definitely related to the device or procedure can be found in Table 10. The percentage of Subjects with non-serious device and/or procedure related adverse events is similar across the ITT (36.3%) and PP (36.0%) population.

Table 10: Non-Serious AEs - Device and/or Procedure Related[1] (ITT)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Seroma	20	19 (13.4%)	27	25 (17.6%)	47	44 (15.5%)
Groin pain	4	4 (2.8%)	12	12 (8.5%)	16	16 (5.6%)
Urinary retention	5	5 (3.5%)	5	5 (3.5%)	10	10 (3.5%)
Post procedural constipation	4	4 (2.8%)	3	3 (2.1%)	7	7 (2.5%)
Dysuria	2	2 (1.4%)	3	3 (2.1%)	5	5 (1.8%)
Hematoma	2	2 (1.4%)	3	3 (2.1%)	5	5 (1.8%)
Procedural nausea	0	0 (0.0%)	5	5 (3.5%)	5	5 (1.8%)
Testicular pain	3	3 (2.1%)	2	2 (1.4%)	5	5 (1.8%)
Musculoskeletal pain	4	4 (2.8%)	0	0 (0.0%)	4	4 (1.4%)
Pain	1	1 (0.7%)	3	2 (1.4%)	4	3 (1.1%)
Swelling	1	1 (0.7%)	3	2 (1.4%)	4	3 (1.1%)
Genital hemorrhage	2	2 (1.4%)	1	1 (0.7%)	3	3 (1.1%)
Cellulitis	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Hypoaesthesia	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Orchitis	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Post procedural haematuria	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Rash	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Spermatic cord inflammation	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Umbilical hernia	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Urinary retention postoperative	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Abdominal pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Abdominal pain lower	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Arthralgia	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Back pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Burning sensation	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Change of bowel habit	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Constipation	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Dermatitis contact	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)

Table 10: Non-Serious AEs - Device and/or Procedure Related[1] (ITT)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Diarrhea	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Dyspepsia	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Flatulence	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Gastrointestinal procedural complication	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Incisional hernia	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Inguinal mass	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Injection site hematoma	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Lymphadenitis	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Muscle strain	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Musculoskeletal chest pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Neuralgia	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Nodule	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Pollakiuria	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Postoperative wound infection	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Reflex test abnormal	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Scrotal hematoma	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Scrotal pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Testicular swelling	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Throat irritation	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urethral pain	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urinary incontinence	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urinary tract infection	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Urinary tract procedural complication	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Vomiting	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Wound dehiscence	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Total	67	46 (32.4%)	97	57 (40.1%)	164	103 (36.3%)

[1]Related includes possibly and definitely related.
[2]MedDRA Preferred Term

Study Conclusions

The US pivotal study was demonstrated to be successful as the primary endpoint as measured by change in VAS pain score from baseline (worst pain experienced within 1 month of screening visit) to 6 months post hernia repair, was met in both the PP and ITT sets. Secondary effectiveness endpoints were all met with non-inferiority to the control or showed improvements comparable to the control arm.

The improvement in pain from baseline to 6 months post-hernia repair in the LIQUIFIX FIX8™ treatment arm was not inferior to the AbsorbaTack™ control arm. Hernia recurrence rate at 6 months measured at the subject level as well as rate of successful hernia mesh fixation and peritoneal closure at time of surgery was not inferior in LIQUIFIX FIX8™ compared to the control arm. Improvement in quality of life including in the pain domain, as recorded in the Carolina Comfort Scale, was observed in LIQUIFIX FIX8™ post-surgery and this was similar to the control arm. In terms of safety, the incidence of safety events in LIQUIFIX FIX8™ were comparable to the control. There were no unanticipated adverse device effects. Based on these results, the probable benefits outweigh the risks; there is an overall benefit to having an atraumatic device for mesh fixation available, which has also demonstrated to be non-inferior in terms of safety and effectiveness to AbsorbaTack™ control.

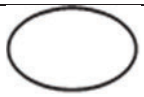
Summary of Supplemental Clinical Information

Additional Clinical Information

Several outside-US clinical studies have been performed with LIQUIFIX FIX8™ to support the safety and effectiveness in hernia mesh fixation and/or peritoneal closure. 504 patients underwent mesh fixation (inguinal or femoral repair) with LIQUIFIX FIX8™ and 348 peritoneal closures were performed with the device outside US. The observed adverse events are described above. A total of two (0.39%) recurrences were reported across the studies. OUS registry data (343 patients) demonstrated perioperative complication rates and 5- year outcomes for laparoscopic inguinal hernia repair with LIQUIFIX device are low and consistent with other OUS similarly marketed fixation devices.

Symbols Glossary

Symbols glossary located at admedsol.com/symbols-glossary

	Manufacturer
	Use by date
	Batch Code
	Catalogue number
	Single Sterile Barrier System
	Sterilized using irradiation
	Sterilized using ethylene oxide

	Do not resterilize
	Consult instructions for use
	Keep dry
	Keep away from sunlight
	Do not use if packaging is damaged
	Do not re-use
	Temperature limit
	Caution
	Date of implantation
	Magnetic Resonance safe
	Medical Device
	Unique Device Identifier

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DRM 06 1098 x02b YYYY-MM-DD

Instruction for Use
LIQUIFIX Precision™ Open Hernia Mesh Fixation Device
Single Use Instrument

Contents

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

Read all directions, precautions and warnings prior to use.

These instructions for use provide directions for the proper use of the Advanced Medical Solutions Limited LIQUIFIX Precision™ Open Hernia Mesh Fixation device. They are not intended to be a comprehensive instruction manual for the performance of a surgical procedure. Surgeons should be fully proficient in hernia repair surgical techniques before using this device.

Device Description

The LIQUIFIX Precision™ Open Hernia Mesh Fixation device is designed for the application of n-butyl-2-cyanoacrylate adhesive to an implanted hernia repair mesh, in order to fix the mesh to the underlying tissue. The LIQUIFIX Precision™ Open Hernia Mesh Fixation Device is intended to be used with polypropylene or polyester mesh to affix the mesh to the underlying tissue.

The device consists of:

a) n-butyl-2-cyanoacrylate adhesive monomer and D&C Violet No.2 dye, in liquid form, supplied in a thin-walled, sealed glass vial; and,

b) a surgical delivery instrument comprising a cannula, with a handle at the proximal end incorporating a loading chamber, filter, piston chamber and trigger.

Both the cyanoacrylate adhesive in the glass vial and the surgical delivery device are supplied sterile, for single use only.

The implanted material contains ≥99.5% n-butyl-2-cyanoacrylate adhesive. Other notable substances include butylated hydroxyanisole, n-butyl cyanoacetate and formaldehyde, which in summation are ≤0.8%.

Principle of Operation

The glass vial containing the liquid cyanoacrylate adhesive monomer comes preloaded into, and is subsequently broken in, a loading chamber in the handle of the delivery instrument. The adhesive is drawn through a filter into the delivery instrument handle. After priming, each press of the trigger on the handle of the delivery instrument dispenses 12.5 mg of adhesive from the distal tip of the cannula. A single device contains sufficient adhesive for at least 45 individual applications of the adhesive. The gauge on the side of the delivery instrument gives an indication of the amount of adhesive delivered and the approximate amount remaining.

Mechanism of Action

When applied to the proximal surface of the mesh the liquid adhesive monomer permeates through the perforations in the mesh to the surface of the underlying tissue, where it polymerizes on contact with moisture on the tissue surface. This process of chemical polymerization fixes the mesh to the surface of the tissue at the site of adhesive contact, maintaining the mesh in position while it is incorporated into the abdominal wall through the normal process of tissue fibrosis.

The adhesive completes its polymerization reaction within approximately 10 seconds. Once completely set, the adhesive no longer possesses adhesive properties such that tissues or surgical instruments may be placed in contact with it without risk of unwanted adhesion.

Indications for Use

The LIQUIFIX Precision™ Open Hernia Mesh Fixation device is intended for use in open surgical repair of groin (inguinal and femoral) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall.

Contraindications

- The device is not intended for use when prosthetic material fixation is contraindicated.

- Do not use on patients with a hypersensitivity to cyanoacrylate adhesives, formaldehyde or D&C Violet No. 2 dye.
- Do not use for the fixation of meshes constructed with polytetrafluoroethylene (PTFE) or materials other than polypropylene or polyester.
- Do not use device for closure or fixation of cerebral tissues, blood vessels or peripheral nerves.

Warnings

- The use of LIQUIFIX Precision™ Open is limited to those healthcare providers who are qualified to perform open hernia repair. A thorough understanding of the operating principles, risks versus benefits, and hazards involved in utilizing surgical approach is necessary to avoid possible hazards to the user and/or patient. It is recommended that any healthcare provider who intends to use LIQUIFIX Precision™ Open read the instructions for use in full, including directions, precautions and warnings.
- This device is provided sterile and is intended for use in a single patient. Do not reuse, reprocess, clean, disinfect or re-sterilize this device as this may compromise the sterility and performance of the device.
- Ensure the device is properly activated and primed before use according to the instructions in the Directions for Use section.
- This device does not contain any user-serviceable parts. Do not attempt to repair or dismantle the device. If at any point the device appears to be damaged or not functioning correctly, check for tip blockage, otherwise discard and replace it with another device.
- Do not dilute or mix the adhesive with other substances.
- During mesh fixation accidental bonding of unwanted tissue may occur due to misapplication of adhesive. Separation of tissues after accidental bonding should only be performed if deemed necessary. Tissues should be separated slowly and carefully with surgical graspers using a peeling motion.
- If adhesive becomes bonded to an unwanted area during mesh fixation, removal is possible after complete polymerization (60 seconds) by slowly and carefully peeling the polymerized adhesive from the tissue with surgical graspers. In vivo animal testing was performed to support this practice.
- Upon adhesive removal, if there is resistance upon peeling, residual adhesive should be left to prevent potential injury.
- The device contains a fast setting adhesive capable of adhering to most body tissues and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, surface and/or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- There is no clinical data to support use for topical skin closure in the United States.
- There is no pre-clinical or clinical data to support use with absorbable meshes in the United States.
- In open inguinal hernia repair, LIQUIFIX Precision™ Open glue should only be applied through the mesh to the muscle, anteriorly placed as an onlay in the inguinal canal.
- Mesh woven from uncoated polyester or polypropylene fibers were evaluated in the United States Clinical study; coated meshes have not been studied.
- Do not use or apply LIQUIFIX Precision™ Open to plug mesh in the retroperitoneum.

Precautions

- The fixation method for any mesh should be determined on the basis of accepted surgical techniques, procedural requirements, and the instruction for use of the mesh.
- Ensure the mesh is held in contact with the underlying tissue during each application of the adhesive for approximately 10 seconds allowing adhesive to polymerize. Polymerization may take longer than 10 seconds depending on the moisture in the environment.

- The viscosity of the adhesive is only slightly greater than that of water, so adhesive should be applied very carefully to prevent it spreading to unwanted areas.
- The adhesive should always be applied in minimal amounts, i.e. avoid multiple applications of adhesive in any given location. A second application of adhesive can be applied over the first only after full polymerization.
- The application of an excessive amount of adhesive in a single location prolongs polymerization and may prevent adherence. After polymerization, any excess adhesive may lead to detachment of the adhesive film and/or give rise to the formation of small fragments of polymerized adhesive.
- The LIQUIFIX Precision™ Open device is designed to fix mesh to soft tissue for hernia repair. Whilst the adhesive will readily adhere to most tissues, the adhesive is not intended to be used directly on exposed bone as the safety and effectiveness have not been established to support this practice.
- The adhesive may not perform as intended if it is being applied to unsuitable locations such as fatty tissues.
- Care should be taken to avoid unwanted contact between surgical instruments and the adhesive during polymerization. Polymerized adhesive can be removed from metal instruments with acetone.
- If the tip of the device comes into contact with excessively wet (e.g. bloody) tissues, the likelihood of tip blockage may increase. This can be mitigated through prior use of a sterile gauze swab to dry the field before applying the adhesive. If the tip becomes blocked, the blockage can be removed by wiping the tip with dry sterile gauze or by using a sterile narrow object (e.g. needle).
- During the hernia repair procedure, care should be taken to ensure that the quality of the hernia repair is not adversely affected when performing other surgical procedures at the same time (which may involve repositioning of the patient).
- LIQUIFIX Precision™ Open adhesive is not intended to be used on top of other fixatives such as sutures or tacks.
- Do not depress the trigger unless the tip is in contact with the intended application site. Doing so could result in unintentional expression of the adhesive outside the intended surgical field. Bench tests have demonstrated acceptable performance for potential adhesive dripping.

Potential Adverse Effects of the Device on Health

As with the majority of implanted devices, adverse reactions associated with the use of this device may include transient local irritation at the implant site and a transitory inflammatory foreign body response. Advanced Medical Solutions has determined the potential adverse effects (e.g. complications) listed below may be associated with the use of the LIQUIFIX Precision™ Open device. These potential adverse events include, but are not limited to, the following:

- Toxic reaction
- Allergic reaction

Observed Adverse Events

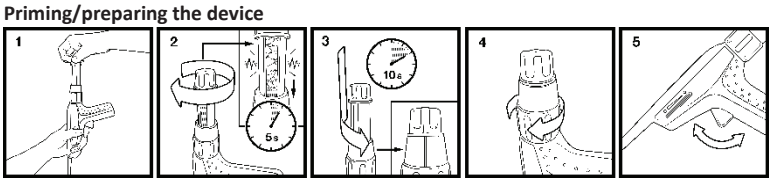
Clinical studies of LIQUIFIX Precision™ Open adhesive using the Laparoscopic model of the device (LIQUIFIX FIX8™) have been conducted inside and outside the United States. Possibly device related adverse events observed during the US pivotal study have been described below; a number of these adverse events were possibly device related and possibly/definitely related to the procedure. In addition, adverse events observed during the LIQUIFIX FIX8™ European clinical studies, but not necessarily related to the device itself, included the following:

- Chronic Pain
- Hernia Recurrence
- Urinary Retention
- Minor Surgical Emphysema
- Seroma

- Port Site Hernia
- Port Site Hemorrhage
- Hematoma
- Swelling
- Neuralgia / Hypoaesthesia
- Groin / Testicular pain
- Intestinal obstruction
- Genital hemorrhage
- Spermatic Cord Inflammation
- Orchitis
- Lymphadenitis
- Mesh infection
- Inadvertent enterotomy
- Intra peritoneal bleeding
- Post-operative ileus
- Urinary bladder injury

Directions for Use

Priming/preparing the device



The device must be properly activated and primed to ensure that it operates correctly.

Priming the device for hernia repair

1. Remove the device from its packaging. Hold the device with the tip of the cannula pointing downwards throughout stages 1-5.
2. Rotate the purple plunger clockwise until a cracking sound of the glass ampoule breaking inside the plunger is heard. The plunger incorporates a visualization window where the complete transfer of the adhesive into the device should be confirmed before proceeding. Adhesive transfer is typically achieved within 5 seconds.
3. Slowly push the plunger into the device handle, rotate plunger anticlockwise at the final portion of the travel to completely align indicators and lock it into the device body.
4. Rotate the purple dial clockwise fully until it comes to a complete stop.
5. Prime the device by actuating the trigger until a drop of adhesive freely emerges. Wipe any excess adhesive from the tip of the cannula onto an appropriate receptacle or on a sterile wipe. The device is now ready for use as a hernia repair device.

Using the device for hernia repair

- Fixation can be achieved with LIQUIFIX Precision™ Open Hernia Mesh Fixation device exclusively or in conjunction with other fixation methods.
- Mesh fixation can be achieved by applying adhesive anchors in discrete locations across the mesh.
- As the adhesive is non-invasive and does not penetrate through the tissue, the adhesive can be applied at any location on the mesh.
- To prepare the site for mesh fixation, excess moisture of the surgical field can be reduced by wiping with a sterile swab.
- For porous mesh, the adhesive can be applied to the proximal surface of the mesh, as the liquid adhesive monomer can permeate through the pores in the mesh to the surface of the underlying

tissue. Ensure the mesh is positioned with minimal overlapping or folding so that the adhesive can easily pass through the mesh pores.

- To deploy a single adhesive anchor, hold the tip of the cannula against the mesh surface and depress trigger and release once. Adhesive should be visualized upon release of the trigger.
- The mesh should be held in contact with the tissue for up to 10 seconds until adhesive has polymerized, as indicated by a change in opacity.

Disposal

After use, dispose of the device according to local procedures and guidelines.

Storage

This device should always be stored in its original packaging.
Store only at temperatures between 5°C (41°F) and 25°C (77°F), away from moisture, direct heat and direct light.
Do not use the device after the expiration date shown on the blister pack.

Sterility

This device is packaged for single patient use and is sterilized by irradiation and ethylene oxide gas with a sterility assurance level (SAL) of 10^{-6}.Do not re-sterilize.
Do not use if package is open or damaged.

Magnetic Resonance Safety Information

LIQUIFIX Precision™ Open adhesive is MR Safe.

Device-related incidents

If a serious incident occurs in relation to the use of the device this should be reported to the manufacturer. The manufacturer should be contacted through the following email address: plymouth.complaints@admedsol.com

Patient Information

Patient Information may be found at https://na.liquiband.com/

Clinical Study Summary

The safety and effectiveness of LIQUIFIX Precision™ Open is derived from one US pivotal study and several clinical studies performed outside-US. These studies have been performed with an equivalent device (LIQUIFIX FIX8™ Laparo) which uses an identical adhesive and anchor size but is used for laparoscopic repair versus open repair. The US pivotal study has been summarized below.

Study Design: A prospective randomized, controlled, single blinded, parallel-group IDE non-inferiority study was conducted to evaluate the clinical performance and safety of LIQUIFIX FIX8™ (LiquiBand FIX8®) versus control for hernia mesh fixation and peritoneal closure in groin hernia repair. Two hundred and eighty-four (284) patients from five investigational sites across the USA were enrolled in the study. 186 patients underwent Transabdominal preperitoneal repairs (TAPP) and 98 patients underwent Totally Extraperitoneal repairs (TEP) equally divided into the two experimental groups for each surgical approach.

The primary endpoint of reduction in pain is evaluated at the 6-month visit and measures the reduction of recorded Visual Analog Scale (VAS) since baseline (worst pain experienced within 1 month of screening visit). The secondary endpoints of mesh fixation and peritoneal closure (TAPP repairs only) is assessed at time of surgery. Following discharge, study subjects entered the follow-up period consisting of in-clinic and remote visits to assess the secondary endpoints of pain, quality of life as well as the incidence of hernia recurrence and adverse events. Follow-up visits were performed at discharge and then post-operatively at week 1, week 2, month 1, month 3, month 6, month 9 and month 12.

The secondary endpoints assessed were:

- To evaluate the incidence of hernia recurrence in patients following laparoscopic (Totally Extraperitoneal (TEP) and TAPP) hernia repair using LIQUIFIX FIX8™ or control device.
- To compare the use of LIQUIFIX FIX8™ to control device for mesh fixation at time of surgery
- To compare the use of LIQUIFIX FIX8™ to control devices for the approximation of the peritoneum (TAPP repairs only) at time of surgery.
- To evaluate the quality of life experienced by subjects following groin hernia repair by LIQUIFIX FIX8™ or control as measured by the Carolina Comfort Scale (CCS) at baseline (prior to surgery), and at 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months following surgery.
- To compare levels of pain experienced following laparoscopic (TEP and TAPP) groin hernia repair by LIQUIFIX FIX8™ or control device, as measured by VAS at discharge, and at 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months following surgery.
- To evaluate the safety of LIQUIFIX FIX8™ and control device for groin hernia repair by comparing incidence of adverse events in patients post laparoscopic groin hernia repair.

Subject Demographics: A total of 284 subjects were treated in a 1:1 ratio with 142 subjects randomized to LIQUIFIX FIX8™ and 142 to control. Subject demographics and baseline characteristics were well matched between arms. The results are based on the completers for both the PP and ITT population.

Table 1. Demographics (ITT set)

	LIQUIFIX FIX8™ (N = 142)	AbsorbaTack™ (N = 142)	All Subjects (N = 284)
Mean ± SD	59.41 ± 13.696	58.47 ± 14.411	58.94 ± 14.041
Median	61.00	59.00	60.00
Min, Max	22.0, 85.0	26.0, 89.0	22.0, 89.0
Race			
American Indian or Alaska Native	0.0% (0 / 142)	0.0% (0 / 141)	0.0% (0 / 283)
Asian	0.7% (1 / 142)	2.1% (3 / 141)	1.4% (4 / 283)
Black or African American	9.2% (13 / 142)	11.3% (16 / 141)	10.2% (29 / 283)
More than One Race	0.0% (0 / 142)	0.7% (1 / 141)	0.4% (1 / 283)
Native Hawaiian or Other Pacific Islander	0.0% (0 / 142)	0.0% (0 / 141)	0.0% (0 / 283)
White	90.1% (128 / 142)	85.8% (121 / 141)	88.0% (249 / 283)
Ethnicity			
Hispanic or Latino	2.8% (4 / 142)	2.8% (4 / 142)	2.8% (8 / 284)
Not Hispanic or Latino	97.2% (138 / 142)	97.2% (138 / 142)	97.2% (276 / 284)

Primary Effectiveness Endpoint Results

Change in VAS from baseline to 6 months post-hernia repair

Subjects were considered enrolled in the study once they were randomized. All randomized subjects are included in the intent-to-treat (ITT) population and analyzed according to the treatment to which they were randomized. Additional supportive analyses were performed on the per-protocol (PP) population. The PP population included all subjects treated as randomized who do not have major inclusion/exclusion violations. Of the 284 patients randomized, the analysis of key (primary) effectiveness was based on 131/131 subjects in the LIQUIFIX FIX8™ treatment arm and 130/133 evaluable patients in the Control arm (in the PP

completers dataset) and 269/284 patients (in the ITT completers dataset). The results are based on the 6-month follow-up completers for both the PP and ITT population.

The mean change in VAS pain score as measured from 6 months compared to baseline (worst pain experienced within 1 month of screening visit) for LIQUIFIX FIX8™ was -4.9 ± 2.5 and the control was -5.1 ± 2.3 for both the PP and ITT completers. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the upper limits of the two-sided 95% CI based on PP and ITT completers for the difference in the mean change in VAS pain score as measured from 6 months compared to baseline were less than the pre-defined non-inferiority margin set at 0.9. The missing data rate for primary effectiveness endpoint was 1.14% (3 Subjects) for the PP population and 5.28% (15 Subjects) for the ITT population.

Table 2.1. Primary Effectiveness Endpoint: Change in VAS from baseline[1] to 6 months post hernia repair in subjects requiring laparoscopic TEP and TAPP hernia repair (PP set)

	LIQUIFIX FIX8™ (N = 131)	AbsorbaTack™ (N = 133)	Difference[2]	p-value[3]	Non-inferior (Yes/No)[4]
n Mean ± SD Median Min, Max	131 -4.9 ± 2.5 -4.7 -10.0, 2.0	130 -5.1 ± 2.3 -5.0 -10.0, -0.5			Yes
Least Squares Mean			0.22	0.011	
95% CI			-0.36, 0.80		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] Worst pain experienced within 1 month of screening visit

[2] LIQUIFIX FIX8™ - AbsorbaTack™

[3] One-sided p-value (Difference < 0.9), based on general linear model for treatment arm adjusted for laparoscopic repair technique with non-inferiority margin of 0.9

[4] Indicated by p-value < 0.025

Table 2.2: Primary Effectiveness Endpoint: Change in VAS from baseline[1] to 6 months post hernia repair in subjects requiring laparoscopic TEP and TAPP hernia repair (ITT set)

	LIQUIFIX FIX8™ (N = 142)	AbsorbaTack™ (N = 142)	Difference[2]	p-value[3]	Non-inferior (Yes/No)[4]
n Mean ± SD Median Min, Max	136 -4.9 ± 2.5 -4.5 -10.0, 2.0	133 -5.1 ± 2.3 -5.0 -10.0, -0.5			Yes
Least Squares Mean			0.25	0.013	
95% CI			-0.33, 0.82		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] Worst pain experienced within 1 month of screening visit

[2] LIQUIFIX FIX8™ - AbsorbaTack™

[3] One-sided p-value (Difference < 0.9), based on general linear model for treatment arm adjusted for laparoscopic repair technique with non-inferiority margin of 0.9

[4] Indicated by p-value < 0.025

Hypothesis Tested Secondary Effectiveness Endpoint Results

Hernia Recurrence at 6 months

A total of three hernia recurrences were recorded in the clinical study; one for LIQUIFIX FIX8™ and two for Control. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the upper limits of the two-sided 95% CI based on PP and ITT completers for the difference in hernia recurrence as measured from 6 months were less than the pre-defined non-inferiority margin set at 10%. The missing data rate for secondary effectiveness endpoint hernia recurrence was 0.38% (1 Subject) for the PP population and 1.06% (3 Subjects) for the ITT population.

Table 3.1. Secondary Effectiveness Endpoint 1: Hernia recurrence rate at 6 months in subjects following TEP and TAPP groin hernia (PP set)

	LIQUIFIX FIX8™ (N = 131 Subjects)	AbsorbaTack™ (N = 133 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	0.8% (1/131)	1.5% (2/132)	-0.8%	<0.001	Yes
95% CI	0.0%, 2.3%	0.0%, 3.6%	-3.3%, 1.8%		

Note: Denominator includes subjects with hernia recurrence by visit or follow-up through the visit window open date.

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin

[3] Indicated by Upper CI Limit < 10%

Table 3.2. Secondary Effectiveness Endpoint 1: Hernia recurrence rate at 6 months in subjects following TEP and TAPP groin hernia repair (ITT set)

	LIQUIFIX FIX8™ (N = 142 Subjects)	AbsorbaTack™ (N = 142 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	0.7% (1/141)	1.4% (2/140)	-0.7%	<0.001	Yes
95% CI	0.0%, 2.1%	0.0%, 3.4%	-3.1%, 1.7%		

Note: Denominator includes subjects with hernia recurrence by visit or follow-up through the visit window open date.

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™

[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin

[3] Indicated by Upper CI Limit < 10%

Recurrence rates up to 12-month follow-up have been presented in Table 3.3 below. There were no additional occurrences of recurrence after 6-month follow-up.

Table 3.3. Secondary endpoint: Hernia Recurrence rate[1] at 2 weeks, 3 months, 6 months, 9 months, and 12 months in subjects following TEP and TAPP groin hernia repair (ITT set)

Visit	LIQUIFIX FIX8™ (N = 142)	AbsorbaTack™ (N = 142)
2 weeks	0.0% (0/142)	0.0% (0/141)
3 months	0.7% (1/142)	0.7% (1/141)
6 months	0.7% (1/141)	1.4% (2/140)
9 months	0.7% (1/139)	1.4% (2/138)

Table 3.3. Secondary endpoint: Hernia Recurrence rate[1] at 2 weeks, 3 months, 6 months, 9 months, and 12 months in subjects following TEP and TAPP groin hernia repair (ITT set)

Visit	LIQUIFIX FIX8™ (N = 142)	AbsorbaTack™ (N = 142)
12 months	0.8% (1/133)	1.5% (2/135)

[1] Rates are cumulative. Subjects having hernia recurrence at earlier timepoints are carried forward to later dates. Denominator includes subjects with hernia recurrence by visit, confirmed visit attendance, and/or follow-up through the visit window open date.

Hernia Mesh Fixation at time of surgery

Both arms (Treatment and Control) achieved 100% successful mesh fixation at time of surgery. Unsuccessful mesh fixation is defined as requiring the use of an alternative fixation device or additional procedure to achieve adequate fixation. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the lower limits of the two-sided 95% CI based on PP and ITT completers for the difference in hernia mesh fixation at time of surgery were greater than the pre-defined non-inferiority margin set at -10%.

Table 4.1: Secondary effectiveness endpoint 2: Rate of successful hernia mesh fixation in subjects undergoing TEP and TAPP laparoscopic groin hernia repair (PP set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 180 Hernias N = 131 Subjects)	AbsorbaTack™ (N = 193 Hernias N = 133 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	100.0% (131/131)	100.0% (133/133)	-0.0%	<0.001	Yes
95% CI	100.0%, 100.0%	100.0%, 100.0%	-0.1%, 0.1%		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.
[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin. 0.001 added to zero-cells to calculate CI and p-value.
[3] Indicated by Lower CI Limit > -10%

Table 4.2: Secondary effectiveness endpoint 2: Rate of successful hernia mesh fixation in subjects undergoing TEP and TAPP laparoscopic groin hernia repair (ITT set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 195 Hernias N = 142 Subjects)	AbsorbaTack (N = 204 Hernias N = 142 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	100.0% (142/142)	100.0% (142/142)	0.0%	<0.001	Yes
95% CI	100.0%, 100.0%	100.0%, 100.0%	-0.1%, 0.1%		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.
[2] Based on a Non-inferiority Farrington-Manning test with a 10% margin. 0.001 added to zero-cells to calculate CI and p-value.
[3] Indicated by Lower CI Limit > -10%

Peritoneal Closure at time of surgery (TAPP repairs only)

Unsuccessful peritoneal closure is defined as requiring the use of an alternative fixation device or additional procedure to achieve adequate fixation. The participating Investigators in the Control arm in the study were able to use AbsorbaTack™, sutures or staples for closure of the peritoneum. LIQUIFIX FIX8™ achieved an

88.4% peritoneal closure success rate in comparison to the Control arms 90.5% when assessed at the Subject Level. Non-inferiority of LIQUIFIX FIX8™ versus AbsorbaTack™ was demonstrated since the lower limits of the two-sided 95% CI based on PP and ITT completers for the difference in peritoneal closure at time of surgery were greater than the pre-defined non-inferiority margin set at -15%.

Table 5.1. Secondary effectiveness endpoint 3: Rate of successful peritoneal closure in subjects undergoing laparoscopic TAPP hernia repair (PP set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 108 Hernias N = 86 Subjects)	AbsorbaTack™ (N = 112 Hernias N = 84 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	88.4% (76/86)	90.5% (76/84)	-2.1%	0.006	Yes
95% CI	81.6%, 95.1%	84.2%, 96.8%	-11.4%, 7.1%		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 15% margin

[3] Indicated by Lower CI Limit > -15%

Table 5.2. Secondary effectiveness endpoint 3: Rate of successful peritoneal closure in subjects undergoing laparoscopic TAPP hernia repair (ITT set) Assessed Per-Subject

	LIQUIFIX FIX8™ (N = 117 Hernias N = 94 Subjects)	AbsorbaTack (N = 122 Hernias N = 92 Subjects)	Difference[1]	p-value[2]	Non-inferior (Yes/No)[3]
% (n/N)	87.2% (82/94)	91.3% (84/92)	-4.1%	0.012	Yes
95% CI	80.5%, 94.0%	85.5%, 97.1%	-13.0%, 4.8%		

Note: The denominator is the number of evaluable data points and may be less than the analysis population size due to missing data.

[1] LIQUIFIX FIX8™ - AbsorbaTack™.

[2] Based on a Non-inferiority Farrington-Manning test with a 15% margin

[3] Indicated by Lower CI Limit > -15%

Ancillary Secondary Effectiveness Endpoints

Quality of Life (Carolina Comfort Scale)

Quality of Life was assessed at each post-operative follow-up visit using a Carolina Comfort Scale questionnaire which assessed pain, sensation of mesh and movement limitations over various activities. A scale of 0 (No symptoms) to 5 (Disabling symptoms) is used to record subject Quality of Life. The accumulative total score can range from 0 to 115 with the higher the score the lower the health-related quality of life. Numerical improvement was observed for comparison of QOL at 12-month post-operative versus 1- week post-surgery, with a mean change of -15.6 ± 16.0 for LIQUIFIX FIX8™ and -15.3 ± 16.1 for control.

Table 6. Secondary endpoint: Carolinas Comfort Scale (CCS) Questionnaire Total Score at 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months (ITT set)

	LIQUIFIX FIX8 (N = 142)		AbsorbaTack (N = 142)	
	Total Score n Mean ± SD Median (p25, p75) Min, Max	Change from 1 week n Mean ± SD Median (p25, p75) Min, Max	Total Score n Mean ± SD Median (p25, p75) Min, Max	Change from 1 week n Mean ± SD Median (p25, p75) Min, Max
1 week	129 16.1 ± 15.7 12.0 (5.0, 22.0) 0.0, 83.0	N/A	129 16.9 ± 16.6 13.0 (5.0, 24.0) 0.0, 80.0	N/A
2 weeks	136 8.6 ± 13.2 3.0 (0.0, 11.5) 0.0, 64.0	126 -7.7 ± 12.4 -5.0 (-13.0, 0.0) -55.0, 26.0	137 10.2 ± 15.2 4.0 (1.0, 12.0) 0.0, 77.0	128 -7.0 ± 13.2 -5.0 (-11.0, -1.0) -61.0, 47.0
1 month	136 4.8 ± 8.2 2.0 (0.0, 6.0) 0.0, 53.0	125 -12.4 ± 12.6 -9.0 (-18.0, -3.0) -55.0, 12.0	134 5.2 ± 10.5 1.0 (0.0, 5.0) 0.0, 82.0	124 -12.2 ± 14.6 -9.0 (-17.5, -3.0) -75.0, 41.0
3 months	137 2.0 ± 7.6 0.0 (0.0, 1.0) 0.0, 75.0	124 -14.6 ± 16.9 -11.0 (-20.5, -4.0) -83.0, 47.0	126 2.7 ± 8.5 0.0 (0.0, 2.0) 0.0, 69.0	117 -14.4 ± 15.9 -10.0 (-21.0, -3.0) -79.0, 28.0
6 months	136 1.2 ± 3.8 0.0 (0.0, 0.0) 0.0, 24.0	123 -15.1 ± 16.0 -12.0 (-22.0, -3.0) -83.0, 15.0	133 1.8 ± 4.4 0.0 (0.0, 1.0) 0.0, 35.0	122 -15.3 ± 16.7 -11.0 (-23.0, -4.0) -80.0, 24.0
9 months	133 0.9 ± 3.1 0.0 (0.0, 0.0) 0.0, 29.0	123 -15.6 ± 16.3 -12.0 (-24.0, -4.0) -83.0, 24.0	130 1.4 ± 3.8 0.0 (0.0, 1.0) 0.0, 27.0	120 -15.7 ± 16.5 -11.0 (-22.0, -4.5) -80.0, 14.0
12 months	131 0.5 ± 1.5 0.0 (0.0, 0.0) 0.0, 11.0	120 -15.6 ± 16.0 -11.0 (-23.0, -4.5) -83.0, 6.0	133 0.8 ± 3.5 0.0 (0.0, 0.0) 0.0, 34.0	122 -15.3 ± 16.1 -11.0 (-22.0, -4.0) -80.0, 23.0

If more than 2 patient responses within a domain were missing, then the summary score is set to missing. Otherwise mean imputation is used for missing responses.
Score unable to be calculated prior to surgery because patient has not had hernia repair.

Pain (VAS)

Pain was assessed at each post-operative follow-up visit using a VAS scale tool. The results of the primary effectiveness endpoint of change in VAS pain at 6 month from baseline is described above. Numerical reduction was observed in the results from the 12 month follow-up period, with LIQUIFIX FIX8™ mean change of -3.6 ± 2.9 (N=132) and Control -3.5 ± 3.1 (N=133) in the ITT completers.

Table 7. Secondary endpoint: VAS at pre-surgery, discharge, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months, and 12 months (ITT set)

	LIQUIFIX FIX8 (N = 142)		AbsorbaTack (N = 142)	
	VAS n Mean ± SD Median (p25, p75) Min, Max	VAS Change from Pre-Surgery n Mean ± SD Median (p25, p75) Min, Max	VAS n Mean ± SD Median (p25, p75) Min, Max	VAS Change from Pre-Surgery n Mean ± SD Median (p25, p75) Min, Max
Pre-surgery	142 3.8 ± 2.9 3.3 (1.5, 6.0) 0.0, 10.0	N/A	142 3.8 ± 3.0 3.0 (1.0, 6.5) 0.0, 10.0	N/A
Discharge	142 3.5 ± 2.1 3.5 (2.0, 5.0) 0.0, 10.0	142 -0.3 ± 3.4 0.0 (-3.0, 2.0) -8.2, 6.5	142 3.7 ± 1.9 4.0 (2.0, 5.0) 0.0, 10.0	142 -0.1 ± 3.5 0.0 (-3.0, 2.9) -8.0, 7.0
1 week	139 2.3 ± 1.9 2.0 (1.0, 3.5) 0.0, 9.0	139 -1.5 ± 2.8 -1.0 (-3.9, 0.5) -10.0, 4.0	140 2.3 ± 1.9 2.0 (1.0, 3.5) 0.0, 7.0	140 -1.5 ± 3.1 -1.0 (-3.3, 1.0) -10.0, 7.0
2 weeks	141 1.0 ± 1.4 0.5 (0.0, 1.5) 0.0, 8.0	141 -2.8 ± 2.8 -2.0 (-4.9, -0.9) -10.0, 2.1	141 1.1 ± 1.3 1.0 (0.0, 2.0) 0.0, 6.0	141 -2.7 ± 2.9 -2.0 (-5.0, -0.5) -9.5, 4.0
1 month	138 0.6 ± 1.0 0.0 (0.0, 1.0) 0.0, 5.0	138 -3.2 ± 2.8 -2.8 (-5.1, -0.9) -10.0, 1.0	137 0.7 ± 1.2 0.0 (0.0, 1.0) 0.0, 7.0	137 -3.1 ± 3.1 -2.5 (-5.5, -1.0) -10.0, 6.5
3 months	138 0.2 ± 0.7 0.0 (0.0, 0.0) 0.0, 5.2	138 -3.6 ± 2.9 -3.0 (-6.0, -1.0) -10.0, 1.0	129 0.4 ± 0.9 0.0 (0.0, 0.0) 0.0, 7.0	129 -3.4 ± 3.1 -2.1 (-6.0, -1.0) -10.0, 3.0
6 months	136 0.2 ± 0.8 0.0 (0.0, 0.0) 0.0, 6.0	136 -3.6 ± 3.0 -3.0 (-6.0, -1.0) -10.0, 3.0	133 0.3 ± 0.7 0.0 (0.0, 0.0) 0.0, 4.0	133 -3.5 ± 3.1 -3.0 (-6.0, -1.0) -10.0, 2.0
9 months	133 0.1 ± 0.3 0.0 (0.0, 0.0) 0.0, 2.0	133 -3.7 ± 2.9 -3.0 (-6.0, -1.4) -10.0, 1.0	131 0.2 ± 0.6 0.0 (0.0, 0.0) 0.0, 3.5	131 -3.5 ± 3.0 -3.0 (-6.0, -1.0) -10.0, 1.0
12 months	132 0.1 ± 0.4 0.0 (0.0, 0.0) 0.0, 3.0	132 -3.6 ± 2.9 -3.0 (-6.0, -1.0) -10.0, 0.0	133 0.1 ± 0.6 0.0 (0.0, 0.0) 0.0, 6.0	133 -3.5 ± 3.1 -3.0 (-6.0, -1.0) -10.0, 6.0

Safety / Adverse Events

A total of 271 adverse events (AEs) have been reported in the clinical study across the two treatment arms. The incidence of device-related AEs by subject were comparable in the treatment (34 subjects; 23.9%) and

control (43 subjects; 30.3%) groups. Out of these, 18 patients (6 Treatment, 12 Control) had more than one possibly device related AE. In terms of Serious AEs (SAEs), the incidence of possibly device-related adverse events were comparable between the treatment and control groups with 5 events in 5 (3.5%) subjects of device related SAEs in the treatment group compared to 4 events in 4 (2.8%) subjects in the control group. The events in the LIQUIFIX FIX8™ group included two neuralgias, one recurrent hernia, one mesh infection and one small bowel obstruction. The control group possible device related adverse events included two hematoma which required further intervention, and two recurrent hernias. No single patient had more than one possibly device-related serious AE.

Table 8. AEs - Device and/or Procedure Related (ITT set)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)	
# Serious Adverse Events (ITT)	N=11		N=16	
Total related to study device[2]	3.5% (5/142)	5	2.8% (4/142)	4
Total related to study procedure[2]	6.3% (9/142)	9	7.0% (10/142)	10
# Adverse Events (ITT)	N= 114		N=157	
Total related to study device[2]	23.9% (34/142)	41	30.3% (43/142)	55
Total related to study procedure[2]	35.9% (51/142)	76	43.0% (61/142)	107
[2]Related includes possibly and definitely related.				

Serious possibly device-related adverse events observed in the clinical study included Neuralgia, hernia recurrence, mesh infection and intestinal obstruction. A summary of serious adverse events adjudicated by an independent Clinical Events Committee (CEC) as related to the device or procedure can be found in Table 9. The percentage of Subjects with serious device and/or procedure related adverse events is similar across the ITT (6.7%) and PP (6.8%) population.

Table 9. Serious AEs - Device and/or Procedure Related[1] (ITT set)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Atrial fibrillation	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Hematoma	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Inguinal hernia	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Neuralgia	2	2 (1.4%)	0	0 (0.0%)	2	2 (0.7%)
Dizziness	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Hernia	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Incisional hernia	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Intestinal obstruction	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Medical device site infection	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Procedural pain	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Tooth abscess	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Urethral injury	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)

Table 9. Serious AEs - Device and/or Procedure Related[1] (ITT set)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Urinary retention	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urinary tract injury	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Vomiting	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Total	9	9 (6.3%)	10	10 (7.0%)	19	19 (6.7%)

[1]*Related includes possibly and definitely related.*
[2]*MedDRA Preferred Term*

The majority of non-serious device and/or procedure related adverse events were seroma formation. Overall, there were 47 events related to seroma in 44 (15.5%) subjects. All cases were mild in severity and none were considered only related to the device in both groups. Other notable frequent non-serious AEs were groin pain with 16 events (16 subjects; 5.6%) and urinary retention with 10 events (10; 3.5%). Possibly Related non-serious AEs were comparable between groups with the following notable differences: the incidence of seroma (13.4% Treatment, 17.6% Control) and groin pain (2.8% Treatment, 8.5% Control) was lower in the treatment group. A summary of non-serious adverse events adjudicated by the CEC as possibly or definitely related to the device or procedure can be found in Table 10. The percentage of Subjects with non-serious device and/or procedure related adverse events is similar across the ITT (36.3%) and PP (36.0%) population.

Table 10: Non-Serious AEs - Device and/or Procedure Related[1] (ITT)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Seroma	20	19 (13.4%)	27	25 (17.6%)	47	44 (15.5%)
Groin pain	4	4 (2.8%)	12	12 (8.5%)	16	16 (5.6%)
Urinary retention	5	5 (3.5%)	5	5 (3.5%)	10	10 (3.5%)
Post procedural constipation	4	4 (2.8%)	3	3 (2.1%)	7	7 (2.5%)
Dysuria	2	2 (1.4%)	3	3 (2.1%)	5	5 (1.8%)
Hematoma	2	2 (1.4%)	3	3 (2.1%)	5	5 (1.8%)
Procedural nausea	0	0 (0.0%)	5	5 (3.5%)	5	5 (1.8%)
Testicular pain	3	3 (2.1%)	2	2 (1.4%)	5	5 (1.8%)
Musculoskeletal pain	4	4 (2.8%)	0	0 (0.0%)	4	4 (1.4%)
Pain	1	1 (0.7%)	3	2 (1.4%)	4	3 (1.1%)
Swelling	1	1 (0.7%)	3	2 (1.4%)	4	3 (1.1%)
Genital hemorrhage	2	2 (1.4%)	1	1 (0.7%)	3	3 (1.1%)
Cellulitis	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Hypoaesthesia	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)

Table 10: Non-Serious AEs - Device and/or Procedure Related[1] (ITT)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Orchitis	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Post procedural haematuria	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Rash	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Spermatic cord inflammation	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Umbilical hernia	1	1 (0.7%)	1	1 (0.7%)	2	2 (0.7%)
Urinary retention postoperative	0	0 (0.0%)	2	2 (1.4%)	2	2 (0.7%)
Abdominal pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Abdominal pain lower	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Arthralgia	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Back pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Burning sensation	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Change of bowel habit	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Constipation	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Dermatitis contact	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Diarrhea	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Dyspepsia	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Flatulence	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Gastrointestinal procedural complication	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Incisional hernia	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Inguinal mass	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Injection site hematoma	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Lymphadenitis	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Muscle strain	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Musculoskeletal chest pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Neuralgia	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Nodule	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Pollakiuria	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Postoperative wound infection	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Reflex test abnormal	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Scrotal hematoma	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Scrotal pain	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)

Table 10: Non-Serious AEs - Device and/or Procedure Related[1] (ITT)

	LIQUIFIX FIX8™ (N = 142)		AbsorbaTack™ (N = 142)		All Subjects (N = 284)	
Adverse Event Term[2]	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events	Number of Events	Number (%) of Subjects with Events
Testicular swelling	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Throat irritation	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urethral pain	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urinary incontinence	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Urinary tract infection	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Urinary tract procedural complication	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Vomiting	1	1 (0.7%)	0	0 (0.0%)	1	1 (0.4%)
Wound dehiscence	0	0 (0.0%)	1	1 (0.7%)	1	1 (0.4%)
Total	67	46 (32.4%)	97	57 (40.1%)	164	103 (36.3%)

[1]Related includes possibly and definitely related.
[2]MedDRA Preferred Term

Study Conclusions

The US pivotal study was demonstrated to be successful as the primary endpoint as measured by change in VAS pain score from baseline (worst pain experienced within 1 month of screening visit) to 6 months post hernia repair, was met in both the PP and ITT sets. Secondary effectiveness endpoints were all met with non-inferiority to the control or showed improvements comparable to the control arm.
The improvement in pain from baseline to 6 months post-hernia repair in the LIQUIFIX FIX8™ treatment arm was not inferior to the AbsorbaTack™ control arm. Hernia recurrence rate at 6 months measured at the subject level as well as rate of successful hernia mesh fixation and peritoneal closure at time of surgery was not inferior in LIQUIFIX FIX8™ compared to the control arm. Improvement in quality of life including in the pain domain, as recorded in the Carolina Comfort Scale, was observed in LIQUIFIX FIX8™ post-surgery and this was similar to the control arm. In terms of safety, the incidence of safety events in LIQUIFIX FIX8™ were comparable to the control. There were no unanticipated adverse device effects. Based on these results, the probable benefits outweigh the risks; there is an overall benefit to having an atraumatic device for mesh fixation available, which has also demonstrated to be non-inferior in terms of safety and effectiveness to AbsorbaTack™ control.

Summary of Supplemental Clinical Information

Additional Clinical Information

Registry data (141 patients) demonstrated perioperative complication rates and 1- year outcome for LIQUIFIX in open inguinal hernia repair are acceptable and consistent with other OUS similarly marketed fixation devices.

Symbols Glossary

Symbols glossary located at admedsol.com/symbols-glossary

	Manufacturer
	Use by date
	Batch Code
	Catalogue number
	Single Sterile Barrier System
	Sterilized using irradiation
	Sterilized using ethylene oxide
	Do not resterilize
	Consult instructions for use
	Keep dry
	Keep away from sunlight
	Do not use if packaging is damaged
	Do not re-use
	Temperature limit
	Caution
	Date of implantation

MR	Magnetic Resonance safe
MD	Medical Device
UDI	Unique Device Identifier

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