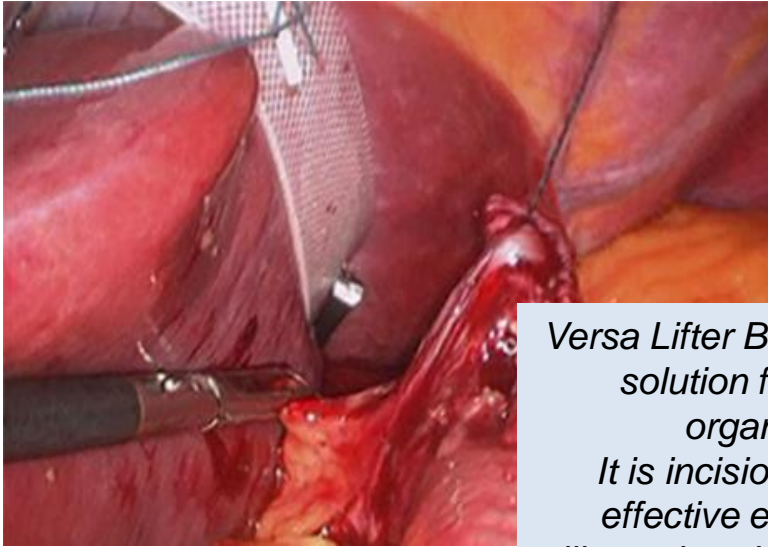


Mediflex[®]

Redefining Retraction.



Versa Lifter Band is an innovative solution for laparoscopic organ retraction. It is incision-less and offers effective exposure with the silicone band providing cushioned contact with the liver.

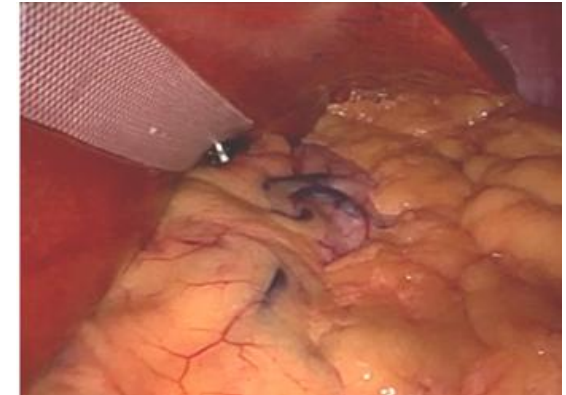


Versa Lifter Band

Port-Free Internal Retractor

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR



PRODUCT OVERVIEW / APPLICATIONS

Versa Lifter Band is a disposable, retraction/suspension system for laparoscopic procedures. Versa Lifter Band is used to suspend the left liver lobe during upper GI surgery.

Versa Lifter Band creates more space in the abdominal cavity and improves visibility during the procedure by lifting the left lobe of the liver out of the way and, reduces the amount of devices needed in the field.



The anchoring clip allows for strong attachment to support the left liver lobe. The ideal clip attachment is to the right crus.

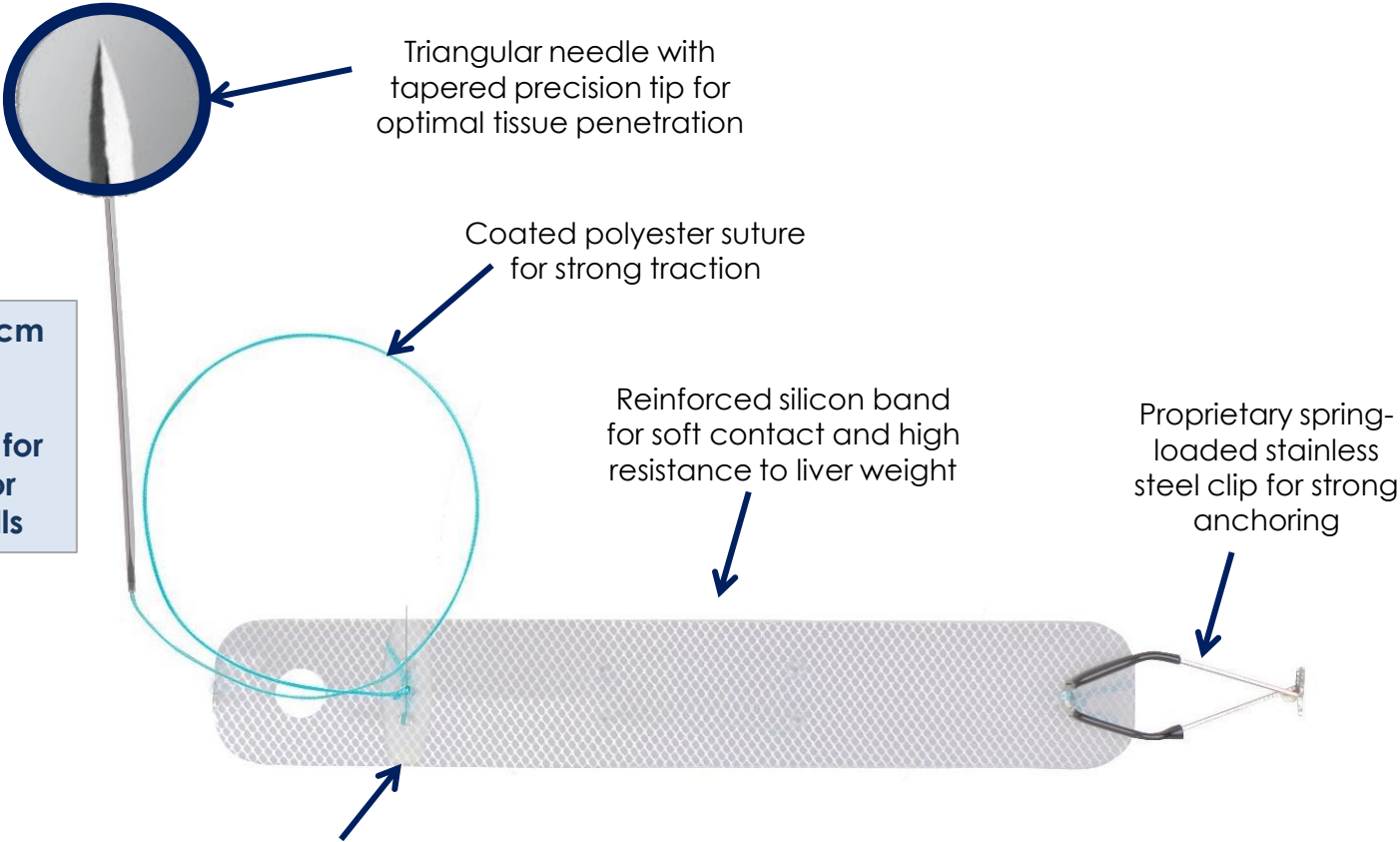
The needle can exit the abdomen wherever needed to adapt to liver/organ size as well as exposure requirements.

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SURGICAL PRODUCTS

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

PRODUCT FEATURES



Needle is available in 5cm and 6.5cm lengths.

6.5cm is most popular - for bariatric procedures or thicker abdominal walls

Triangular needle with tapered precision tip for optimal tissue penetration

Coated polyester suture for strong traction

Reinforced silicon band for soft contact and high resistance to liver weight

Proprietary spring-loaded stainless steel clip for strong anchoring

Silicone stabilizing device for band rigidity and stable liver / tissue suspension

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

PRODUCT BENEFITS

- Easy to use, rapid set-up
- Fully internal system – no incision, eliminates port dedicated to retraction
- Hands-free solution for optimal surgical field exposure
- Shortened procedure / OR time
- Fully compatible with robotic procedures
- Allows for specific angle of retraction with adjustable suspension height
- Silicone band provides atraumatic liver, organ or tissue suspension
- Prevents instrument and robotic arm interference
- Reduced patient discomfort and scarring, better cosmetic result
- Two needle lengths to accommodate different abdominal wall thicknesses

Versa Lifter Band

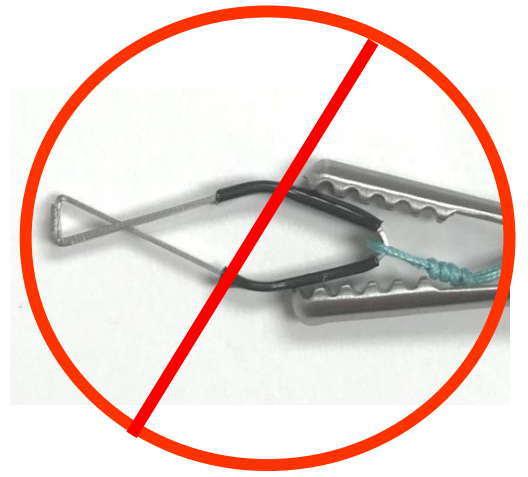
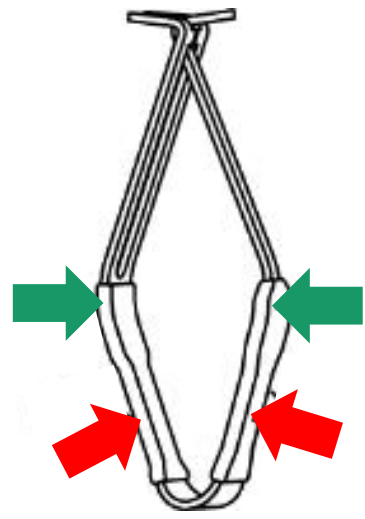
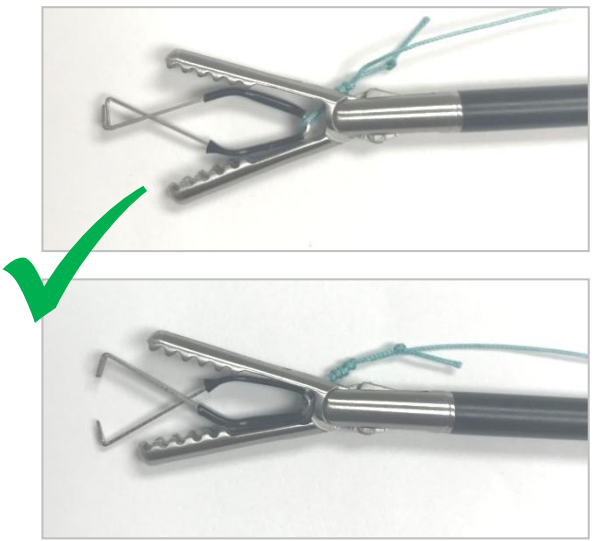
PORT-FREE INTERNAL RETRACTOR

CLIP APPLICATION GUIDE

Use a grasper with a minimum tip length of 10mm such as:
Fenestrated MediClinch, DeBakey
or Hunter Grasper



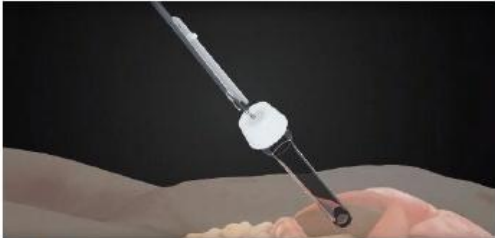
Proper Clip grasping is required to prevent damage to the clip and, permit secure clip attachment to tissue.



Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

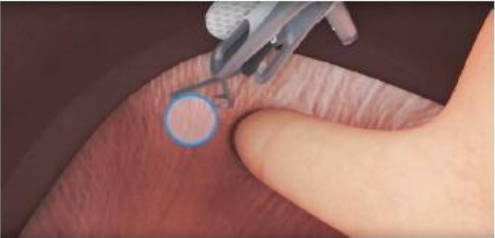
APPLICATION OF VERSA LIFTER BAND FOR LIVER SUSPENSION IN UPPER GI SURGERY



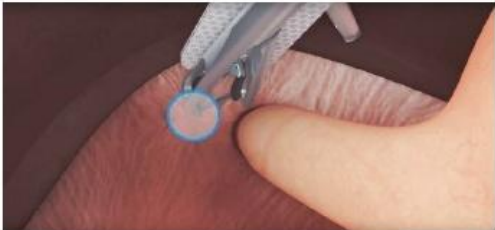
VLB is passed into the abdomen with a grasping forceps through a 10mm port



Retract the liver to expose the right crus



The clip is opened using a fenestrated grasper for attachment to right crus



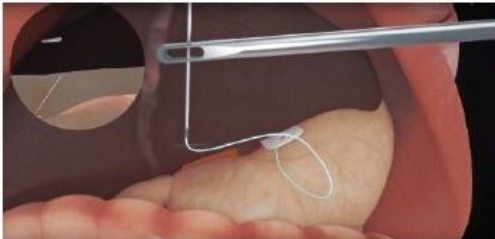
Once positioned, the clip is closed by releasing the grasping forceps



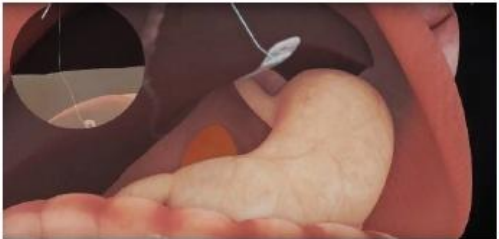
VLB is oriented to provide optimal surgical field exposure once the liver is suspended



The needle is grasped using forceps to prepare for final fixation



The target exit point is evaluated to determine retraction angle for maximum field exposure



The needle penetrates the abdominal wall and suture is pulled to control desired amount of retraction



A hemostat is used to secure the suture and the procedure is ready to start

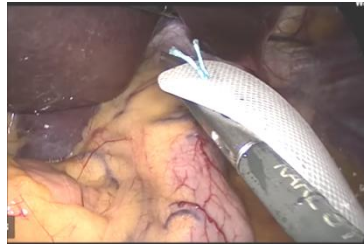
Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

CLINICAL APPLICATION – Partial Fundoplication



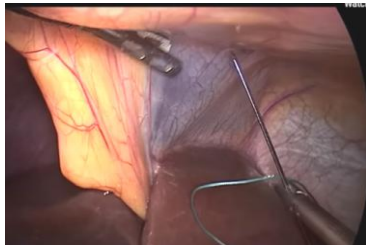
Clip is grasped and directed towards attachment point – right crus



Grasper is rotated to bring band towards liver surface



Band is grasped to determine angle of retraction needed for exposure



Needle penetrates abdominal wall



Suture is pulled externally to position VLB for optimal exposure



Suture is clamped when desired exposure is achieved



Tailoring the wrap and suturing to the esophagus, right



Suturing the wrap to the left crus

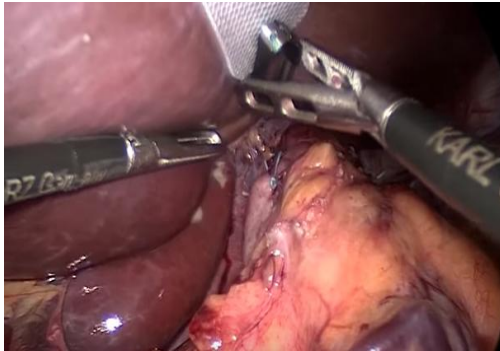


Result with bougie removed

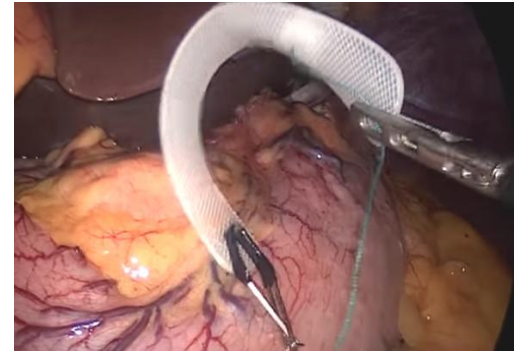
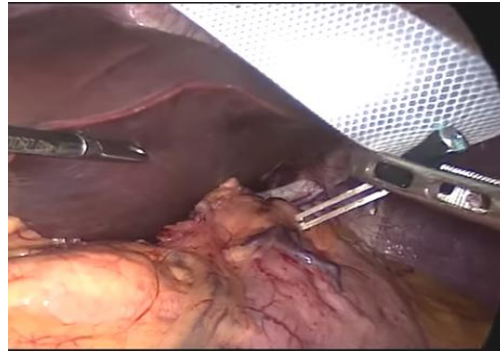
Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

CLINICAL APPLICATION – Removal of Versa Lifter Band



Clip is grasped at the center (widest point) to open and release from the tissue



Suture is cut from outside to release Versa Lifter Band from the needle



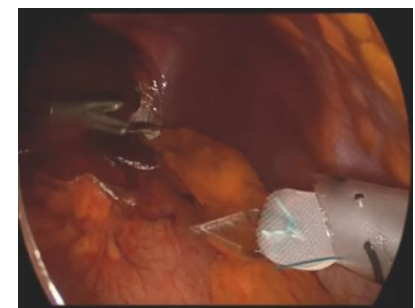
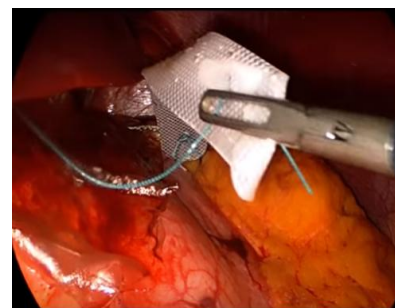
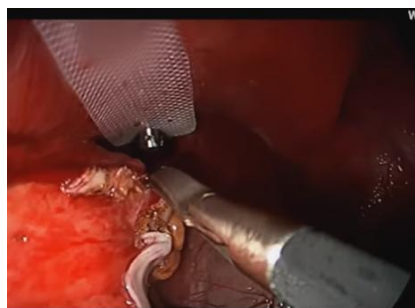
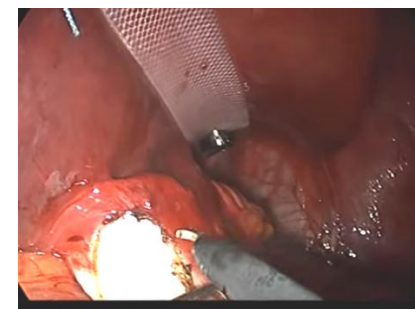
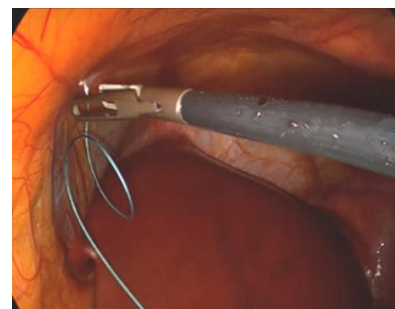
Grasper withdraws Versa Lifter Band (non-clip side) through 8/10mm port



Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

CLINICAL APPLICATION – Gastric Band Retrieval



Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

Possible Extra-Abdominal Needle Management



Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

TIPS & TRICKS: TO AVOID PITFALLS

- Put the needle into the trocar first, grab it internally with a needle holder or course grasper, view where it is/goes and only then pull the band through, to avoid needle stick injury intra-abdominally
- Make certain to place the Clip firmly, and deep enough into the right crus - otherwise the weight of the lobe may cause the Clip to rupture out of the diaphragm.
- Hard/rigid and heavy livers/left lobes (bariatric surgery, cirrhosis) can be very difficult to lift by VBN. In such a case, switch to more rigid retractors.
- When exiting the abdominal cavity, make sure no one is touching the area of exit, to avoid needle-stick injury.
- Take and remove the exiting needle with a needle holder or coarse clamp, to avoid damaging fine mosquitos.
- When clamping the suture, make one or more turns around the clamp's tip, before closing the ratchet.

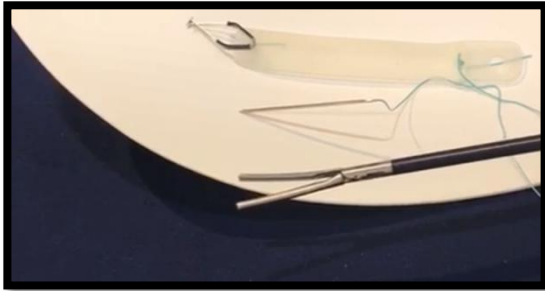


Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

HOW TO DEMONSTRATE

- Make sure you use a prop/object to demonstrate the product on, e.g. a Surgeons Sturgeon (see below)
- When handing product over, make sure to *offer the needle with the blunt /suture side*. Never point/pass the needle tip first
- Have a laparoscopic grasper present, a DeBakey or Hunter type suits clip maneuvering best
- Clip should be placed firmly and deeply for secure suspension. Use edge of prop, not surface (as pictured below)



A grasper is used in the application of the Versa Lifter Band



The Clip is grasped at the widest area



Place clip at the right crus of the diaphragm, being sure to involve enough tissue for clip security



The needle is grasped (use fingers to mimic the left lobe positioned on the band) to determine optimal angle of retraction for field exposure



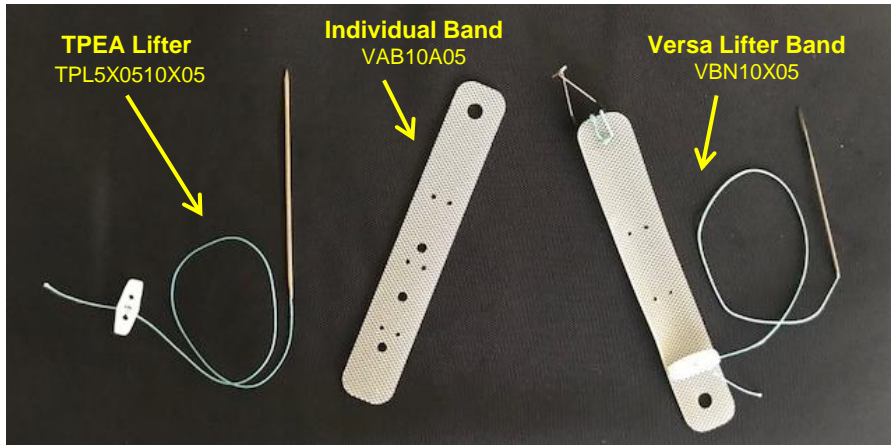
The needle is passed through the abdominal wall and suture is clamped by a mosquito - to be held in place

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

VLB EXTENSION PROCEDURE – For Extra Large Livers

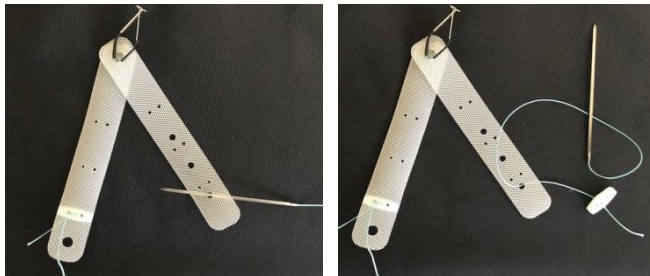
In most cases, the standard Versa Lifter Band provides sufficient suspension of the liver for effective surgical field exposure. For extra large, floppy livers, an extension of VLB is possible to permit more retraction support



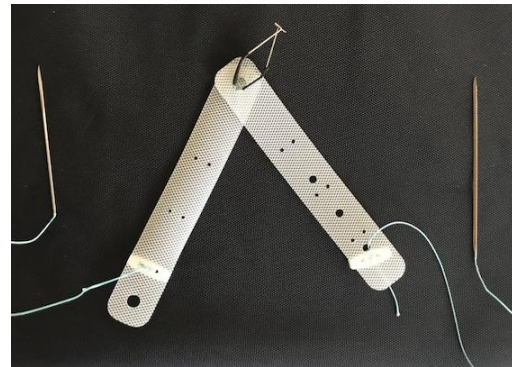
Products needed to create VLB extension – before passing into abdomen



VLB Clip is passed through large hole of Individual Band



The TPEA Lifter Needle can be placed through one of three large holes - to support extra Band suspension



Extension procedure complete



Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

OVERVIEW OF PRODUCT BENEFITS

Cost-Effective

- low-cost disposable device
- eliminates purchase, care and maintenance of several retractor instruments for back-to-back cases
- reduces 1 trocar
- eliminates use of a robotic arm dedicated to retraction

Improved Efficiency

- rapid set-up
- hands-free solution for effective retraction
- reduces procedure and OR time
- eliminates staff person dedicated to retraction
- prevents instrument and robotic arm interference

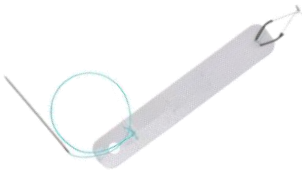


Improved Quality of Care

- less traumatic to liver / organ being suspended
- reduced healing time and discomfort
- better cosmetic result

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

PRODUCT LINE SELECTION GUIDE

Product Type	Product Image	Product Code / Specification	Static Retraction	Dynamic Retraction	Liver Suspension	Bariatric
Versa Lifter Band		VBN10A05 5.0cm Needle	✓		✓	
		VBN10X05 6.5cm Needle	✓		✓	✓
Versa Lifter Needle		VN10A05 5.0cm Needle	✓	✓		
		VN10X05 6.5cm Needle	✓	✓		✓
TPEA Lifter		TPL5A180-B10 5.0cm Needle	✓			
		TPL5X180-B10 6.5cm Needle	✓			✓

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

STERILE PACKAGING

Manufactured for
Mediflex[®]
SURGICAL PRODUCTS

250 Gibbs Road
Islandia, NY 11749 - USA
USA Toll Free: 800-764-0474
Tel: +1-631-582-6424

50 mm

VERSALIFTER BAND
with needle

REF VBN10A

EN Laparoscopic retractor
FR Ecarteur laparoscopique
DE Laparoskopischer Retraktor
ES Retractor laparoscópico
NL Laparoscopische retractor
IT Retratore laparoscopico
PT Retrator laparoscópica

PROTOMEDLABS - Bâtiment Energie
24-26, Bd Gay Lussac - 13014 Marseille - France

1x

STERILE

Rx only

CE 0088

VERSALIFTER BAND
with needle

50 mm


REF VBN10A

LOT XXXXX

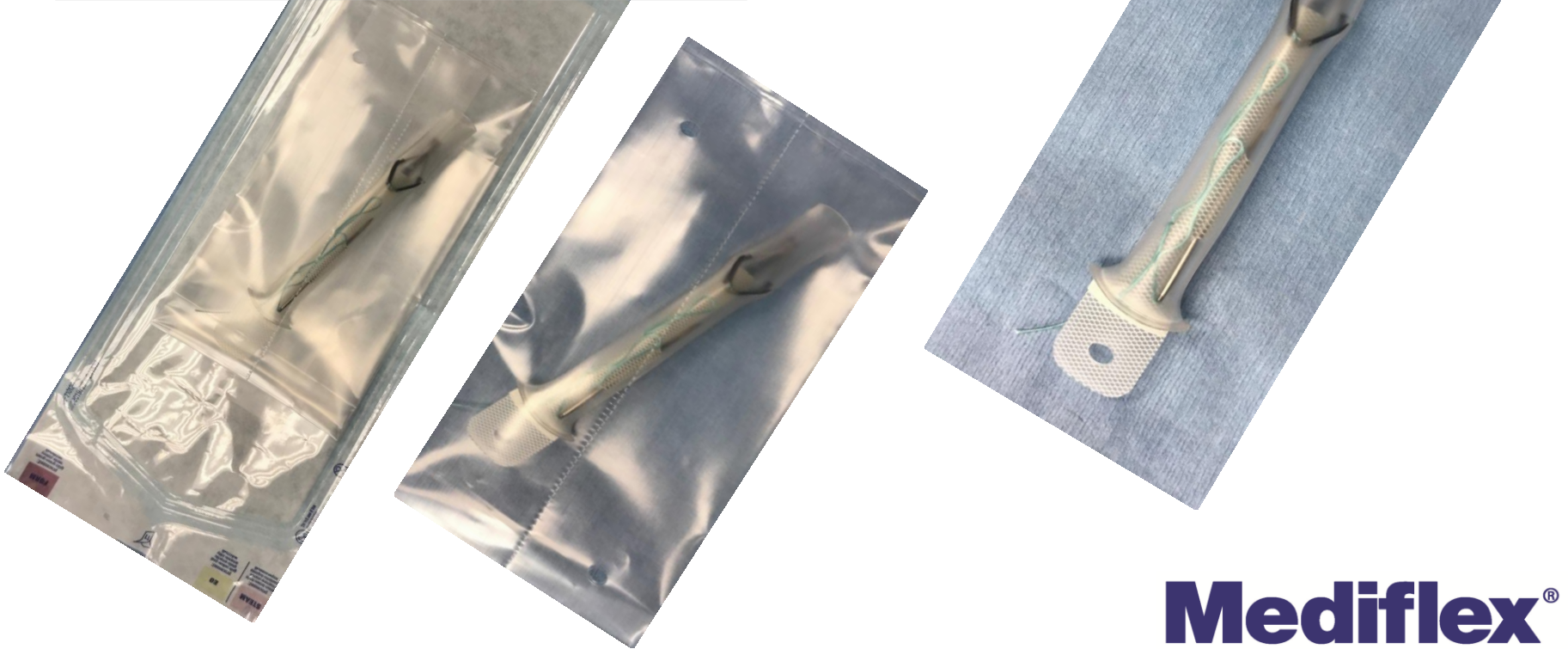
AAAA-MM

CTIN 033700744820649

VBN10AM_ET02a



5 individually wrapped products per box

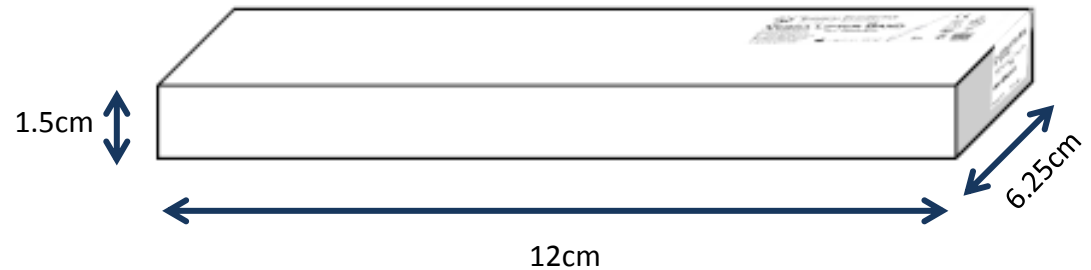
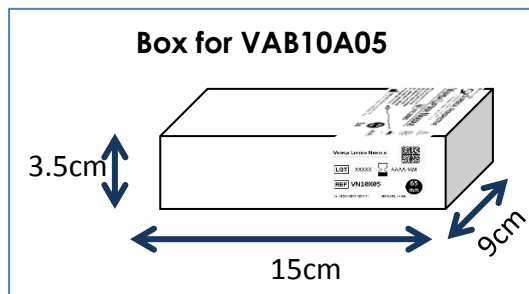
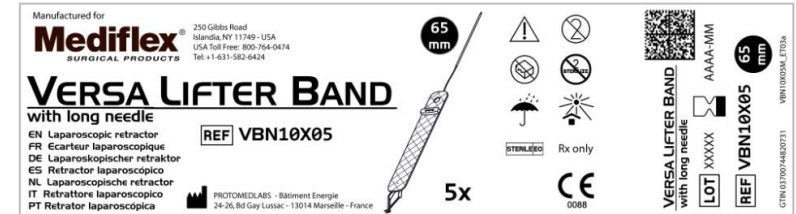
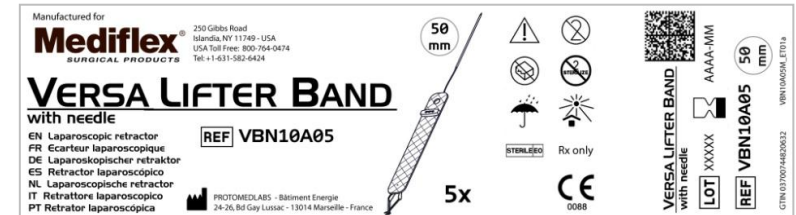


Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

ORDERING INFO & BOX PACKAGING

REF. NO.	DESCRIPTION	MINIMUM TROCAR SIZE	UOM
VBN10A05	Versa Lifter Band – 5cm Needle 18cm Suture, 9.5cm Band	8mm	5/Box
VBN10X05	Versa Lifter Band – 6.5cm Needle 18cm Suture, 9.5cm Band <i>(for bariatric or thicker abdominal wall)</i>	8mm	5/Box
VAB10A05	Individual Versa Lifter Band, 9.5cm Band <i>(for extension purposes - no clip or needle)</i>	8mm	5/Box



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Versa Lifter Band

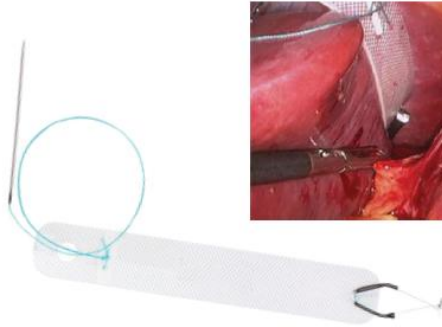

PORT-FREE INTERNAL RETRACTOR

BROCHURE

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SURGICAL PRODUCTS

Versa Lifter Band

DISPOSABLE, PORT-FREE INTERNAL RETRACTORS

- Hands-free solution for optimal surgical field exposure
- Atraumatic, cushioned liver suspension
- Adjustable distance and angle of retraction
- Eliminates port dedicated for retraction – saving time and money
- Fully compatible with robotic procedures
- Easy, rapid set-up


COST-EFFECTIVE • ATRAUMATIC • SECURE

Scan for brochure



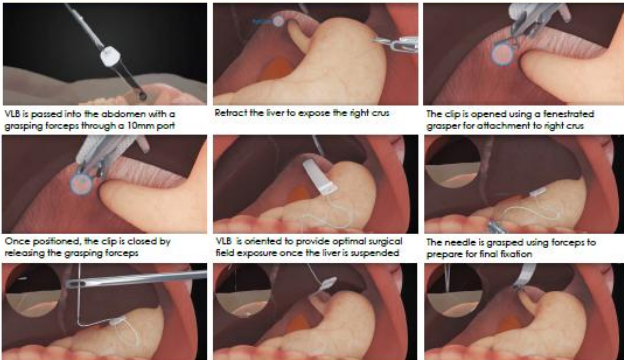
Versa Lifter Band

DISPOSABLE, PORT-FREE INTERNAL RETRACTORS



Versa Lifter Band is a simple, effective solution for atraumatic liver or other organ retraction/suspension during laparoscopic surgery. Versa Lifter Band is set up rapidly and is adjustable intraoperatively. The anchoring clip allows for a strong attachment to support the liver/organ. The needle can be exited through the abdomen wherever needed to adapt to liver/organ size and shape.

APPLICATION OF VERSA LIFTER BAND FOR LIVER SUSPENSION IN UPPER GI SURGERY



VLB is passed into the abdomen with a grasping forceps through a 10mm port

Retract the liver to expose the right crus

The clip is opened using a fenestrated grasper for attachment to right crus

Once positioned, the clip is closed by releasing the grasping forceps

VLB is oriented to provide optimal surgical field exposure once the liver is suspended

The needle is grasped using forceps to prepare for final fixation

The target exit point is evaluated to determine retraction angle for maximum field exposure

The needle penetrates the abdominal wall and suture is pulled to control desired amount of retraction

A hemostat is used to secure the suture and the procedure is ready to start

REF. NO.	DESCRIPTION	MINIMUM TROCAR SIZE	UOM
VBN10A05	Versa Lifter Band – 5cm Needle, 18cm Suture, 9.5cm Band	10mm	5/Box
VBN10X05	Versa Lifter Band – 6.5cm Needle, 18cm Suture, 9.5cm Band (for bariatric or thicker abdominal wall)	10mm	5/Box

www.mediflex.com
Toll-Free USA: 1.800.764.0474
Phone: +1.631.582.6424
Fax: +1.631.582.4520
Email: sales@mediflex.com

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VLB-0318



Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

GENERAL INFO

PRODUCT DESCRIPTION	Versa Lifter Band is an intra-abdominal retractor used in laparoscopic surgery that allows for suspension/retraction of biological tissue for maximum operating field exposure
INTENDED PURPOSE	Laparoscopic surgery, predominantly for liver retraction
ITEM NUMBERS	VLB10A05 – Versa Lifter Band, 5cm Needle VLB10X05 – Versa Lifter Band, 6.5cm Needle VAB10A05 – Individual Versa Lifter Band (for extension)
UOM	Box of 5
HOW SUPPLIED	<ul style="list-style-type: none">▪ Packaged sterile▪ Single-use, disposable▪ Does not require capital equipment
MATERIALS	<ul style="list-style-type: none">▪ Stainless Steel (needle and clip)▪ Coated Polyester (suture)▪ Silicone (band and button) <p><u>Does not contain mercury or latex</u></p>

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

TARGET USER / SPECIALTY	Laparoscopic, bariatric and robotic surgeons
WHERE WILL IT BE USED	Operating room / theater
CLINICAL INDICATIONS	<ul style="list-style-type: none">▪ Liver retraction
CLINICAL BENEFITS	Low-cost, low-profile, sterile retractors which are ready to use and easy to use. Eliminates a port/robotic port and assistant/robotic arm for retraction – all saving time and money.
CONTRA-INDICATIONS	Surgeon is responsible for the choice of biological tissue(s) to be retracted and its piercing location.
WHAT IT REPLACES	<ul style="list-style-type: none">▪ Staff dedicated to manually hold retraction/instrument▪ Robotic arm dedicated to retraction▪ Laparoscopic instrument that needs to be cleaned, sterilized and maintained

Versa Lifter Band

PORT-FREE INTERNAL RETRACTOR

REGULATORY

FDA CLASSIFICATION

Class 1

GMDN TERM NAME

Externally anchored laparoscopic retraction

GMDN CODE

61069

REGISTRATIONS /
CERTIFICATIONS

- FDA
- ISO 13485*
- CE 93/42/EEC*
- Australia – Therapeutic Goods Administration*

The screenshot shows the FDA's public database for Establishment Registration & Device Listing. The page header includes the U.S. Department of Health & Human Services logo and the FDA U.S. Food & Drug Administration logo. A search bar is visible with a 'SEARCH' button. Below the header, there are navigation tabs for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled 'Establishment Registration & Device Listing' and shows a search result for the Versa Lifter Band. The search results include the following information:

Proprietary Name:	ADDITIONAL BAND FOR VBN10, T-PEA LIFTER, TPEA LIFTER, VERSA LIFTER, VERSA LIFTER BAND, VERSA NEEDLE
Classification Name:	RETRACTOR
Product Code:	GAD
Device Class:	1
Regulation Number:	978.4500
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	PROTOMECLABS
Registered Establishment Number:	3010805627
Owner/Operator:	SURGICAL PERSPECTIVE
Owner/Operator Number:	10049264
Establishment Operations:	Manufacturer

** Certificates available upon request*

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Scan to view clinical cases
incorporating Port-Free Retractors



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