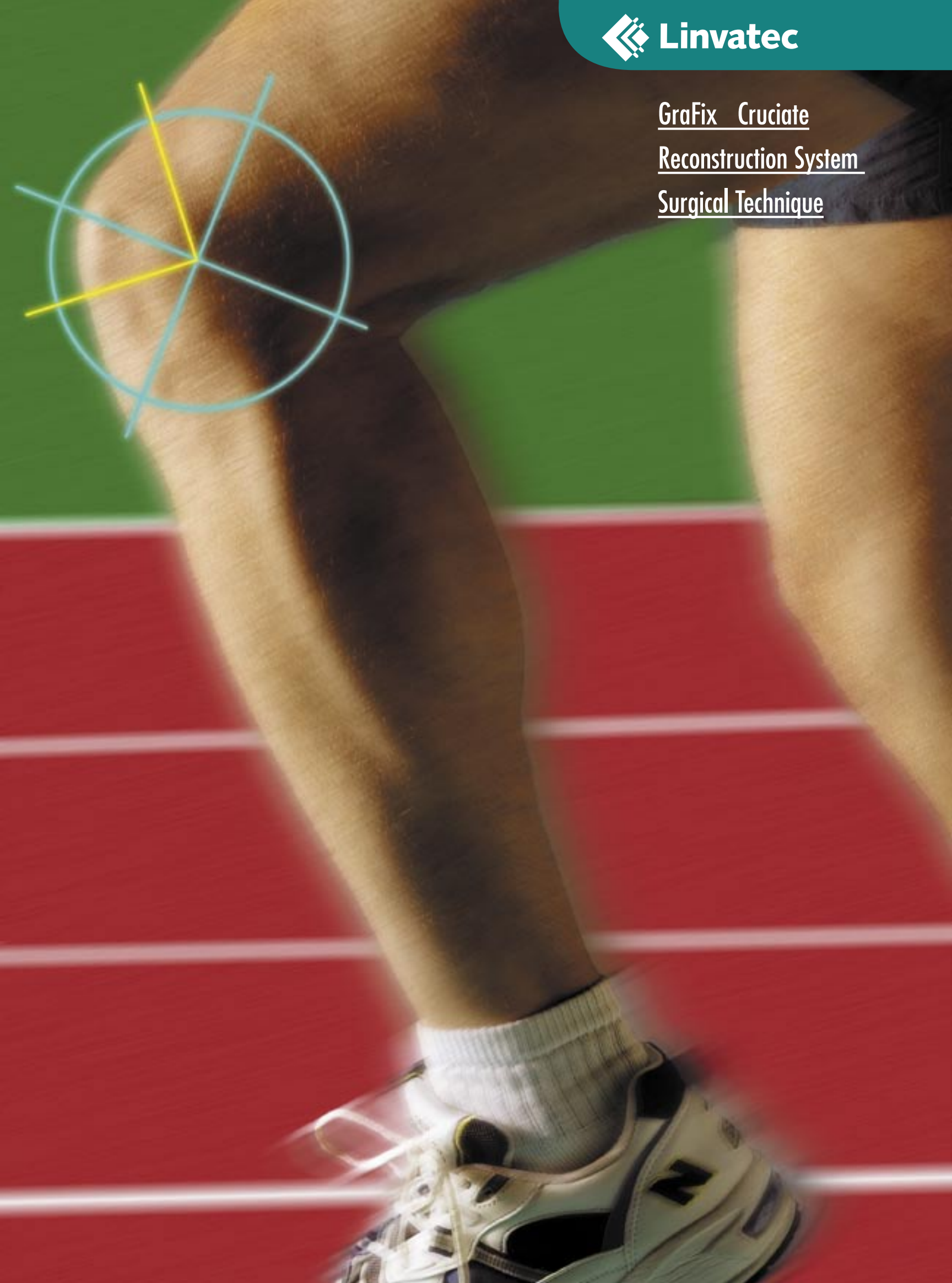


GraFix Cruciate
Reconstruction System
Surgical Technique





GRAFIX™ CRUCIATE RECONSTRUCTION SYSTEM

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GRAFIX CRUCIATE RECONSTRUCTION SYSTEM

SURGICAL TECHNIQUE

INTRODUCTION

The GraFix™ ACL System is designed to facilitate arthroscopic anterior cruciate ligament reconstructions.

Using the Linvatec Pinn-ACL® Cruciate Guide^{1, 2} and Bullseye® Femoral Guide,^{3, 4} this system enables the surgeon to accomplish precise, reproducible guide pin and subsequent tunnel placement.

The 2-Pin Passer³ allows for parallel interference screw placement alongside the graft without divergence.

Linvatec interference screws are available in the most complete variety of sizes, materials and configurations to accommodate all preferences.

GRAFT HARVESTING AND PREPARATION

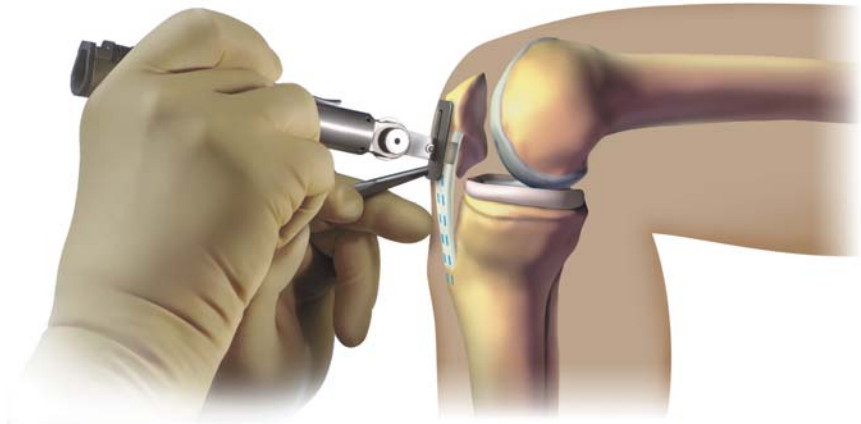
FOR PATELLAR TENDON & HAMSTRING TENDON

STEP 1 – GRAFT HARVESTING

PATELLAR TENDON

A vertical incision is made to adequately expose the patellar tendon and to allow access for tibial tunnel drilling. Two small incisions may be used instead of one longer one. The peritenon is divided and retracted. The tendon is measured and marked.

The appropriate *Graft-Harvesting Template*⁵ (9, 10, 11, or 12mm) is selected and secured with the screw drills. A Linvatec Sawblade is used equipped with an 8mm-depth stop, to produce consistent sized bone blocks.

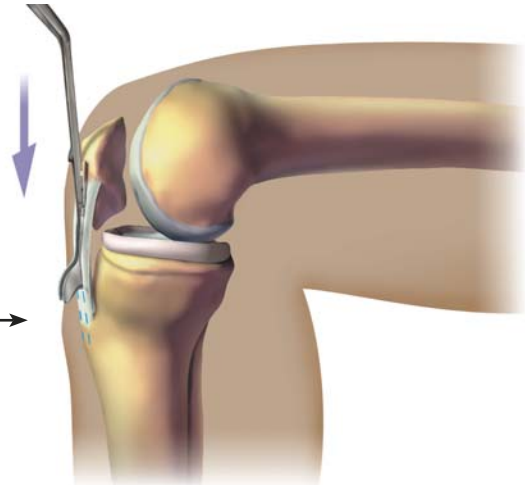


1a

The *Parasmillie*^{®3} double blade graft harvester (9,10,11, and 12mm) is used to resect the tendon. The unique smillie design allows reproducible tendon resection in-line with the tendon's fibers without cutting across the fibers (as is often the case with a standard double blade knife).

An alternate method may be employed harvesting the tibial tubercle first using the *Parasmillie*^{®3} knife in a retrograde fashion and finally harvesting the patellar bone plug.

1b

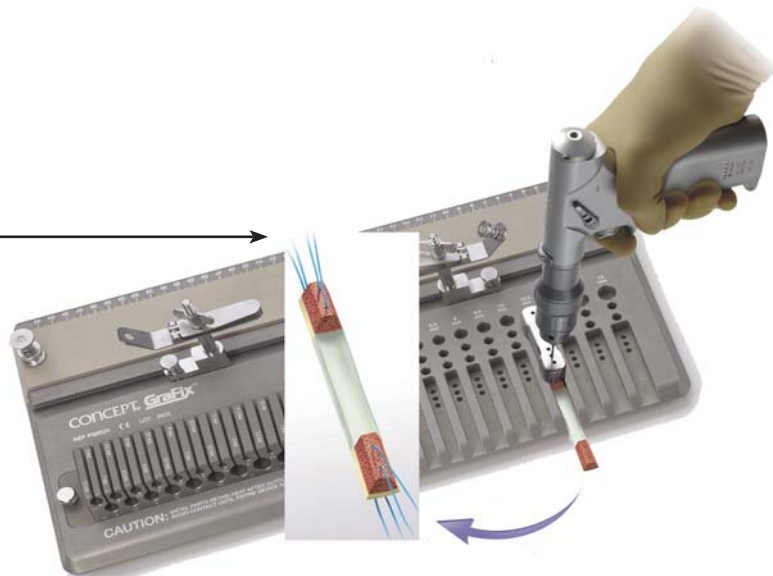


STEP 2 – GRAFT PREPARATION

PATELLAR TENDON

Graft preparation and sizing is accomplished on the Linvatec *GraFix*[™] *PrepStand*.³ Passing/ tensioning sutures are placed and the graft is wrapped in a moist sponge.

2a



STEP 1 – GRAFT HARVESTING

HAMSTRING TENDON

A 3-4cm incision is made over the Pes Anserinus insertion. This incision should also incorporate the entrance for the tibial tunnel.

The sartorius fascia is incised in-line with the pes tendons and retracted, exposing the sartorius, gracilis and semi-tendinosus tendons. Each tendon is isolated with a right angle hemostat and may be tagged with a penrose drain.

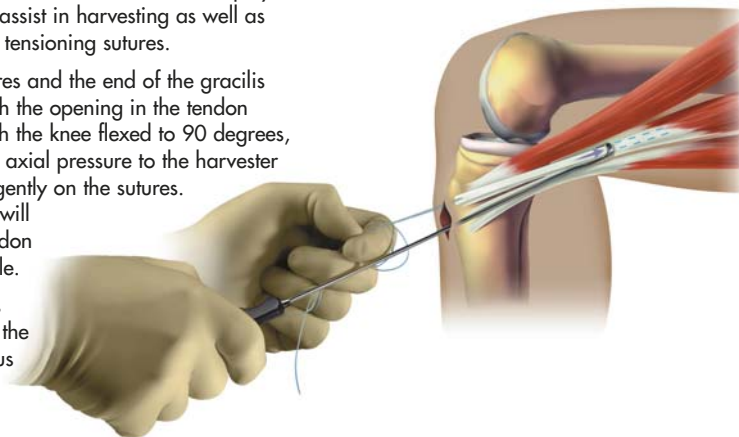
The tendons are mobilized using blunt finger dissection and Metzenbaum scissors to excise the accessory bands running to the gastrocnemius. These bands, if not excised, could cause the tendon harvester to prematurely amputate the graft.

While grasping the tendon with an Allis clamp, dissect the distal attachment from the tibial

tubercle. Traction sutures of #2 braided polyester are placed to assist in harvesting as well as functioning as tensioning sutures.

Place the sutures and the end of the gracilis tendon through the opening in the tendon harvester. With the knee flexed to 90 degrees, apply inward, axial pressure to the harvester while pulling gently on the sutures. The harvester will dissect the tendon from the muscle.

This process is repeated with the semi-tendinosus tendon.



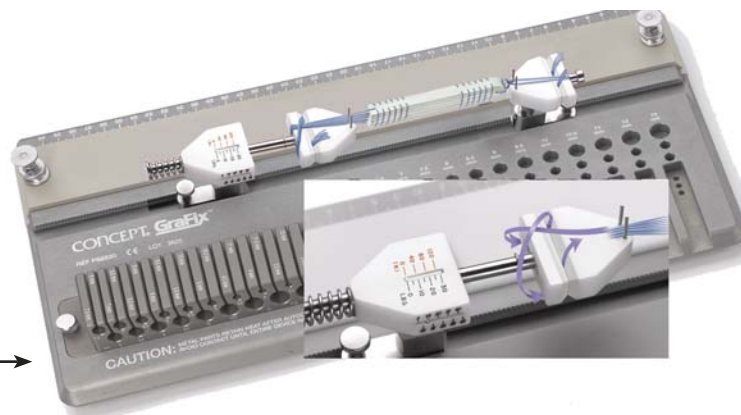
1a

STEP 2 – GRAFT PREPARATION

HAMSTRING TENDON

The graft is prepared and sized to the nearest .5mm on the *GraFix™* PrepStand, then tensioned in the usual fashion.

2a

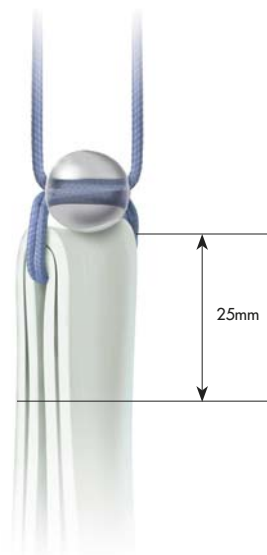


The Linvatec *EndoPearl™* 6 fixation device was designed to prevent graft slippage, and enhance fixation within the femoral socket. The *EndoPearl™* (7, 8, and 9mm) diameter should be selected to match the graft diameter.

The *EndoPearl™* is secured to the graft with 1 or 2 #5 braided sutures. The knot that is created by tying the sutures together is hidden within the graft construct. A separate #5 braided suture is passed through the eyelet of the *EndoPearl™* to be used as a pull through suture. The graft is then marked correlating to the selected Linvatec *BioScrew®* length.

During femoral fixation, the lead end of the *BioScrew®* interference screw comes into contact with the *EndoPearl™*, securing it and the graft within the femoral socket, preventing slippage.

2b



GRAFIX™ CRUCIATE RECONSTRUCTION SYSTEM

TIBIAL TUNNEL PLACEMENT

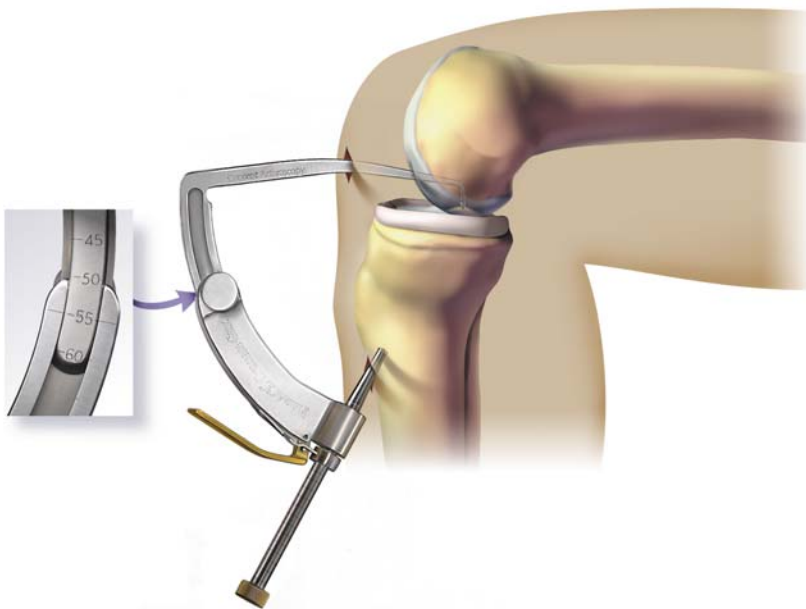
STEP 3 – TIBIAL TUNNEL GUIDE PIN PLACEMENT

The *Pinn-ACL*® Tibial guide is used to place a guide pin in the anatomically correct position for the tibial tunnel.

With the knee in 90 degrees of flexion, insert the stylus through the anteromedial portal and position the tip in the desired location. The remaining ACL stump, the anterior horn of lateral meniscus or PCL, may be used as a reference for this position. If the PCL is used, select a point 5-7mm anterior to the fibers of the PCL. A point 7mm anterior to the PCL should be selected **ONLY** for a 10mm tunnel. A point 5mm or 6mm should be selected for an 8mm or 9mm tunnel, respectively.*

The calibrated pin sleeve is advanced to the anterior tibial cortex. The correct position, on the tibial cortex, should be approximately 1.5cm medial to the center of the tibial tubercle and 1cm superior to the Pes Anserinus. Over tightening of the guide pin sleeve against the cortex could cause the guide to torque, and the guide pin to diverge and miss the desired position. NOTE: For a BTB graft, verify that the calibration markings on the guide pin sleeve added to 60 (30mm of inter-articular distance + 30mm femoral socket depth) is at least equivalent to the overall length of the graft to insure adequate tibial tunnel length and avoid graft tunnel mismatch.

3a



The 3/32" guide pin is drilled through the sleeve, into the joint. If desired, the pin may be advanced carefully into a non-articulating portion of the femoral condyle, stabilizing the lead end of the guide pin. This will increase the accuracy of reaming the tibial tunnel. Proper placement is verified visually with the arthroscope. The guide pin sleeve is removed and the *Pinn-ACL*® guide removed from the joint.

3b

TIBIAL TUNNEL PREPARATION

METHOD 1

STEP 4 – TIBIAL TUNNEL PREPARATION WITHOUT DILATION

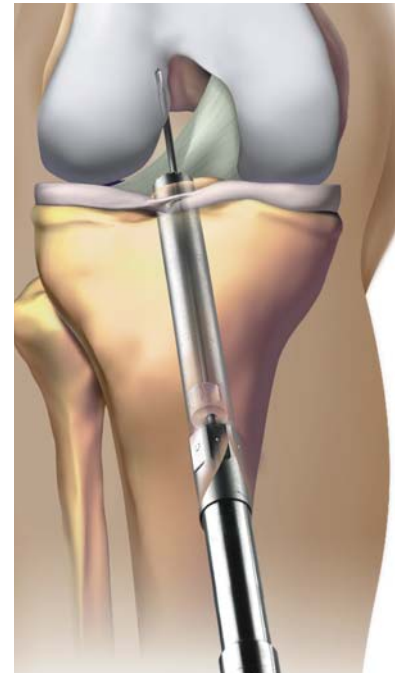
METHOD 1

ACCUDRILL™

Select the correct size Reamer and drill over the guide pin.⁸

GRAFIX™ CORING SYSTEM⁹

When using the Coring System, it is necessary to pre-drill the cortex with a drill bit
4a ~~reamer~~ to a depth of 1cm and the diameter of the desired tunnel.



The appropriate sized disposable coring tip is inserted onto the reusable shaft. The Coring Reamer and centering sleeve are positioned over the guide pin past the cortex and drilled into the joint.

Excessive forward pressure should be avoided to prevent divergence of the coring reamer. A gentle
4b ~~centering motion~~ should be employed and the surgeon must maintain proper hand / arm alignment to insure an accurately placed tunnel.

Completely penetrate the tibial plateau with the coring reamer to insure that the bone core will be removed within the reamer.



4c

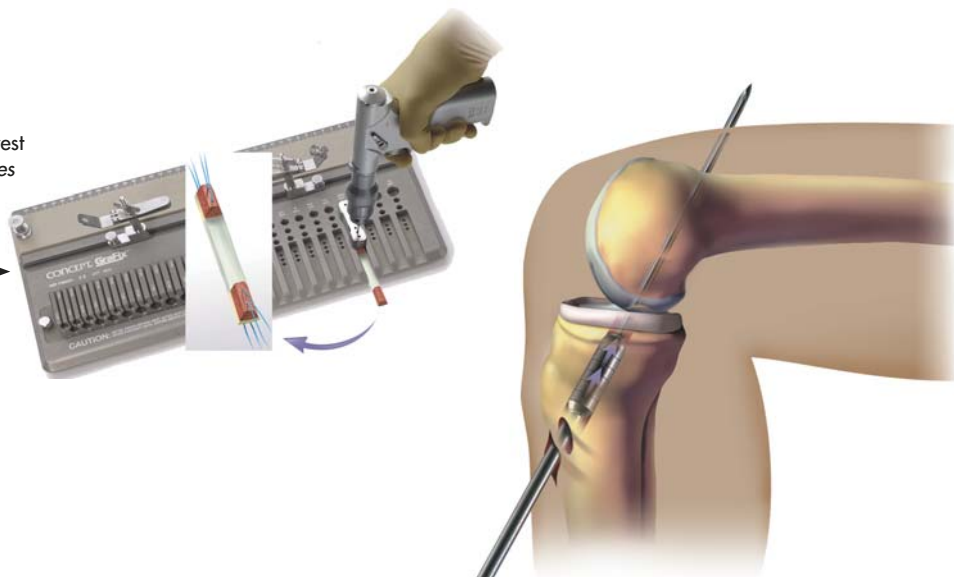
TIBIAL TUNNEL PREPARATION METHOD 2

STEP 4 – TIBIAL TUNNEL PREPARATION WITH DILATION

METHOD 2

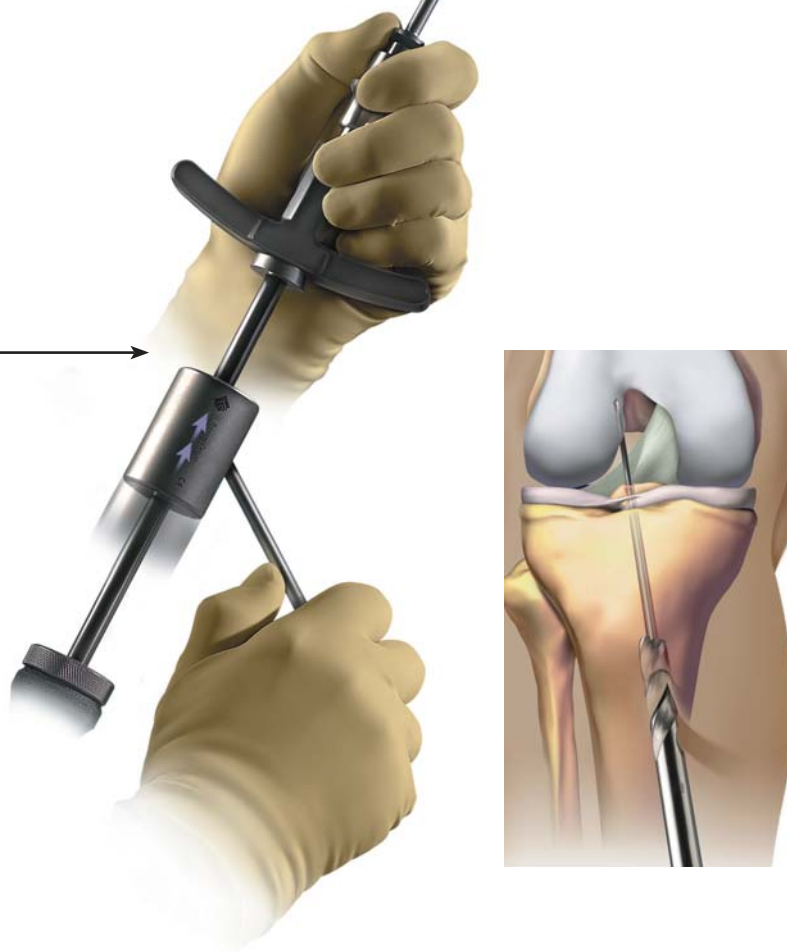
The graft should be tightly sized to the nearest 1/2mm using the Linvatec *Graft Sizing Tubes* or the removable sizing block on the *GraFix™ PrepStand*.

4a



The tunnel should be initially reamed 1.5-2mm smaller than the desired diameter using a standard *AccuDrill™*. Prior to dilating, the anterior tibial cortex must be drilled to the final diameter, to allow passage of the larger dilators. The tunnel should be dilated, using the *GraFix™ Dilators*, to the desired diameter. (i.e. if the graft measures 8mm, drill a 6mm tunnel, over-drill the anterior cortex to 8mm, then dilate the tunnel to 8mm) The *GraFix™ Dilators* have a quick connect shank for rapid changing of sizes throughout the dilation process. A slaphammer is available to insure axial positioning and aid in dilator extraction.

4b

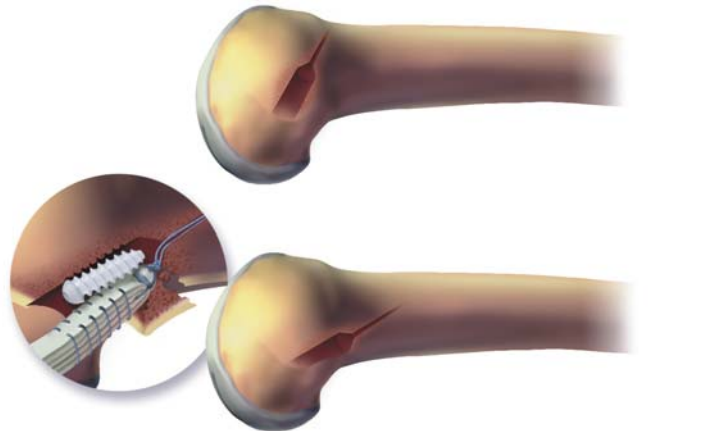


FEMORAL TUNNEL PREPARATION & GRAFT PASSING METHOD 1

STEP 5 – FEMORAL TUNNEL PREPARATION AND GRAFT PASSING

METHOD 1

GRAFT PASSING GUIDE PIN TECHNIQUE



The proper *Bullseye*® guide and knee flexion angle will ensure a 1-2mm backwall and eliminate the potential for “backwall blowout”. The guides are identified by their offsets and by the tunnel size to be drilled (based on graft size), eliminating the guesswork.

5a

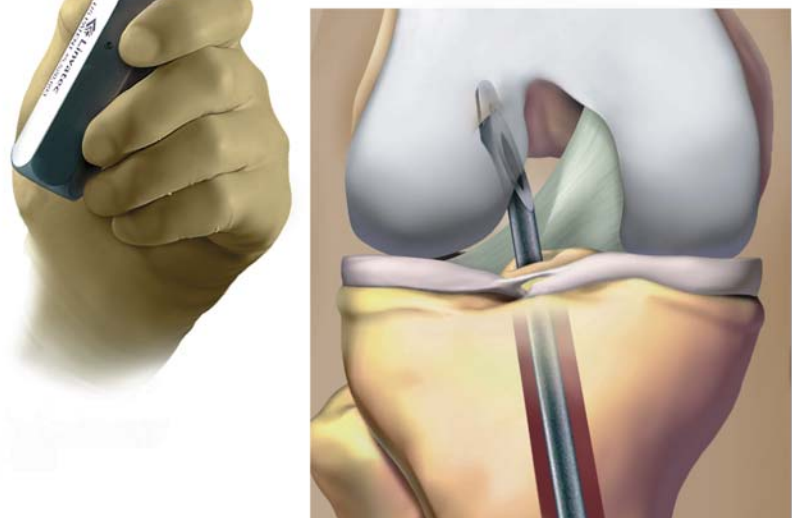
Bullseye® Guide

Description	Tunnel Diameter
5mm Offset	6 & 7mm
6mm Offset	8 & 9mm
7mm Offset	10 & 11mm
8mm Offset	12 & 13mm

To insure proper guide pin position, the over-the-top position must be clearly visible prior to femoral guide placement.

With the knee flexed to approximately 90 degrees, the appropriate size *Bullseye*® Femoral Guide is inserted through the tibial tunnel and the tongue positioned in the over-the-top position. Once proper position is verified, advance the stylus into the bone. An alternative method to the trans-tibial-tunnel technique for creating the femoral tunnel is to utilize the antero-medial portal with the knee flexed to 120 degrees.

5b



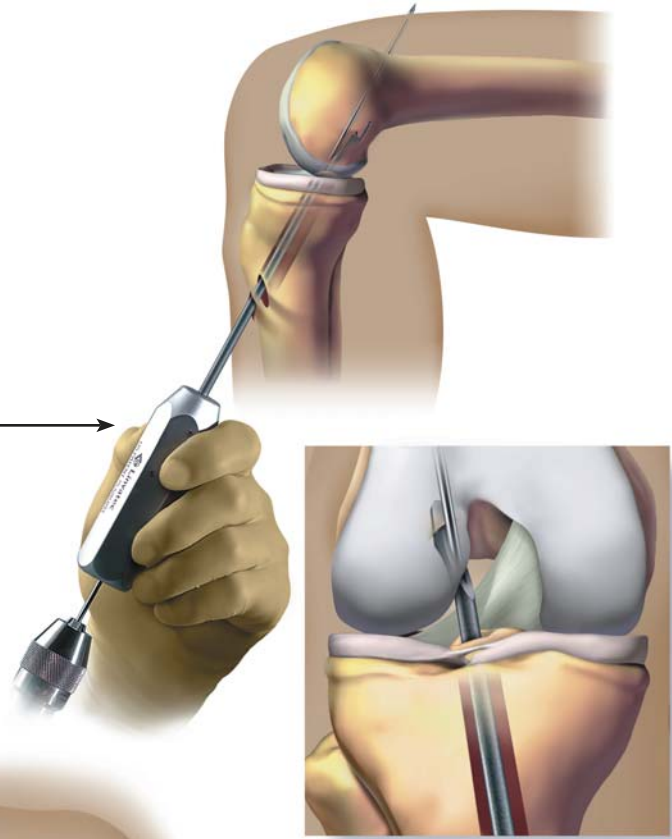
**STEP 5 – FEMORAL TUNNEL
PREPARATION AND GRAFT PASSING**
(CONTINUED)

METHOD 1

GRAFT PASSING GUIDE PIN TECHNIQUE

Insert the Graft Passing Guide Pin through the handle of the Bullseye® guide and drill until it exits the lateral femur and skin.

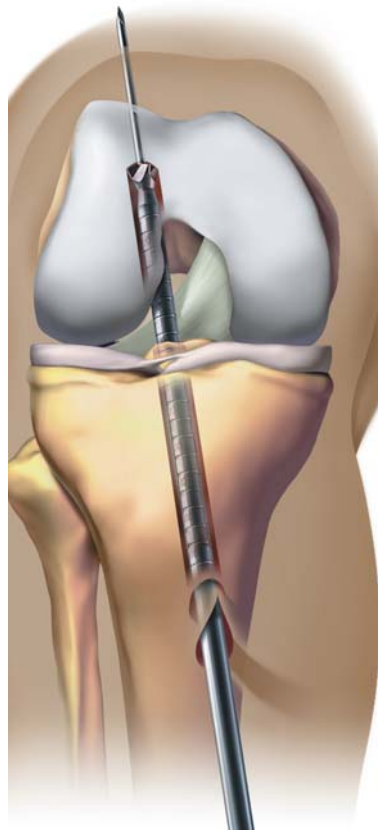
5c



Remove the Bullseye® guide and advance the appropriate size C-Reamer®, or Badger® Drill Bit, over the guide pin. If desired, a footprint of the reamer may be made prior to socket creation to verify accurate position.

The femoral socket is reamed

5d



BioScrew® length	EndoPearl™ Diameter		
	7mm	8mm	9mm
20mm	30mm	35mm	35mm
25mm	35mm	35mm	35mm
30mm	40mm	40mm	40mm

Tunnel length

**STEP 5 – FEMORAL TUNNEL
PREPARATION AND GRAFT PASSING**
(CONTINUED)

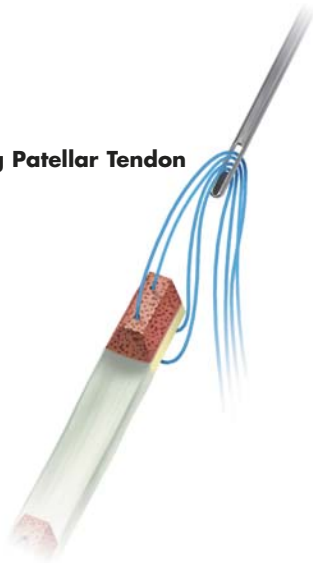
METHOD 1

GRAFT PASSING GUIDE PIN TECHNIQUE

The graft passing sutures are placed through the suture eye in the graft passing guide pin and pulled cephalad using the Linvatec Wirehandler. This will pull the graft into position within the femoral socket.

5e →

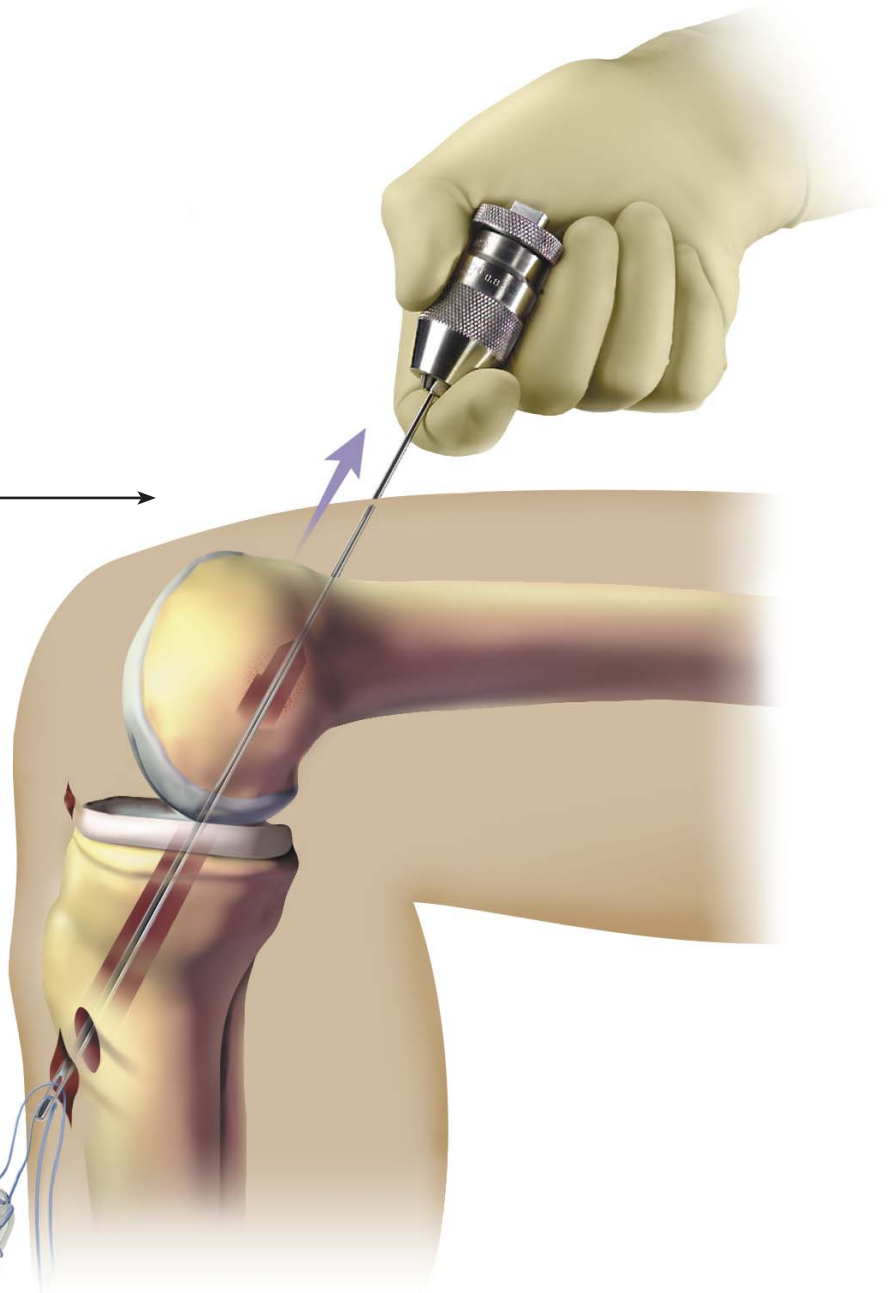
Utilizing Patellar Tendon



**Utilizing Quadriceps
Tendon with EndoPearl™ ****



**Utilizing Hamstrings
with EndoPearl™**



FEMORAL TUNNEL PREPARATION & GRAFT PASSING

METHOD 2

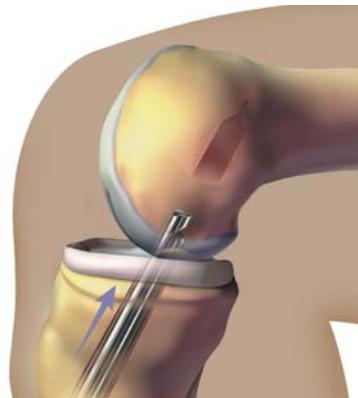
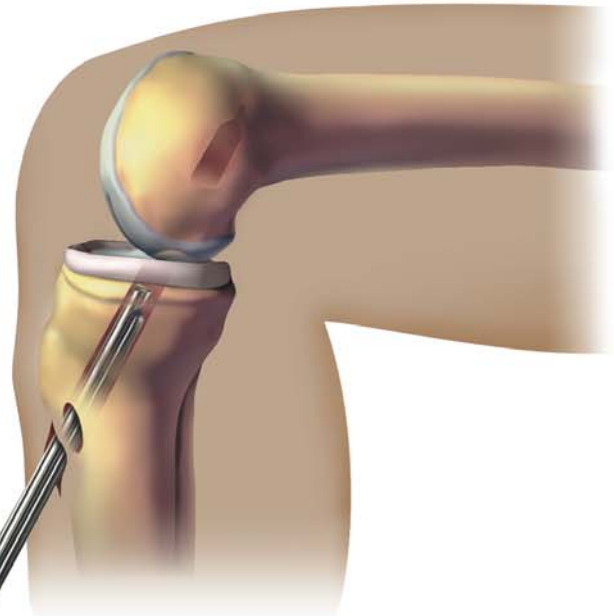
STEP 5 – FEMORAL TUNNEL PREPARATION AND GRAFT PASSING

METHOD 2

2 PIN PASSING TECHNIQUE

The femoral guide pin is removed and the appropriate size Eccentric Guide³ and Tunnel Notcher³ are placed through the tibial tunnel into the femoral socket. The Tunnel Notcher should be pointed posterior before inserting into the tibia to prevent notching the entire tibial tunnel.

5a



STEP 5 – FEMORAL TUNNEL PREPARATION AND GRAFT PASSING

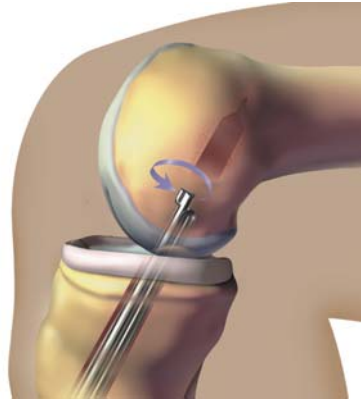
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METHOD 2

2 PIN PASSING TECHNIQUE

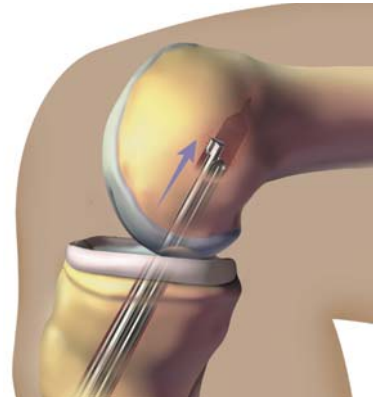
Once in the joint space, rotate the Tunnel Notcher anterior.

5b



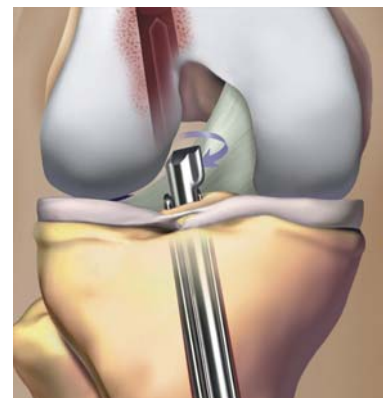
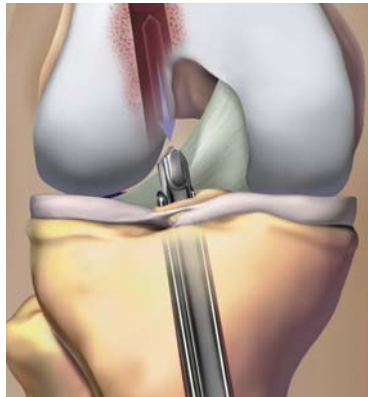
Seat the Eccentric Guide within the socket and notch a channel for the interference screw.

5c



The Tunnel Notcher and Eccentric Guide are removed in reverse fashion rotating the Notcher to protect the tibial tunnel from being notched.

5d



STEP 5 – FEMORAL TUNNEL PREPARATION AND GRAFT PASSING

(CONTINUED)

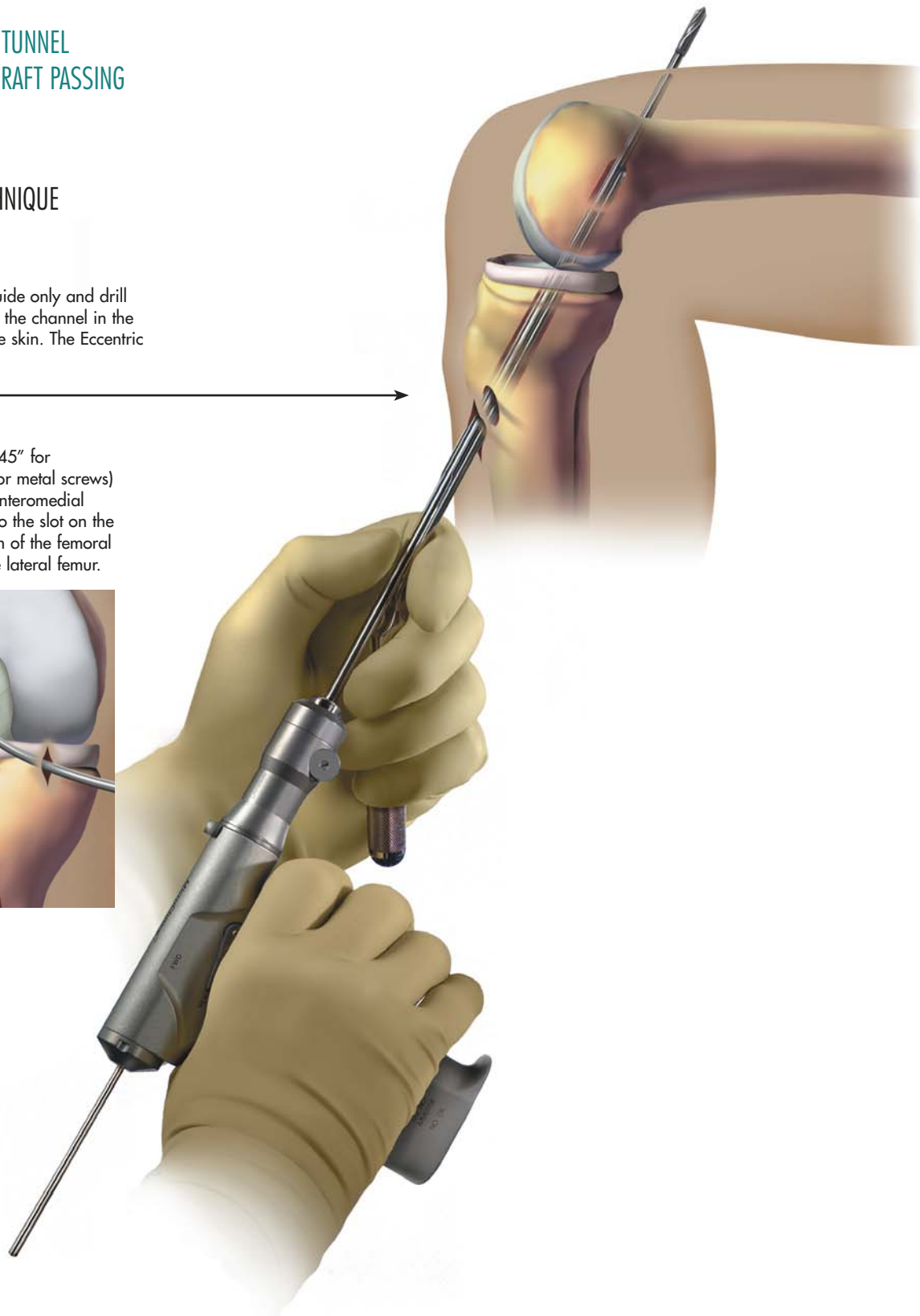
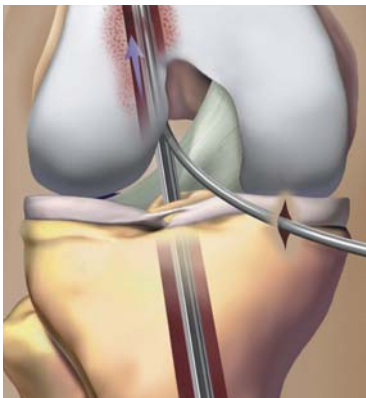
METHOD 2

2 PIN PASSING TECHNIQUE

Reinsert the Eccentric Guide only and drill the 2-Pin Passer through the channel in the femoral socket, out of the skin. The Eccentric Guide is removed.

5e

A Flexible guidewire (.045" for BioScrew® and .062" for metal screws) is inserted through the anteromedial portal and advanced into the slot on the 2-pin passer to the depth of the femoral socket or until it exits the lateral femur.



STEP 5 – FEMORAL TUNNEL PREPARATION AND GRAFT PASSING

(CONTINUED)

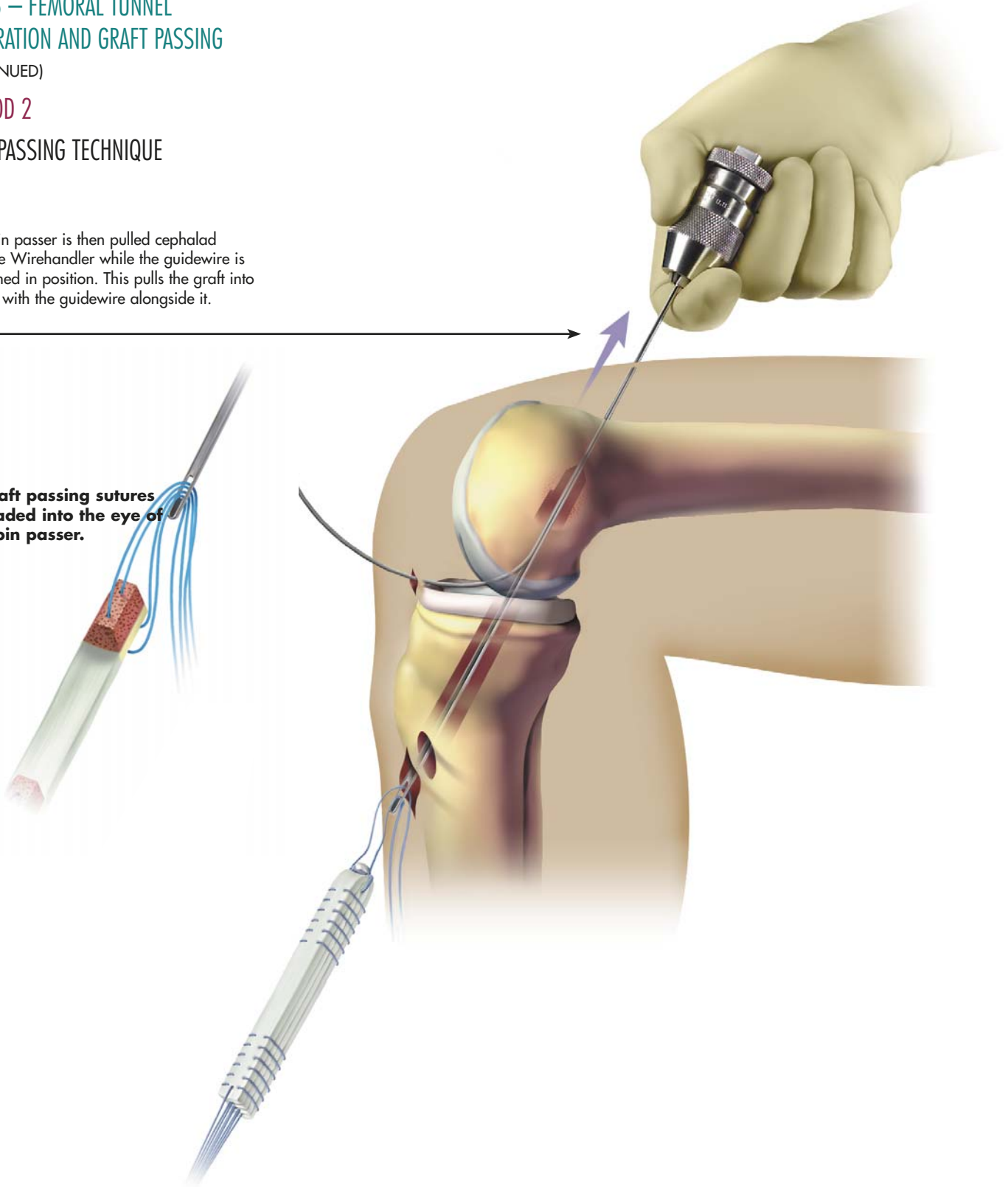
METHOD 2

2 PIN PASSING TECHNIQUE

The 2-pin passer is then pulled cephalad using the Wirehandler while the guidewire is maintained in position. This pulls the graft into position with the guidewire alongside it.

5f

The graft passing sutures are loaded into the eye of the 2-pin passer.



GRAFT FIXATION

STEP 6 – GRAFT FIXATION (BTB)

FEMUR

A Linvatec interference screw, titanium or PLLA *BioScrew*®, which is 2mm smaller than the diameter of the tunnel and graft, is selected. If the bone is extremely dense, it may also be necessary to pre-tap for the *Bioscrew*®. Linvatec offers round-head (*Guardzman*®) metal and bioabsorbable screws to protect the graft.

The knee must now be hyperflexed to approximately 120 degrees. This hyperflexion must be maintained throughout the femoral screw insertion procedure. Altering this position may result in screw divergence, screwdriver or screw failure.

The screw is placed over the guidewire and engaged with the *GraFix*™ Universal Modular Screwdriver. It is then inserted through the anteromedial portal and screwed into the femoral socket. The screw should be anterior to the graft and inserted so the head is just inside the socket opening. The driver and guidewire are then removed being careful not to extend the knee prior to removal.

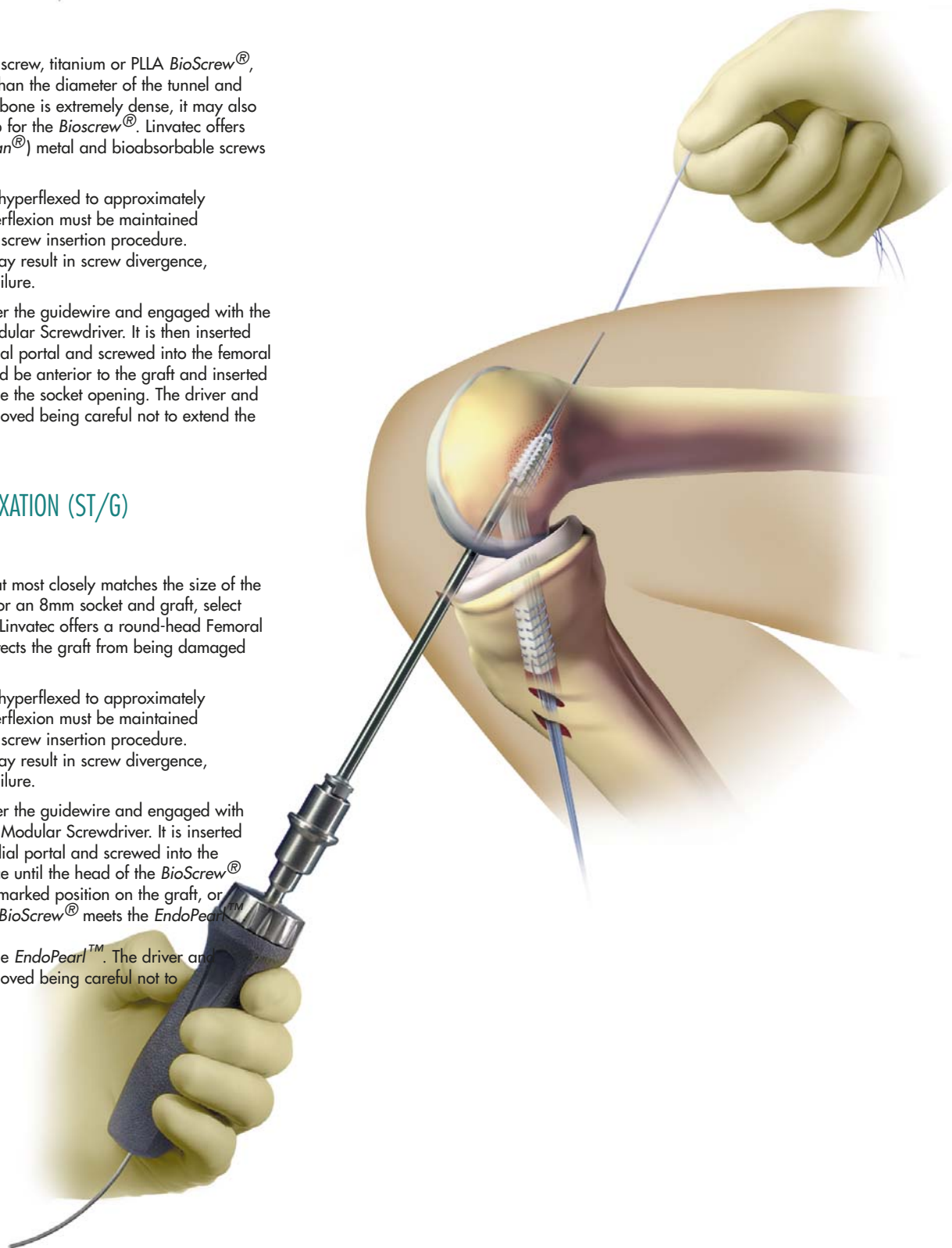
STEP 6 – GRAFT FIXATION (ST/G)

FEMUR

Select a *BioScrew*® that most closely matches the size of the socket and graft. (i.e. for an 8mm socket and graft, select an 8mm *Bioscrew*®). Linvatec offers a round-head Femoral *BioScrew*®, which protects the graft from being damaged during screw insertion.

The knee must now be hyperflexed to approximately 120 degrees. This hyperflexion must be maintained throughout the femoral screw insertion procedure. Altering this position may result in screw divergence, screwdriver or screw failure.

The screw is placed over the guidewire and engaged with the *GraFix*™ Universal Modular Screwdriver. It is inserted through the antero-medial portal and screwed into the femoral socket. Advance until the head of the *BioScrew*® reaches the previously marked position on the graft, or resistance is felt as the *BioScrew*® meets the *EndoPearl*™. The tip of the screw is now against the *EndoPearl*™. The driver and guidewire are then removed being careful not to



STEP 7 – GRAFT FIXATION (BTB)

TIBIA

Tension is placed on the distal end of the graft via the sutures and the knee is cycled to remove any laxity within the graft. With the knee in approximately 20-30 degrees of flexion, position the guidewire anterior to the graft in the tibial tunnel. Maintain tension on the graft sutures and insert the screw over the guidewire.

STEP 7 – GRAFT FIXATION (ST/G)

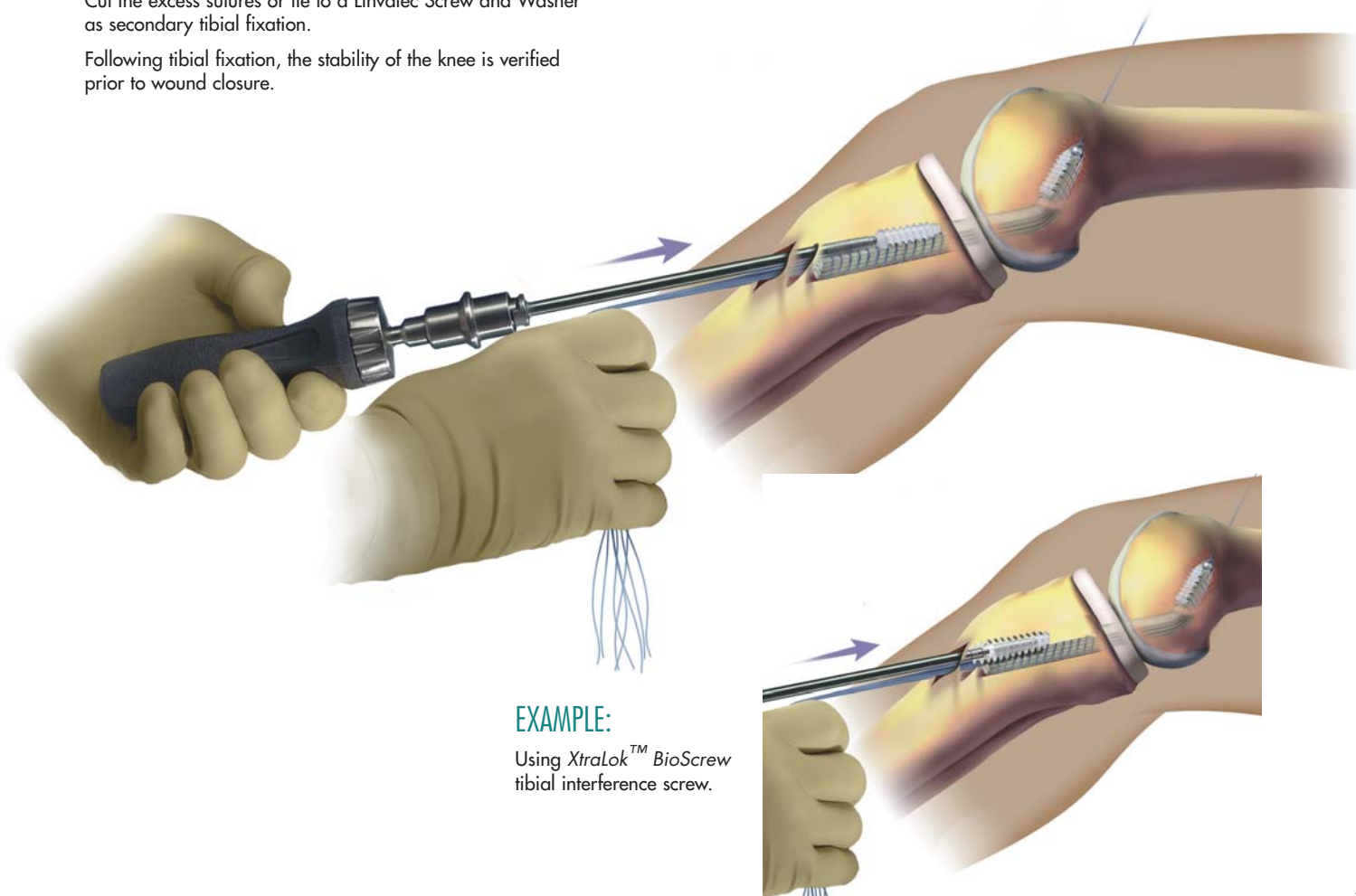
TIBIA

Tension is placed on the distal end of the graft via the sutures and the soft tissue graft should be cycled, under tension, prior to placing tibial fixation.

On the tibial side, select a *Bioscrew*® that is 1-2mm larger in diameter than the tunnel and graft. Less dense bone will require a larger screw diameter for optimum fixation.

Cut the excess sutures or tie to a Linvatec Screw and Washer as secondary tibial fixation.

Following tibial fixation, the stability of the knee is verified prior to wound closure.



EXAMPLE:

Using *XtraLok*™ *BioScrew* tibial interference screw.

Acknowledgements:

Various components of this Grafix™ System, as indicated by the footnotes, have been designed in conjunction with the following surgeons:

- 1) James F. Silliman, M.D.
- 2) Richard Steadman, M.D.
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- 4) Roger Paterson, M.D.
- 5) William G. Carson, M.D.
- 6) Andreas Weiler, M.D.
- 7) E. Marlowe Goble, M.D.
- 8) Russell F. Warren, M.D.
- 9) Cor van der Hart, M.D.
- 10) Don Johnson, M.D.
- 11) Christopher D. Harner, M.D.

* "

Definitive landmark for reproducible Tibial Tunnel Placement in Anterior Cruciate Ligament Reconstruction", C.D. Morgan, et al. Arthroscopy, Vol. II, No. 3, 1995: pp 275-288

** Fulkerson JP, Langeland R: An alternative cruciate reconstruction graft: the central quadriceps tendon. Arthroscopy 11:252-254, 1995

The products and techniques shown, mentioned or described in this brochure are covered by one or more of the following U.S. Patents: Re. 34,871; 5,154,720; 5,190,548; 5,257,996; 5,366,457; 5,391,169; 5,391,170; 5,470,334; 5,520,693; patent pending.



11311 Concept Boulevard
Largo, Florida 33773-4908
Phone: (727) 392-6464
Customer Service: (800) 925-4255
USA Fax: (727) 399-5256
International Fax: (727) 397-4540
www.linvatec.com



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