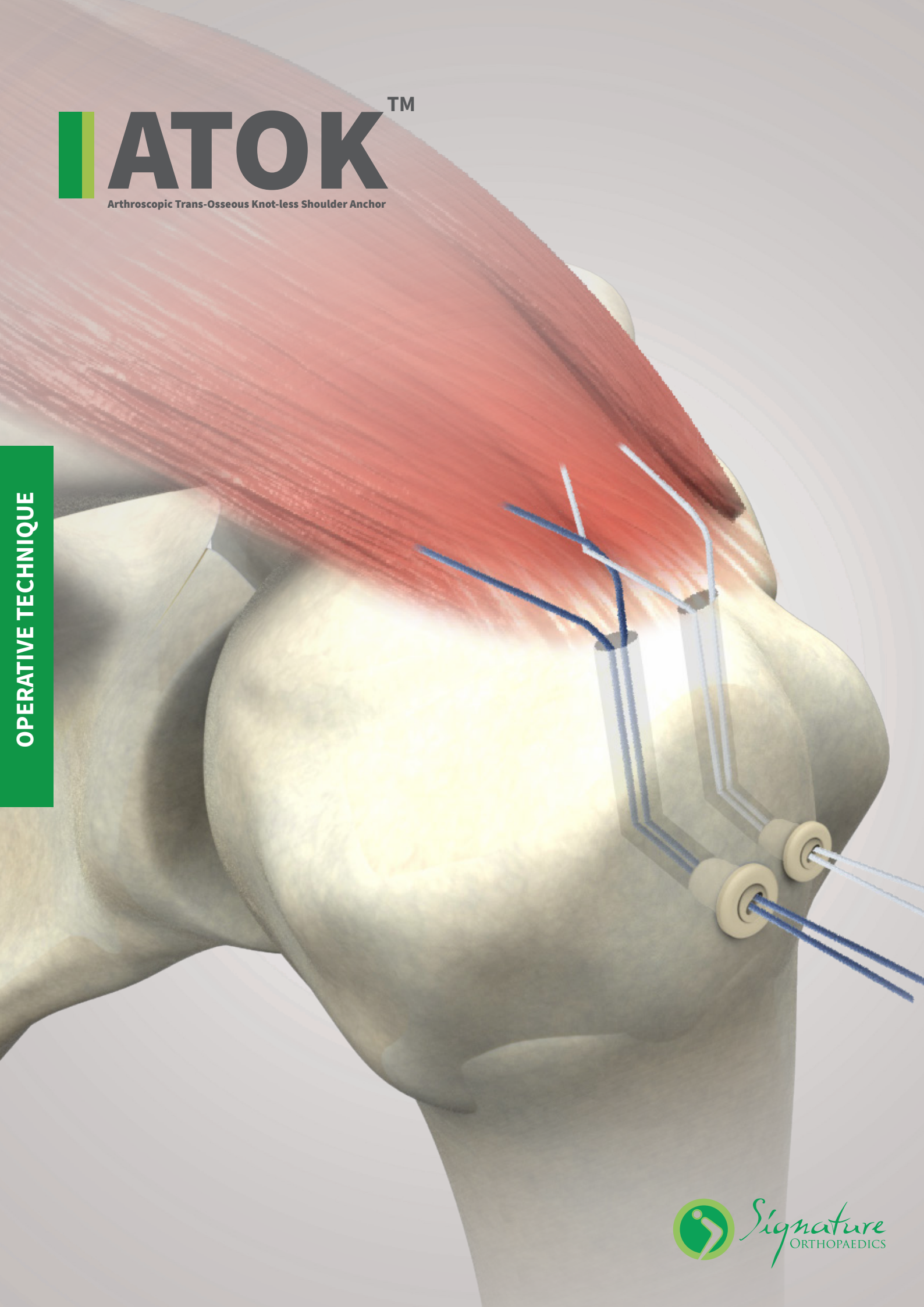


ATOK™

Arthroscopic Trans-Osseous Knot-less Shoulder Anchor

OPERATIVE TECHNIQUE



Introduction

Components of the Signature Orthopaedics range of soft tissue fixation devices are intended to reattach ligament, tendon or soft tissue to bone. Specifically, the BI-ON Screw and Anchor, BI-ON Bio-screw and Bio-staple, Vector Knotted, PEEKay Anchor, ATOK™ and Shoulder Suture Anchor are indicated for use in the shoulder, including:

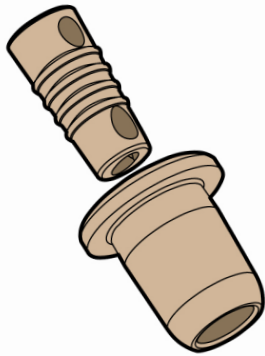
- Capsular stabilization
- Bankart Repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

The range of Signature Orthopaedics shoulder soft tissue fixation devices are contraindicated for:

- Infection
- Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions
- Foreign body sensitivity: Where material sensitivity is suspected, testing is to be completed prior to implantation of the device

ATOK™ Anchor

The Signature Orthopaedics ATOK™ anchor is designed to perform a transosseous rotator cuff repair, using a knot-less arthroscopic approach. The traditional technique to repair a disrupted rotator cuff was via an open surgical approach, securing the disrupted rotator cuff tendon margin using sutures, and then passing those sutures through bone tunnels to be tied over the lateral humeral cortex (figure 1).



This produces a reliable repair, but with the morbidity and compromised access inherent in the open surgery. The option to perform the repairs using an arthroscopic approach necessitated a change in the actual repair technique. This generally involves tying the tendon onto antigrade inserted anchors, or more recently with the TOE – Trans- Osseous Equivalent repairs.

There are a number of compromises that have become apparent, including the challenges of intracorporeal knot tying, reduced tendon vascularity, reduced contact with the cancellous bone and sub-optimal anchor hold in osteoporotic bone.

By combining the advantages of an open transosseous approach (close approximation of the tendon to the cancellous bone and a strong hold on osteoporotic bone) with the benefits of doing this arthroscopically, the ATOK™ anchor provides the optimal solution.

Open Trans-osseous

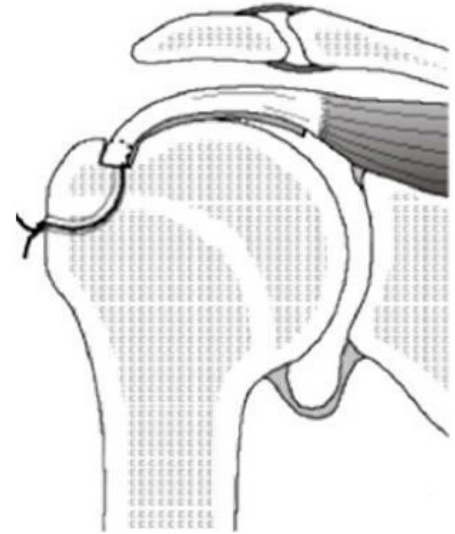


Figure 1

Arthroscopic

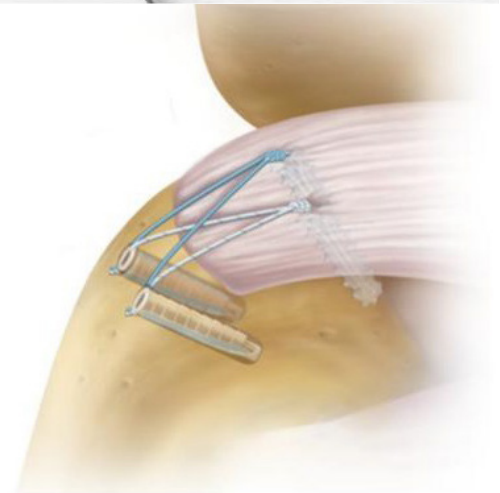
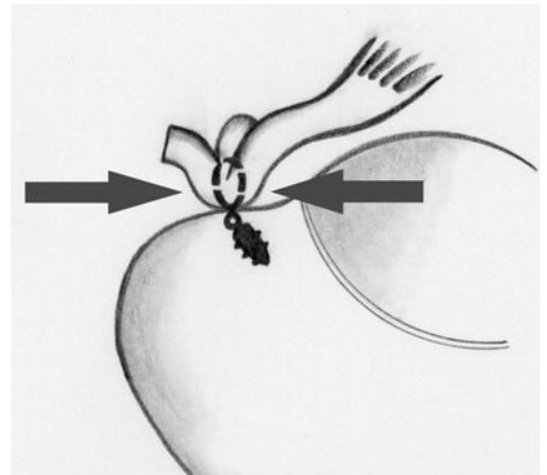


Figure 2

Surgical Technique

1

Patient Positioning

Place the patient in the beach chair or the lateral decubitus position.



2

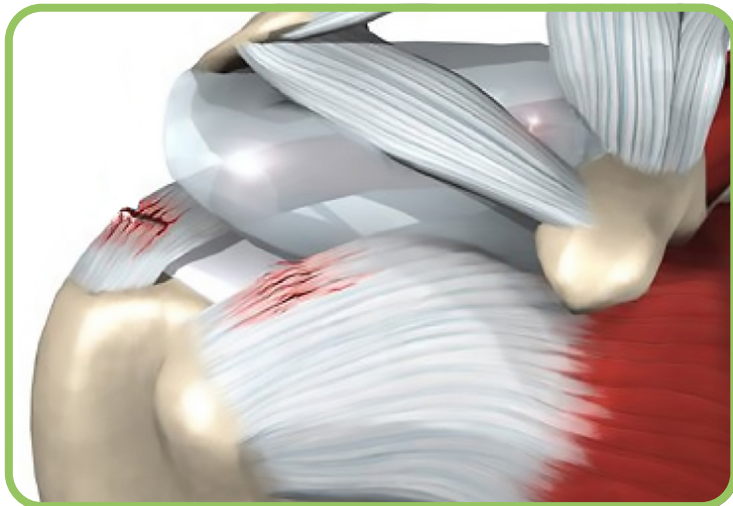
Portal Placement

Portal placement is at the surgeon's discretion, but should be placed to allow optimum examination of the gleno humeral joint and the subacromial space. Often multiple portals may be required, particularly with a complex rotator cuff tear repair.

Although accessory portals are often required to “park” sutures during alternate repairs, when using the ATOK™, the sutures can be passed through the definitive transosseous tunnels as they are inserted. This avoids the need to park, retrieve and then untangle previously inserted sutures.

3 | Assess rotator cuff

The rotator cuff tear is mobilized, debrided and characterized. The tension on the repair is assessed, and the likely location of the relatively tension free repair is determined.



4 | Suture Insertion

The first set of sutures is inserted into the retracted margin of the disrupted rotator cuff using an appropriate suture passing device.

The suture morphology and bite style is at the surgeon's discretion, but the recommendation is a horizontal mattress with a minimum wide 1cm bite and about 2cm from the tear margin, or alternatively a Mason Allen suture grasp can be utilized.



Appropriate Suture Insertion Equipment:

Appropriate Sutures

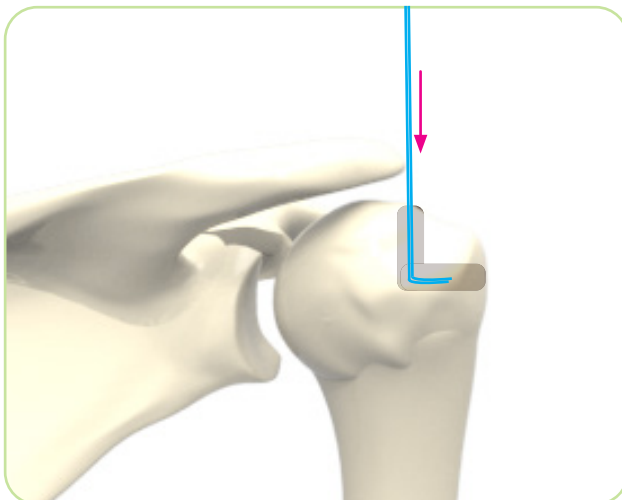
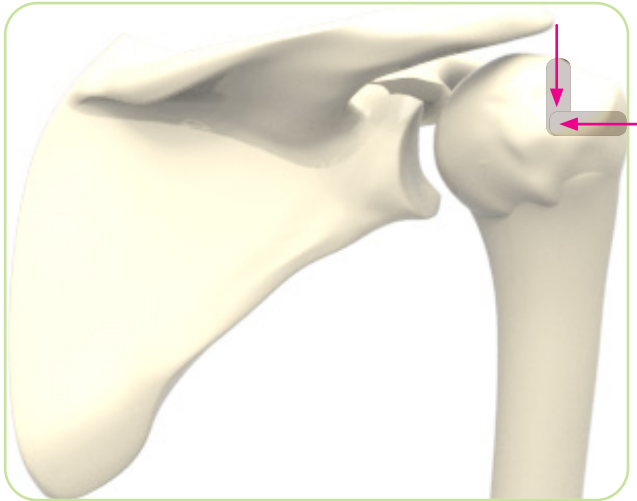
- a. # 2 Braided polyethylene
- b. # 2 Braided polypropylene

Third party suture passing device:

- a. Scorpion™
- b. Bypass™

5 | Rotator Cuff foot print

The rotator cuff footprint is defined and scarified. A shallow trench is created into the cancellous bone, at the planned location of tendon re-attachment. Sutures are passed transosseously as they are inserted. They are “parked” in their definitive situation.



6 | Transosseous Guide Insertion

The ATOK™ Transosseous guide is inserted through the lateral portal, and the tip of the guide is advanced into the cancellous trench.



7 | Capture Drill and Relay Suture Insertion

The Capture Drill is positioned over the skin of the lateral shoulder at an angle of approximately 45 degrees to the top of the shoulder. A stab incision is made in the skin to allow the Capture Drill to engage the lateral humeral cortex and create a drill hole in the lateral cortex.

The relay suture is then passed down the shaft of the ATOK™ Transosseous guide, and if positioned correctly, passes into the Capture Drill, to be retrieved laterally out through the lateral humeral cortex. Insertion of a flexible cleaning rod may be required to facilitate passage of the relay suture.

The ATOK™ Transosseous guide is then carefully removed, ensuring the relay suture remains in place.



8 | Tendon Repair Suture Insertion

The tendon repair sutures are then attached to the relay suture as appropriate, and passed transosseously to exit through the lateral shoulder muscle and skin.

Subsequent tendon repair sutures are inserted as required, and advance transosseously as per steps 5 – 10.



9 | ATOK™ Anchor Preparation

Once all sutures have been placed and taken transosseously, the ATOK™ anchors are inserted sequentially.

The ATOK™ Cannulated rod is passed over a set of sutures, and advanced through the lateral humeral hole, and into the cancellous bone. The ATOK™ Anchor Hub is then slid down the cannulated rod, and using the ATOK™ Hub Inserter/ tensioning device, the ATOK™ Hub is advanced into the lateral humeral drill hole, impacting against the lateral cortex.

The ATOK™ Cannulated rod is then withdrawn, and the sutures are threaded through the locking plug. The locking plug is then advanced down the sutures.



10 | ATOK™ Anchor Insertion

The sutures are then attached to the ATOK™ Hub inserter / tensioning device and appropriate tension is applied to reduce the rotator cuff tear as planned. This is monitored by observing arthroscopically.

Once the appropriate tendon reduction has been confirmed, the ATOK™ locking plug is advanced using the ATOK™ Plug Inserter to lock the suture into the ATOK™ Anchor.

Once the appropriate tendon reduction has been confirmed, the ATOK™ locking plug is advanced using the ATOK™ Plug Inserter to lock the suture into the ATOK™ Anchor.

When the correct tension on the repair has been confirmed, the suture can then be cut off flush with the ATOK™ anchor using the Suture cutting device.



11 | ATOK™ Anchor Tensioning

If the tension on the sutures is deemed to be too loose, the ATOK™ Hub inserter / tensioning device is inserted over the sutures, and engages the ATOK™ Anchor Hub. Tension is applied to the sutures to disengage the ATOK™ Locking plug, the suture tension adjusted, and the ATOK™ Locking Plug re-advanced.

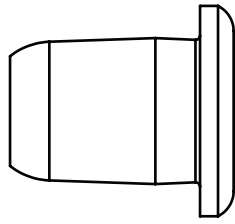
Subsequent sutures are secured using the same technique. Various combinations of suture configuration can be utilized at the surgeon's discretion.



12 | Closure and post-operative immobilisation

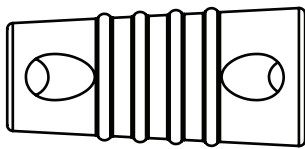
Wounds are then closed with cutaneous sutures as appropriate.
Post-operative immobilization is performed at the surgeon's discretion and protocol.

Implant List



ATOK™ Shoulder Anchor Washer

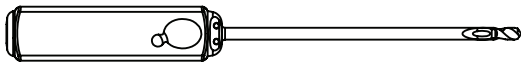
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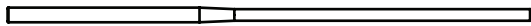
ATOK™ Shoulder Anchor Locking Plug

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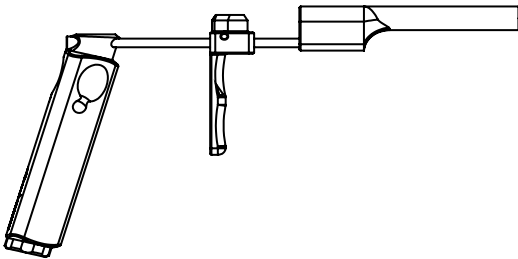
Instruments List



ATOK™ Drill
191-28-0023



ATOK™ Suture Protection
191-28-0025



ATOK™ Tensioning Device
191-28-0001

ATOK™ Cannulated Rod
191-XX-XXXX



ATOK™ Targeting Arm
192-28-0018

ATOK™ Plug Inserter
192-28-0010

**** Note** – The optimum or most recent technique may vary from that shown in this guide as the instruments are progressively refined and improved. Prior to performing this technique, review the latest instruments and ensure you are familiar with the optimum surgical technique, and the individual components and application — including indications, contraindications, warnings, cautions, and instructions.

Caution: Australian and U.S. Federal law restricts this device to sale by or on the order of a physician.

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