GENERAL WARNING

As with all surgical procedures, there are risks and benefits while performing a Burch Sling procedure using Tri-Lift.

- Medical personnel should yield careful consideration to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents
- Vaginal and urinary tract infection should be treated prior to the Burch Sling procedure
- User should be well-versed and familiar with surgical procedures and techniques using surgical sutures and non-absorbable and absorbable meshes
- Pristine surgical practices should be followed to prevent contamination or infection

PRECAUTIONS

- The use of surgical sutures in urogynecologic procedures such as the treatment of stress urinary incontinence regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with causes of erosion and certain risk factors that need to be considered when determining whether the patient is an appropriate candidate for this procedure using Tri-Lift
- Standard surgical procedures, followed by the standard management of contamination or infected wounds should be followed
- Bleeding may occur. It is vital to check the patient carefully before discharging them from the hospital
- Physician should determine when it is most suitable for each patient to resume normal activities, as well as vigorous activities and intercourse after the surgical procedure

POST PROCEDURAL WARNING

- If subsequent infection occurs, follow appropriate medical intervention practices as advised by medical personnel
- The patient should be advised that future pregnancies may or may not negate the effects of the Burch Sling procedure and the patients may again become incontinent

ADVERSE EFFECTS

The following adverse effects have been reported due to the Burch Sling procedure, but are not limited to:

- Irritation at the wound site and/or a foreign body response
- Allergic reaction
- Tissue responses including, but not limited to scarring and inflammation
- Known risks of surgical procedures for the treatment of incontinence include:
- Temporary and ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
- Infection
- Voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
- Bruising, bleeding (vaginal, hematoma formation)
- Abscess
- Vaginal discharge
- Edema and erythema at the wound site
- Perforation or laceration of vessels, nerves, bladder, urethra, bowel or other tissues may occur during placement
- The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention

Tri - Lift

INSTRUCTION MANUAL

INDICATION FOR USE

- Non-absorbable or absorbable suture is intended for the surgery of burch sling procedure for the treatment of a pelvic organ prolapse that causes urinary incontinence by using the TriLift device.
- The suture is intended to be used to lift the bladder neck and anchor it back up, connecting it to the cooper's ligament for the correction of urinary incontinence and pelvic organ prolapse.

DEVICE DESCRIPTION

TriLift consists of three pieces:
Body, Double Prong Stylet, Ligature Carrier Needle and comes in two types--disposable and non-disposable

WARNING

- Product is sterile - do not use if the sterile barrier is defected or damaged
- One time use only, do not reuse or re-sterilize. This can create risk to the patient that may lead to patient injury or even death
- After use of the device, dispose of packaging and excess materials following the hospital guidelines

CONTRAINDICATIONS

Birch Sling procedure is prohibited in the following patients :

- Pregnant patients, patients with potential for future growth of patients that are considering future pregnancies
- Any patients with soft tissue pathology into which the suture is to be placed
- Patients with any pathology which would compromise suture placement
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing

HOW SUPPLIED:
TriLift is supplied either in sterile disposable package or as a non-sterile stainless steel.

HANDLING AND STORAGE:
Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to expiration date on package label.

DIRECTIONS FOR USE

Prior To Use

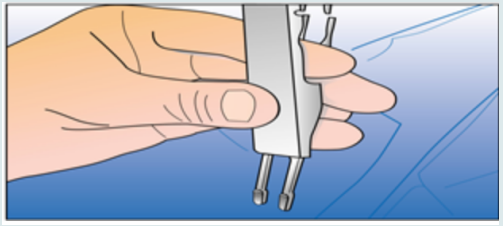
Carefully examine the disposable TriLift to verify neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately discard. If using stainless steel TriLift, then follow sterilization steps in IFU prior to use.

Prepare and drape the patient using standard surgical practice.

Warning:
Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

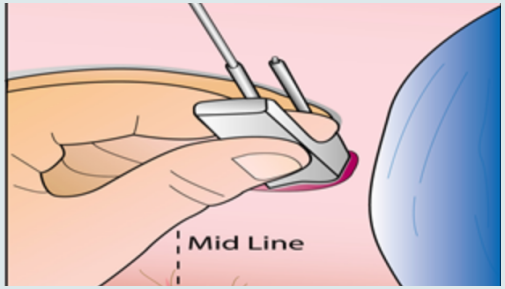
STEPS

The procedure involves retropubic urethropexy using FDA registered TriLift device.

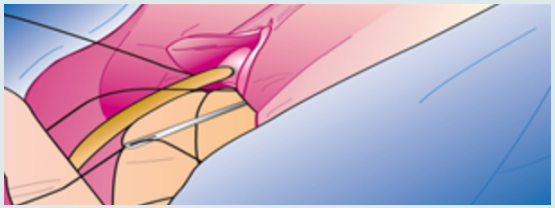


- Locate the ureterovesical junction, and Bilateral Suprapubic incision

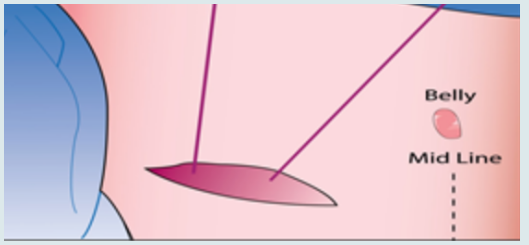
- TriLift device is gently positioned at the edge of the iliopectineal line



- The double- pronged stylet is withdrawn and the double-pronged sleeve is left in place. The ligature carrier then passes through the inner sleeve of the sling

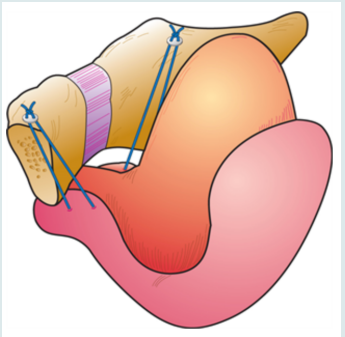


- One end of the previously placed suture is threaded through the eye of the ligature carrier



- The ligature carrier is than passed through the outer sleeve of the sling device. The other end of the suture is brought to the outer side of the suprapubic incision.

- The suspension suture should be tied after cystoscopy



- Suspension sutures fixed under the endopelvic fascia are anchored to the pectineal line or coopers ligament

CAUTION

- Federal law restricts this device to authorized sale by or on the order of a clinician **trained properly using TriLift device** in the Birch Sling cystouresthropexy procedure for the repair of female pelvic organ prolapse and/or urinary incontinence