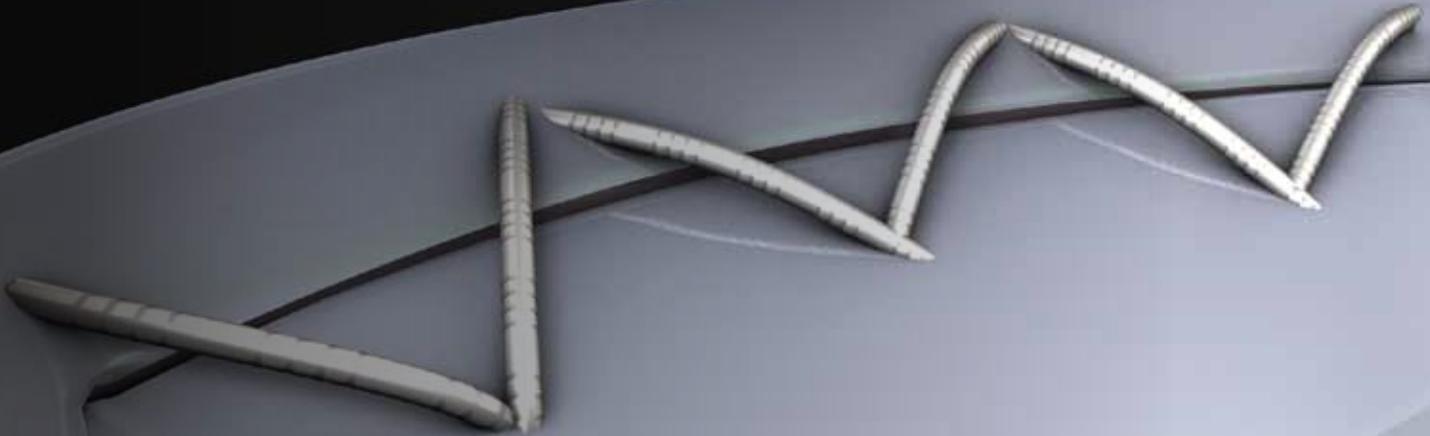


Sequent[™]

All-Inside, Stay-Inside
Meniscal Repair



Surgical Technique:
Sequential Meniscal Running Stitch

 **CONMED**
LINVATEC

The Sequent™ All-Inside, Stay-Inside Meniscal Repair Device affords simplicity (completely all-inside knotless repair), versatility (multiple continuous stitches) and predictability (individually fixed and tensioned stitches) in a cost effective, time efficient manner.

– David Caborn, MD
Department of Orthopaedic Surgery
University of Louisville

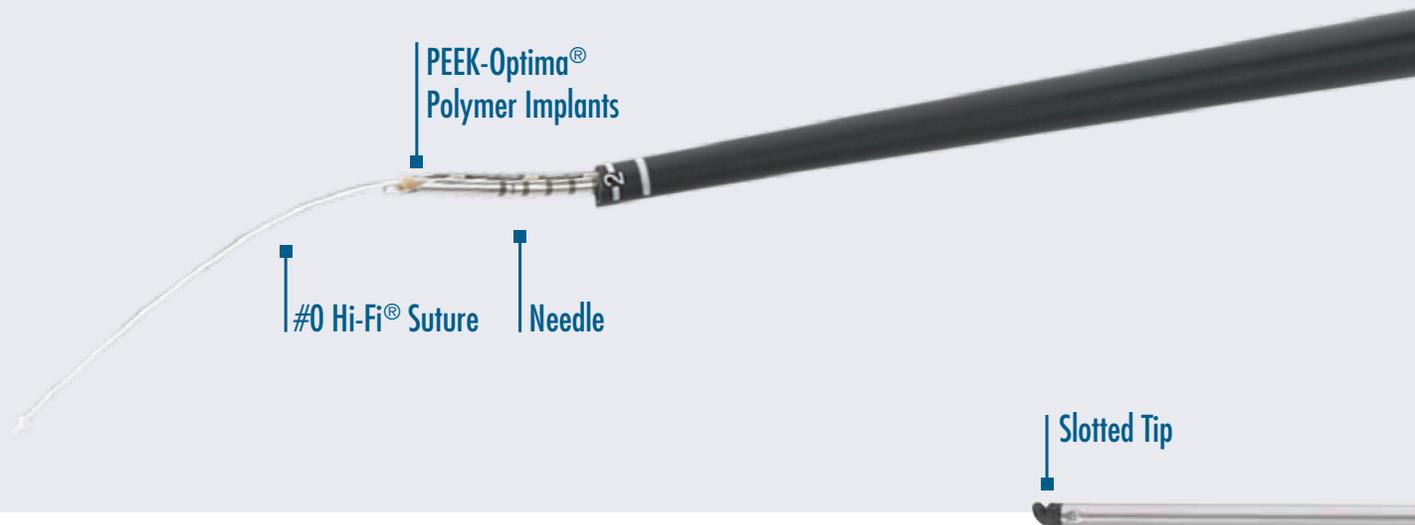
The Sequent™ All-Inside, Stay-Inside Meniscal Repair Device allows for versatility in approaching meniscus tears. The flexibility of multiple stitches that can be placed in almost an infinite number of configurations allows the arthroscopist to confidently address almost any type of meniscus tear, providing a strong and stable repair that allows the patient to rehabilitate aggressively.

– Akbar Nawab, MD
Ellis and Badenhause Orthopaedics
Louisville, KY

Sequent™ Meniscal Repair System Overview

The new Sequent™ Meniscal Repair Device is an *All-Inside, Stay-Inside* continuous stitching system that allows surgeons to complete the repair of virtually any meniscal tear using only one device without having to leave the joint.

The Sequent™ device is loaded with multiple implants, each with suture locking technology, allowing for individually tensioned and fixed stitches creating a knotless repair in any configuration. This technology provides surgeons with an opportunity for reduced risk of failures, reduced risk of meniscal trauma and reduced risk of chondral damage while using a simple meniscal repair technique.

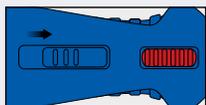


Sequent™ Meniscal Repair Device Features:

Depth Stop Sheath: Functions as an entry cannula and needle depth limiter

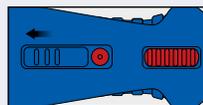
Switch: Controls the function of the red thumb wheel

Switch positions:



Forward = Freewheel Position:

The red thumb wheel is not engaged and suture flows freely within the device



Back = Ratchet Position:

Engages the red thumb wheel to reel in suture
Note: Red dot is exposed when in ratchet mode

Thumb Wheel: Used to tension and reel in suture

Trigger: Used to deploy an implant

Note: There is a triggerlock feature to prevent misfire of an implant. The trigger must first be advanced forward to make ready for implant deployment.



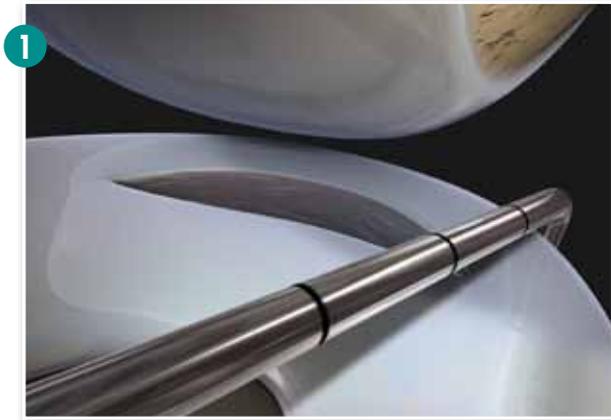
Sequent™ Suture Cutter Features:

Ergonomic Handle with Thumb Rest: Prevents premature suture cutting

Red Cutting Lever: One motion suture cutting

Slotted Tip: Side-loads suture eliminating the need for threading and saves suture waste when using the Changing Portal Technique

Sequential Meniscal Running Stitch Technique



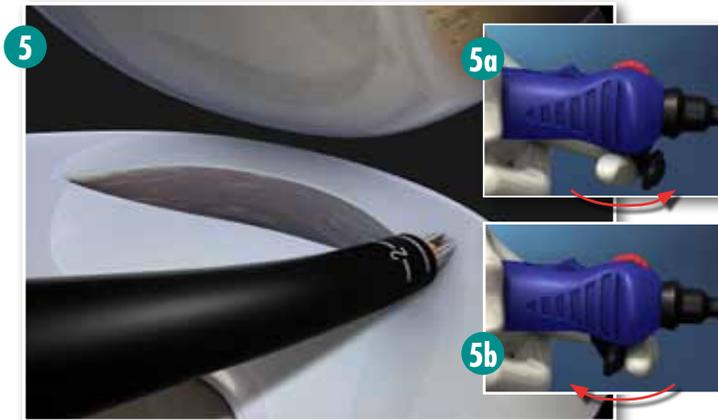
Use a probe to approximate the deepest depth of penetration needed.

NOTE: This should be from the needle entry point on the meniscus to the capsule.



Cut the Depth Stop Sheath to the appropriate graduation marking.

NOTE: Ensure that the Depth Stop Sheath will allow the needle to penetrate through the meniscus at the deepest portion of the tear.



Ensure the switch is forward in the Freewheel position. Insert the needle completely through the meniscus using the needle markings to ensure the proper depth of penetration.

5A: Advance the trigger forward to prepare the device for implant deployment.

5B: Pull back and release the trigger to deploy an implant.

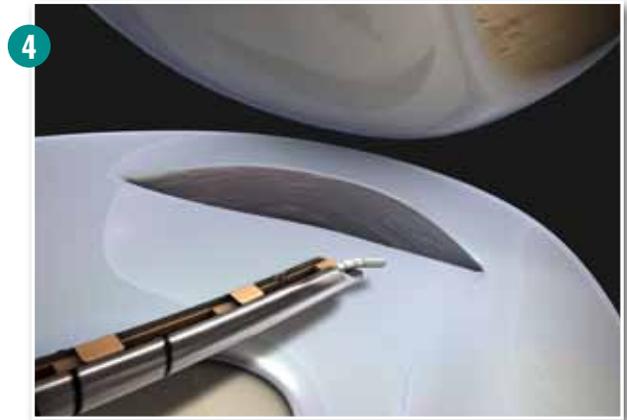


Withdraw the needle from the meniscus.

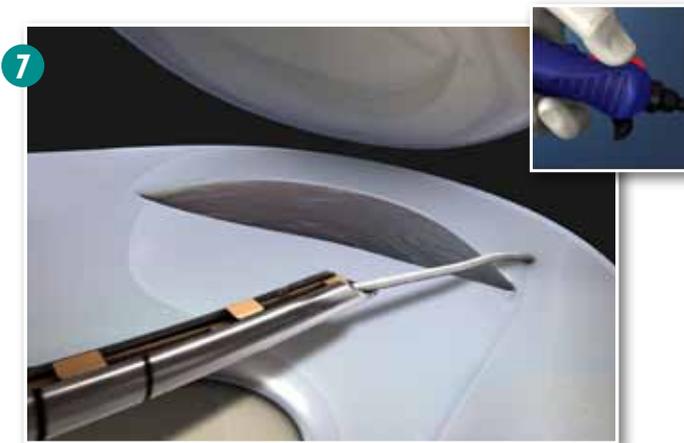
Then move the switch backwards to the Ratchet position. The red dot should be exposed.



3
Position the Depth Stop Sheath so that it covers the tip of the needle. Use the sheath as a protective entry cannula while entering the joint space.



4
Once near the meniscal repair site pull back on the Depth Stop Sheath until it engages fully onto the handle.



7
Tension the suture and ensure that the implant is set by pulling back on the device and using the thumb wheel to reel the suture in.



8
Move the switch forward into Freewheel position. Create slack (1 cm-2cm) in the suture and target the position of the next implant.

Creating the Sequential Stitches



Insert the needle into the meniscus.



Rotate the device two full revolutions initiating the knotless fixation.



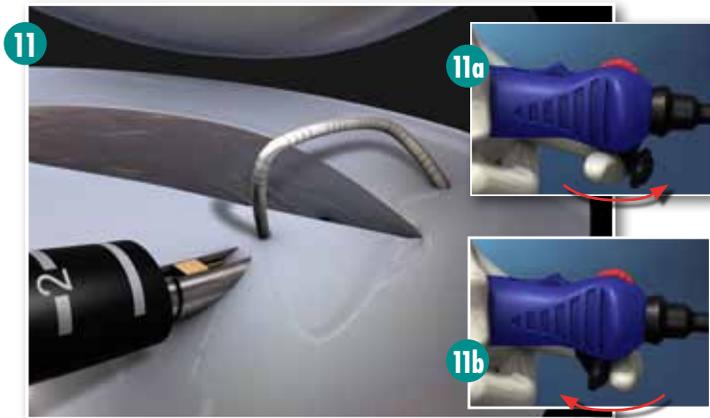
Move the switch backwards to the Ratchet position. Tighten the stitch by pulling back on the device and reeling the thumb wheel to remove excess suture slack.

Completing the Sequence

Repeat Steps 8 through 13 to create stitches until the repair is complete

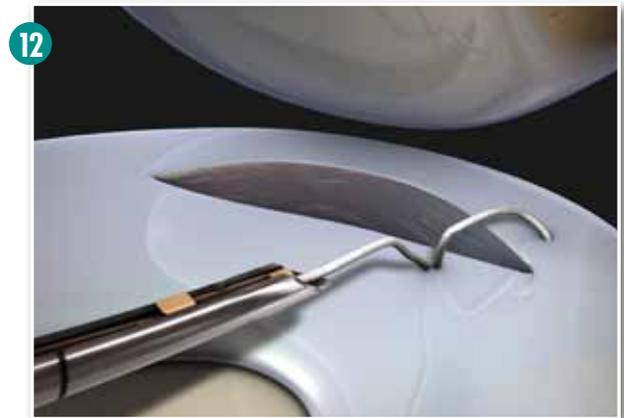
- **Pierce** through the meniscus
- **Rotate** the device twice
- **Deploy** an implant
- **Tension** the stitch





11A: Advance the trigger forward to prepare the device for implant deployment.

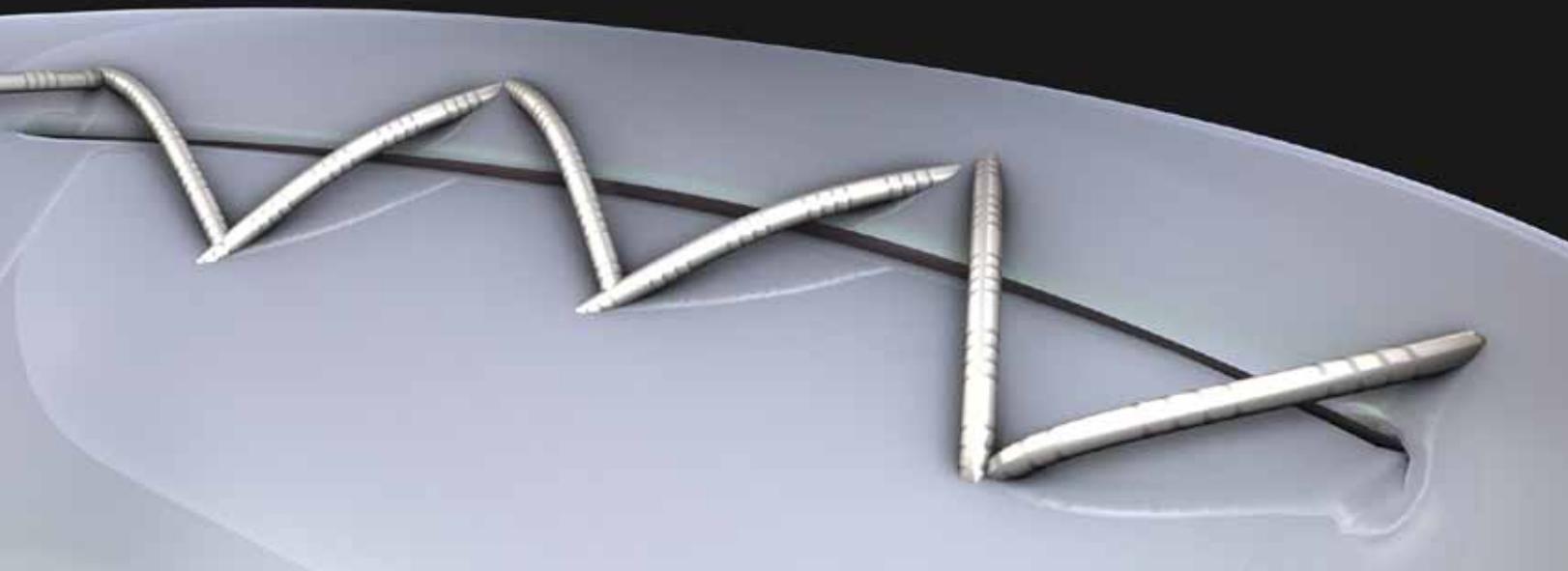
11B: Pull back and release the trigger to deploy an implant.



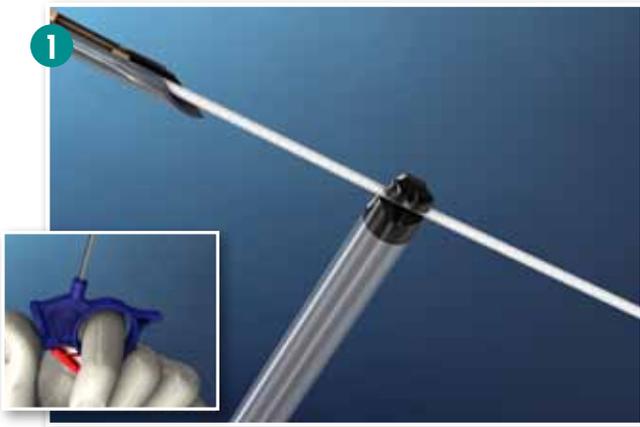
Withdraw the needle from the meniscus.

Anterior Meniscal Running Stitch

multiple sequential



Cutting the Suture Tail



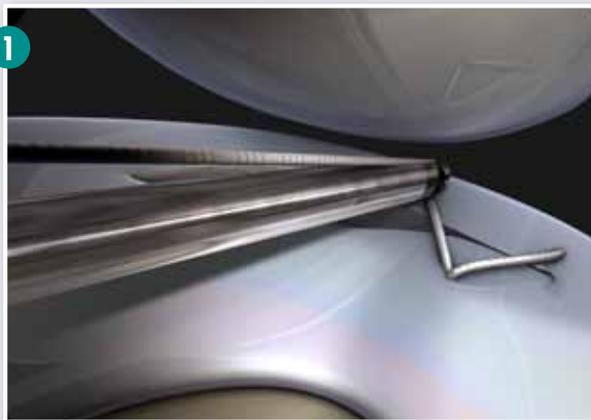
Once the repair is complete, remove the Sequent device from the joint, and move the switch backwards to the Ratchet position so that the suture can be pulled taut. Place the Sequent Disposable Suture Cutter on to the suture outside of the joint.

Hold the cutter perpendicular and the suture taut and place the suture into the cutter slot.



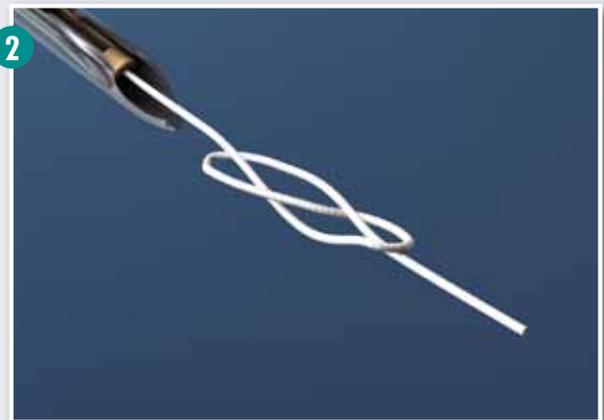
Rotate the cutter shaft to align it axially with the suture. Keep the thumb resting on the thumb rest until you are ready to cut the suture.

Changing Portals Technique

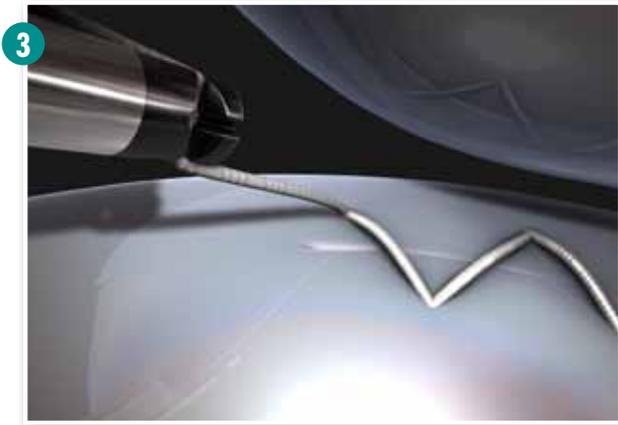


Remove the Sequent device from the joint and move the switch backwards to the Ratchet position so that the suture can be pulled taut. Cut the suture tail flush using the Sequent Disposable Suture Cutter.

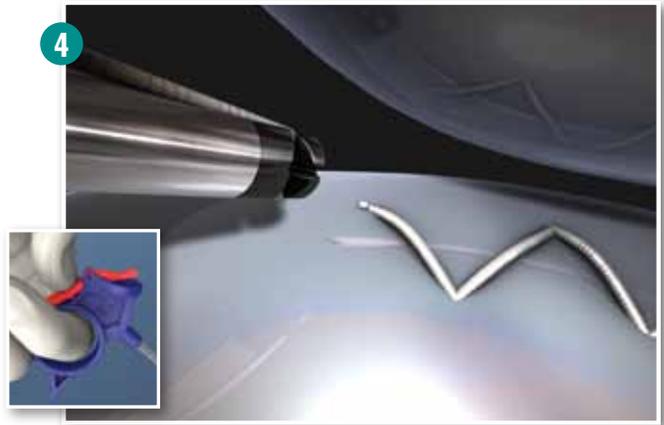
Note: Ensure there are enough implants remaining to create the desired number of stitches.



Tie a figure of eight knot leaving approximately 1 cm or less of suture tail.



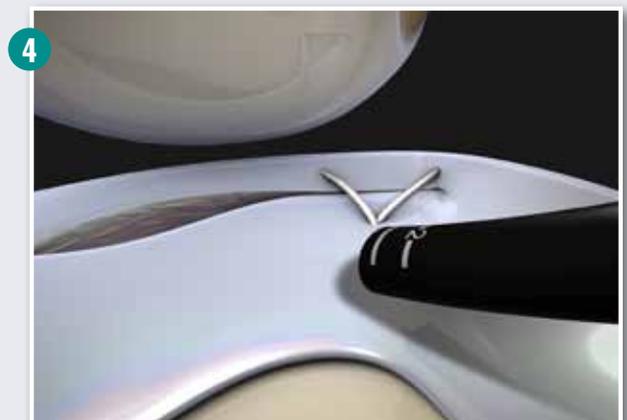
3 Keeping the suture taut, slide the suture cutter down the suture and into the joint until it is flush with the meniscus.



4 When ready, press the red lever to cut the suture and then remove the suture and cutter from the joint.



3 In Ratchet mode, reel the suture in until the knot engages snugly into the first implant.



4 Use the Depth Stop Sheath as an entry cannula to re-enter the joint and continue the repair.

ORDERING INFORMATION

Sequent™ Meniscal Repair System

| | |
|--------|--|
| MR004S | Sequent™ Meniscal Repair Device, Straight Needle, 4 Implants |
| MR007S | Sequent™ Meniscal Repair Device, Straight Needle, 7 Implants |
| MR004C | Sequent™ Meniscal Repair Device, Curved Needle, 4 Implants |
| MR007C | Sequent™ Meniscal Repair Device, Curved Needle, 7 implants |
| SC047D | Sequent™ Disposable Suture Cutter |

Manual Instruments

| | |
|----------|---|
| 31.10034 | Aggressor Forceps 3.4mm dia., 130mm Straight |
| 31.16337 | Aggressor Forceps 3.4mm dia., 130mm 15° Up |
| 31.16136 | Aggressor Forceps 3.4mm dia., 130mm 15° Left |
| 31.16235 | Aggressor Forceps 3.4mm dia., 130mm 15° Right |

Meniscal Rasps

| | |
|---------|-------------------------------|
| C8542.1 | 30° Top Serrations |
| C8541.1 | 30° Bottom Serrations |
| C8537.1 | 30° Top and Bottom Serrations |
| C8536.1 | 90° Top and Bottom Serrations |

Other Meniscal Fixation Systems

| | |
|--------|---|
| RS2500 | Disposable SharpShooter® Handle |
| RS2535 | Disposable Double Arm Needles |
| RS2532 | Reusable Cannula, Right, Anterior |
| RS2533 | Reusable Cannula, Left, Anterior |
| RS2539 | Reusable Cannula, Right, Middle |
| RS2540 | Reusable Cannula, Left, Middle |
| RS2530 | Reusable Cannula, Right, Posterior |
| RS2531 | Reusable Cannula, Left, Posterior |
| RS2538 | Sterilization Cannula Tray |
| 8532 | Zone Specific® II, Right Anterior |
| 8539 | Zone Specific® II, Right Middle |
| 8530 | Zone Specific® II, Right Posterior |
| 8533 | Zone Specific® II, Left Anterior |
| 8540 | Zone Specific® II, Left Middle |
| 8531 | Zone Specific® II, Left Posterior |
| 8570 | Meniscal Repair Needles, Nitinol, 10 per box |
| 8535 | Double-Arm Meniscal Repair Needles, Stainless steel, 10 per box |
| 8538 | Instrument Tray with lid |



*Some accessories may not be available in all countries.

INTENDED USE / INDICATIONS FOR USE

The Sequent Meniscal Repair Device is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.

CONTRAINDICATIONS

1. Insufficient quality and quantity of tissue.
2. Blood supply limitations and/or previous infections, which could retard healing.
3. Foreign body sensitivity, known or suspected allergies to implant and/or instrument materials.
4. Patients with active sepsis or infection.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing and rehabilitation period.
6. Soft tissue tears which would not be appropriate to repair.

WARNINGS

1. Preoperative and operating procedures, including knowledge of surgical techniques and proper placement of the implants are important considerations in the successful utilization of this device.

2. The surgeon who implants these devices must give the patient appropriate instructions for postoperative care and rehabilitation in order to prevent premature load bearing and other complications.

3. Patient should be advised that product materials may cause allergic reactions including but not limited to, foreign body reaction, tissue irritation/inflammation or other allergic reactions. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.

4. The repair device and implants are sterile unless the package is damaged. Discard any open, unused devices.

5. Do not use beyond the expiration date listed on the label. The performance, safety, and/or sterility of the device cannot be assured beyond the expiration date.

6. Remove the Sequent Meniscal Repair Device from the sterile package, within the sterile field, using aseptic techniques.

7. Until tissue healing is complete, all fixation achieved with this device should be considered as only temporary and may not withstand weight bearing or other unsupported stresses. Appropriate immobilization/controlled mobilization should be used until clinical determination of meniscus healing.

8. Any decision to remove the implants should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.

9. Do Not Re-sterilize. Single Use Only. The ability to effectively clean and re-sterilize this single use device has not been established and subsequent re-use may adversely affect the performance, safety and/or sterility of the device.

PRECAUTIONS

1. The Sequent Meniscal Repair Device should only be used with the designated surgical instruments as outlined above.
2. The device should be inspected for damage prior to use. Do not use a damaged device.
3. It is the surgeon's responsibility to be familiar with the appropriate surgical technique prior to use of this device.
4. The risk of premature failure is reduced by following the specified Instructions For Use listed below.
5. Do not bend the device needle before insertion or during the operation. This may prevent proper insertion and / or damage the implants and / or suture.

The device should not be used as a lever.

6. Improper insertion technique may cause breakage of the device, implants and / or suture or premature failure.

7. Do not reload anchors into device. Reloading of anchors may cause repair device and/or implant damage. In the event of unintentional implant deployment, refer to instructions below for changing portals or starting a new group of stitches.

8. After use, the device should be disposed of according to hospital policy for sharp instruments.

9. Federal Law restricts this device to sale by or on the order of a physician.

10. The Sequent Meniscal Repair Device has not been evaluated for safety and compatibility in the MR environment.

11. The Sequent Meniscal Repair Device has not been tested for heating or migration in the MR environment.

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