

RESTORE™

ACL Reconstruction System



■ *Optimal Results, Innovative Design*



Mitek®
PRODUCTS

SURGICAL

CONSISTENCY

Acorn Reamers

Confident, precise drilling

- Long tip minimizes anterior migration during tibial drilling
- Smooth atraumatic shoulder maximizes femoral drilling confidence

Fully Fluted Reamers

Greater versatility, ease-of-use

- Unique flute orientation simplifies collection of bone chips for grafting

Consistency in ACL, regardless of graft selection, is assured with the Restore™ ACL Reconstruction System. Superior classic instrumentation has been enhanced with innovative instrument design to create a system that complements, and is unique to ACL reconstruction.

Precise, reproducible results are the cornerstone to optimum surgical outcomes: from graft harvesting to fixation. Procedural success begins with the harvest of a patellar tendon graft using the patented twin bladed ACL Graft Knife, and culminates with graft fixation using the classic titanium Advantage® Interference Screw. Likewise, a hamstring graft can be harvested with the trigger activated Target® Tendon Harvester, and then fixated with an atraumatic Phantom™ SofThread™ Absorbable Interference Screw and Intrafix™ Tibial Fastener.

From start to finish, the Restore ACL Reconstruction System combined with the Mitek procedure specific ACL accessories and fixation devices provide a solid foundation upon which the surgeon can experience a continued history of success.

ASSURED...



TO THE



Tibial Drill Guide

Consistent results with increased stability

- Ratchet mechanism allows one-handed placement of guide
- Guide pin accurately passes between prongs without deflection
- Two pronged tip combines with ratchet mechanism to create a stable platform



FINISH

Femoral Offset Aimers

Optimize tunnel location to minimize "back wall blow out"

- Low profile shaft complements arthroscopic manipulation

INTERFERENCE SCREWS

INDICATIONS

The Advantage®, Profile™, and Big Advantage® Interference Screws are intended to be used to provide interference fixation of bone-patellar tendon-bone grafts in ACL reconstruction. The Profile Interference Screw, 20 mm and longer, is also intended to provide interference fixation of bone-patellar tendon-bone grafts in PCL reconstruction and to provide fixation of soft tissue grafts in ACL reconstruction.

CONTRAINDICATIONS

These devices are contraindicated for use in:

1. Bone-to-bone fracture fixation;
2. Fixation of other devices, such as bone plates;
3. Spinal fixation;
4. The presence of active/acute infection.

WARNINGS AND PRECAUTIONS

Appropriate precautions should be taken to prevent the following occurrences which have been reported in the medical and scientific literature for similar devices:

1. Inadvertent movement of the graft during screw insertion, resulting in loss of tension on the graft;
2. Laceration of the tendonous portion of the graft by the screw threads;
3. Damage to the passing sutures used to position the graft;
4. Misplacement of the screw, which reduces the amount of graft/screw contact, potentially resulting in loss of graft fixation;
5. Encroachment of the screw within the joint space caused by screw migration and/or improper positioning;
6. Backing out of the screw, resulting in loss of graft fixation and/or soft tissue irritation;
7. Breakage of the screw during insertion, resulting in inadequate graft/screw contact and possible migration of screw fragments into the knee joint;
8. Stripping of the screw head and/or the driver instrument during screw insertion.

In using partial weight bearing and nonweight bearing orthopaedic fixation devices, the surgeon should be aware of the following:

1. No partial weight bearing or nonweight bearing fixation device can be expected to withstand the unsupported stresses of full weight bearing. Until final healing is achieved, the patient should employ adequate external support and restrict physical activities that could place stresses upon the implant, allow movement at the reattachment site and delay healing;
2. Correct selection of the implant is extremely important. The potential for success in soft tissue fixation is increased by the selection of the proper size, shape, and design of the implant. The size and shape of the bones may present restrictions on the size and strength of the implants;
3. Preoperative and operating procedures, including knowledge of the surgical techniques to be used, are important considerations in the successful utilization of soft tissue fixation devices;
4. In selecting patients for orthopaedic fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
 - An overweight or obese patient can produce loads on the device which can lead to failure of the device and the surgical repair;
 - Patient occupations or activities which include substantial walking, running, lifting, or muscle straining can cause failure of the device or surgical repair;
 - Conditions such as senility, mental illness, alcoholism, or drug abuse may cause the patient to ignore necessary limitations and precautions, leading to implant failure or other complications;
 - In some cases, the progression of degenerative diseases may be so advanced at the time of implantation that the expected useful life of the fixation device may be substantially reduced;
5. Correct handling of the implant is extremely important. Damage of any kind can potentially weaken the screw;
6. Detailed written instructions and precautions should be given to the patient. The patient should be warned that breakage or dislodgment of the device prior to complete biologic healing may occur as a result of activity.

ABSOLUTE® SCREW

INDICATIONS

The Mitek Absolute Absorbable Interference Screw is intended for attachment of soft tissue grafts or bone-tendon grafts to the tibia and/or femur during cruciate ligament reconstruction surgeries.

CONTRAINDICATIONS

1. This device is not cleared for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. Insufficient quantity or quality of bone, comminuted bone surfaces, or pathologic bone conditions such as cystic change or severe osteopenia that would impair the ability of the Absolute Absorbable Interference Screw to securely fixate to the bone.
3. Physical conditions which would eliminate, or tend to eliminate, adequate implant support or retard healing, i.e., blood supply limitations, infections, etc.
4. Implant/material sensitivity/foreign body sensitivity.
5. Conditions which tend to pre-empt the patient's ability or healing period, such as senility, mental illness or alcoholism.

PRECAUTIONS

1. The Mitek Absolute Absorbable Interference Screw should not be used without prior review of the procedure and Instructions for Use.
2. The Mitek Absolute Absorbable Interference Screw implant is supplied STERILE and is intended for single use only. Do not resterilize.

WARNINGS

1. Inspect instruments for damage prior to use. Replace damaged or worn instruments. Do not attempt to repair.
2. If resistance is felt during the insertion of an Absolute Absorbable Interference Screw over a guidewire, stop and confirm that the guidewire is not entrapped. If entrapped, back out the screw and withdraw the guidewire.

MITEK INTRAFIX™ TIBIAL TAPERED SCREW, INTRAFIX TIBIAL SHEATH, TIE TENSIONER

INDICATIONS

The Mitek Intrafix Tibial Tapered Screw and Intrafix Tibial Sheath are indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

CONTRAINDICATIONS

1. This device is not cleared for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
2. Insufficient quantity or quality of bone, comminuted bone surfaces, or pathologic bone conditions such as cystic change or severe osteopenia that would impair the ability of the Tibial Tapered Screw and Tibial Sheath to securely fixate to the bone.
3. Physical conditions, which would eliminate, or tend to eliminate, adequate implant support or retard healing, i.e., blood supplies limitations, infections, etc.
4. Conditions which tend to pre-empt the patient's ability or healing period, such as senility, mental illness or alcoholism.

PRECAUTIONS

1. Inspect the reusable instruments for damage prior to use. Replace damaged or worn instruments. Do not attempt to repair.
2. The Tibial Tapered Screw and Tibial Sheath are supplied STERILE, and are intended for single patient use only. Do not resterilize.

WARNINGS

1. Failure to use the Sheath Trial may cause difficulty inserting the Tibial Sheath to its full depth, particularly in small tunnels.
2. The suture loops must be between 4.5" - 6". If they are smaller, it may prevent placement of the suture loops over the suture arms on the Tie Tensioner. If they are larger, it may inhibit the instruments from fully inserting the implants into the tibial tunnel. If one loop is undersized, and the other loop is oversized, the Tie Tensioner may shift too far to one side of the tunnel preventing the instruments from passing through the center cannula in line with the tunnel.

Mitek[®]
PRODUCTS

ACL GRAFT KNIVES LIGAMENT GRAFT KNIVES & GRAFT PASSERS

WARNING

ALWAYS DRILL THE BONE TUNNELS AT LEAST 1 MM LARGER IN DIAMETER THAN THE BONE PLUGS TO ALLOW FOR THE THICKNESS OF THE GRAFT PASSER/PROTECTOR.

PHANTOM™ ABSORBABLE INTERFERENCE SCREWS & SET SCREWS

INDICATIONS

The Phantom SofThread Screw is intended to be used to provide interference fixation of soft tissue grafts in ACL reconstruction.

CONTRAINDICATIONS

These devices are contraindicated for use in:

1. Bone-to-bone fracture fixation;
2. Fixation of other devices, such as bone plates;
3. Spinal fixation;
4. The presence of active/acute infections.

WARNINGS

When using the Phantom SofThread Screw, use of a screw with a diameter that is 1 mm less than the tunnel diameter is recommended to reduce the chance of screw breakage. When using a guidewire with the Phantom Absorbable Screws, it is important that the guidewire is not kinked or bent as breakage of the screw can then occur. Refer to the table below in choosing the correct diameter of guidewire for each Phantom:

Phantom Screw	Correct Diameter of Guidewire
7 & 8 mm Phantom SofThread Int Scw	0.045 in (1.14 mm)
9 & 10 mm Phantom SofThread Int Scw	0.062 in (1.57 mm)

Absorbable Screw

DO NOT USE A GUIDEWIRE WITH A DIAMETER LARGER THAN THAT RECOMMENDED; USE OF A LARGER GUIDEWIRE CAN RESULT IN BREAKAGE OF THE SCREW.

- It is important that the driver/insertor instrument be fully seated for screw insertion to reduce the potential for over-stressing and fracturing the screw. Examine the driver/insertor for excessive wear, bending or other damage prior to screw engagement.

PRECAUTIONS

Appropriate precautions should be taken to prevent the following occurrences which have been reported in the medical and scientific literature for similar devices:

1. Inadvertent movement of the graft during screw insertion, resulting in loss of tension on the graft;
2. Laceration of the tendinous portion of the graft by the screw threads;
3. Damage to the passing sutures used to position the graft;
4. Misplacement of the screw, which reduces the amount of graft/screw contact, potentially resulting in loss of graft fixation;
5. Encroachment of the screw within the joint space caused by screw migration and/or improper positioning;
6. Backing of the screw, resulting in loss of graft fixation and/or soft tissue irritation;
7. Breakage of the screw during insertion, resulting in inadequate graft/screw contact and possible migration of screw fragments into the knee joint;
8. Stripping of the screw head and/or driver instrument during screw insertion.

In using partial weight bearing and nonweight bearing orthopaedic fixation devices, the surgeon should be aware of the following:

1. No partial weight bearing or nonweight bearing fixation device can be expected to withstand the unsupported stresses of full weight bearing. Until final healing is achieved, the patient should employ adequate external support and restrict physical activities that could place stresses upon the implant, allow movement at the reattachment site and delay healing;

2. Correct selection of the implant is extremely important. The potential for success in soft tissue fixation is increased by the selection of the proper size, shape and design of the implant. The size and shape of the bones may present restrictions on the size and strength of the implants;
3. Preoperative and operating procedures, including knowledge of surgical techniques to be used, are an important consideration in the successful utilization of soft tissue fixation devices;
4. In selecting patients for orthopaedic fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
 - An overweight or obese patient can produce loads on the device which can lead to failure of the device and the surgical repair;
 - Patient occupations or activities which include substantial walking, running, lifting, or muscle straining can cause failure of the device or surgical repair;
 - Conditions such as senility, mental illness, alcoholism, or drug abuse may cause the patient to ignore necessary limitations and precautions, leading to implant failure or other complications;
 - In some cases, the progression of degenerative diseases may be so advanced at the time of implantation that the expected useful life of the fixation device may be substantially reduced;
5. Correct handling of the implant is extremely important. Damage of any kind can potentially weaken the screw;
6. Detailed written instructions and precautions should be given to the patient. The patient should be warned that breakage or dislodgment of the device prior to complete biologic healing may occur as a result of activity.

MITEK® THREADED TIBIAL CANNULA (KNEE CANNULA)

INDICATIONS

Intended for arthroscopic surgical use to plug the tibial tunnel and/or maintain portals during insertion or extraction of instruments.

WARNINGS

Do not re-sterilize. The Mitek Threaded Tibial Cannula is provided sterile, for single use only. Discard any open, unused product.

PRECAUTIONS

1. A surgeon should not begin clinical use of the Mitek Threaded Tibial Cannula without reviewing the instructions for use.
2. Wear eye protection during the use of this device.

CAUTION

FEDERAL (USA) LAW RESTRICTS THESE DEVICES
TO SALE BY OR ON THE ORDER OF A PHYSICIAN.



Notchplasty

Unsurpassed selection
for every need

- Extensive offering of instruments to facilitate Notchplasty and tunnel chamfering

Mitek[®]
PRODUCTS

FROM THE START



Accessories

Mitek offers a comprehensive selection of products for harvesting, preparation, fixation and passing of ACL Grafts. Please reference the Mitek Price List for a complete listing.

Mitek[®]
PRODUCTS

Rear Entry Drill Guide System

Adaptable drill guide for alternative tunnel placement



- Classic drill guides position femoral tunnels for two incision technique



Interference Screw Fixation

- Advantage[®] assures strong titanium bone-tendon-bone fixation
- Big Advantage[®], in 11mm and 13mm diameters, addresses revision challenges
- Profile[™] offers titanium fixation of both bone-tendon-bone and soft tissue grafts
- Absolute[®] delivers "titanium style" confidence in the bioabsorbable fixation of bone-tendon-bone and soft tissue grafts
- Phantom[™] SofThread[™] maximizes fixation strength with an atraumatic thread design

Product Ordering Information

RESTORETM
ACL Reconstruction System

Cat. No.	Description
219301	Tibial Guide
219312	Back Cutting Burr

Acorn Reamers

219338	8mm
219339	9mm
219335	10mm
219331	11mm
219332	12mm
219333	13mm

Fully Fluted Reamers

219346	6mm
219347	7mm
219348	8mm
219349	9mm
219340	10mm
219341	11mm
219342	12mm
219343	13mm

Notchplasty Instruments

219303	5mm Osteotome with Millimeter Scale
219304	Mallet
219305	Arthroscopic Gouge
219308	Cup Curette
219306	Ring Curette, 4mm
219307	Ring Curette, 7mm
219302	Flat Rasp
219309	Curved Rasp
219311	Graft Harvest Gouge
219313	Femoral Awl, 45° Round
219314	Tibial Awl 90° Round
219315	Articular Cartilage Awl, 90° Flat Edge

Femoral Aimers

219335	5mm Offset
219356	6mm Offset
219357	7mm Offset
219358	8mm Offset

Cat. No.	Description
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Rear Entry Drill Guide System

219361	Rear Entry Right Guide
219362	Rear Entry Left Guide
219363	Medial Portal Introducer
219364	Lateral Portal Introducer

ACL Accessories

214660	6mm x 5mm Clear Cannula System
219224	Bayonet Point Pin w/ Eyelet, 14 [°] *
219321	Drill Point w/ Eyelet, 14 [°] *
219322	Bayonet Point Pin w/ Eyelet, 12 [°] *
219328	Bayonet Point Pin w/ Eyelet, 18 [°] *
219332	Trocar Point Pin, Thin Shaft, 14 [°] *
219351	Tunnel Notcher
219352	Pin Puller
219377	Knee Cannula*
232002	Pigtail Tendon Peeler
232004	Target [®] Tendon Harvester
254730	Closed Tendon Stripper
232015	Graft Sizer (8 – 12mm)
232024	Malleable Retractor*
254728	Calibrated Trocar Point w/ Eyelet, 15 [°] *
254729	Calibrated Drill Point w/ Eyelet, 15 [°] *
<i>ACL Graft Knives</i>	
232108	8mm, Tan
232109	9mm, Copper
232110	10mm, Green
232111	11mm, Blue
232112	12mm, Black

Revision Instruments

Please refer to the Mitek Price List for complete offering of trephines, curettes and easy outs.

Container System and Accessories

Please refer to the Mitek Price List for a comprehensive system of sterilization trays, mats, and instrument organizers.

*For single use only.

Innovation Defined by Experience

For more information, call your Mitek representative at 1-800-382-4682 or visit us at www.mitek.com. Mitek Products, Division of ETHICON, Inc. • 60 Glacier Drive, Westwood, Massachusetts 02090

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Mitek[®]
PRODUCTS
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