

In-Fast™ Ultra

Transvaginal Bladder Neck Support System

Instructions for Use

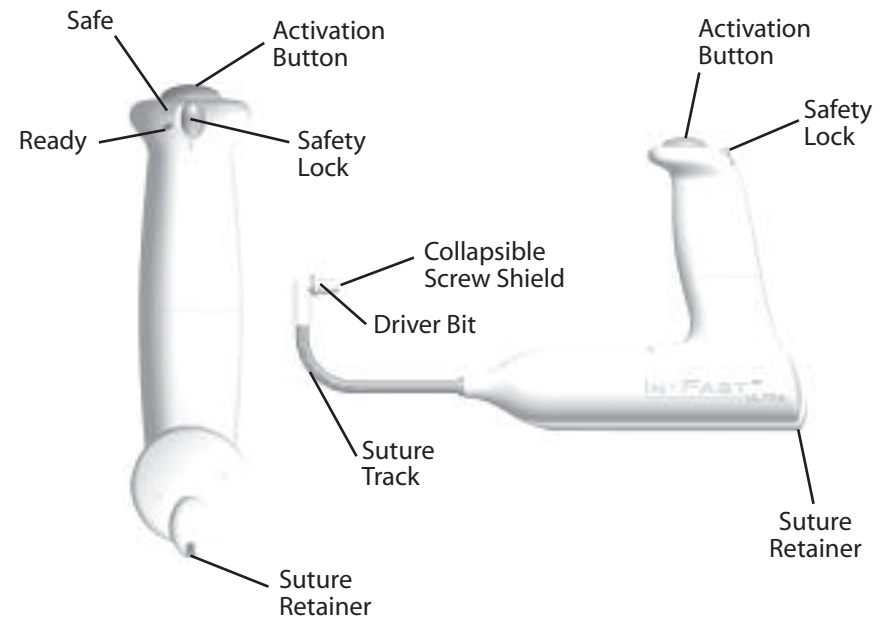
In-Fast™ Ultra Transvaginal Bladder Neck Support System
Instructions for Use

DESCRIPTION

The In-Fast™ Ultra Transvaginal Bladder Neck Support System is an innovative technology that allows sling and concomitant repair surgery to be performed using a minimally invasive transvaginal approach, thus avoiding abdominal incisions and their associated recovery. The In-Fast Ultra Transvaginal Bladder Neck Support System accommodates a variety of sling materials and dissection techniques.

The In-Fast Ultra Transvaginal Bladder Neck Support System consists of the following:

- In-Fast Ultra Inserter
- Two In-Fast Ultra Screws with attached polypropylene suture or Teflon-impregnated, polyester, braided suture



PRINCIPLE OF OPERATION

The In-Fast Ultra Transvaginal Bladder Neck Support System utilizes the Inserter to place two In-Fast Ultra Screws into the pubic bone. Sutures attached to the In-Fast Ultra Screws are used to suspend the physician's preferred sling material from the pubic bone. The Inserter, a battery powered disposable tool, allows the screws to be driven into the bone medulla. The screw, a miniature titanium screw, has a sharp tip that facilitates its penetration into bone and a self-tapping design to eliminate the need for pre-drilling. The standard screw has a #1 polypropylene suture attached. A screw with #1 braided, Teflon-impregnated, polyester suture attached is also available.

INDICATIONS

The In-Fast Ultra Transvaginal Bladder Neck Support System is intended for soft tissue fixation to the pubic bone by means of bone screws with attached suture. The In-Fast Ultra Transvaginal Bladder Neck Support System is indicated for vaginal sling and cystourethropexy procedures for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

The device is contraindicated in patients with:

- Pubic bone deformation or other pathological conditions of the bone, such as severe osteoporosis, which would impair secure screw fixation.
- Blood coagulation disorders.
- Compromised immune system.
- Urinary tract or vaginal infections.
- Previous or active osteomyelitis.
- Renal insufficiency and upper urinary tract relative obstruction.

PRECAUTIONS

The following precautions should be taken:

1. The In-Fast Ultra Transvaginal Bladder Neck Support System should be used only by trained physicians and staff.
2. Inspect the sterile packaging of the screws and Inserter for visible damage prior to use. Do not use if damage is suspected.
3. Do not reuse either the Inserter or the screws. These are single-use products.
4. Thoroughly disinfect the vaginal surgical field before screw insertion.
5. Cystoscope after placing the screws to verify that there are no bladder or urethral perforations.
6. Ensure that there is space between the neck of the Inserter and the pubic bone,

when positioning the device. If there is inadequate space, the neck of the inserter may interfere with the deployment of the screws.

7. Counsel the patient to avoid physical strain and lifting for two to three months after the procedure.
8. Note the distance between the In-Fast Ultra head and the curve in the neck; use care when determining where to position the screws on the pubic bone.
9. Patients who are planning future pregnancies should be carefully considered and counseled prior to receiving a stress urinary incontinence procedure.

PACKAGING AND STERILITY

The In-Fast Ultra Transvaginal Bladder Neck Support System is supplied sterile(EtO) for single-patient use only. It is available in a package that includes the In-Fast Ultra Inserter and two (2) screws with attached suture. In addition, all components are supplied separately. All sterile packaging should be inspected for damage and expiration prior to use. Do not use if it is suspected that sterility has been compromised.

COMPLICATIONS

Complications associated with the In-Fast Ultra Transvaginal Bladder Neck Support System include those associated with current surgical procedures for the treatment of stress urinary incontinence. There is the possibility of continued or worsened stress incontinence symptoms and/or the onset, worsening, or continuation of urge incontinence symptoms. Overcorrection may cause temporary or permanent lower urinary obstruction. There are known risks of surgical infection. Osteitis pubis and osteomyelitis are rare but potential complications. If screw insertion results in bladder perforation, the threads should be cut with scissors cystoscopically, or simply pulled out from the vaginal direction and a replacement screw inserted.

POLYPROPYLENE SUTURE/SCREW LOADING PROCEDURE

1. Confirm that the safety lock of the Inserter is in the V (Safe) position.
2. Thread the looped end of the attached suture through the hole in the bit of the Inserter and advance the suture until it is pulled through to the other side of the bit.
3. Pull on the end of the suture until the screw approaches the bit of the Inserter. Then, grasping the screw by its holder, seat the base of the screw into the inserter bit, ensuring that the screw base and the inserter bit are properly aligned. Be sure to seat the screw fully in the inserter bit. Full seating occurs when the screw holder dislodges with a click; the holder is then discarded.
4. Grasping the end of the suture once more, lay the suture flat inside the external suture track.
5. At the end of the suture track is a plastic suture retainer. This retainer holds the

suture in place and keeps it taut. Make sure both sutures are retained.

6. With the suture and screw in place, move the safety lock to the V (Ready) position. Depress the activation button and visually confirm screw rotation as the inserter bit turns. The screw should not wobble.
7. Return the safety lock to the V (Safe) position. The inserter is now ready for use.

This procedure is repeated for each subsequent screw loaded into the Inserter.

BRAIDED SUTURE/SCREW LOADING PROCEDURE

1. Confirm that the safety lock of the Inserter is in the V (Safe) position.
2. Using the metal threader, thread the braided suture through the hole in the bit of the Inserter.
3. Pull the threader with attached suture until the screw approaches the bit of the Inserter. Then, grasping the screw by its holder, seat the base of the screw into the inserter bit, ensuring that the screw base and the inserter bit are properly aligned. Be sure to seat the screw fully in the inserter bit. Full seating occurs when the screw holder dislodges with a click; the holder is then discarded. At this point, no screw wobble should be seen.
4. Grasping the end of the suture once more, lay the suture flat inside the external suture track.
5. At the end of the suture track is a plastic suture retainer. This retainer holds the suture in place and keeps it taut. Make sure both sutures are retained.
6. Cut the metal threader from the suture.
7. With the suture and screw in place, move the safety lock to the V (Ready) position. Depress the activation button and visually confirm screw rotation as the inserter bit turns. The screw should not wobble.
8. Return the safety lock to the V (Safe) position. The inserter is now ready for use.

This procedure is repeated for each subsequent screw loaded into the Inserter.

ALTERNATIVE SUTURE/SCREW LOADING PROCEDURE

For maximum device performance, size #1 suture is recommended.

1. Remove the suture provided with the screw.
2. Thread suture of choice through the eyelet of the screw.
3. Confirm that the safety lock of the Inserter is in the V (Safe) position.
4. Grasp the cut ends of the suture and feed them through the hole in the bit of the Inserter and advance the suture until it is pulled through to the other side of the bit.
5. Pull on the ends of the suture until the screw approaches the bit of the Inserter. Then, grasping the screw by its holder, seat the base of the screw into the inserter bit, ensuring that the screw base and the inserter bit are properly

aligned. Be sure to seat the screw fully in the inserter bit. Full seating occurs when the screw holder dislodges with a click; the holder is then discarded.

6. Grasping the cut ends of the suture, lay the suture flat inside the external suture track.
7. At the end of the suture track is a plastic suture retainer. This retainer holds the suture in place and keeps it taut. Make sure both sutures are retained.
8. With the suture and screw in place, move the safety lock to the V (Ready) position. Depress the activation button and visually confirm screw rotation as the inserter bit turns. The screw should not wobble.
9. Return the safety lock to the V (Safe) position. The inserter is now ready for use.

This procedure is repeated for each subsequent screw loaded into the Inserter.

SLING PROCEDURE

1. I.V. antibiotics should be administered prophylactically. The patient is placed in the lithotomy position and receives general or spinal anesthesia.
2. After the patient has been prepped and draped, a Foley catheter is placed in the bladder and the balloon is inflated to approximately 20 cc.
3. Pulling downward on the catheter, palpate the balloon to identify the level of the bladder neck.
4. Using this location as a reference point, incise the anterior vaginal wall to create exposure from midurethra to bladder neck. A midline, inverted "U", or "T", incision may be performed.
5. Create a defect of adequate size to allow passage of the index finger alongside the Inserter in order to guide it into proper position on the posterior pubic bone.
6. Laterally dissect to gain access to the retropubic space and place the Inserter up against the bone. The extent of endopelvic fascia dissection is left to the surgeon's discretion.
7. Pass the Inserter through this defect and finger-guide it into position just below the bladder neck and approximately 2 cm lateral to the midline.
8. Following the curvature of the pubic bone, position the Inserter perpendicular to the posterior surface.
9. Firmly pull the Inserter upward against the bone surface to collapse the protective screw shield and pierce the bone cortex with the tip of the screw.
10. Release the safety lock of the Inserter and maintaining upward traction, depress the activation button continuously for 5 to 15 seconds to drive the screw completely into the bone. A distinct change in motor tone indicates unimpeded rotation of the Inserter's drill bit and full screw deployment. Release the activation button and remove the Inserter from the vagina.

CAUTION: Excessive twisting or knotting of the suture may occur if activation button is engaged for an excessive amount of time. If suture cannot be adequately untwisted, or if fraying or nicking of the suture is observed, DO NOT USE the screw/suture assembly. Reload the driver with a new screw/suture assembly.

11. Reload the Insertter with a second screw. Repeat the positioning of the Insertter on the contralateral side of the urethral axis and complete the second screw placement.
12. Cystoscope the patient to confirm integrity of the bladder and urethra.
13. Prepare a piece of sling material of the physician's choice.
14. Thread the sutures through one end of the sling material. Tie the sutures, sliding the knots upward and posteriorly behind the bone to ensure juxtaposition of the sling end to the bone surface.
15. With the sling lying beneath the urethra just below the bladder neck, place a small right-angle clamp between the sling and the urethra. Using a second clamp, bring the sling material end up to the pubic bone to determine where along its length the sling should be tied to the bone.
16. With this measurement as a guide, thread the remaining suture pair through the sling material at the point determined. Maintaining position of the clamp between the sling and the urethra, tie the sutures securely to the pubic bone. Trim any excess sling material at this time.
17. If desired, the distal aspect of the sling material can be secured to the periurethral fascia with absorbable suture to prevent the graft from curling or migrating.
18. Close the vaginal wall incision with a running absorbable suture. Vaginal packing may be appropriate, especially in the case of concomitant vaginal surgery; it is removed within 24 hours.
19. Leave a suprapubic or urethral catheter in place for drainage. Leave the catheter in place until complete bladder emptying is demonstrated by successful voiding trial, generally one to two days.
20. Discard the Insertter upon completion of the procedure. Directions for battery removal are below.
21. Record the lot numbers of the screws on the patient's chart.
22. Continue prophylactic oral antibiotics for five to seven days postoperatively.
23. Physical strain and lifting by the patient should be avoided for two to three months.

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

BATTERY REMOVAL

In order to comply with state and federal regulations for hazardous waste removal, the lithium battery should be removed before device disposal. Follow hospital guidelines for battery waste disposal. The battery may be removed by inserting a flat screwdriver into the short groove between the top of the handle and the centerline indicator and prying until the casing breaks open. The battery is then removed and discarded as stipulated by hospital policy.

STERILIZATION METHOD ETO

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