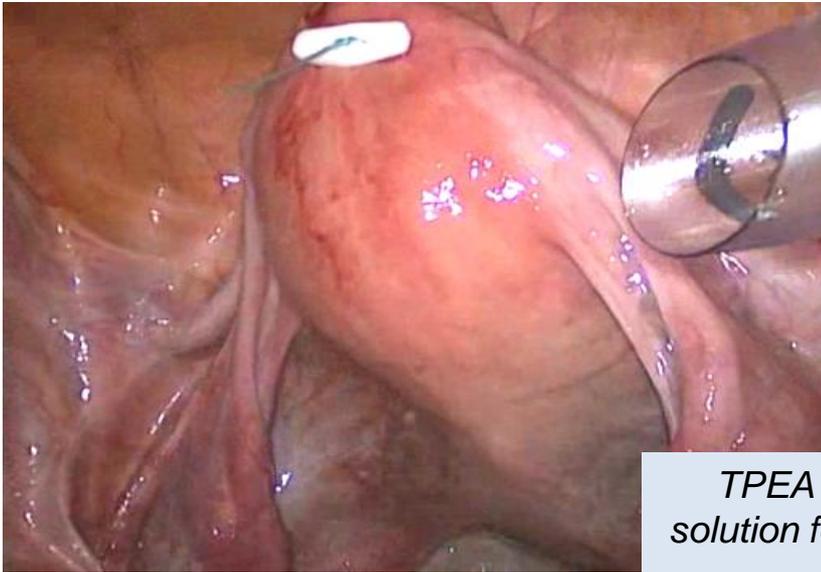


**Mediflex<sup>®</sup>**  
Redefining Retraction.



*TPEA Lifter is an innovative solution for effective laparoscopic retraction. It is incision-less and provides optimal surgical exposure.*

# TPEA Lifter

## Port-Free Internal Retractor



# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### PRODUCT INTRODUCTION



TPEA Lifter is a disposable retractor used to lift organs during laparoscopic procedures. It creates greater space in the abdomen and, improves visibility during the procedure - moving organs or tissues out of the way and, reduces the amount of devices needed in the field.

The TPEA Lifter has a firm, large contact surface and equal pressure distribution design. TPEA Lifter allows up to 2Kg of retraction force, in order to suspend and manipulate the organ.



TPEA Lifter is currently used to suspend the following organs: uterus, sigmoid colon, peritoneum, stomach, gallbladder, bladder - and is fully compatible with robotic procedures.

TPEA Lifter can replace other devices (i.e. uterine manipulator ) in selected procedures, minimizing the uterine cannulation associated risks while giving the surgeon excellent control of the surgical field - in his/her own hands.

# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

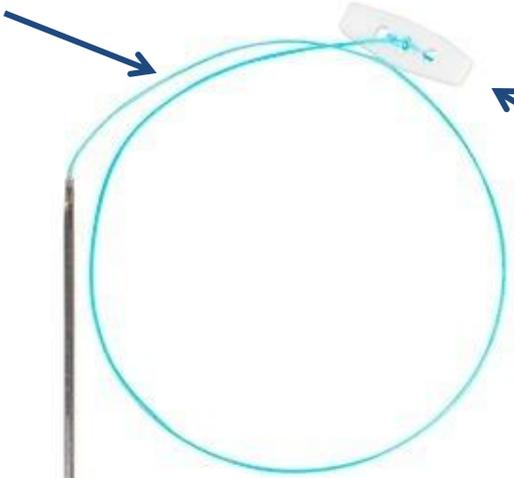
### PRODUCT BENEFITS

- 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 / operating room time
- Fully compatible with robotic procedures
- Adjustable traction, as required by procedure
- Prevents instrument and robotic arm interference
- Reduced patient discomfort and scarring, better cosmetic result
- Two needle lengths to accommodate different abdominal wall thicknesses

# TPEA Lifter

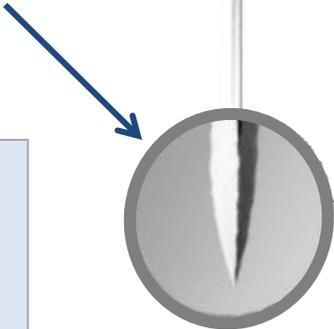
## PORT-FREE INTERNAL RETRACTOR

Coated polyester suture for strong traction



Silicone stabilization device for strong, atraumatic organ suspension/retraction

Triangular needle with tapered precision tip for optimal tissue penetration



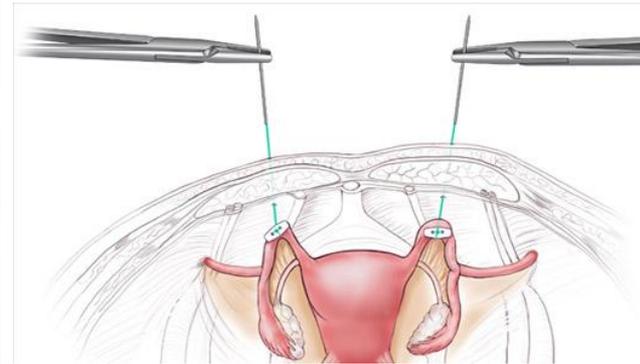
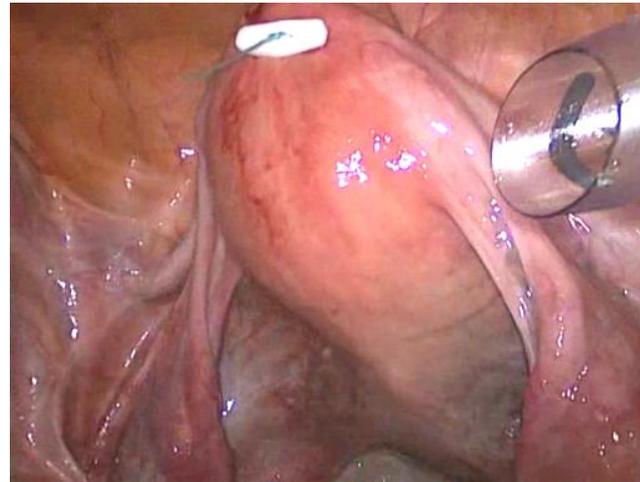
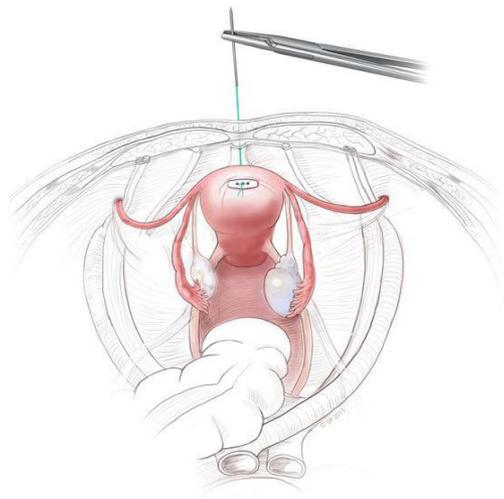
**Needle is available in 5cm and 6.5cm lengths.**

**6.5cm for bariatric procedures or thicker abdominal walls**

# TPEA Lifter

PORT-FREE INTERNAL RETRACTOR

## APPLICATION: Uterus & Adnexa Suspension

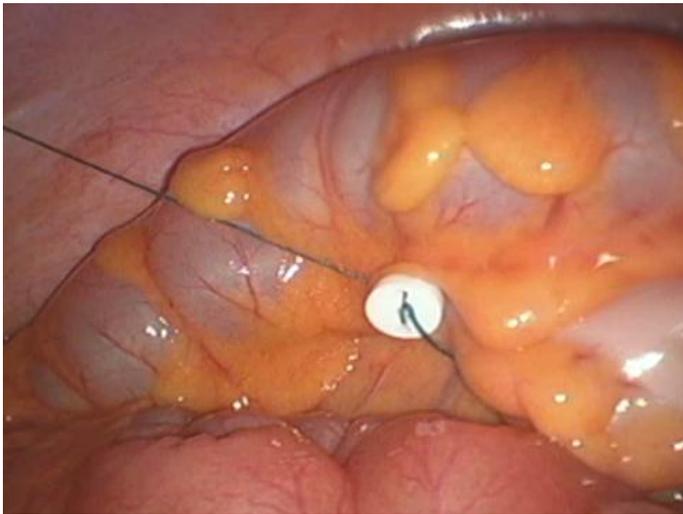


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# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### APPLICATIONS



Sigmoid Colon Retraction

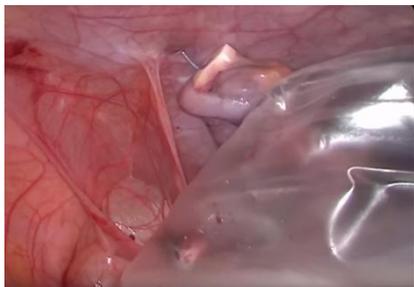


Temporary Mesh Positioning

# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

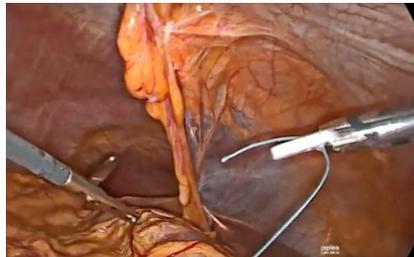
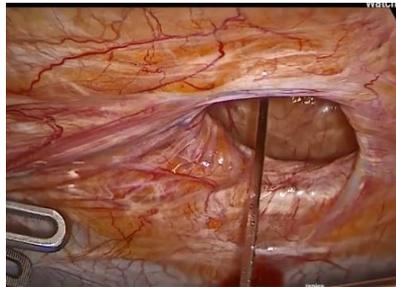
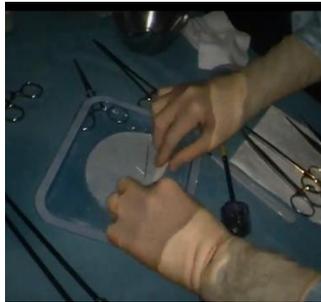
### APPLICATION: Reduced Port Appendectomy



# TPEA Lifter

PORT-FREE INTERNAL RETRACTOR

## APPLICATION: Temporary Mesh Fixation in Lap. Hernia Repair



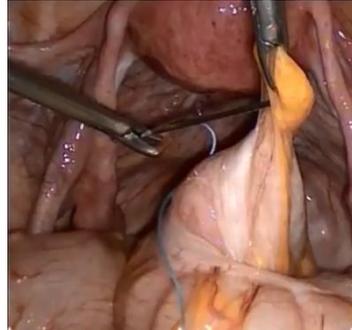
# TPEA Lifter

PORT-FREE INTERNAL RETRACTOR

## APPLICATION: Rectal (Colon) Vaginal Prolaspe



TPEA Lifter is deployed into the abdominal cavity through a 5mm (or greater) port



The retracted tissue can be stitched once...



Twice...



Or more...



Exit point is located, needle is passed through the abdominal wall



Tissue is safely retracted away from the surgical field



Suture is secured using a hemostat once desired retraction is achieved

# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### Possible Extra-Abdominal Needle Management



# TPEA Lifter

## 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 silicone disk through, to avoid needle stick injury intra-abdominally
- 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.

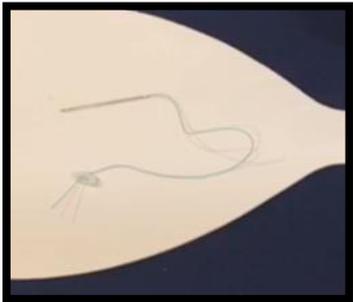


# TPEA Lifter

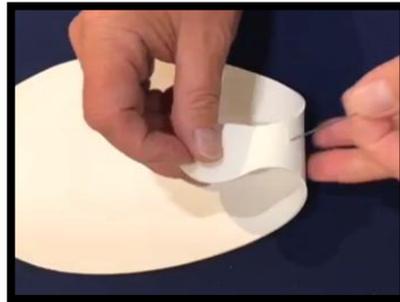
## PORT-FREE INTERNAL RETRACTOR

### HOW TO DEMONSTRATE

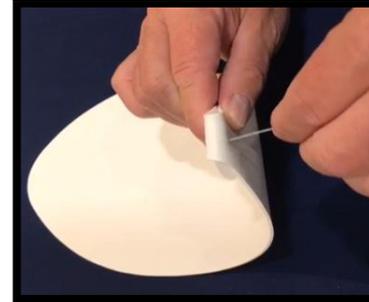
- Make sure you use a prop/object to demonstrate the product on, e.g. a Surgeons Sturgeon (see below)
- When handing product over, make sure to *offer the needle with the blunt /suture side*. Never point/pass the needle tip first
- Have a laparoscopic grasper present, a DeBakey or Hunter type suits clip maneuvering best
- Use the 'tail' of the SS to show how strong it can hold tissue. Let the interested person feel the atraumatic suture – it does not tear tissue when pulled through



TPEA Lifter is highly suitable for colon or uterine retraction



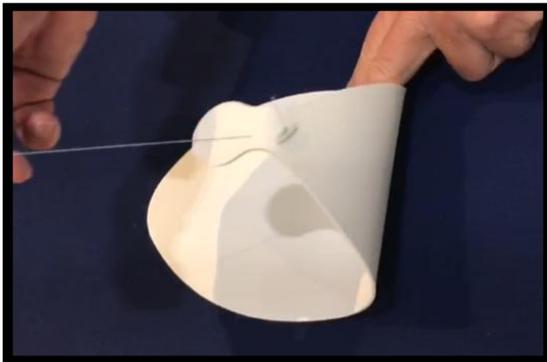
End of SS is used to mimic a uterine fundus



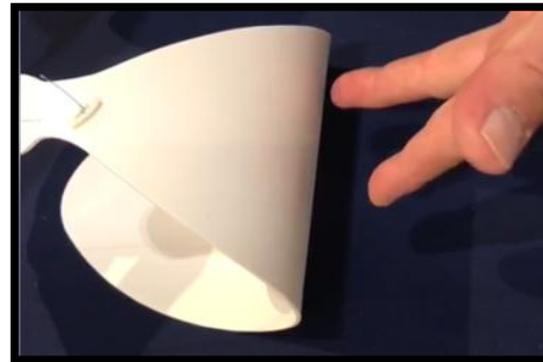
Use a needle holder or forceps to push needle through the tissue



TPEA silicone disc provides strong, atraumatic tissue retraction



TPEA Lifter takes the uterus out of the way



Retraction is achieved by pulling on the suture – making sure you have access under the uterus.

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

# TPEA Lifter

## 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 one trocar
- Eliminates one 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 organ / tissue being retracted
- reduced healing time and discomfort
- better cosmetic result

# TPEA Lifter

## 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	✓			✓

# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### STERILE PACKAGING



10 individually wrapped products per box

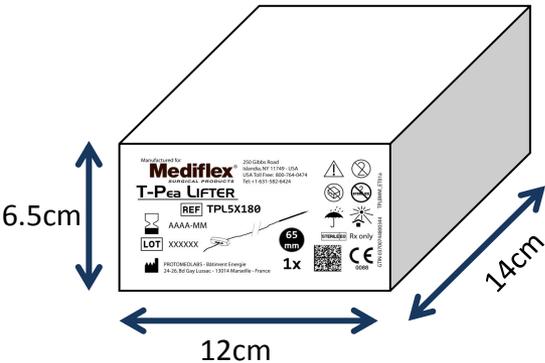


# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### ORDERING INFO & BOX PACKAGING

REF. NO.	DESCRIPTION	MINIMUM TROCAR SIZE	UOM
TPL5A180-B10	<b>TPEA Lifter – 5cm Needle, 18cm Suture</b> 15 x 5mm Elongated Silicone Device	5mm	10/Box
TPL5X180-B10	<b>TPEA Lifter – 6.5cm Needle, 18cm Suture</b> 15 x 5mm Elongated Silicone Device <i>(for bariatric or thicker abdominal wall)</i>	5mm	10/Box



Manufactured for  
**Mediflex**<sup>®</sup>  
 SURGICAL PRODUCTS  
 250 Gibbs Road  
 Islandia, NY 11749 - USA  
 USA Toll Free: 800-764-0474  
 Tel: +1-631-582-6424

**T-Pea LIFTER**

REF TPL5X180

AAAA-MM

LOT XXXXXX

65 mm

1x

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

STERILE EO Rx only

CE 0088

GTIN 03700744800344 TPLBMM\_LF01a

# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### BROCHURE

Scan for brochure



## TPEA Lifter

DISPOSABLE, PORT-FREE INTERNAL RETRACTORS

Ref. No.  
TPLSA180-B10  
For use with min.  
5mm port

Ref. No.  
TPL10A180-B10  
For use with min.  
10mm port

- Hands-free solution for optimal surgical field exposure
- Dynamic suspension with adjustable distance and angle of suspension
- Ideal for uterine suspension or sigmoid retraction in lower pelvic surgeries
- Eliminates port dedicated for retraction – saving time and money
- Fully compatible with robotic procedures
- Easy, rapid set-up

COST-EFFECTIVE • IMPROVED VISIBILITY • SECURE

## TPEA Lifter

### DISPOSABLE, PORT-FREE INTERNAL RETRACTORS

**SIMPLICITY**  
TPEA Lifter provides a simple, effective solution to create more space during laparoscopic surgery

**MAXIMUM EFFICIENCY**  
TPEA Lifter offers secure, low-profile static suspension without interference of operating instruments or robotic arms

**COST-EFFECTIVE**  
By eliminating a port, retraction instrument and assistant – TPEA Lifter saves OR time and money

**VERSATILE**  
TPEA Lifter is highly effective for retraction / suspension of all organs and tissue including: uterus, ovaries, sigmoid colon, peritoneum, colon, stomach, gallbladder and bladder

SIGMOID COLON RETRACTION

TEMPORARY MESH POSITIONING

UTERUS AND ADNEXA SUSPENSION

REF. NO.	DESCRIPTION	MINIMUM TROCAR SIZE	UOM
TPLSA180-B10	TPEA Lifter – 5cm Needle, 18cm Suture, 15 x 5mm Elongated Silicone Device	5mm	10/Box
TPLSX180-B10	TPEA Lifter – 4.5cm Needle, 18cm Suture, 15 x 5mm Elongated Silicone Device (for peritoneal or thicker abdominal wall)	5mm	10/Box
TPL10A180-B10	TPEA Lifter – 5cm Needle, 18cm Suture, 10mm Round Silicone Device	10mm	10/Box

Scan to view Port-Free Internal Retractor video library

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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# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### GENERAL INFO

<b>PRODUCT DESCRIPTION</b>	TPEA Lifter is a disposable intra-abdominal retractor that allows for lifting or retraction of biological tissue for maximum operating field exposure during laparoscopic surgery
<b>INTENDED PURPOSE</b>	To lift/retract organs/tissue for maximum surgical field viewing
<b>ITEM NUMBERS</b>	TPL5A180-B10 – TPEA Lifter, 15x5mm Device, 5cm Needle TPL5X180-B10 – TPEA Lifter, 15x5mm Device, 6.5cm Needle
<b>UOM</b>	Box of 10
<b>HOW SUPPLIED</b>	<ul style="list-style-type: none"><li>▪ Packaged sterile</li><li>▪ Single-use, disposable</li><li>▪ Does not require capital equipment</li></ul>
<b>MATERIALS</b>	<ul style="list-style-type: none"><li>▪ Stainless Steel (needle)</li><li>▪ Coated Polyester (suture)</li><li>▪ Silicone (button device)</li></ul> <p><b><u>Does not contain mercury or latex</u></b></p>

# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

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

# TPEA Lifter

## 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\*

*\* Certificates available upon request*

The screenshot shows the FDA's public database interface. At the top, it displays the U.S. Department of Health & Human Services logo and the FDA U.S. Food & Drug Administration header. A search bar is present with a 'SEARCH' button. Below the header, there are navigation tabs for various FDA categories. The main content area is titled 'Establishment Registration & Device Listing'. A search result is displayed for the 'TPEA Lifter' device. The details listed are:

- 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

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SURGICAL PRODUCTS

# TPEA Lifter

## PORT-FREE INTERNAL RETRACTOR

### INSTRUCTIONS FOR USE

- English
- French
- Italian
- German
- Spanish
- Netherlands

Scan for IFU



REF TPL30B0

REF TPL30B0

REF TPL30B0

PROTEZIONE  
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Mediflex Group  
P - 1024 MARSEILLE

### T-pea Lifter : Laparoscopic retractor

**FR - ECARTEUR LAPAROSCOPIQUE**

**EN - LAPAROSCOPIC RETRACTOR**

**IT - RETRAITORE LAPAROSCOPICO**

**Description**  
Le T-pea Lifter se compose de 2 entités : une pince en alliage radio opaque (P), une tresse polyester (T) sur laquelle une aiguille (A) est aectée (S). Les 2 éléments sont reliés par un trocar.

**Indications d'usage**  
T-pea Lifter s'utilise dans le cadre d'opérations au niveau abdominal compte par voie laparoscopique. Il permet d'écarter des tissus synthétiques ou biologiques dans la limite de 2 kg afin d'offrir un espace opératoire dégagé.

La mise en place de T-pea Lifter par voie mini-invasive se fait au travers d'un trocar de 5mm ou plus, sous contrôle de la caméra au moyen d'une pince de coelioscopie en le saisissant par la partie (P).

Les précautions usuelles de manipulation d'une aiguille sont à respecter par l'équipe chirurgicale.

**Recommandations / Avertissement**  
Pour la première utilisation, les utilisateurs doivent avoir pris connaissance de la présente notice d'utilisation.  
Vérifier l'intégrité du conditionnement primaire avant utilisation. Ne pas utiliser au-delà de la date de péremption indiquée sur l'étiquette de l'emballage.  
Utiliser le produit avec les mêmes précautions que celles requises pour la manipulation des aiguilles.

**Contre Indications**  
Le choix des tissus biologiques à écarter au moyen de T-pea Lifter et le lieu de ponction sont du ressort du chirurgien.

**Méthode**  
La mise en place de T-pea Lifter par voie mini-invasive se fait au travers d'un trocar sous contrôle de la caméra. Le chirurgien saisit la partie (P) à l'aide d'une pince de coelioscopie et l'introduit jusqu'à ce que l'aiguille ait franchi le trocar.

**Instructions d'utilisation**  
Saisir la partie (P) à l'aide d'une pince de coelioscopie et introduire celui-ci au travers d'un trocar avec l'aiguille tenant jusqu'à ce qu'elle ait franchi le trocar.

Saisir et manipuler l'aiguille en le saisissant à sa plus près de la zone de sectionage (S).

Transpercer le tissu à écarter à l'endroit approprié, puis transpercer le paroi abdominale. Un assistant récupère, tend et bloque le fil par une pince de maintien à l'extérieur de l'abdomen et coupe le fil afin de séparer la partie supérieure.

Pour retirer T-pea Lifter, saisir le fil sous la partie (P) à l'aide d'une pince de coelioscopie pendant qu'un assistant oblique le fil à l'extérieur de l'abdomen. Sortir le T-pea Lifter au travers du même trocar en le tenant au moyen d'une pince de coelioscopie préférentiellement par la partie (P) (à défaut par le fil) et vérifier son intégrité.

**Complications / Risque / Effets secondaires**  
Pas de complications, pas d'effets secondaires connus à ce jour. L'utilisation peut être indiquée à un patient de forte corpulence.

**Conditionnement / Stérilisation**  
T-pea Lifter est livré stérile. Le T-pea Lifter est un dispositif à usage unique. La réutilisation du dispositif peut permettre pas de garantir la résistance de la liaison entre la pince en alliage (P) et le fil et peut entraîner le déconditionnement de celui-ci pendant l'acte chirurgical.

**Stockage**  
Conserver précautionneusement les T-pea Lifter dans leurs emballages d'origine. Stocker les produits en attente d'utilisation dans un endroit frais et sec à l'abri de la lumière et des chocs en veillant à respecter les procédures de maintien de la stérilité.

Le conditionnement primaire ne doit être ouvert qu'au moment de l'utilisation dans un environnement aseptique.

**Mise au rebut**  
Respecter les exigences réglementaires locales en vigueur pour la mise au déchet. Après usage, le système T-pea Lifter doit être considéré comme un déchet d'activité de soins. Les aiguilles sont à considérer comme des déchets perforants.

**Garantie**  
T-pea Lifter est garanti dans la limite du délai de péremption contre tout défaut de fabrication et de fonctionnement. (S un défaut se produit durant cette période, les remplacements seront effectués sous la réglementation et les conditions de vente).

La garantie ne couvre pas les défauts ou dommages causés par :  
- un non respect de la présente notice  
- l'usage d'instruments et de matériel incompatibles avec le produit  
- des circonstances accidentelles

**Description**  
T-pea Lifter consists of 2 entities: a radio-opaque alloy piece (P), a braided polyester thread (T) with crimped (S) needle (A). The 2 elements are connected by a hook.

**Indications of use**  
T-pea Lifter is used during operations at the abdominal level including laparoscopic surgery. It is designed to retract synthetic or biological tissues up to 2kg to increase surgical field space.

Introduction of T-pea Lifter by laparoscopic surgery is done through a 5mm trocar or larger under control of the camera using a laparoscopic grasper by holding the piece (P).

Usual precautions when handling needles must be carefully respected by the surgical team.

**Recommendations / Warning**  
Read instructions herein before using the device.  
Check packaging integrity before use.  
Do not use the product after the expiration date indicated on the label.  
Use standard precautions when handling needles and sharps.

**Contraindications**  
Surgeon is responsible for the choice of biological tissues to be retracted and its piercing location.

**Method**  
Introduction of T-pea Lifter by laparoscopic surgery is done through a 5 mm trocar or larger under control of the camera. The surgeon holds the section (P) using laparoscopic graspers and introduces the retractor through the trocar until the needle crosses the trocar.  
Then the surgeon handles the T-pea Lifter using a laparoscopic grasper to hold the needle close to the crimped end (S).

**Instructions for use**  
Hold the retractor from section (P) using a laparoscopic grasper.  
Introduce the retractor through a 5 mm trocar or larger leaving the needle trailing behind until it has entirely crossed the trocar.  
Then hold the needle close to the crimped end (S).  
Pierce the tissue to be retracted at the appropriate location. Then pierce through the abdominal wall. Recover, tighten and block the thread by holding it outside the abdomen. Cut the needle from its thread (P) using a laparoscopic grasper while releasing the thread outside the abdomen.  
Remove the T-pea Lifter through the same trocar and check its integrity.

**Complications/Risks/Side effects**  
No complications, no side effects reported to date. Use of product may not be indicated for corpulent patient.

**Packaging / Sterilization**  
T-pea Lifter is delivered sterile.  
T-pea Lifter is a single use device. Re-use of the device may compromise the strength of the connection between pin and suture strength and can involve disconnection of those during the surgical act.

**Storage**  
Store the T-pea Lifter in its original packaging.  
Store the device in a fresh dry area, keep away from sunlight and shocks.  
Preserve devices aseptically.  
Packaging should only be opened at the time of the use in a sterile environment.

**Waste management**  
Respect the local requirements for surgical waste disposal and management.  
After use, the T-pea Lifter must be handled as a surgical waste. Needles are to be handled as perforating surgical waste.

**Guarantee**  
T-pea Lifter is guaranteed until its expiration date against any manufacturing and functional defects. (If a defect occurs during this period, the replacement will be carried out according to purchasing agreements and in compliance with regulations.)

The guarantee does not cover defects or damage caused by:  
- Misuse  
- Use against instructions herein  
- Use with incompatible or defective instruments and material  
- Accidental circumstances

**Controindicazioni**  
Il chirurgo è responsabile della scelta nell'incrocio dei tessuti e della relativa trazione.

**Metodo**  
L'insertamento mini-invasivo del T-pea Lifter avviene attraverso l'uso di un trocar di almeno di 5 mm, con l'aiuto di un trocar. Il chirurgo afferra la parte (P) del T-pea Lifter, utilizzando un trocar, inserendo il trocar facendo passare l'ago per tutta la sua lunghezza.  
Poi il chirurgo tiene il T-pea Lifter con una pince e trattando l'ago vicino la cruna dell'ago (S).  
Trifurare il tessuto per essere retractor per poi successivamente perforare la parete addominale. Un assistente recupera, stringe e blocca le suture esternamente all'addome e taglia il filo in modo da rimuovere l'ago.  
Per ritirare il T-pea Lifter, afferrare il filo sotto la parte (P) con un grasper mentre un assistente rilascia il filo fuori dall'addome.  
Per uscire il T-pea Lifter dal trocar di almeno 5mm, tenendo premuto la parte (P) (se non fosse possibile tenere premuto il filo) utilizzando una pince di presa verificandone la sua integrità.

**Complicanze / Rischio / Effetti collaterali**  
Nessuna complicazione, nessun effetto collaterale conosciuto ad oggi. Il suo utilizzo può essere indicato nei pazienti obese.

**Imballaggio / Sterilizzazione**  
Il prodotto viene consegnato sterile. T-pea Lifter è un dispositivo monouso. Non riutilizzare il prodotto al fine di garantire l'integrità il risultato del dispositivo non è possibile in quanto potrebbe non garantire la forza delle suture e la tenuta di la parte in alliage (P), evitando addirittura a causare la disconnessione durante l'uso.

**Conservazione**  
Conservare il prodotto nel suo imballaggio originale. Conservare il prodotto in un luogo asciutto al riparo dai raggi del sole ed evitare colpi. Manipolare con cura per garantire la sterilità.  
La confezione può essere aperta solo nel momento dell'utilizzo in un luogo sterile.

**Smaltimento**  
Seguire le regole locali per la gestione dei rifiuti, utilizzando le normali norme dei rifiuti chirurgici. Gli aghi possono perforare i contenitori dei rifiuti.

**Garanzia**  
T-pea Lifter viene garantito in caso di difetti di fabbricazione o funzionali, fino alla data di scadenza riportata sull'etichetta. Se il difetto si presenta durante questo periodo la sostituzione sarà effettuata secondo al regolamento e le condizioni di vendita.  
La garanzia non copre difetti o danni causati da uno dei casi sotto riportati:  
- un uso scorretto  
- non rispetto delle istruzioni sulla presente nota  
- l'impiego di strumenti e materiali incompatibili con il prodotto;  
- circostanze accidentali



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