

Precautions:

- Do not exceed 12 atmospheres.
- This device should be used only by surgeons having adequate training in hand surgery.
- The Inflatable Balloon Elevator/Expander and inflation device are provided sterile and are intended for single use only. Discard after use. Do not re-sterilize.

How Provided:

- The Inflatable Balloon Elevator/Expander and inflation device are provided sterile and are intended for single use only. Discard after use. Do not re-sterilize.

STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES

CONTRINDICATIONS

1. This device is intended for use only as indicated
2. This device is contraindicated in patients with previous fractures of the hand or wrist, history of previous open or endoscopic carpal tunnel surgery, metabolic disorder such as diabetes, renal failure, thyroid dysfunction, or pregnancy.

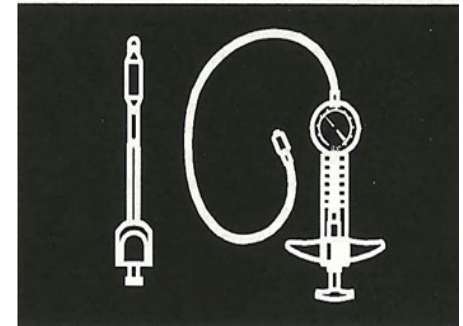
STERILIZATION

The LB Medical Hand/Restraint Stabilizer is provided NONSTERILE and MUST be sterilized prior to use. The LB Medical Hand/Restraint Stabilizer should be disassembled prior to sterilization. Please refer to the information booklet for the LB Medical Hand/Restraint Stabilizer for cleaning and sterilization information, as this product is sold separately.

Manufacturer:
LB Medical, LLC
895 Mohawk Road
Franklin Lakes, New Jersey 07417



**LB Medical
Inflatable Tissue Elevator
Expander System**



Instructions for Use

General Description:

The LB Medical Inflatable Tissue Elevator/Expander System consists of a balloon preloaded on an elevator (the Balloon Elevator Assembly). The balloon is inflated with sterile solution, thereby increasing the space between adjacent tissues. The LB Medical Inflatable Tissue Elevator/Expander System also includes a syringe and tubing used for balloon inflation and a gauge to monitor the pressure inside the balloon during inflation and deflation

Directions:

1. Open sterile package and remove the Inflatable Tissue Elevator/Expander.
2. Remove the protective tube covering the balloon.
3. Attach the female end of the Inflatable Tissue Elevator/Expander to the inflation syringe that is filled with sterile saline solution.
4. Prior to balloon expansion the Inflatable Tissue Elevator/Expander can be used as a traditional manual elevator (or blunt probe, freer, dilator, or grooved director).
5. For tissue elevation/expansion, insert the blunt end of the Tissue Elevator/Expander under the tissue to be elevated.
6. For use in hand surgery: When there is a need to protect tissue structures under the Inflatable Tissue Elevator/Expander (such as to protect the median nerve when dilating the carpal tunnel), then the shaft of the Inflatable Tissue Elevator/Expander should be placed into the guide of the associated Hand Positioner device prior to balloon inflation. Placing the Inflatable Tissue Elevator/Expander in the guide of the Hand Positioner ensures that the Inflatable Tissue Elevator/Expander will not be moved or displaced during balloon inflation.
To secure the Inflatable Tissue Elevator/Expander into the Hand Positioner guide:
 - Place the shaft of the Inflatable Tissue Elevator/Expander into the Hand Positioner guide and lock in place by sliding the lock over the shaft.
 - Turn the adjusting screw clockwise to secure the shaft within the guide.
7. For all uses: Confirm the position of the Inflatable Tissue Elevator/Expander by visualization and/or digital palpation. When the Inflatable Tissue Elevator/Expander is in the desired location, inflate the balloon to move the tissue. The balloon can be serially inflated and deflated and the Inflatable Tissue Elevator/Expander can be manually moved along the desired tissue plane. To inflate the balloon:
 - Fill the syringe with sterile solution and purge the air from the connecting catheter.
 - Connect the catheter to the luer connector of the Inflatable Tissue Elevator/Expander.
 - Inject the sterile solution into the balloon by turning the syringe knob clockwise to achieve a balloon pressure of up to 12 atmospheres.
 - Monitor balloon expansion by observing the pressure gauge monitor attached to the syringe. (Do not exceed the maximum balloon pressure of 12 atmospheres marked on the gauge.)

- After tissue elevation or expansion is completed or when dilation is no longer needed for the surgical procedure, deflate the balloon by turning the syringe knob counterclockwise. After deflating the balloon, remove the Inflatable Tissue Elevator/Expander and proceed with the surgical procedure as planned.



BEFORE USING PRODUCT READ THE FOLLOWING INFORMATION THOROUGHLY AND THE INFORMATION BOOKLET FOR THE LB MEDICAL INFLATABLE ISSUE ELEVATOR/EXPANDER SYSTEM

IMPORTANT!

This booklet is designed to assist in using the LB Medical inflatable Tissue Elevator Expander System. It is not a reference to surgical arthroscopic techniques

CAUTION: Federal (USA) law restricts this device to sale and use by or on the order of a physician

INDICATIONS

The LB Medical inflatable Tissue Elevator Expander System consists of a balloon which is inflated with sterile saline, thereby stretching the transverse carpal ligament and relieving pressure on the median nerve

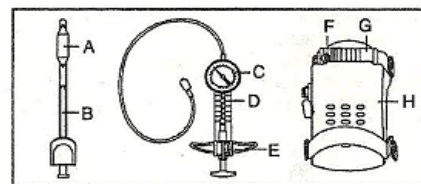
EFFECTS

The balloon is placed percutaneously using a nerve protector tube which fits into the adjustable nerve protector guide on the LB Medical Hand/Restraint Stabilizer. This system contains a syringe to deliver sterile saline into the balloon and a gauge to monitor the pressure of the balloon during inflation and deflation.

Indications for Use:

The LB Medical Inflatable Tissue Elevator/Expander System is a surgical tool intended for use as a conventional manual elevator for orthopedic or general surgery, including use to access the carpal tunnel region during carpal tunnel release procedures.

Schematic of Inflatable Tissue Elevator/Expander (A, B), Inflation Device (C,D,E), and Hand Stabilizer (sold separately for use in hand surgery, shown in F,G,H):



- A – Inflatable Tissue Elevator/Expander, Balloon Component
- B – Inflatable Tissue Elevator/Expander, Shaft Component
- C – Inflation Device, Gauge
- D – Inflation Device, Syringe
- E – Inflation Device, Release Lever

Optional components for use during hand surgery:

- F – Associated Hand Stabilizer (sold separately), Adjusting Screw
- G – Associated Hand Stabilizer (sold separately), Guide/Lock Assembly
- H – Associated Hand Stabilizer Assembly (sold separately)