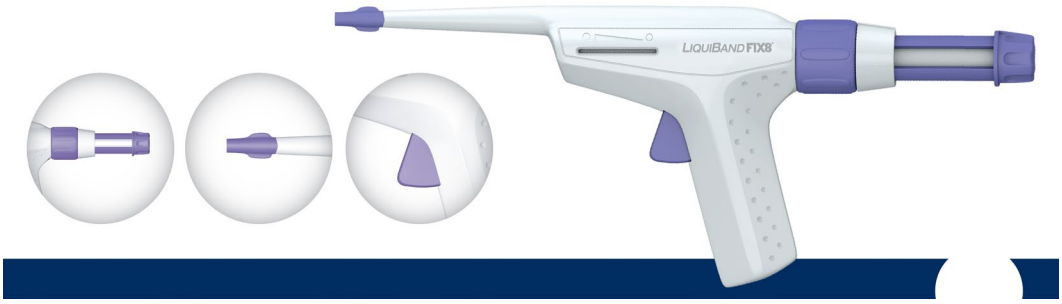
LiquiBand FIX8® Open

HERNIA MESH FIXATION DEVICE

PATIENT INFORMATION LEAFLET
Australia



MANUFACTURER'S CONTACT DETAILS
Advanced Medical Solutions Limited, Western Wood Way, Langage Science Park, Plymouth, Devon, PL7 5BG, UK Phone : +44(0)8444 125754 Fax : +44(0)1752 209956 e-mail : enquiries@plymouth.com

CONTACT FOR THE REPORT OF SERIOUS INCIDENTS
Manufacturer's contact details e-mail: complaints-plymouth@admedsol.com **Competent Authority's contact details** Website: https://www.tga.gov.au/

PRINCIPLES OF SURGERY:

A hernia is a when an internal part of the body pushes through a weakness in the abdominal wall. This causes a bulge that may or may not be painful. Initially hernias contain internal fat but as the "gap" increases in size, occasionally the bowel can push through, which can cause an ache or pains.

There are various sites where a hernia may occur and the name of the hernia indicates the site. The inguinal hernia is the most common and occurs in the groin. A ventral (abdominal) incisional hernia may also occur following previous surgery at a weak point in the scar.

If left alone, the bulge (contents) might increase in size but the weakness can remain the same size. Sometimes fat or bowel can get stuck in the narrow "neck" of this weak point. If not treated, hernias can result in complications of blockage of the bowel (obstruction) or loss of the blood supply.

To repair a hernia through surgery, the hernia contents or other protruding tissues are returned to their normal position and the weakness in the abdominal wall is repaired. Sometimes it is necessary to support the repair with a mesh which is fixed to the abdominal wall at the site of the hernia. There is also a non-mesh option, where the hernia is repaired with a suture technique at the site of the weakness. Today, a mesh repair is more commonly used.

To gain access to the hernia so it can be repaired, there are two surgical techniques. Open surgery is where a cut is made to allow the surgeon to push the lump back in the abdomen and repair the hernia. Laparoscopic (keyhole) surgery is a less invasive method where several smaller cuts are made allowing the surgeon to use special instruments and a camera to repair the hernia. In some types of laparoscopic hernia repair surgery sections of the peritoneum (a membrane that lines the abdominal wall) is cut to access the abdomen. The peritoneum is closed at the end of the operation.

For a hernia repair using a mesh, a loosely woven sheet of flexible synthetic plastic is placed over the weakness in the abdominal wall, essentially 'plugging' it up. Tension is created in the abdominal wall during the repair, but the mesh allows this tension to be spread out. The mesh needs to be secured until it becomes integrated with the surrounding tissue.

More recently, a number of medical adhesives or 'tissue adhesives' have been developed and can provide an alternative to the mesh fixation options described above. One is made from Fibrin, which is of biological origin, although, can be formed synthetically. The other is a synthetic (manmade) adhesive, called a Cyanoacrylate (LiquiBand FIX8® is a Cyanoacrylate adhesive). When a tissue adhesive is used, the mesh is fixed to the abdominal wall without penetrating the tissues.

Following the open surgical repair of a hernia, the surgeon will have to close the incision made to access the hernia. In primary wound closure, the standard of care is suturing, which involved the closure of wounds via a needle thread combination. Sutures are available in a vast number of needle and thread combinations, which a surgeon will select, based on a number of factors, including the size of the incision, the location of the incision, the condition of the patient and a surgeon's individual preference.

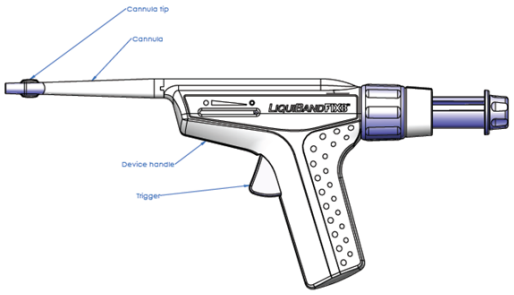
Another quick and effective method of wound closure is the use of surgical staples that hold together the edges of a wound whilst providing excellent relief of wound tension. Stapling requires a small amount of skin penetration, and hence compared to suturing, fewer microorganisms are carried into the deeper skin layers. However, staples can be more expensive than traditional sutures and require great care in placement, especially in ensuring the eversion (slight turning inside out to improve cosmetics) of wound edges. Skin staples are useful as a timesaving device for long incisions or to position a skin closure flap temporarily before suturing. It is important that staples be removed promptly to prevent skin marks.

A less traumatic method of wound closure is the use of surgical tissue adhesives, including cyanoacrylate (the adhesive used in LiquiBand FIX8® Open), which support the approximated edges of wounds for a period to allow the natural wound healing process to take place.

The benefit of using LiquiBand FIX8® Open Hernia Mesh Fixation device for mesh fixation and for the closure of the hernia repair incision is the non-traumatic nature of the device. As there is no tissue penetration when fixing the

mesh or closing the wound, the use of LiquiBand FIX8® Open Hernia Mesh Fixation device will reduce the risk of post-operative pain for the patient.

LIQUIBAND FIX8® OPEN MODEL USED IN HERNIA MESH FIXATION SURGERY

REFERENCES	DESIGNATIONS	ILLUSTRATION
FX002	LiquiBand FIX8® Open	

INFORMATION ON LIQUIBAND FIX8® OPEN HERNIA MESH FIXATION DEVICE

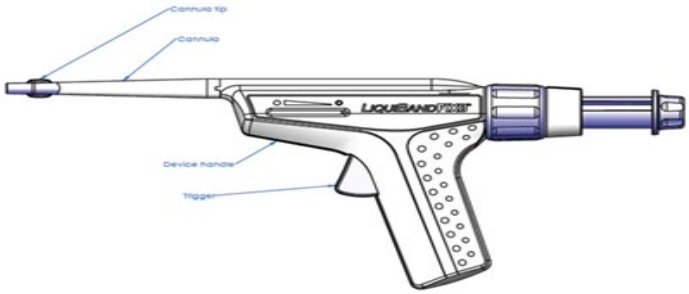
What is LiquiBand FIX8® Open device?

The LiquiBand FIX8® Open Hernia Mesh Fixation device is designed for the application of cyanoacrylate adhesive to an implanted hernia repair mesh, in order to fix the mesh to the underlying tissue and to hold closed easily approximated wound edges closed. The device consists of:

a) n-butyl-2-cyanoacrylate adhesive

b) a delivery instrument which dispenses the adhesive

The image below shows the key components of the applicator designed to dispense the adhesive:



Material/substances in contact with patient tissues:

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%.

Information about medicinal substances in the device

Not applicable, the device contains no medicinal substances.

Description of how the device achieves its intended mode of action

The cyanoacrylate adhesive bonds the hernia mesh to the tissue. The adhesive may also be used to hold closed easily approximated skin edges of wounds from the hernia repair incision.

Description of any accessories which are intended to be used in combination with the device

The device is not used in combination with an accessory or other medical device.

What is the role of the device in hernia mesh surgery?

The LiquiBand FIX8® Open Hernia Mesh Fixation device is intended for use in open surgical repair of inguinal and ventral incisional hernias, achieved through the fixation of prosthetic mesh to the abdominal wall and to hold easily approximated skin edges of wounds from the hernia repair incision.

For whom kind of patient the device is intended to be used?

The target population of the LiquiBand FIX8® Open Hernia Mesh Fixation device is for use on patients who are having their hernias treated through prosthetic mesh fixation.

Use of prosthetic mesh for hernia repair should be in alignment with the indications of the prosthetic mesh.

The target population of the device has been appropriately reflected in the indications and contraindications:

- Indications:
    - The LiquiBand FIX8® Open Hernia Mesh Fixation device is intended for use in open surgical repair of inguinal and ventral incisional hernias, achieved through the fixation of prosthetic mesh to the abdominal wall and to hold closed easily approximated skin edges of wounds from the hernia repair incision.
- 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 or formaldehyde.
    - Do not use for the fixation of meshes constructed with polytetrafluoroethylene (PTFE) or absorbable materials.
    - Do not use device for closure or fixation of cerebral tissues, blood vessels or peripheral nerves.
    - Do not use on any wounds with evidence of microbial, bacterial or fungal infections or gangrene.
    - Do not use topically on mucosal surfaces or across mucocutaneous junctions or on skin which may be regularly exposed to bodily fluids.
    - Do not inject intravascularly or ingest.
    - Do not use topically on decubitus ulcers, animal or human bite wounds, or stab wounds.

Device lifetime and follow-up

The in-use lifetime of the implanted adhesive is approximately 2 weeks. The adhesive is only required to temporarily hold the mesh in place until it is integrated with the surrounding tissue.

The adhesive is not require to be removed after this time and as it does not degrade, and will remain within the body.

Any follow-up after the procedure should be as recommended by the operating clinician.

Following topical application for the closure of the incision, the adhesive film will naturally slough off naturally (usually in 7-10 days).

Special operating instructions for the use of the device

- Warnings:
    - Only physicians having adequate training and familiarity with surgical techniques should use this device. 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.
    - 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 by slowly and carefully peeling the polymerized adhesive from the tissue with surgical graspers.
    - 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. Polymerization of the adhesive may be accelerated by water or fluids containing alcohol: the adhesive should not be applied to wet wounds.
    - Treated wounds should be monitored for signs of infection. Wounds with signs of infection such as, erythema, edema, warmth, pain and/or drainage should be evaluated and treated according to standard practice for infection.
    - The adhesive should always be applied sparingly topically, bridging the wound and the aligned wound edges. Avoid pressure on the applicator to prevent wound edge separation, which could cause the topical skin adhesive to be interposed between the wound edges. Application and/or migration (leak) of the topical skin adhesive below the surface of the skin between the wound edges may impair the healing process by forming a barrier.
- 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.
    - The viscosity of the adhesive is only slightly greater than that of water, so adhesive should be applied very carefully to prevent its spread 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 adhesive will readily adhere to most tissues, however the adhesive may not perform as intended if it is being applied to unsuitable locations such as bone or 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.

- There is only limited clinical data for meshes other than polypropylene and titanium coated mesh. Bench tests have demonstrated compatibility with meshes made from polyvinylidene fluoride (PVDF).
- 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).
- Care should be taken to ensure that when performing other surgical procedures (which may involve repositioning of the patient) in conjunction with the procedure that in moving the patient the quality of the hernia repair or topical wound closure is not adversely affected.
- Safety and effectiveness of the device has not been evaluated for use on topical wounds of patients with uncontrolled diabetes mellitus, diseases or conditions that are known to interfere with the wound healing process, or a personal or family history of keloid formation or hypertrophic scarring.
- Safety and effectiveness has not been evaluated on topical wounds that have been treated with the adhesive and then exposed for prolonged periods of time to direct sunlight and tanning lamps.
- The adhesive's permeability by topical medications or other fluids is not known and has not been studied.
- Liquid, ointment or cream medications should not be applied to the topical wound after closure with the adhesive, as these substances may weaken the polymerized film which may lead to wound dehiscence.
- During topical wound approximation if unintended bonding of intact skin with the adhesive should occur, removal may be accomplished by using either acetone or petroleum jelly. Typical cleansers such as soap and other agents such as water, saline, Betadine® or chlorhexidine gluconate are not expected to loosen the bond. Peel, do not pull skin apart.

- Patient instructions for topical wound closure:
  - No additional or special care is needed for the topical wound closed using the adhesive; however, it is recommended that the following information be shared with the patient as necessary; a dry semi-permeable protective dressing should be applied for children or other patients who may not be able to follow these instructions for proper wound care.
  - Do not pick or pull at the wound or polymerized film. Picking at the film can disrupt the adhesion to the skin and cause dehiscence of the wound.
  - Light showering or bathing is permitted, however do not scrub, soak or expose the wound site to prolonged wetness (including swimming) until after the film has sloughed off naturally (usually in 7-10 days).
  - Do not apply any liquid, ointment or cream medication to the wound.
  - Report any discomfort or other concerns regarding your wound to your doctor.

Information regarding reciprocal interference with external influences, medical examinations or environmental conditions.

There are no warnings, precautions or measures to be taken by the patient or surgeon with regards to the implanted adhesive interfering with external influences, medical examinations or environmental conditions.

The LiquiBand FIX8® adhesive has also been tested for any metallic elements to assess the suitability of a patient having an MRI scan after the adhesive has been implanted. The results of this testing found that a patient can undergo an MRI scan safely after having a hernia repair with LiquiBand FIX8® adhesive.

What are the residual risks and undesirable side-effects?

Residual risks and undesirable effects

- Following the standard compliant risk management procedure, there are no residual risks (i.e. risks remaining, that are not already referenced in the instructions for use delivered with every device, after risk

control measures have been taken which could cause physical injury or damage to the health of the patient) related to the use of the device.

Potential Adverse Reactions

- The following information is taken from the instructions for use, which is provided with the device. A glossary of the terms is provided below; however, it is recommended to contact your healthcare professional with any questions.
- Hernia mesh fixation: 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.
    - Transitory inflammatory foreign body response – A non-permanent reaction caused by an object that is not typically found in the body.
    - Current post-market clinical follow-up has observed an occurrence of only 0.002%.
- Topical wound closure: Clinical use of cyanoacrylate-based topical skin adhesives for wound closure has suggested that the following adverse events may occur: wound dehiscence; infection; acute inflammation including erythema, edema and drainage; bonding to unintended tissues such as the eye; thermal discomfort during polymerization; allergic reaction; foreign body reaction and chronic non-healing of a wound.
    - Transient Local Irritation - Inflammation or discomfort at the site of surgery, caused by a reaction to an irritant substance, lasting for a short time only.
    - Transitory inflammatory foreign body response – A non-permanent foreign body reaction
    - Erythema – redness of the skin
    - Edema – swelling caused by excess fluid in body tissues

If you experience any adverse effect between two visits or after the follow-up timeline, do not hesitate to contact your surgeon or any other health professional in relation to the surgery you underwent.

Any serious incident occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration (please find the contact details on the first page of this patient information leaflet).

No changes to this document are authorized without manufacturer's consent