Inion Hexalon™

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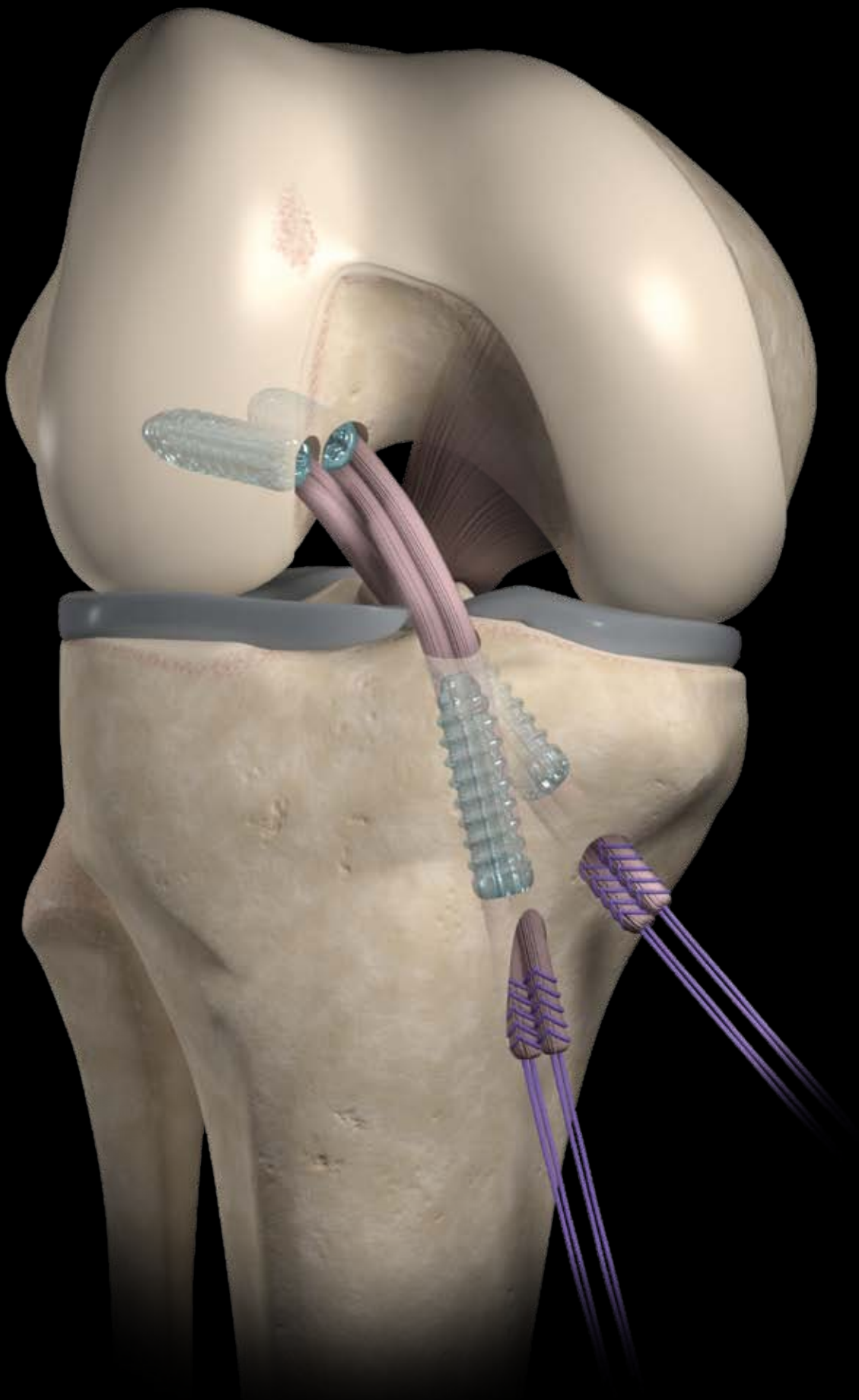


Biodegradable Interference Screw
Surgical Technique

Product Overview

Description

Inion Hexalon™ is the first coloured biodegradable interference screw which allows clear visibility during arthroscopic cruciate ligament reconstruction. In addition to traditional single-bundle procedures, Inion Hexalon™ screws can also be used for the fixation of soft tissue tendon grafts in double-bundle ACL reconstruction. The new Inion Hexalon™ 6 mm screw is small, yet strong enough even for posterolateral bundle grafts which are typically slightly thinner.

Indications

The Inion Hexalon™ Biodegradable interference screw is intended for soft tissue fixation to bone in surgeries of the knee, shoulder, elbow, ankle, foot, hand and wrist where the offered screw sizes are patient appropriate. This includes interference fixation in anterior and posterior cruciate ligament reconstruction using soft tissue or bone-tendon-bone grafts.

Inion Hexalon™ is contraindicated in the following cases:

- Insufficient quality or quantity of bone for interference screw attachment
- Active or potential infections
- Patient conditions such as limited blood supply or chronic disease causing insufficient bone quality or where patient co-operation cannot be guaranteed (e.g.: alcoholism, drug abuse).

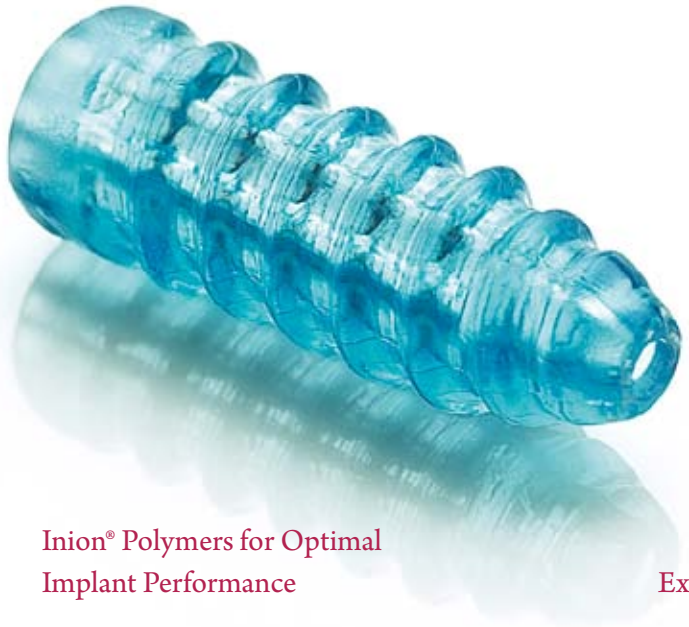
Bio-advantage with Inion® Technology

Inion's core technology is founded on the biological and mechanical principles of bone healing. The company's expertise in biodegradable polymers is based on several decades of experience with these materials and is exemplified by the proprietary Inion® Family of Biodegradable Polymers.

Inion® polymers are made by blending rigid and elastic polymer components to create implants with optimal strength, malleability and degradation profiles to meet their specific clinical requirements.

A key benefit of Inion® polymers is that they degrade in the body and are metabolised into carbon dioxide and water. The rate of degradation is predictible and tailored to provide initial stability and then, as the implant loses its strength, to progressively transfer the load to bone to stimulate regeneration.

Product Overview



Inion® Polymers for Optimal Implant Performance

L-lactide provides high strength and durability. D,L-lactide and TMC provide the required ductility and degradation rate. These basic ingredients of the Inion® polymers have long, successful clinical histories.

The Inion Hexalon™ Biodegradable ACL/PCL screw maintains its strength essentially unchanged for a minimum of 12 weeks after implantation and gradually loses its strength thereafter. Bioresorption takes place within two to four years. Observations of a published study suggest that the Inion Hexalon™ screws degrade fully in 2 years in vivo.[1]

Excellent Visibility During Insertion

Inion Hexalon™ is the first coloured biodegradable interference screw. The use of colour guarantees first-class visibility both during insertion and in its final position.

The pigment, added in trace amounts, has been used routinely in biodegradable sutures for over two decades.

Reduced Risk of Screw Breakage

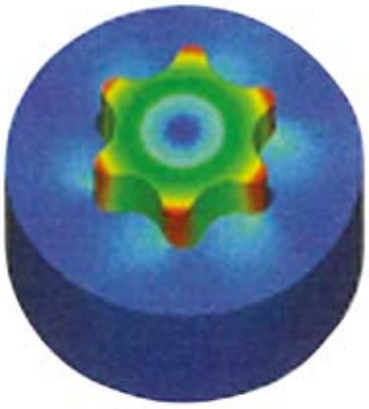
Until now, one of the key disadvantages of biodegradable interference screws has been a tendency to break during insertion. Inion Hexalon™ combines optimal screw design with optimal material composition to achieve significantly reduced risk of screw breakage.

Inion Hexalon™ is designed so that the shape of the socket is highly resistant to torque forces.

The area of red (below) quantifies the tendency of the screw driver to rotate inside the screw causing an increased risk of breakage.

Optimised Thread Design

- Self-tapping
- Designed for both hamstring and BTB graft fixations
- Rounded thread design limits damage to the graft



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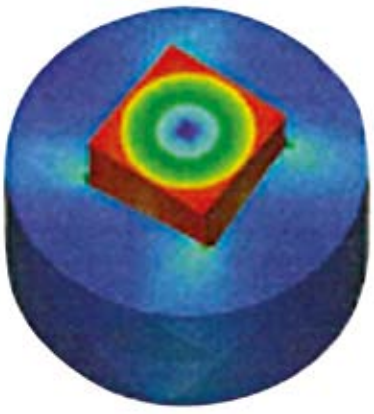
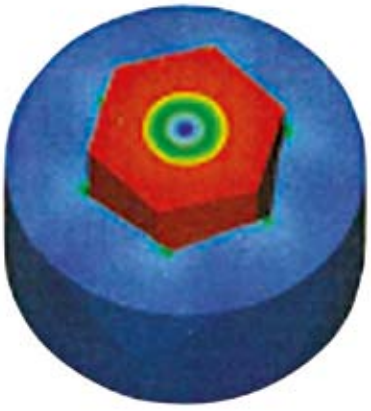
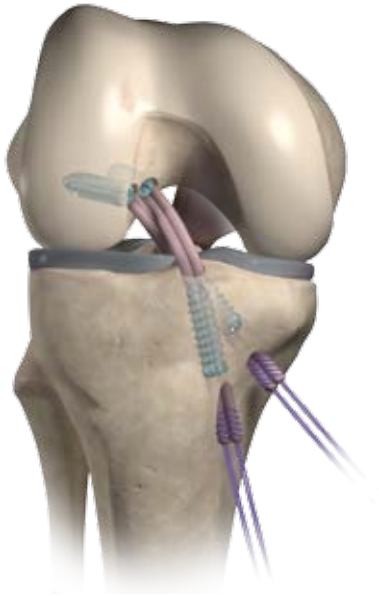




Sockets of other commercially available interference screws

Introduction to the Double-Bundle Technique



Introduction

The double-bundle technique is an arthroscopic procedure where the damaged ligament is replaced with two bundles (grafts), the posterolateral (double Gracilis graft) and the anteromedial bundle (double Semitendinosus tendon graft), instead of the standard single bundle graft typically used in the traditional single bundle ACL reconstruction.

This new procedure allows for a more complete restoration of the ACL thereby improving knee function, especially the rotational stability of the knee joint post-operatively. During this reconstruction, the surgeon will remove the damaged ACL and replace it with two new graft bundles. Hence the name 'double-bundle' technique.

Most patients achieve acceptably good results from single-bundle ACL reconstructions but several studies, both clinical and cadaveric, have shown that normal knee joint kinematics is not fully restored.[3-6]

In 14-30% cases there is also a persistent pivot glide[7-10] and this has raised doubts as to whether subsequent arthrosis can be prevented. In an effort to address these issues, there has been much interest in anatomic, double-bundle ACL reconstruction.

It is now generally recognised that the native ACL does not behave as a simple band of fibres. The seperation of the ligament into anteromedial (AM) and posterolateral (PL) fibre bundles has now been widely accepted as a basis for its understanding.[11-17]

The double-bundle ACL reconstruction technique utilises separate grafts to reconstruct both AM and PL bundles and this has been shown to function more like the native ACL.[5,6]

Surgical Technique of the Double-Bundle ACL Reconstruction[1,18]

Figure 1. Arthroscopic portals and skin incisions in the right knee:
1. Anterolateral portal
2. Standard anteromedial portal
3. Additional anteromedial portal
4. Skin incision for the harvesting of the hamstring grafts and for drilling of the tibial tunnels

Surgical Set-Up

Place the patient supine on the operating table with a pneumatic tourniquet around the proximal thigh. A lateral post controls external rotation of the hip and the foot rests against a distal support to maintain the knee at 90° flexion. This set-up allows the knee to be moved throughout its complete range of flexion/extension.

Arthroscopic Portal Placement

A complete diagnostic arthroscopy is performed first to confirm the ACL tear and possible other findings (meniscal or chondral injury) inside the injured knee.

The standard anterolateral arthroscopic portal (#1 in Figure 1) is established adjacent to the lateral patella tendon border at the level of inferior pole of the patella. Accordingly, the standard AM portal (#2) is placed adjacent to the medial patella tendon border, but about 1 cm below the anterolateral portal, because femoral tunnels are drilled through AM portals (AM tunnel through the standard AM portal, and PL tunnel through an additional AM portal (#3), which is placed about 1 cm medially from the standard AM portal). This has not only been shown to allow improved anatomical placement[19-21] but allows femoral and tibial tunnels to be made independent of each other. The ruptured ACL is examined with an arthroscopic probe, dissected, and debrided.

The tibial footprint of the ACL is left intact. Also, the anatomic footprints of the AM and PL bundles of the ACL on the lateral wall of the intercondylar notch are identified. A bony notchplasty is not performed unless there are osteophytes in the intercondylar space.

Surgical Technique of the Double-Bundle ACL Reconstruction[1,18]

Figure 2. All bone tunnels are drilled before graft preparation.

Bone Tunnel and Graft Preparation

In the double-bundle technique, the AM femoral tunnel is drilled first using the standard AM portal and a freehand technique without a guide (Figure 2). The AM femoral tunnel is placed as posterior as possible, without breaking the posterior wall of the femoral condyle, in the posterior part of the intercondylar notch, at approximately 10 o'clock in the right knee and at approximately 2 o'clock in the left knee. The optimal placement of the tunnel is marked with a 30° awl. Then, a guide wire is placed to the marked optimal position and drilled through the femoral condyle at 120° of knee flexion. The tunnel is drilled with a cannulated drill (diameter of 4 mm) over the guide wire. The final drilling of the tunnel is made after harvesting and measuring the diameter of the hamstring autografts. The diameter of the AM femoral tunnel is typically 7 mm, and the depth of the tunnel is 30 mm.

The PL femoral tunnel is drilled using the previously noted additional AM portal and a free-hand technique without a guide. The anatomical femoral footprint of the PL bundle is identified arthroscopically and marked with a 30° awl, as previously described. If the PL femoral footprint is difficult to identify, as it sometimes can be in a chronic case, the PL femoral tunnel is placed as close as possible to the AM femoral tunnel, without breaking the wall between these tunnels. The PL femoral tunnel is located anteriorly and inferiorly from the AM femoral tunnel. The drilling of the tunnel is performed using the same technique as in AM tunnel. However, the flexion angle of the knee should be 90° when creating the PL femoral tunnel. The diameter of the PL femoral tunnel is 6 mm, and the depth of the tunnel is 30 mm. The wall between these two tunnels (AM and PL) at the femoral side has to be at least 1 to 2 mm, otherwise the inside-out fixation with interference screws is not possible.

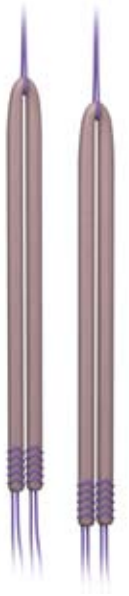


Figure 3. After harvesting the semitendinosus and gracilis tendons, each graft is doubled and whip-stitched with sutures at both ends of the graft.

After creating the femoral tunnels, a 3 cm oblique skin incision (#4 in Figure 1) is made over the AM surface of the tibia for harvesting the semitendinosus and gracilis tendons, and for creation of the tibial tunnels and passage of the grafts. The tendons are harvested with a standard tendon stripper approximately 22 cm above the tibial insertion of the tendons. Each graft is individually cleaned, doubled and whip-stitched with sutures at both ends of the graft (Figure 3, biodegradable sutures on the femoral side of the graft, and non-degradable sutures on the tibial side of the graft). The graft diameters are measured (in 0.5 mm increments). The diameter of the doubled semitendinosus autograft is usually approximately 7 mm, and that of the doubled gracilis autograft approximately 6 mm. The optimal length of each graft is 10 cm because that allows proper fixation of the grafts inside the tunnels. However, because the PL graft can be shorter than that, the minimum length of the graft is 7 cm. Otherwise the fixation of the graft may not be sufficient.

Drilling the tibial tunnels is done with a tibial guide. First, the tibial tunnel for the AM bundle is drilled. An ACL tibial drill guide is placed on the AM aspect of the ACL tibial footprint with the angle set approximately to 55°. The starting point of the AM tibial tunnel is the same as in standard ACL single bundle technique. Once acceptable placement of the AM tibial pin is obtained (no impingement in knee extension), the PL tibial guide wire is placed on the PL aspect of the ACL tibial footprint with the angle set approximately to 55°. The PL tibial tunnel has a more medial starting point on the tibial cortex than standard ACL tibial tunnel. An osseous bridge of approximately 1 to 2 cm should remain on the tibial cortex between these two tunnels. The AM tibial tunnel is drilled first followed by the PL tunnel. The diameter of the AM tibial tunnel is typically 7 mm, and that of the PL tunnel 6 mm. All the tunnels on the tibial side, as well as on the femoral side, can be created by using extraction drilling because cadaveric studies have shown that there is no need to perform either compaction drilling or serial dilation of the tunnels when interference screws are used.[22-23]

Surgical Technique of the Double-Bundle ACL Reconstruction[1,18]

Figure 4. The gracilis tendon graft is inserted first to form the PL bundle.

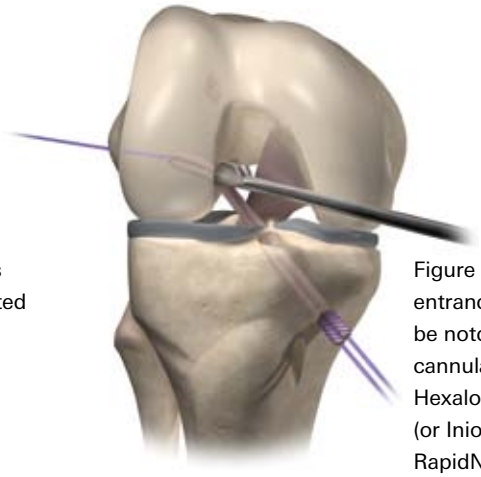


Figure 5. The tunnel entrance should always be notched with the cannulated Inion Hexalon™ Notcher (or Inion Hexalon™ RapidNotcher or Starter) before screw insertion.

Graft Passage and Fixation

Grafts are inserted retrograde via the tibial tunnels into the femoral tunnels. The graft for PL bundle (doubled gracilis tendon autograft) is passed first (Figure 4). Flex the knee maximally and use a standard Beath pin to pass a loop of strong suture material via the AM arthroscopy portal through the PL femoral tunnel and through the skin of the distal thigh. A second loop (preferably of different colour) is similarly passed through the femoral AM bundle tunnel. Using grasping forceps, retrieve the intra-articular portions of each loop through their corresponding tibial tunnel. Use the PL bundle suture loop to pull the prepared PL bundle graft up into its corresponding tunnels. Before the graft is pulled into the femoral bone tunnel, the Inion Hexalon™ Guide wire should be inserted into the femoral bone tunnel where the screw is desired. When the graft is pulled in place, the Inion Hexalon™ Guide wire should remain between the graft and the femoral bone tunnel wall, parallel to the long axis of the bone tunnel. This is important to ensure that the screw will be inserted in correct direction, i.e., parallel to the long axis of the bone tunnel.

Before screw insertion, the tunnel entrance is notched with the cannulated Inion Hexalon™ Notcher (or with the Inion Hexalon™ RapidNotcher or appropriate size Inion Hexalon™ Starter) instrument over the Inion Hexalon™ Guide wire (Figure 5, for more detailed notching instructions see the instructions for use of the Inion Hexalon™ screws). Thereafter the fixation of the PL bundle is done by inserting the biodegradable Inion Hexalon™ interference screw with the cannulated Inion Hexalon™ screwdriver over the Inion Hexalon™ Guide wire (Figure 6, inside-out). The diameter of the screw is usually 6 mm, and the length of the screw is 25 mm. Then the graft for AM bundle (doubled semitendinosus tendon autograft) is passed and fixed with a same technique as PL femoral graft. With the AM bundle fixation in femoral side, the diameter of the screw is usually 7 mm, and the length of the screw is 25 mm. The knee angles, while performing the fixation of each bundle in femoral side, are the same as when drilling the femoral tunnels.

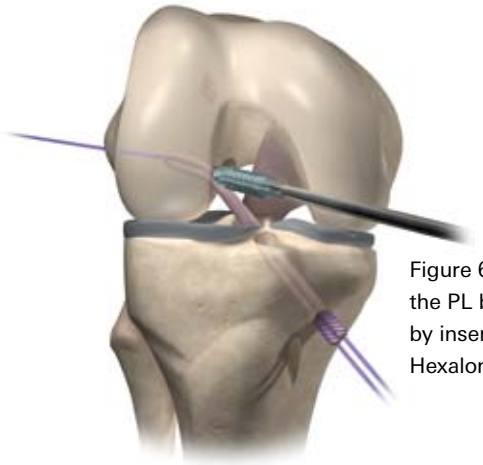


Figure 6. Fixation of the PL bundle is done by inserting Inion Hexalon™ screw

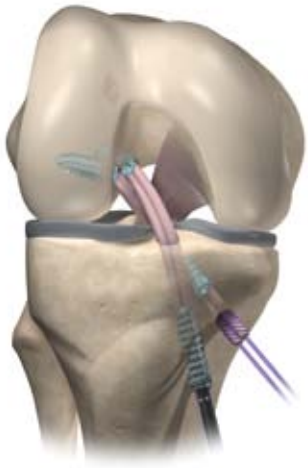


Figure 7. After fixing the PL graft, the semitendinosus tendon graft is inserted to form the AM bundle. The graft is fixed with Inion Hexalon™ screws after notching.

On the tibial side, the PL bundle is tensioned by pulling with a hand and fixed first the knee in full extension, followed by the AM bundle at 30° of knee flexion with tensioning by pulling with a hand. Please note that manual tensioning is sufficient because it has been shown that specific devices designed for tensioning of tendon grafts are not needed[24]. The biodegradable Inion Hexalon™ interference screws are also used for fixation on the tibial side (Figure 7). The diameter of the screw is typically 7 mm in the PL tunnel, and 8 mm in the AM tunnel. The length of the screws is 30 mm. The screws are inserted as close to the joint line as possible (outside-in). An additional fixation is made with the non-degradable sutures coming from each graft to tie them together over the cortical bone bridge between the tibial tunnels. Finally, the knee is taken through the final full range of motion, and the graft is examined arthroscopically to exclude graft impingement.

Please note that to avoid difficulties with screw insertion and the risk of screw breakage it is very important to ensure that:

1. The bone tunnel entrance is properly notched before screw insertion.
2. The tip of the screwdriver is inserted all the way down to the bottom of the screw socket before screw insertion.
3. The guide wire, the screwdriver and the screw are all held parallel to the long axis of the bone tunnel during screw insertion.

If there is difficulty to insert the screw (e.g., due to high bone density), do not try to drive in the screw with force. Instead of using extraordinary force, remove the screw, double-check that the screw size is appropriate, repeat notching, and try again. When using soft tissue grafts (e.g., hamstring tendon grafts), depending on the bone quality, the screw diameter should be 0-1 mm larger than the diameter of the graft/bone tunnel. Note, to avoid complications, the screw must always be implanted completely inside the bone (i.e., below or flush with the bone surface).

Post-operative Rehabilitation

Immediate full weight bearing and full range of motion is permitted. Crutches are used for 3 to 4 weeks.

No rehabilitation brace is used. Closed-chain exercises are started immediately post-operatively. Cycling is permitted with an ergometer bicycle at 4 weeks, running at 3 months, and pivoting sports at 6 months post-operatively, provided that the patient has regained full functional stability. If meniscal repair is performed at the same operation, the range of motion of the knee is allowed 0 to 90° for the first 6 weeks. Otherwise the rehabilitation is carried through as described above.

Advantages of the Double-Bundle ACL Reconstruction with 4 Inion Hexalon™ Screws

- More anatomical reconstruction of the anteromedial and posterolateral bundles of the ACL
- Increased rotational stability
- Maximizes graft stiffness with true joint line fixation
- Inion Hexalon™ combines optimal screw design with optimal material composition to achieve superior torsional strength and reduced screw breakage risk compared to previous biodegradable screws[2]
- The Inion Hexalon™ has been designed such that the shape of the socket is the most resistant to torque forces
- The presence of TMC in the Inion® polymer blend makes the product tough and resistant to torque forces
- The innovative design taper of the screw and optimized screw thread design provides grip and stability during insertion and once in place
- Inion Hexalon™ is self-tapping and suited for all graft types
- Inion Hexalon™ comes in range of sizes starting from 6 mm

Surgical Technique of the Single-Bundle ACL Reconstruction

Figure 8. Single-bundle ACL reconstruction with two Inion Hexalon™ screws.

In the single-bundle technique, a single-incision arthroscopic technique described by Pinczewski et al[25] is used with standard AM and anterolateral arthroscopy portals, and with biodegradable screw fixation as described above. First the femoral tunnel is drilled through the AM portal with free-hand technique without a guide in the same manner as described above when doing the AM femoral tunnel. Then the tibial tunnel is drilled in the middle of the footprint of the ACL tibial insertion using a tibial drill guide. Semitendinosus and gracilis tendons are harvested, as described above, and quadrupled. The diameter of the 4-stranded autograft is typically 8 mm, and the length is 10 cm.

The graft is inserted retrograde via the tibial tunnel into the femoral tunnel, and fixed with the biodegradable Inion Hexalon™ interference screws proximally and distally, as described above for the fixation of the AM bundle. Tunnel size equals the diameter of the graft (typically 8 mm). The diameter of the screw is typically 8 mm in the femoral side, and 8 to 9 mm in the tibial side. The length of the screw is 25 mm in the femoral side, and 30 mm in the tibial side. The procedure is completed as described above for the double-bundle technique.

Ordering information

Inion Hexalon™ Screws

Art. No.	Description
ACL-4113	Single packed Screw 6 x 20 mm
ACL-4114	Single packed Screw 6 x 25 mm
ACL-4115	Single packed Screw 6 x 30 mm
ACL-4101	Single packed Screw 7 x 20 mm
ACL-4102	Single packed Screw 7 x 25 mm
ACL-4103	Single packed Screw 7 x 30 mm
ACL-4104	Single packed Screw 8 x 20 mm
ACL-4105	Single packed Screw 8 x 25 mm
ACL-4106	Single packed Screw 8 x 30 mm
ACL-4107	Single packed Screw 9 x 20 mm
ACL-4108	Single packed Screw 9 x 25 mm
ACL-4109	Single packed Screw 9 x 30 mm
ACL-4112	Single packed Screw 10 x 30 mm

SET-4000 Set (4 Screws)

Description
7 x 25 mm
7 x 25 mm
8 x 30 mm
9 x 30 mm

Inion Hexalon™ Instruments

Art. No.	Description
INS-9200	Screwdriver
INS-9201	Notcher
INS-9202	24 cm guide wire
INS-9203	38 cm guide wire
INS-9205	Starter 6/7 mm
INS-9206	Starter 8/9 mm
INS-9207	RapidNotcher

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INION OY
Lääkärinkatu 2
FI-33520 Tampere, FINLAND
tel: +358-10-830 6600
fax: +358-10-830 6601
email: info@inion.com
internet: www.inion.com

INION INC
2800 Glades Circle
Suite 138, Weston
FL 33327
USA
Toll-free tel: 866-INION-US
tel: 954-659-9224
fax: 954-659-7997

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