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PRODUCT TECHNICAL DATASHEET

PRODUCT NAME

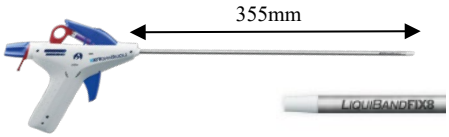
Liquiband FIX8® / Liquiband FIX8 Open®

DESIGNATION

Cyanoacrylate glue delivery systems

CODE(S):

- **Liquiband FIX8®:** FX001
- **Liquiband FIX8® Open:** FX002



Atraumatic & & non adhesive tip

FIX8® Laparoscopy



Detachable & non adhesive tip

FIX8® Open

INDICATIONS

Liquiband FIX8® : 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.
Liquiband FIX8® Open: 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 wound from the hernia repair incision.

COMPOSITION (no substances of human or animal origin – No Latex nor Phtalate)

- **Glue**: N butyl cyanoacrylate
- **Body**: ABS / **Tip**: POM / **Canula** (⇔ FX001) : Stainless steel

DESCRIPTION

The **LiquiBand FIX8®** 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 device consists of: a n-butyl-2-cyanoacrylate adhesive monomer, in liquid form, supplied in a thin-walled, sealed glass vial; and a surgically invasive, laparoscopic delivery instrument comprising a 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 for introduction and use through a 5 mm diameter laparoscopic port sleeve. A larger diameter sleeve will require the use of a converter.

The **LiquiBand FIX8® 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 and topical application to hold easily approximated wound edges closed. The device consists of: a n-butyl-2-cyanoacrylate adhesive monomer, in liquid form, supplied in a thin-walled, sealed glass vial; and, a surgical delivery instrument comprising a 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 distal tip is designed to apply adhesive to mesh and can be removed when topically applying adhesive to skin.

PACKAGING / STORAGE CONDITION

Box of 6 sterile units.
Storage temperature: Store only at temperatures between 5°C (41°F) and 25°C (77°F) in its original packaging.

CARTON OF 6 UNITS

Description/ref	FX001	FX002
GTIN code	05036912000581	05036912001205
Dimension	600*210*230mm	410*180*260mm
Carton weight	2740gr	1680gr

INDIVIDUAL BOX

Description/ref	FX001	FX002
Delivery type	Drop by drop	Drop by drop
Glue volume	1,5ml (⇔ 40^{++} drops)	1,5ml (⇔ 45^{++} drops)
GTIN code	05036912000574	05036912001212
Canula length	355mm	X
Dimension	562*247*32mm	379*176*40mm
Weight	460gr	280gr

STERILIZATION / SHELF LIFE

Sterility : irradiation (vial only) then Ethylene Oxide (complete set)
Shelf life: 2 years

CONTRAINDICATION

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

CLASSIFICATIONS

Liquiband FIX8® & Liquiband FIX8 Open®: Class IIb (according to European Council Directive 93/42/CEE)
GMDN code: 58777 / CND code: H90010102

Legal manufacturer : AMS/Advanced Medical Solutions Ltd. AMS is certified ISO 13485.

CE 2797