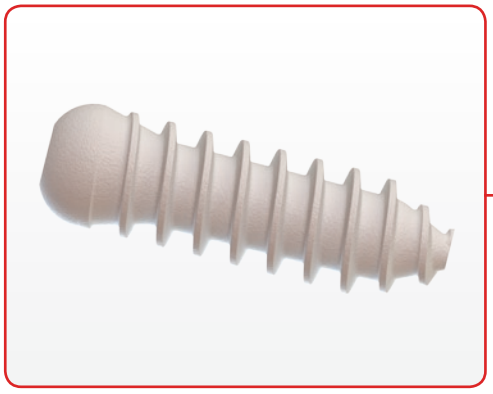
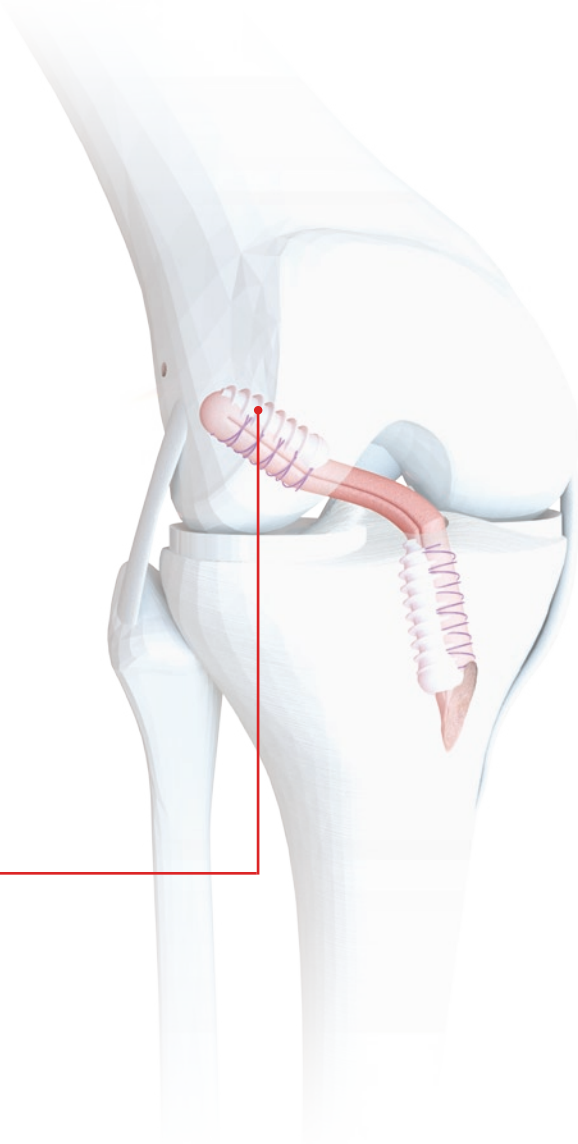
ACL reconstruction

Osteoconductive absorbable interference screws

LIGAFIX®





- **Unique material**
- **Optimal design**
- **Adapted to different surgical techniques**

SBM
Science & Bio Materials

+ complete instrumentation set

Controlled resorption

Material

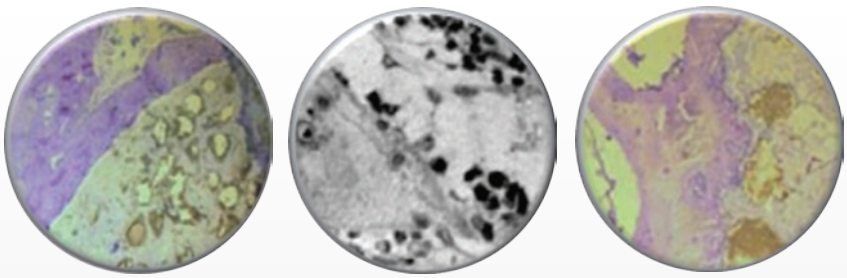
LIGAFIX® interference screws are made out of Duosorb®, a biocomposite material made of **β-TCP** (Tricalcium Phosphate) and **PDLLA** (Poly DL Lactic Acid). This combination provides an osteoconductive, absorbable and bioactive material while ensuring excellent mechanical resistance and elasticity[1].

Tricalcium Phosphate (β-TCP) + Poly DL Lactic Acid (PDLLA)

100 % Osteoconductive
100 % Absorbable
100 % Bioactive

Mechanical strength
Elasticity

In vitro and *in vivo* comparative study [1]



1 week
Toluidine Blue x400

1 week
Toluidine Blue x400

3 months
Toluidine Blue x400

After 1 week, bone tissue is observed directly on the surface of the material. There is no sign of inflammation on the Trabecular bone in contact with the composite material.
After 3 months, implants are partially fragmented with bone growth between the fragments. Bone remodeling is similar to that for ceramics in pure β-TCP.

1 week
Toluidine Blue x400

Comparatively, pure PDLLA implants do not show signs of degradation and retain their initial structure, whatever the duration of implantation. Implants are surrounded by connective tissue in which numerous macrophages have phagocytized crystalline-like particles.

Screws adapted to your technique

LIGAFIX® 30

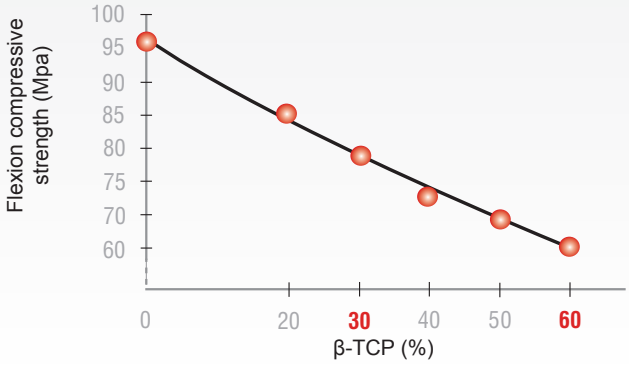
30% β-TCP + 70% PDLLA
For all types of grafts, ideal for the Kenneth Jones technique.
Optimizes mechanical strength, the screw is in direct contact with the bone plug.

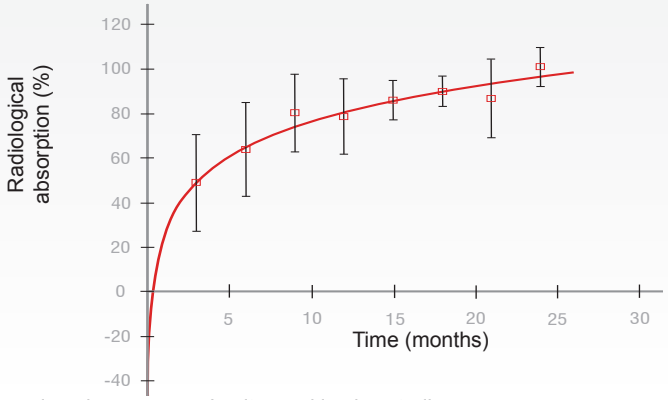
LIGAFIX® 60

60% β-TCP + 40% PDLLA
Only for soft tissue grafts.
Optimizes the kinetics of absorption.

2 heads for femoral and tibial fixation
Lengths: from 20 to 35 mm
Diameters : from 7 to 11 mm

Performance [2]





[1] Biological performance of a new β-TCP/PLLA composite material for applications in spine surgery : In vitro and in vivo studies, AUNOBLE S., CLEMENT D., FRAYSSINET P., HARMAND M-F., LE HUEC J-C. Journal of Biomedical Materials Research, Part A, Art. 30749, 1-7, 2006.

[2] Data on file, SBM.

Surgical technique (Kenneth Jones)

1 - Patellar tendon harvest and preparation

A skin incision is made along the medial border of the patellar tendon.

The peri-tendon is opened with an inverted-L incision and raised. One third of the medial patellar tendon is harvested with a patellar bone plug and a tibial bone plug in “a trapezoidal shape”.

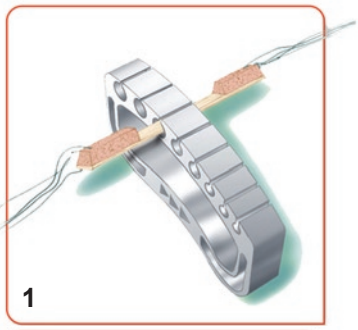
A Bio 1® implant for patellar filling (10 x 10 x 6 mm) can be used to fill the harvesting site.

Sizing the bone plugs with the gauge using femoral tunnels drilling techniques (Picture 1):

Outside - Inside
The patellar osseous fragment is adjusted to the diameter of the tibial tunnel and must pass freely through the femoral tunnel. The tibial osseous fragment is adjusted in a trapezoidal shape in order for it to jam by “press fit” in the femoral tunnel.

Inside – Outside (Blind Tunnel)
The bone plugs are respectively sized to the tibial and femoral tunnel diameter; the femoral tunnel bone plug must pass through the tibial tunnel.

Drill one or two holes through the bone plugs to pass the traction threads.

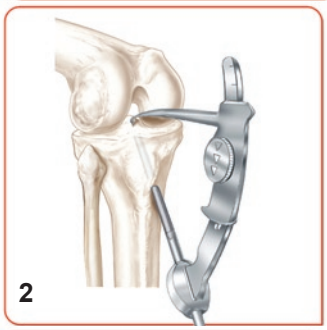

1

2 - Arthroscopic use (assessment and cleaning)

Meniscus inspection.

Notch preparation.

Test the remaining of the Anterior Cruciate Ligament by trying to preserve the anteromedial and posterolateral bundle.


2

3 - Tibial tunnel

Position the tibial aiming device (Picture 2)

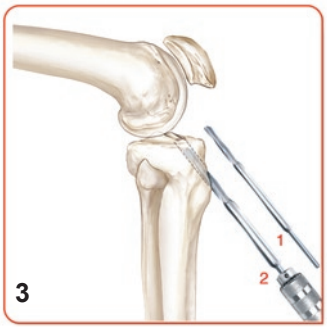
Place the hook of the tibial aiming device through the anteromedial portal into the posterior fibres of the remaining ACL (form an angle of approximately 55° to 65° with the axis of the tibial shaft, the superior branch of the aiming device must be parallel with the tibial plateau).

Next, mount the guide pin sleeve on the aiming device and insert the ø 2.5mm Kirchner guide pin. The articular surface can be protected by a curette. The guide pin is removed under arthroscopic control.

Drilling of the tibial tunnel (Picture 3)

Remove the aiming device by keeping the guide pin in place, then drill the tibial tunnel on guide pin, first with the Ø 6mm drill bit (1) and then with the definitive diameter of drill bit required (2). Between the two drillings, the guide pincan be repositioned under arthroscopic control to ensure the best anatomical position.

Once the tibial tunnel has been drilled, it can be plugged up with a stopper to restrict irrigation fluid loss.



3

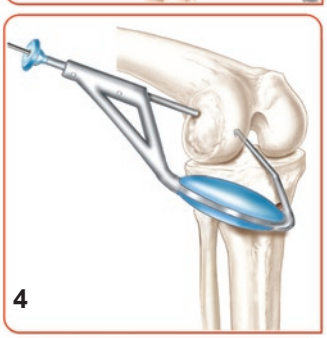
4 - Femoral tunnel: two options:

OUTSIDE-INSIDE TECHNIQUE

Position of the femoral aiming device (Picture 4)

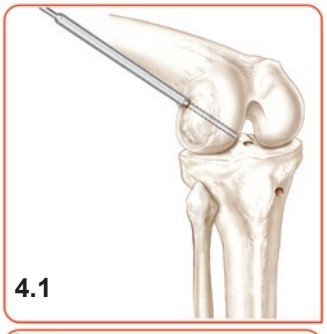
With the knee in 70 degrees of flexion, pass the femoral aiming device through the anteromedial portal and position the hook under arthroscopic control in order to obtain an anatomical position of the guide pin. Classically, the aiming device is placed against the posterior edge of the lateral condyle at 11 o’clock with a 45° angle with respect to the tibial plateau and oriented 20° from back to front.

Then, place the guide pin sleeve on the aiming device and insert the ø 2.5mm Kirchner guide pin with a powered tool, the palette of the aiming device serves as protection.


4

Drilling of the femoral tunnel (Picture 4.1)

Remove the aiming device by keeping the guide pin in place, then drill the tunnel on the guide pin, first at a diameter of 6 mm and then at the definitive diameter.

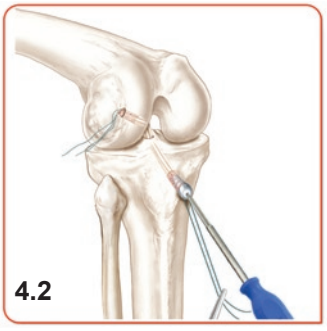

4.1

Passing the graft through the tibial and femoral tunnels

Using a metal thread guide, pass a traction thread from the tibial tunnel towards the femoral tunnel. Next, recover the traction thread, using a Kelly pliers for example, through the femoral tunnel and tie it to the traction thread of the graft.
The graft is gradually passed from the femur to the tibia, patellar fragment first, checking the intra-articular passage.

Once the patellar fragment is introduced into the tibial tunnel, the trapezoidal femoral bone plug is softly impacted to the graft-puncher into the femoral tunnel until the intra-articular part of the condyle is level with the surface.
Throughout this action, the plug in the tibia is kept under permanent traction in order to facilitate the graft passage.

In this technique, femoral graft fixation is obtained by the transplant press-fitting into the femoral tunnel and by fitting with an interference screw through the tibial tunnel (Picture 4.2).


4.2

BLIND TUNNEL TECHNIQUE

Positioning the pistol-grip aiming device (Picture 4)

Trans-tibial approach

With the knee in flexion between 70 degrees and 90 degrees, pass the pistol-grip femoral aiming device through the tibial tunnel and position the hook against the posterior edge of the lateral condyle (aiming device ø 9 mm = tunnel ø 9mm or less, aiming device ø 10 mm = tunnel ø 10mm or greater).

Antero-medial approach

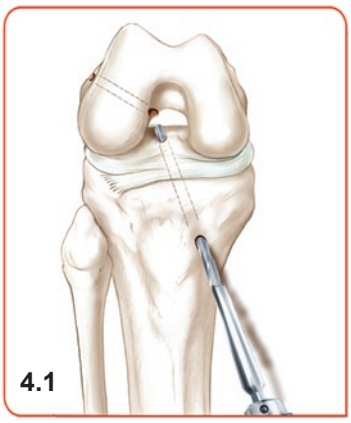
With the knee in hyperflexion at 120 degrees, pass the pistol grip femoral aiming device through the anteromedial portal and position the hook of the pistol grip femoral aiming device against the posterior edge of the lateral condyle.

The gap between the hook of the pistol grip femoral aiming device and the posterior edge of the lateral condyle is 6.4 mm with the ø 9 mm aiming device and of 6.9 mm with the ø 10 mm aiming device.

Drilling the femoral tunnel (Picture 4.1)

With the knee hyperflexed, introduce the 2.5 mm the eyelet pin into the pistol grip aiming device and push it to just beyond the lateral femoral cortex, then through the skin.

Under arthroscopic control, retrieve the pistol grip aiming device and ream on the guide pin through the femoral tunnel to a depth matching the length of the graft bone plug, with the corresponding drill bit. It may be necessary to pass a drill bit with an intermediary diameter.



Passing the graft through the tibial and femoral tunnels (Picture 4.2)

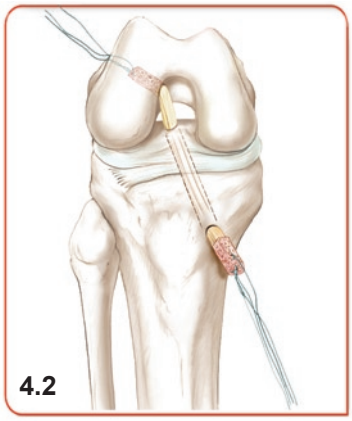
Trans-tibial approach

One of the threads, previously fastened to the patellar fragment and passed through the eye of the drill, is pulled with the guide pin from the tibial tunnel to the femoral tunnel.

Progressively pass the transplant from the tibial tunnel to the femoral tunnel with the traction thread.

Antero-medial approach

A traction thread, previously passed through the eye of the pin, is pulled with the guide pin from the antero-medial portal to the femoral tunnel, and then recovered in the tibial tunnel with Kellys pliers. The traction thread fixed to the graft is progressively passed from the tibial tunnel to the femoral tunnel from the bottom to the top.



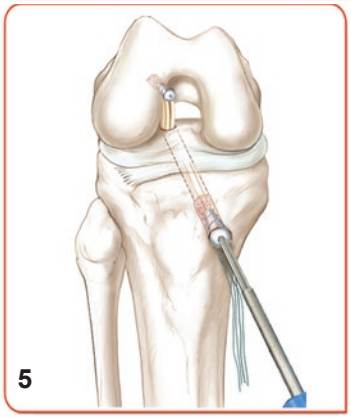
Femoral fixation with LIGAFIX 30 screw (Picture 5)

Keep the knee in the proper position of flexion. With the graft in place, the guide pin of the screw is pulled through the anteromedial portal between the face of the tunnel and the cancellous face of the graft bone plugs (ø 0.9 mm for the screws less than or equal to 8 mm in diameter, and ø 1.4 mm for screws equal to or greater than 9 mm in diameter). The use of the guide pin sleeve (for the ø 0.9 mm guide pin) can be necessary to guarantee proper positioning of the guide pin. It is recommended to set the guide pin in the cancellous bone.

Prepare the entrance of the tunnel by using the cannulated tap screwdriver.

Fix the graft with the absorbable Ligafix 30 interference screw and the adapted screwdriver (green screwdriver for ø 7, 8 mm screws and blue screwdriver for ø 9, 10 and 11 mm screws). The screw is introduced on the guide pin between the tunnel face and the cancellous face of the graft bone plug so that the screw comes to the limit of the articular surface, at 1 mm behind the joint surface. The screw diameter must be 1 mm less than the diameter of the tunnel.

Remove the guide pin. Check for proper kinematics of the graft before tibial fixation.



Tibial fixation with LIGAFIX 30 screw for both techniques (Picture 6)

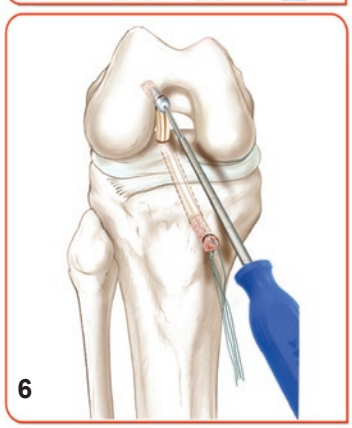
Under arthroscopic control, pass the guide pin (ø 0.9 mm for screws with a diameter less than or equal to 8 mm, and ø 1.4 mm for screws with a diameter greater than or equal to 9 mm) between the tunnel face and the cancellous face of the graft bone plug.

Prepare the entrance of the tunnel by using the cannulated tap screwdriver.

The screw is placed on the screwdriver. The chosen screw diameter should be 1 mm less than the tunnel diameter.

Using the guide pin as a guide, screw the interference screw until it is level with the articular exit of the tunnel, but without passing through it. It is recommended to maintain the guide pin with intra-articular pliers during the screwing process.

Remove the guide pin.



Surgical technique (soft tissue)

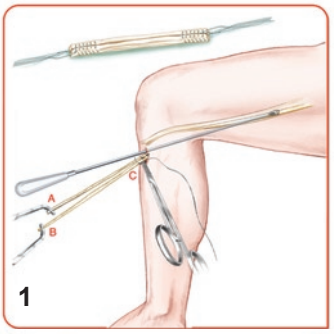
1 - Hamstring tendon harvest and preparation (Picture 1)

Perform a 2 to 3 centimeter skin incision, harvest the gracilis with a stripper to break it off along its entire length.

Next, harvest the semitendinosus.

Once harvested and cleaned, these tendons are folded in two and sutured in order to obtain a quadruple ligament.

Ajust the graft size using the graft gauge.



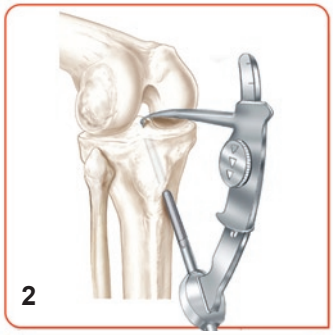
1

2 - Arthroscopic use (assessment and cleaning)

Meniscus inspection.

Notch preparation.

By means of an intra-articular procedure, the remaining Anterior Cruciate Ligament is cleaned with a powered shaver.


2

3 - Tibial tunnel

Positioning the tibial aiming device (Picture 2)

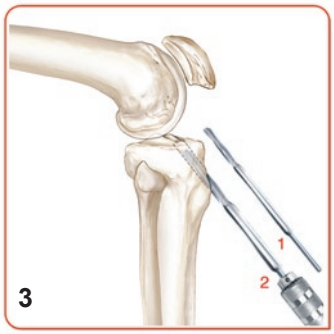
Place the hook of the tibial aiming device through the anteromedial portal into the posterior fibres of the remaining ACL (forming an angle between approximately 55° and 65° with the axis of the tibial shaft, the superior branch of the aiming device must be parallel with the tibial plateau).

Next, mount the guide pin sleeve on the aiming device and insert the ø 2.5 mm Kirchner guide pin with a powered tool. The articular surface can be protected by a curette. The guide pin is removed under arthroscopic control.

Drilling of the tibial tunnel (Picture 3)

Remove the aiming device by leaving the guide in place and drill the tibial tunnel on the guide pin, first with the ø 6 mm drill bit (1) and then with the definitive diameter of drill bit required (2). Between the two drillings, the guide pin can be repositioned under arthroscopic control to ensure the best anatomical position.

Once the tibial tunnel has been drilled, it can be plugged up with a stopper, to restrict irrigation fluid loss.



3

4 - Femoral tunnel

Positioning the pistol-grip aiming device (Picture 4)

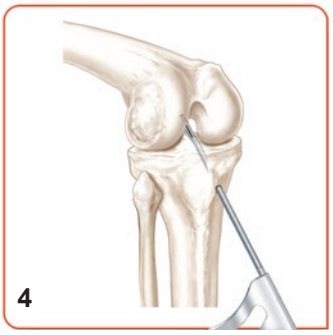
Trans-tibial approach

With the knee in flexion between 70 degrees and 90 degrees, pass the pistol-grip femoral aiming device through the tibial tunnel and position the hook against the posterior edge of the lateral condyle (aiming device ø 9 mm = tunnel ø 9 mm or less, aiming device ø 10 mm = tunnel ø 10 mm and greater).

Antero-medial approach

With the knee in hyperflexion at 120 degrees, pass the pistol grip femoral aiming device through the anteromedial portal and position the hook of the pistol grip femoral aiming device against the posterior edge of the lateral condyle.

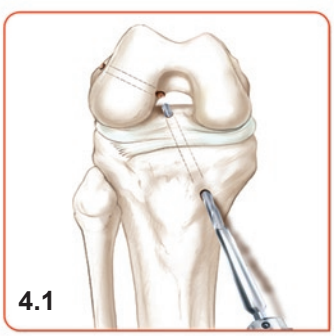
The gap between the hook of the pistol grip femoral aiming device and the posterior edge of the lateral condyle is 6.4 mm with the ø 9 mm aiming device, and of 6.9 mm with the ø 10 mm aiming device.


4

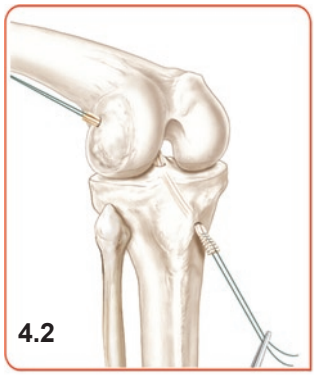
Drilling the femoral tunnel (Picture 4.1)

The knee in hyperflex position, introduce the 2.5 mm eyelet pin into the pistol grip aiming device and push it to just beyond the lateral femoral cortex, then through the skin.

Under arthroscopic control, retrieve the pistol grip aiming device and ream the tunnel on the guide pin with a graduated drill bit to a depth matching the length of the transplant initially measured. The passage of an intermediary drill bit could prove necessary.


4.1

Passing the graft through the tibial and femoral tunnels (Picture 4.2)



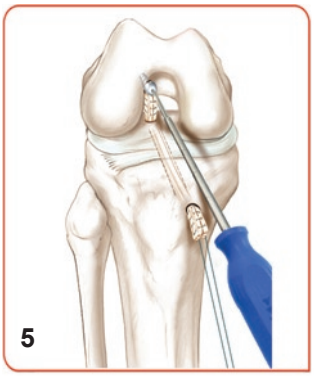
Trans-tibial approach

The traction thread, previously fastened to the transplant and passed through the eye of the pin, is pulled with the guide pin from the tibial tunnel to the femoral tunnel.
Progressively pass the transplant from the tibial tunnel to the femoral tunnel with the traction thread.

Antero-medial approach

The traction thread, previously passed through the eye of the pin, is pulled with the guide pin from the anteromedial portal to the femoral tunnel, and then recovered in the tibial tunnel with Kellys pliers. The traction thread fixed to the graft is progressively passed from the tibial tunnel to the femoral tunnel from the bottom to the top.

Femoral fixation with LIGAFIX 60 screw (Picture 5)



Keep the knee in the proper position of flexion. With the graft in place, the guide pin of the screw is pulled through the anteromedial portal between the face of the tunnel and the face of the bundle of the ligament (ø 0.9 mm for the screws less than or equal to 8 mm in diameter and ø 1.4 mm for the screws equal to or greater than 9 mm in diameter). The use of the guide pin sleeve (for the ø 0.9 mm guide pin) can be necessary to properly position the guide pin. It is recommended to set the guide pin in the cancellous bone.

Prepare the entrance of the tunnel by using the cannulated tap screwdriver.

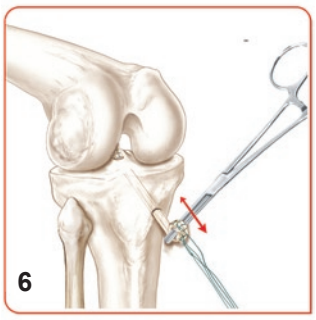
Fix the graft with the absorbable Ligafix 60 interference screw and the adapted screwdriver (green screwdriver for ø 7, 8 mm screws and blue screwdriver for ø 9, 10 and 11 mm screws). The screw is introduced on the guide pin between the tunnel face and the face of the bundle of the ligament. The screw diameter must be at least equal to the diameter of the tunnel.

Remove the guide pin.

Once the graft is attached at the femoral level, exert tension on the graft at the tibial level with pliers (Picture 6).

Check for proper kinematics of the graft before tibial fixation.

Tibial fixation with LIGAFIX 60 screw (Picture 7)



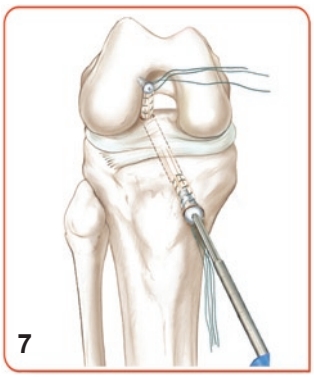
Under arthroscopic control, pass the guide pin (ø 0.9 mm for the screws with a diameter less than or equal to 8 mm, and ø 1.4 mm for screws with a diameter equal to or greater than 9 mm) between the tunnel face and the face of the bundle of the ligament.

Prepare the entrance of the tunnel by using the cannulated tap screwdriver.

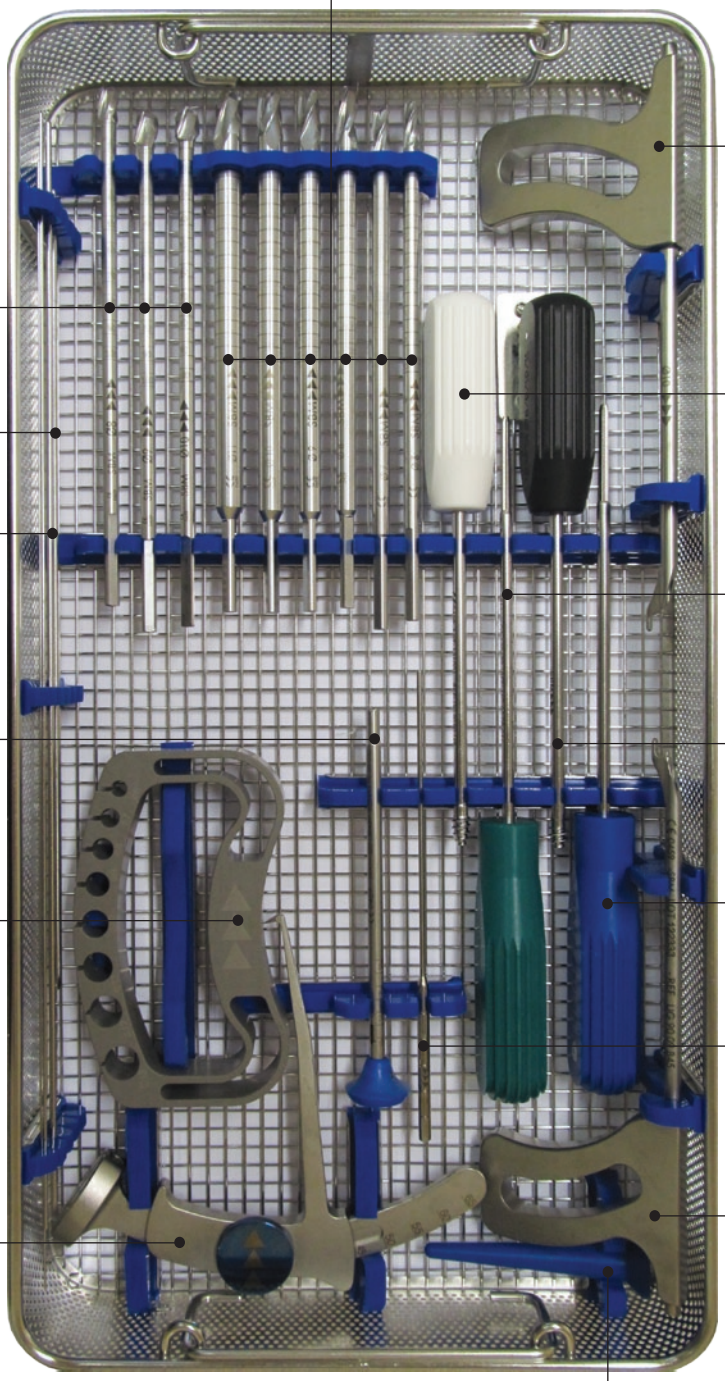
The screw is placed on the screwdriver. The chosen screw diameter should be at least equal to the tunnel diameter.

With the pin serving as a guide, screw the interference screw until it is level with the articular exit of the tunnel, but without passing through it. It is recommended to maintain the guide pin with intra-articular pliers during the screwing procedure.

Remove the guide pin.



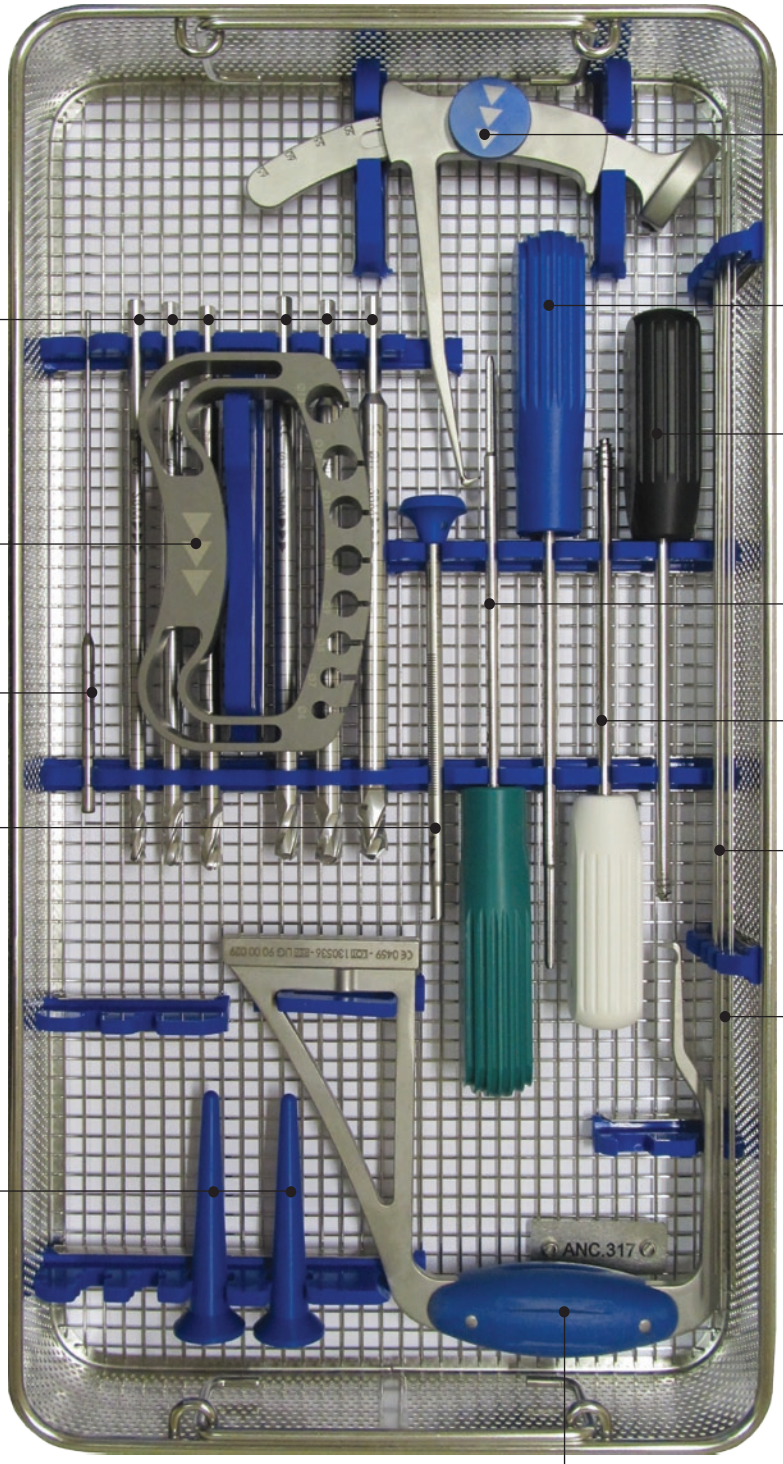
Blind tunnel instrumentation



Bling tunnel instrumentation - ordering information

Codes	*Designation*	*In the basket*
LIG9000034	Tibial aiming device	1
LIG9000032	Guide pin sleeve for aiming device	1
LIG9008046	Green screwdriver for screws ø 7, 8 mm	1
LIG9009017	Blue screwdriver for screws ø 9, 10 and 11 mm	1
LIG9006048	Drill bit ø 6 mm	1
LIG9007048	Drill bit ø 7 mm	1
LIG9008048	Drill bit ø 8 mm	1
LIG9009048	Drill bit ø 9 mm	1
LIG9010048	Drill bit ø 10 mm	1
LIG9011048	Drill bit ø 11 mm	1
LIG9109400	Rigid guide pin ø 0,9 mm - length 400 mm for ø 7, 8 mm screws screwdriver	2
LIG9114400	Rigid guide pin ø 1,4 mm - length 400 mm for ø 9, 10, 11 mm screws screwdriver	2
LIG9125300	Guide pin (K-Wire) ø 2,5 mm for drill bits	1
LIG9000035	Graft gauge	1
LIG9000051	Stopper	1
LIG9000041	Eyelet pin - length 400 mm	1
LIG9008049	Reamer ø 8 mm	1
LIG9009049	Reamer ø 9 mm	1
LIG9010049	Reamer ø 10 mm	1
LIG9009B45	Pistol-grip femoral aiming device ø 9 mm	1
LIG9010B45	Pistol-grip femoral aiming device ø 10 mm	1
LIG9000169	White tap screwdriver for ø 7 mm screws	1
LIG9000093	Black tap screwdriver for ø 8, 9, 10 & 11 mm screws	1
LIG9000092	Guide pin introducer for guide pin ø 0,9 mm	1
LIG90TB001	LIGAFIX Blind Tunnel stainless steel basket with silicone holders	1
LIG90TB000	**LIGAFIX complete Blind Tunnel instrumentation set**	

Outside-inside instrumentation



Drill bits Ø 6, 7, 8, 9, 10, 11 mm

Graft gauge

Guide pin introducer for Ø 0.9 mm guide pin

Guide pin sleeve for aiming device

Stoppers

Tibial aiming device

Blue screwdriver for Ø 9, 10 &11 mm screws

Black tap screwdriver for Ø 8, 9, 10, 11 mm screws

Green screwdriver for Ø 7 and 8 mm screws

White tap screwdriver only for Ø 7 mm screws

Guide pin (K-Wire) Ø 2.5 mm for drill bits

Rigid guide pins Ø 0.9 & 1.4 mm

Femoral aiming device

Outside-inside instrumentation - ordering information

Codes	*Designation*	*In the basket*
LIG9000034	Tibial aiming device	1
LIG9000029	Femoral aiming device	1
LIG9000032	Guide pin sleeve for aiming device	1
LIG9008046	Green screwdriver for screws ø 7, 8 mm	1
LIG9009017	Blue screwdriver for screws ø 9, 10 and 11 mm	1
LIG9006048	Drill bit ø 6 mm	1
LIG9007048	Drill bit ø 7 mm	1
LIG9008048	Drill bit ø 8 mm	1
LIG9009048	Drill bit ø 9 mm	1
LIG9010048	Drill bit ø 10 mm	1
LIG9011048	Drill bit ø 11 mm	1
LIG9000092	Guide pin introducer for guide pin ø 0,9 mm	1
LIG9109400	Rigid guide pin ø 0,9 mm - length 400 mm for ø 7, 8 mm screws screwdriver	2
LIG9114400	Rigid guide pin ø 1,4 mm - length 400 mm for ø 9, 10, 11 mm screws screwdriver	2
LIG9125300	Guide pin (K-Wire) ø 2,5 mm for drill bits	1
LIG9000035	Graft gauge	1
LIG9000051	Stopper	2
LIG9000169	White tap screwdriver for ø 7 mm screws	1
LIG9000093	Black tap screwdriver for ø 8, 9, 10 & 11 mm screws	1
LIG90DD001	LIGAFIX Outside Inside stainless steel basket with silicone holders	1
LIG90DD000	**LIGAFIX complete Oustide Inside instrumentation set**	

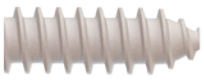
Ligafix 30 ordering information

Rounded head screw
adapted to femoral and tibial fixation

Optimal protection of the graft.
Femoral level: preserves the graft during articular flexion.
Tibial level: ensures optimal locking.

Codes	*Designation*	*Packaging*
COM3007020	LIGAFIX 30 rounded head interference screw ø 7 mm - length 20 mm	1
COM3007025	LIGAFIX 30 rounded head interference screw ø 7 mm - length 25 mm	1
COM3007030	LIGAFIX 30 rounded head interference screw ø 7 mm - length 30 mm	1
COM3008020	LIGAFIX 30 rounded head interference screw ø 8 mm - length 20 mm	1
COM3008025	LIGAFIX 30 rounded head interference screw ø 8 mm - length 25 mm	1
COM3008030	LIGAFIX 30 rounded head interference screw ø 8 mm - length 30 mm	1
COM3008035	LIGAFIX 30 rounded head interference screw ø 8 mm - length 35 mm	1
COM3009020	LIGAFIX 30 rounded head interference screw ø 9 mm - length 20 mm	1
COM3009025	LIGAFIX 30 rounded head interference screw ø 9 mm - length 25 mm	1
COM3009030	LIGAFIX 30 rounded head interference screw ø 9 mm - length 30 mm	1
COM3009035	LIGAFIX 30 rounded head interference screw ø 9 mm - length 35 mm	1
COM3010R25	LIGAFIX 30 rounded head interference screw ø 10 mm - length 25 mm	1
COM3010R30	LIGAFIX 30 rounded head interference screw ø 10 mm - length 30 mm	1
COM3010R33	LIGAFIX 30 rounded head interference screw ø 10 mm - length 33 mm	1
COM3010R35	LIGAFIX 30 rounded head interference screw ø 10 mm - length 35 mm	1

Flat head screw
adapted to tibial fixation



Optimal protection of the graft.
Insertion facilitated at the end of the screwing.

Codes	*Designation*	*Packaging*
COM3010030	LIGAFIX 30 flat head interference screw ø 10 mm - length 30 mm	1
COM3010035	LIGAFIX 30 flat head interference screw ø 10 mm - length 35 mm	1
COM3011030	LIGAFIX 30 flat head interference screw ø 11 mm - length 30 mm	1
COM3011035	LIGAFIX 30 flat head interference screw ø 11 mm - length 35 mm	1

For an optimal use, the diameter of the tunnel drilling has to be adapted to the screw's diameter and to the technique:
KJ's Technique: ø of the screw inferior of 1 mm to ø of the drill.
Hamstrings Tendons Technique: ø of the screw equal to ø of the drill.

Patellar filling

Code	*Designation*	*Packaging*
P822694220	Implant for patellar filling - 10 x 10 x 6 mm	1

Ligafix 60 ordering information

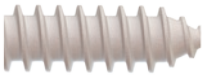
LIGAFIX® 60

Rounded head screw
adapted to femoral and tibial fixation

Optimal protection of the graft.
Femoral level: preserves the graft during articular flexion.
Tibial level: ensures optimal locking.

Codes	*Designation*	*Packaging*
COM6007020	LIGAFIX 60 rounded head interference screw ø 7 mm - length 20 mm	1
COM6007025	LIGAFIX 60 rounded head interference screw ø 7 mm - length 25 mm	1
COM6007030	LIGAFIX 60 rounded head interference screw ø 7 mm - length 30 mm	1
COM6008020	LIGAFIX 60 rounded head interference screw ø 8 mm - length 20 mm	1
COM6008025	LIGAFIX 60 rounded head interference screw ø 8 mm - length 25 mm	1
COM6008030	LIGAFIX 60 rounded head interference screw ø 8 mm - length 30 mm	1
COM6008035	LIGAFIX 60 rounded head interference screw ø 8 mm - length 35 mm	1
COM6009020	LIGAFIX 60 rounded head interference screw ø 9 mm - length 20 mm	1
COM6009025	LIGAFIX 60 rounded head interference screw ø 9 mm - length 25 mm	1
COM6009030	LIGAFIX 60 rounded head interference screw ø 9 mm - length 30 mm	1
COM6009035	LIGAFIX 60 rounded head interference screw ø 9 mm - length 35 mm	1
COM6010R25	LIGAFIX 60 rounded head interference screw ø 10 mm - length 25 mm	1
COM6010R30	LIGAFIX 60 rounded head interference screw ø 10 mm - length 30 mm	1
COM6010R33	LIGAFIX 60 rounded head interference screw ø 10 mm - length 33 mm	1
COM6010R35	LIGAFIX 60 rounded head interference screw ø 10 mm - length 35 mm	1

Flat head screw
adapted to tibial fixation



Optimal protection of the graft.
Insertion facilitated at the end of the screwing.

Codes	*Designation*	*Packaging*
COM6010030	LIGAFIX 60 flat head interference screw ø 10 mm - length 30 mm	1
COM6010035	LIGAFIX 60 flat head interference screw ø 10 mm - length 35 mm	1
COM6011030	LIGAFIX 60 flat head interference screw ø 11 mm - length 30 mm	1
COM6011035	LIGAFIX 60 flat head interference screw ø 11 mm - length 35 mm	1

For an optimal use, the diameter of the screw has to be at the minimum equal to the drill's diameter.

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Carefully read the instructions for use that comes with the medical device or labeling provided to medical professionals. Class III device.
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