NovoStitch® Pro
Meniscal Repair System

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

DESCRIPTION
The NovoStitch Pro Meniscal Repair System passes size 2-0 or size 0 braided, non-absorbable, surgical suture through soft tissue in arthroscopic surgery. It is comprised of a handheld surgical instrument to which cartridges preloaded with suture are attached (see Figure 1). The device has a diameter less than 7.0 mm.

INDICATION FOR USE
The NovoStitch Pro Meniscal Repair System is intended for approximation of soft tissue in meniscal repair procedures and for passing suture through soft tissue in orthopaedic surgery.

CONTRAINDICATIONS
- The device is not to be used on bone or other hard tissue.
- Surgical procedures other than those listed in the INDICATION FOR USE section.
- Presence of infection.
- Patient conditions including insufficient quantity or quality of tissue.
- Insufficient blood supply or previous infections which may hinder the healing process.
- Foreign body sensitivity. If material sensitivity is suspected, testing should be completed prior to suture implantation.
- Conditions which may limit the patient’s ability or willingness to follow postoperative care instructions.

STORAGE
Store in a cool, dry area.

SUTURE MATERIAL
Non-absorbable surgical suture is supplied sterile in 80 cm lengths preloaded in the device.
- The size 2-0 suture is composed of undyed (white) ultra-high-molecular-weight polyethylene braided with one or two strands of blue polypropylene to add color. The blue colorant is [phthalocyaninato (2-)] copper with a concentration not to exceed 0.5% by weight. Suture exceeds USP specifications for size 2-0 diameter. (Maximum average oversize diameter is 0.363 mm.)
- The size 0 suture is composed of undyed (white) ultra-high-molecular-weight polyethylene braided with two strands of green polyethylene terephthalate to add color. The green colorant is D&C Green #6 with a concentration not to exceed 0.75% by weight. Suture exceeds USP specifications for size 0 diameter. (Maximum average oversize diameter is 0.406 mm.)

WARNINGS
- The device is provided STERILE for SINGLE USE ONLY. It has not been designed to be resterilized. Reprocessing may lead to changes in material characteristics such as corrosion and dulled edges which may impact the strength of the device and compromise performance. Reprocessing of single-use devices can also cause cross contamination leading to patient infections. These risks may potentially affect patient safety.
- Visually verify that the package sterile barrier is intact and not broken prior to removing the device from the package.
- Detailed instructions regarding the use and the limitations of the device should be given to the patient.
- Whether used arthroscopically or in open surgery, the device must be used under direct visualization.
- Do not force the device into tight joint spaces. Excessive pushing, twisting or levering may cause breakage.
- Do not force the upper jaw open or closed.
- Do not force the lower jaw into position.
- Arthroscopic suturing requires specialized knowledge of knot tying and suture passing techniques. Knowledge of these and other appropriate techniques are important considerations for successful utilization of this device.
- Non-absorbable sutures may elicit a minimal acute inflammatory reaction in tissues which is followed by gradual encapsulation of the suture by fibrous connective tissue.
- Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing polyethylene surgical suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
ADVERSE REACTIONS INCLUDE BUT ARE NOT LIMITED TO:

- Adverse effects associated with the use of this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occur, infected wounds, minimal acute inflammatory tissue reaction and transitory local irritation.
- As with any foreign body, prolonged contact of this suture with salt solutions, such as those found in urinary or biliary tracts, may result in calculus formation.
- Allergies and other reactions to device materials.

PRECAUTIONS

- Avoid excessive handling, i.e. crushing or crimping resulting from use of surgical instruments such as forceps and needle holders.
- Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.
- Strong familiarity with surgical procedure and techniques for non-absorbable sutures is required before use.
- This device should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.
- A surgeon should not begin clinical use of the device without reviewing the instructions for use.
- Careful attention must be devoted to avoiding all surgical hazards including, but not limited to, infection, neurovascular damage, thermal/frictional trauma to cutaneous structures, improper suture position and inappropriate suture deployment.
- Use caution when tensioning the suture. Excessive tensioning may cause suture breakage.
- Place sutures in meniscal tissue using steady, deliberate motion. Excessive speed or movement during use may result in unsuccessful suture passing.

PREPARATIONS FOR USE

- Read the instructions for use in its entirety prior to use of the device.
- Inspect the device prior to use to ensure proper mechanical function.
- Ensure portal placement and preparation is appropriate to access the region of the meniscus to be sutured.

Figure 1: The Ceterix NovoStitch Pro Meniscal Repair System

CAUTION

When the lower jaw is extended, do not squeeze the black handle until the device is in position to deploy suture. Doing so will deploy the suture prematurely. If this occurs, replace the cartridge before attempting to place the next stitch.

SUTURE SIZE SELECTION

NovoStitch Pro Meniscal Repair Systems are compatible with the NovoStitch Meniscal Repair Cartridge, size 2-0 (CTX-R001) and the NovoStitch Meniscal Repair Cartridge, size 0 (CTX-R002). Choice of suture size is at the discretion of the surgeon.

- When using NovoStitch Pro with 2-0 suture, ensure that the package labeling is marked 2-0 in the blue-colored box. After opening the packaging and placing the NovoStitch Pro in the sterile field, confirm the cartridge has a blue suture spool and has “2-0” written inside the black mark used in cartridge loading.
- When using NovoStitch Pro with 0 suture, ensure that the package labeling is marked 0 in the green-colored box. After opening the packaging and placing the NovoStitch Pro in the sterile field, confirm the cartridge has a green suture spool and has “0” written inside the black mark used in cartridge loading.

DIRECTIONS FOR PASSING SUTURE THROUGH MENISCAL TISSUE

1. Squeeze the orange handle (see Figure 1) to keep the upper jaw parallel with the shaft, and pass the device into the surgical site under arthroscopic visualization.
2. Advance the upper jaw along the superior surface of the meniscus following the radius of the femoral condyle. The angle of the upper jaw can be controlled by squeezing the orange handle.
3. When the upper jaw is in position, release the orange handle. Fully extend the lower jaw by pressing downward on the grey thumb lever (see Figure 1). Ensure that the lower jaw slides underneath the meniscus and then release the grey thumb lever.

4. When both upper and lower jaws are in position, simultaneously squeeze the orange handle and apply slight forward pressure to prevent the tissue from migrating distally. Arthroscopically observe upper jaw movement. Lack of upper jaw compression during upper jaw clamping is a sign that the tissue is too thick to reliably deliver the suture. If the jaw does not compress and if there is an appropriate target more centrally, reposition the device in thinner tissue so that the upper jaw shows compression when squeezing the orange handle.

5. When in position, continue to firmly squeeze the orange handle and apply slight forward pressure on the device to ensure tissue stability. Slowly deploy the needle and suture limb by simultaneously squeezing the orange and black handles (see Figure 1) until the black handle fully advances (indicated with a click). Tissue migration during deployment may lead to suture misfire. Also, positioning the lower jaw beyond the meniscus may lead to suture misfire. Release both the orange and black handles to finish placing the first end of the stitch. Ensure the black handle fully retracts before proceeding with the second end of the stitch.

**CAUTION**
If the black handle does not fully retract after it is released, the needle may still be engaged in the meniscal tissue. This can occur when the upper jaw is overly constrained by the femoral condyle.

**CAUTION**
The lower jaw will not retract, and the device cannot be repositioned, until the black handle is fully retracted.

**TROUBLESHOOTING**
If the black handle does not fully retract after it is released, perform the following steps sequentially or simultaneously until the black handle fully retracts:
- Apply varus or valgus force to open the lateral or medial compartment where the device is positioned.
- Advance the device more peripherally to where the femoral condyle slopes up, allowing the upper jaw to open.
- Pull back on the black handle to assist the retraction spring until the handle is fully retracted.

6. Perform ONE of the following options.

6A. To place the second end of the stitch, repeat steps 4 and 5 in the desired location. When placing the second end of the stitch, avoid engaging the first end of the stitch. If needed, retract the lower jaw before repositioning the device by pushing the grey thumb lever downward. This will require repeating step 3 to extend the lower jaw and finish the deployment. Retract the lower jaw by pushing the grey thumb lever downward.* Carefully remove the device from the joint. Keep the orange handle engaged when withdrawing the device from the joint to keep the upper jaw parallel with the shaft. Remove the suture ends from the upper jaw by pulling in the proximal direction.

6B. If placing only one end of the suture is desired, retract the lower jaw by pushing the grey lever downward.* Carefully remove the device from the joint. Keep the orange handle engaged when withdrawing the device from the joint to keep the upper jaw parallel with the shaft. Remove the suture end from the upper jaw by pulling in the proximal direction. Remove the suture leg that remains in the lower jaw by pulling this leg in the distal direction.

*CAUTION
The lower jaw is fully retracted when the suture spool is housed within the handle. If the lower jaw does not retract, ensure that the black handle is fully retracted (see CAUTION and TROUBLESHOOTING above). If the lower jaw does not retract after ensuring that the black handle is fully retracted, perform the following steps sequentially or simultaneously until the lower jaw retracts:
- Apply varus or valgus force to open the compartment where the device is positioned.
- Advance the device more peripherally to where the femoral condyle slopes up allowing the upper jaw to open.
- Pull back on the suture spool to assist the retraction spring until the lower jaw is fully retracted.
- Repeat pushing the grey thumb lever downward.

7. Using standard surgical techniques and the Ceterix NovoCut Suture Manager, advance a knot to the surface of the tissue until tissue approximation at the tear is observed. Place the appropriate number of additional throws to ensure that the knot is secure.

8. Trim the suture limbs from the knot using the Ceterix NovoCut Suture Manager.

9. To place additional stitches, see the section below on removing and loading cartridges. Bench deployment testing has demonstrated that the device can reliably deliver up to six stitches. This includes the cartridge delivered with the handle assembly and up to five additional cartridges. Cycling the device more than six cartridges may affect device integrity and compromise performance.

10. Immediately discard the device after completion of the surgery. The device is SINGLE USE ONLY.
DIRECTIONS FOR REMOVING AND LOADING CARTRIDGES

1. If not already in the forward position, advance the lower jaw into the forward locked position by pressing down on the grey thumb lever.
2. Grasp the suture spool as shown in Figure 2 and pull it both down and forward towards the distal end of the device until it is free from the device shaft.

Figure 2: Removing the cartridge from the handle

3. Discard used cartridge and procure a new cartridge preloaded with size 2-0 or size 0 suture.
4. Flip the handle over so that the underside of the shaft is visible.
5. Align the black mark on the cartridge so that it is over the shaft mark as shown in step 1 of Figure 3.

Figure 3: Cartridge loading

6. With the cartridge seated in the shaft, slide the cartridge toward the handle until the cartridge snaps in place as shown in step 2 of Figure 3.
7. Confirm the lower jaw is loaded properly by checking that the lower jaw is flush with the shaft.
8. If the lower jaw is not flush, remove the cartridge by repeating step 2. Reload the cartridge by repeating steps 4 through 7.
9. Once confirmed that the lower jaw is flush with the shaft, turn the device upright and retract the lower jaw by pushing down on the grey thumb lever. The device is now ready to place another stitch.