

Surgical Technique Guide

BIOCINCH[®] AI2

All-inside Meniscal Repair



Introduction

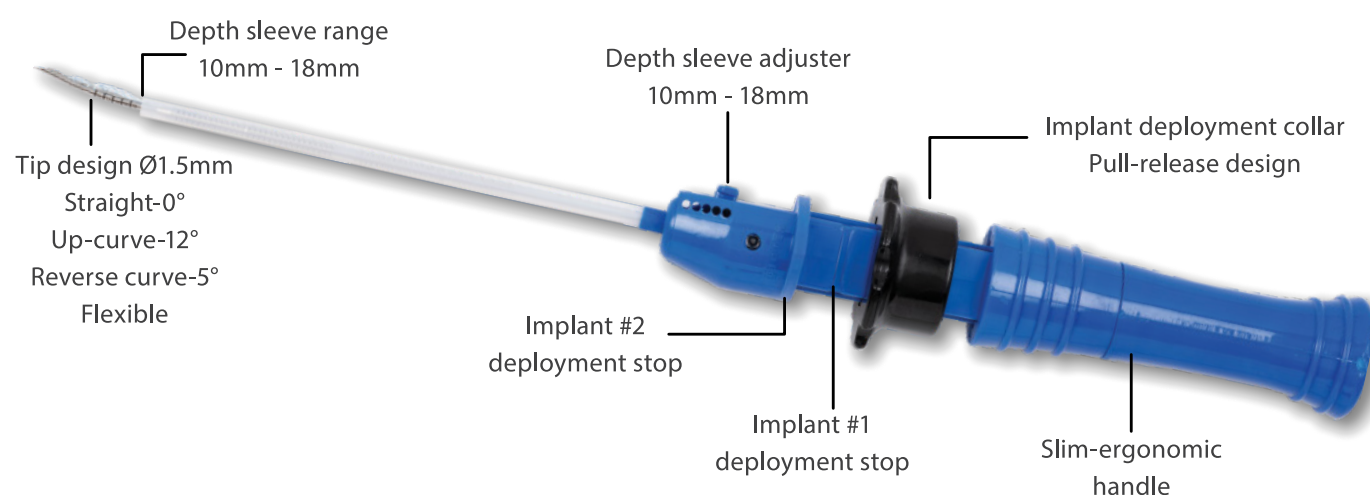
Meniscus tears are a common orthopedic condition with an increasing prevalence. Knee meniscal injuries have an incidence of 61 cases per 100,000 persons and a prevalence of 12% to 14%. The all-inside meniscus repair is an advanced, all-arthroscopic technique that provides a minimally invasive approach for effective treatment.

BIOCINCH® AI2:

BIOCINCH® AI2 is a device for all-in-one, all-inside, all-zone meniscus repair. This cutting-edge device consists of an ergonomic handle for seamless single-handle use and efficient implant delivery.

New **BIOCINCH® - AI2 Flex** is an innovative device designed to bend needle and shaft to reach all zone, all-inside for a secure repair of meniscus tears.

Anatomy of **BIOCINCH® AI2**



Indications

FEATURES:

Small-Implant Size: BIOCINCH® A12 features 2x PEEK implants (1.2mm x 5mm) with USP 2-0 high-strength Biofiber® suture and a self-locking pre-tied knot for a secure construct.

Reliable Deployment: offers single-handed 360° active deployment with an audible click and visible laser mark for confirmation.

Small Needle: The 1.5mm needle ensures minimal tissue disruption* and penetrative trauma to the meniscus.

Active Implant Deployment: The simple pull-and-release mechanism allows for easy one-handed operation, ensuring quick and secure anchor deployment.

Versatile Options: Includes 12° up-curved, straight, and 5° reverse curved needles with laser markings for easy access to meniscus tears.

Innovative: The New BIOCINCH® A12 Flex adapts to various angles for accessing all meniscus zones, minimizing inventory with multiple repair configurations.



Indications

- Vertical tear repairs
- Bucket handle tear repairs
- Ramp lesion tear repairs
- Radial Tear Repairs
- Meniscal allograft transplant

Surgical Technique

Step 1: **Preparation**

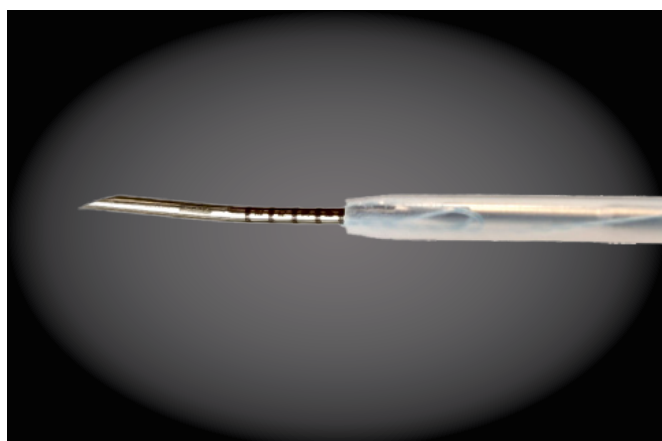


The Calibrated Meniscal Probe is utilized to assess the meniscus for tear patterns and to measure the tear using an arthroscopic probe.

It is recommended that a meniscal rasp (BAK-7199) or a meniscal curette (BAK-7204) be utilized to prepare the tear site and establish an optimal environment for healing.



Depth-stop setting



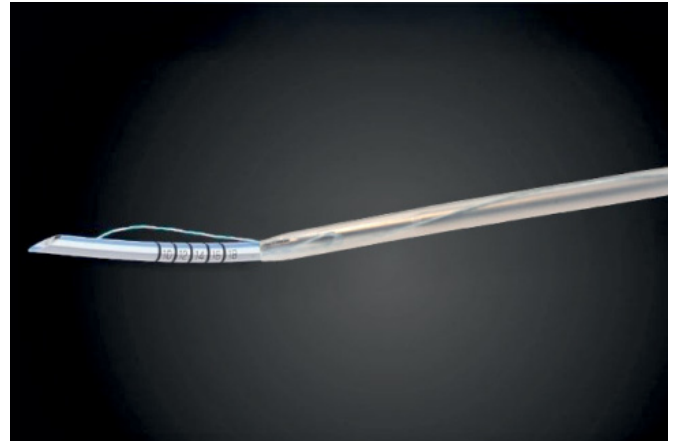
The adjustable tapered depth stop is designed to improve the insertion process into the joint.

The design of the needle tip includes 2 mm increment depth laser markings, which facilitate intraoperative measurement and provide visual feedback regarding the depth of needle penetration.

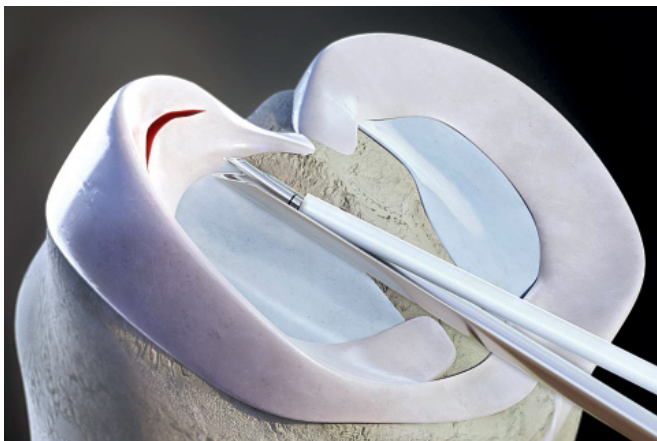
To avoid damage to the condyle and to reduce soft tissue entanglement, the slotted cannula is employed to effectively advance the needle into the joint space.

Note:

- In sterile packaging, the depth stop of the **BIOCINCH® AI2** is calibrated to a maximum depth setting of 20 mm.
- Check the repair suture for any entanglement with depth gauge distal tip.



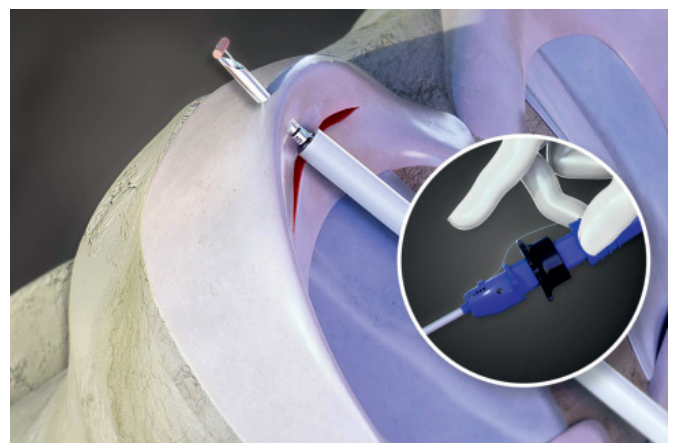
Step 2: Needle Insertion

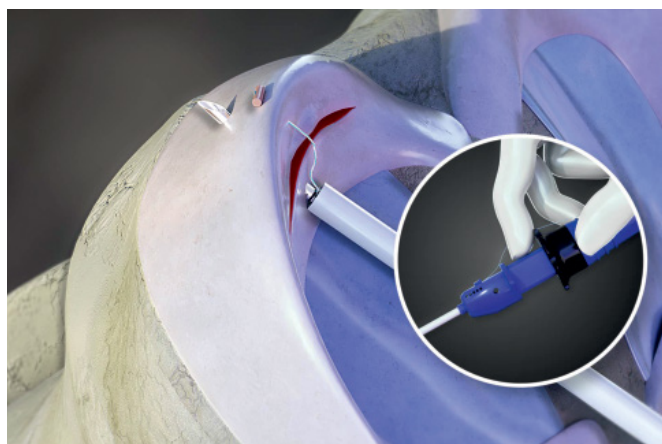


To facilitate a safe introduction and reduce the risk of articular cartilage damage, it is recommended that a slotted sleeve (10256) be introduced into the knee. This device serves as a guide to assist in the precise placement of the needle tip of the **BIOCINCH® AI2** at the location of the tear.

Step 3: Implant Deployment (E.g. – For a vertical mattress configuration)

Typically, implant #1 is initially passed on the peripheral (Superior) side of the tear. The needle tip is advanced through the meniscus using gentle prosupination (side to side) movements until the depth limit sleeve makes contact with the meniscal tissue.





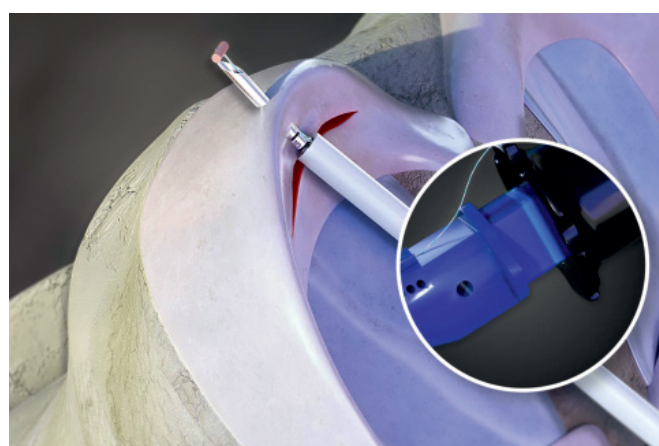
The black collared 360° trigger is quickly pulled to the backstop and then immediately released.

Note: Allowing the spring action to deliver Implant #1 through the meniscus is important.

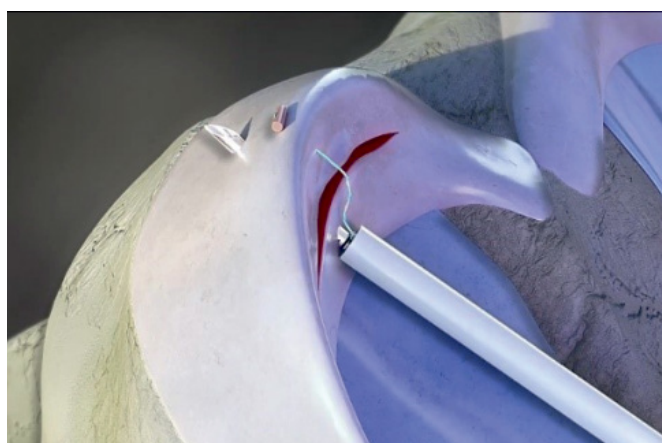
After release, it should be confirmed that the black collared 360° trigger has fully reached the depth mark for implant #1.

(If it has not, the collared 360° Trigger should be manually advanced to this mark. Implant #1 will be fully deployed and ready to flip.)

The needle tip is gently withdrawn from the meniscus in wiggling motion and reposition the **BIOCINCH® AI2** needle for the passing of implant #2.



Step 4: **Second Implant Preparation**



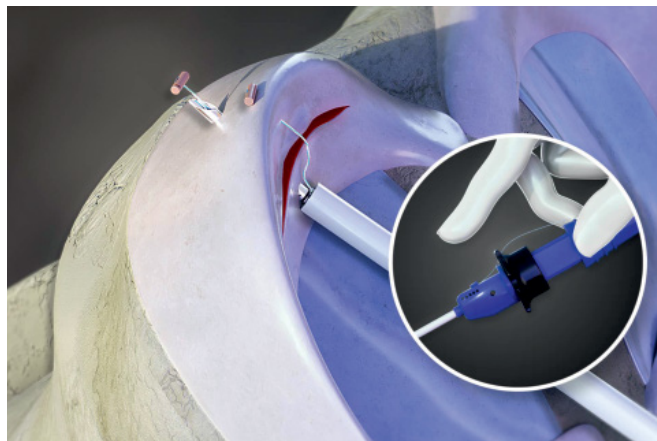
The needle tip of the **BIOCINCH® AI2** may now be used to control and reduce the tear fragment prior to the passing of the implant #2.

The needle for the second implant is inserted into the meniscus with a pronosupination (side to side) movement until reaching the depth-stop limit that was set earlier for Implant 1.

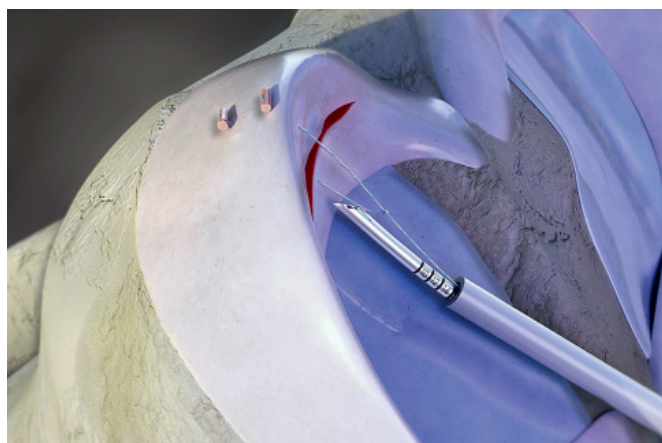
The black collared 360° trigger is pulled quickly to the back stop and immediately released. A click sound can be heard as confirmation that the second implant is deployed properly.

(**Note:** Allowing the spring action to deliver Implant #2 through the meniscus is important.)

After release, it should be confirmed that the black collared slider has fully reached the depth stop for Implant #2. If it has not, the collared slider should be manually advanced to mark.

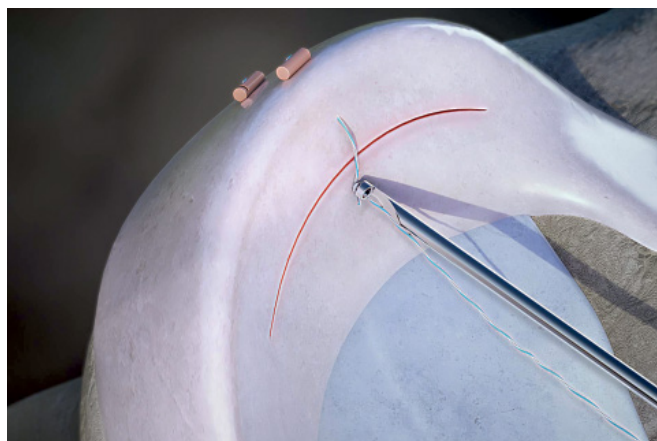


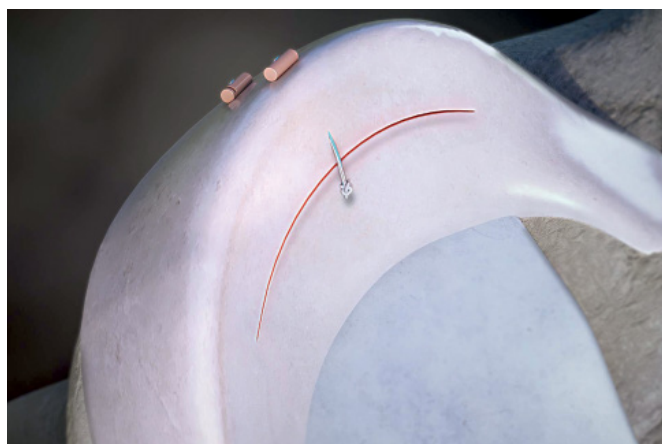
Reduction, Cinching and completing the repair



The device is withdrawn from the joint space, leaving one suture standing outside the joint. That limb is then fed into the Biotek knot pusher.

The use of a knot pusher is recommended to assist in advancing the locking knot until the repair is reduced and the knot is seated directly over the meniscus.

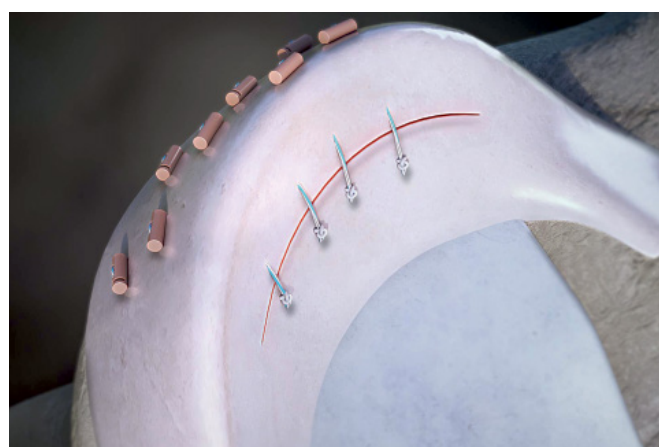




The single limb of the #2-0 repair suture is utilized to reduce and cinch the repair construct. The Biotek knot pusher/cutter (10255) is used to cut the suture.

Additional BIOCINCH® AI2 may be required to complete the repair. Depending on the size of the tear, multiple **BIOCINCH® AI2** may be required to complete the repair and achieve a stable construct.

Steps 2 – 6 are repeated as required.



How to use **BIOCINCH® AI2 FLEX**

Step 1:



Flex device needle should be inserted into sleeve Bender slot until it reaches the edge of the depth sleeve, aligning with arrows (Up & Down) while ensuring that the loaded peek implants remains secure and does not become dislodged from needle.

Step 2:

Apply gentle downward pressure on the handle (without engaging Trigger) to attain the desirable bending angle.

Note: Maximum angle that can be achieved with the needle is 45°

Excessive bending of the needle beyond the Bend Tool may compromise implant deployment.



Order Information

Cat Code	Description
BAK-7004	BIOCINCH® AI2 Meniscal repair set, Fiber USP Size 2-0, Straight
BAK-7005	BIOCINCH® AI2 Meniscal repair set, Fiber USP Size 2-0, Curved, 12°
BAK-7142	BIOCINCH® AI2, Meniscal repair set, Fiber USP Size 2-0, Reverse Curved 5°
10471	BIOCINCH® AI2, Meniscal repair set Fiber USP Size 2-0, Flexible

Instrumentation

- BAK-7199 Meniscal rasp
- BAK-7204 Meniscal curette
- 10154 Knot Pusher for Meniscus Repair
- 10255 Meniscus sleeve knot pusher/cutter.
- 10256 Slotted Sleeve for BIOCINCH®-AI2 Meniscal Repair Set (All Inside)



The information in this document is for educational purposes only. It is not intended to serve as comprehensive medical advice or a full description of the procedure. It is the responsibility of the operating surgeon to determine and utilize the appropriate products and techniques in accordance with their clinical experience and evaluation of each patient. Review and understand all product and safety information including indications for use, contraindications, effects, precautions and warnings.



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An ISO 13485 : 2016 Company
All Implants specified in the catalogue are CE certified

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