LiquiBand FIX8® Laparo

HERNIA MESH FIXATION DEVICE

PATIENT INFORMATION LEAFLET
Australia

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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.

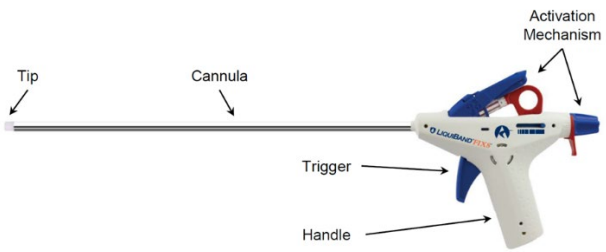
To gain access to the hernia so it can be repaired, there are two surgical techniques. Open surgery is where a cut is made to allow the surgeon to push the lump back in the abdomen and repair the hernia. Laparoscopic (keyhole) surgery is a less invasive method where several smaller cuts are made allowing 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 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.

For the laparoscopic procedures where the peritoneum is cut, closure of this tissue can be performed with Cyanoacrylate tissue adhesive.

LIQUIBAND FIX8® MODEL USED IN HERNIA MESH FIXATION SURGERY

REFERENCES	DESIGNATIONS	ILLUSTRATION
FX001	LiquiBand FIX8® Laparo	

INFORMATION ON LIQUIBAND FIX8® LAPARO HERNIA MESH FIXATION DEVICE

What is LiquiBand FIX8® device?

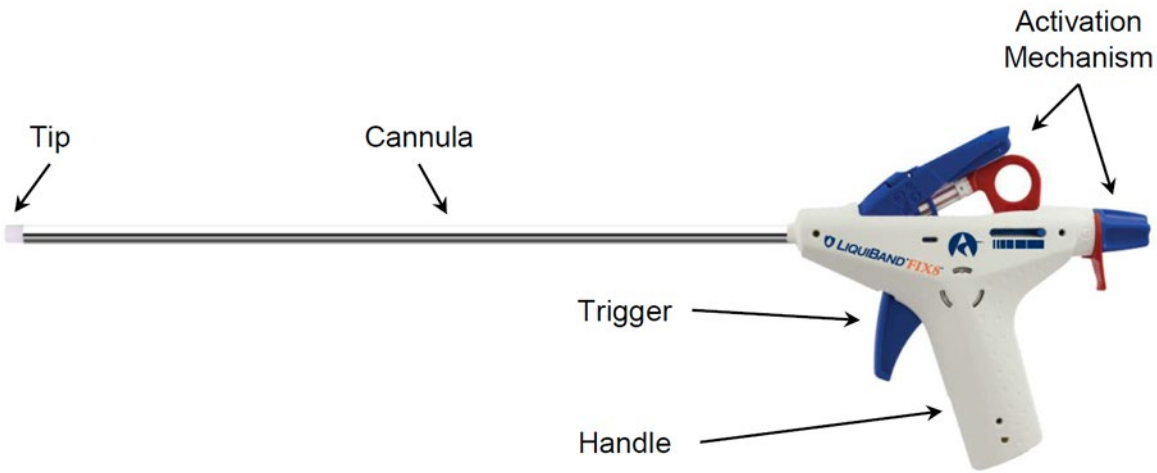
The LiquiBand FIX8® Laparo Hernia Mesh Fixation device is designed for the application of cyanoacrylate adhesive to an implanted hernia repair mesh, in order to fix the underlying tissue. The device consists of:

a) n-butyl-2-cyanoacrylate adhesive

b) a delivery instrument which dispenses the adhesive

The device is designed for introduction and use through a laparoscopic port sleeve.

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.

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

The device is designed for introduction and use through a laparoscopic port sleeve.

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

The LiquiBand FIX8® device is intended for use in laparoscopic surgical repair of inguinal and ventral incisional hernias achieved through the fixation of prosthetic mesh to the abdominal wall and the approximation of the peritoneum.

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

The target population of the LiquiBand FIX8® Laparo 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® device is intended for use in laparoscopic surgical repair of inguinal and ventral incisional hernias, achieved through the fixation of prosthetic 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 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.

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

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

Special operating instructions for the use of the device

- Warnings:
    - Only physicians having adequate training and familiarity with endoscopic techniques should use this device. 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.
    - 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 for use (i.e IFU, provided with every device) 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.
- 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 by slowly and carefully peeling the polymerized adhesive from the tissue with surgical graspers.

- Precautions:
  - The fixation method for any prosthetic mesh 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 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 suitable 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 hernia repair procedure that in moving the patient the quality of the hernia repair is not adversely affected.
  - If the peritoneum is thick/heavy or under excess tension, approximation may be aided by reduction in pneumoperitoneum pressure or re-positioning of the patient.

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.
- 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%.

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