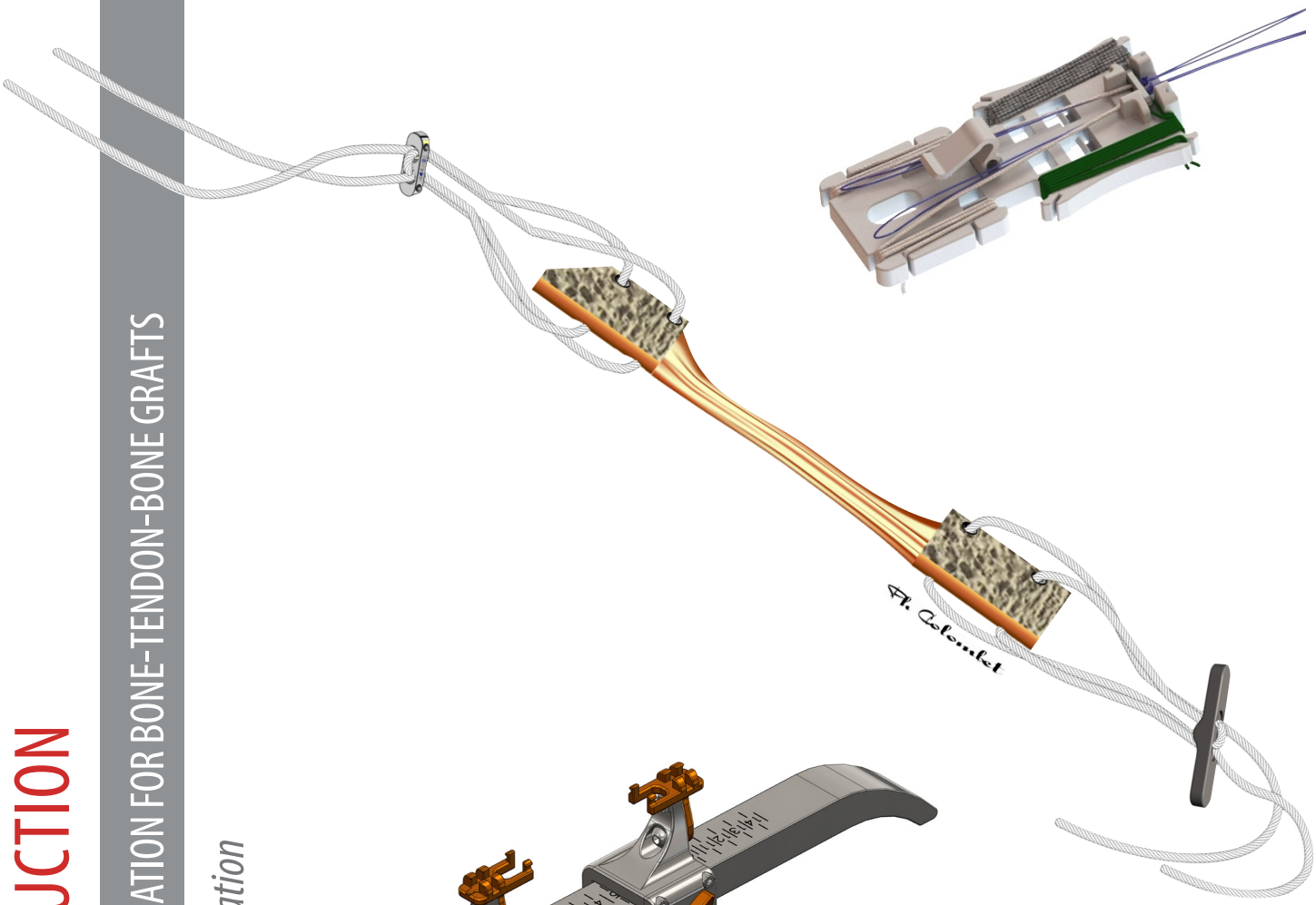
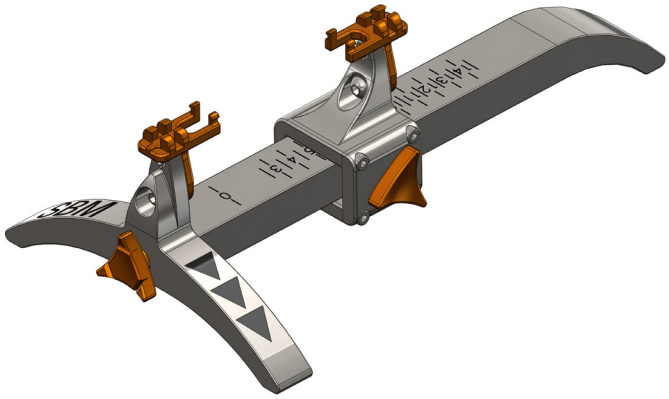
BTLOOP®
BTLOOP® XL

- Strength and rigidity
- Adjustable: one-size-fits-all
- 360° graft/tunnel contact



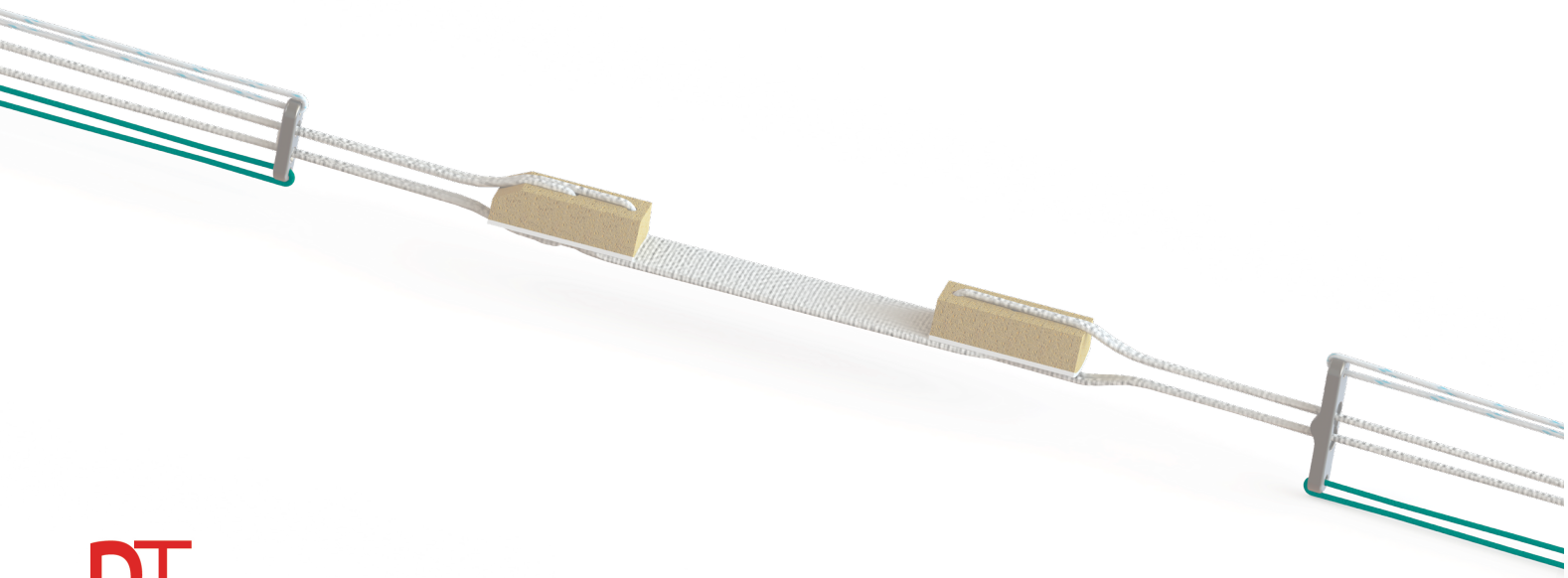


ACL RECONSTRUCTION

ADJUSTABLE CORTICAL FIXATION FOR BONE-TENDON-BONE GRAFTS

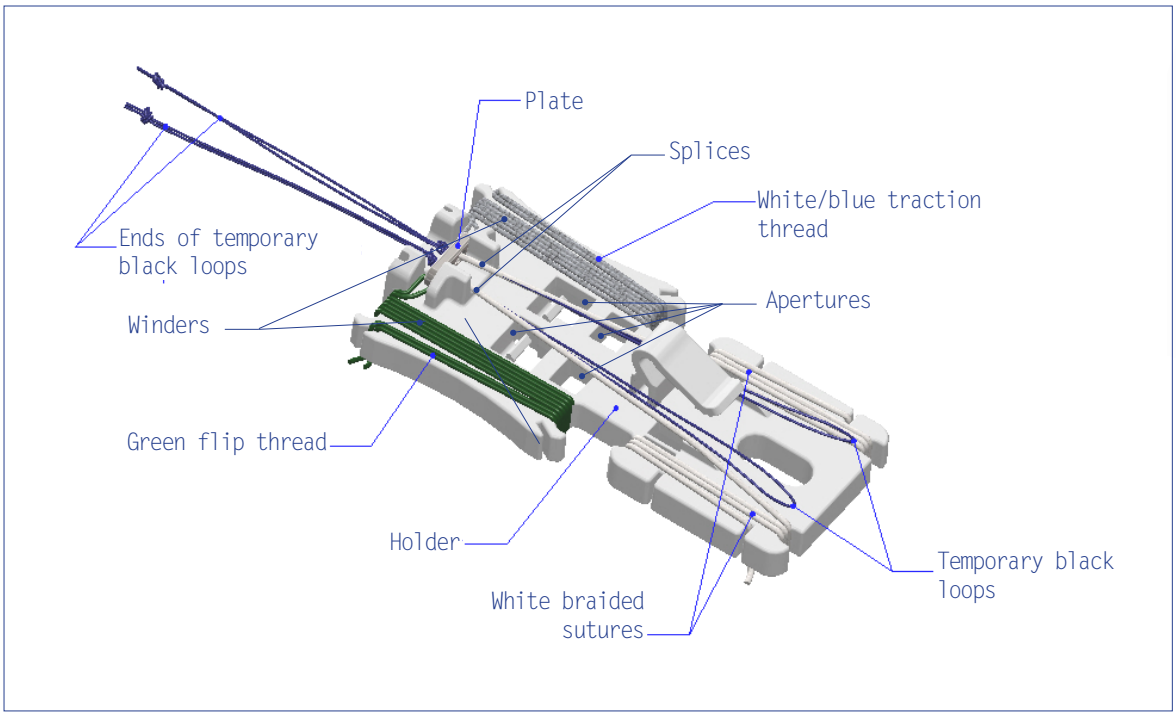
Assembly on GraftTech® station

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BTLOOP® : Product description

Due to the nature of the transplant (bone plug), the BTloop® loops must be mounted on the bone plug in the operating room.



Pull, flip, adjust.

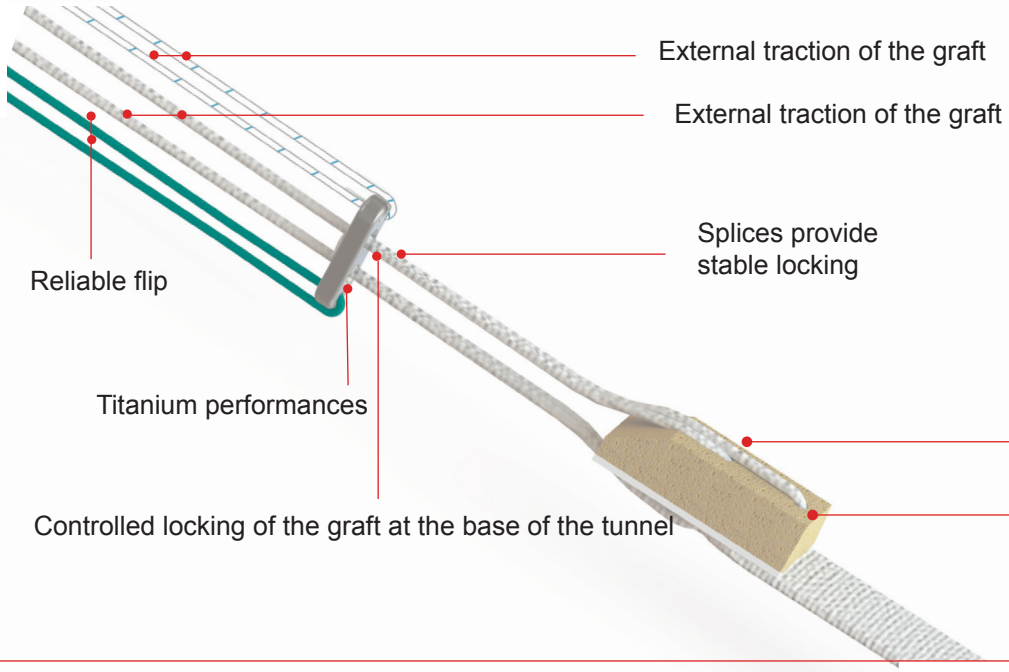
BTLOOP®

Fixation solution for knee ligament reconstructions:

Reproducible
Controlled locking at base of blind tunnel, conservation of bone stock

Simple
No pre-op planning of tunnel length, perioperative length adjustment

Reliable
Stable locking system, renowned materials



Double fixation of the bone-tendon-bone graft:

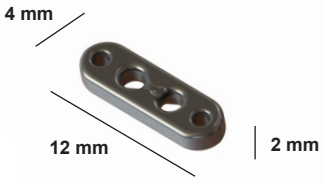
- through the bone plug

- through the bone plug near the tendon

A system that can be adapted to your surgical technique

The BTloop® system is available in two versions:

BTLOOP®



For cortical tunnel ø 4.5 mm

BTLOOP® XL



For cortical tunnel ø 5 to 10 mm

Surgical technique

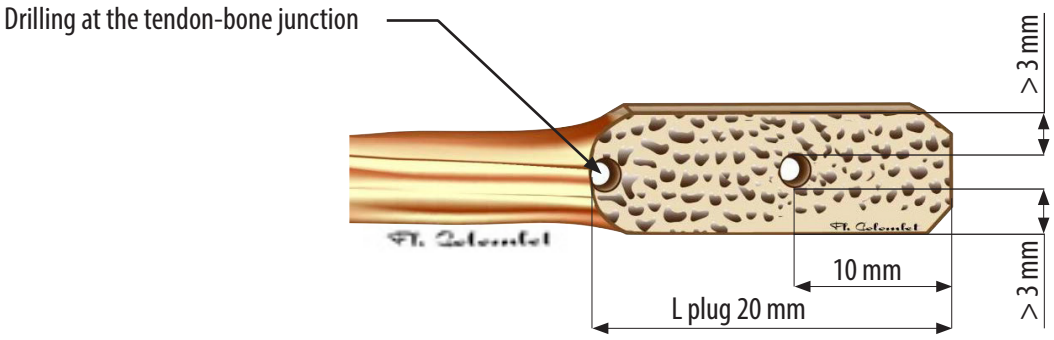
BTloop® fixation characteristics

1. GRAFT HARVESTING

An incision is made along the medial border of the patellar tendon.
The peri-tendon is opened with an inverted-L incision and raised.
The central third of the patellar tendon is harvested with bone plugs in a parallelepiped shape.

2. GRAFT PREPARATION

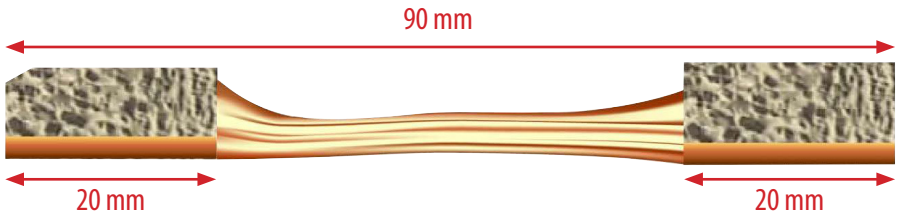
After making the saw cuts, and without detaching the bone plug from the patella, drill two 1.5mm-diameter holes in the patellar bone plug (for fixation in the femur) respecting the following dimensions:



Repeat the process with the other bone plug.

Harvest and gauge the graft.
The patellar bone plug must have a smaller diameter than the tibial tunnel to enable easy insertion.

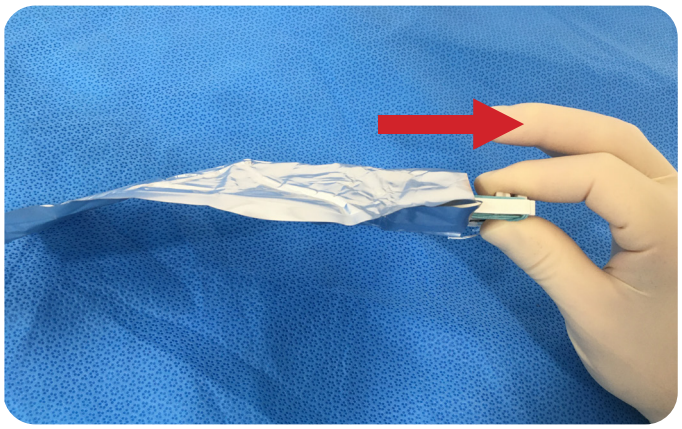
A BIO 1® implant for patellar filling (10 x 10 x 6 mm) can be used to fill the harvesting site.



When the overall length of the graft exceeds 90 mm, you must adapt your surgical technique: 3 possible solutions.

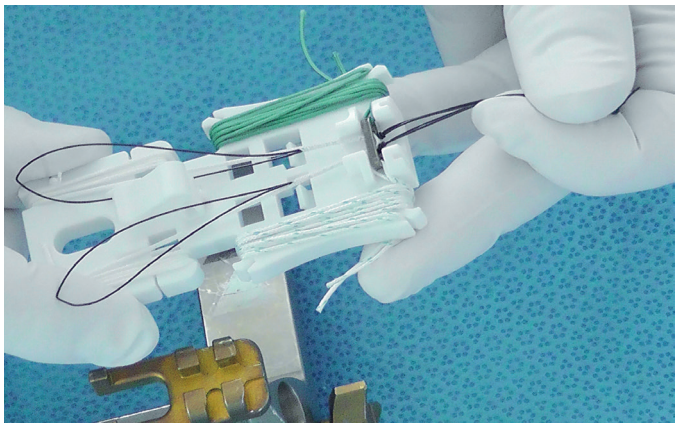
1. Extend the femoral tunnel
2. Extend the tibial tunnel
3. Manage the excess graft outside the tibial tunnel

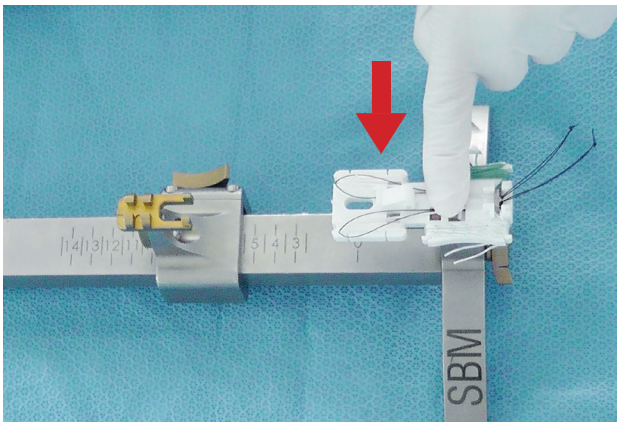
3. INSTALLING THE IMPLANT ON THE GraftTech®



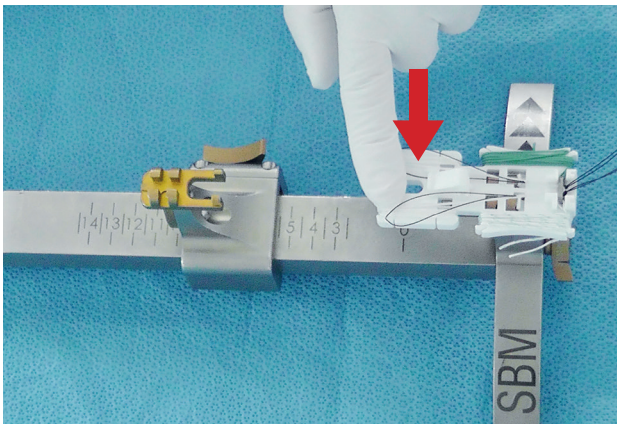
Take the BTloop® out of its sterile envelope, grasping it with two fingers as shown above to avoid pulling the temporary black loops out of the assembly.

The BTloop® is assembled on the GraftTech® preparation station SLIDER, lining up the four apertures in the holder with the four pins of the GraftTech® slider bracket.





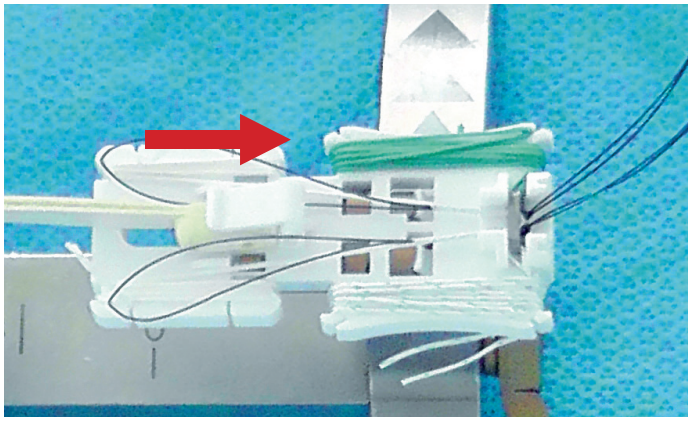
Pull out the ends of the two temporary black loops, as well as the traction and flip threads (to prevent them from getting stuck between the holder and the GraftTech®) then push in the middle of the apertures to clip the holder on the bracket until a click is heard.

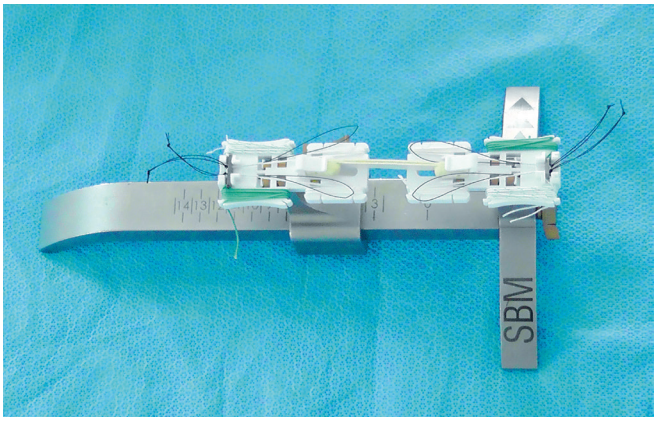


Push on the front part of the holder to make sure it is entirely clipped on the bracket:
a second click must be heard.

Repeat the steps to position the second implant.

4. POSITIONING OF THE GRAFT ON THE BTloop® HOLDER



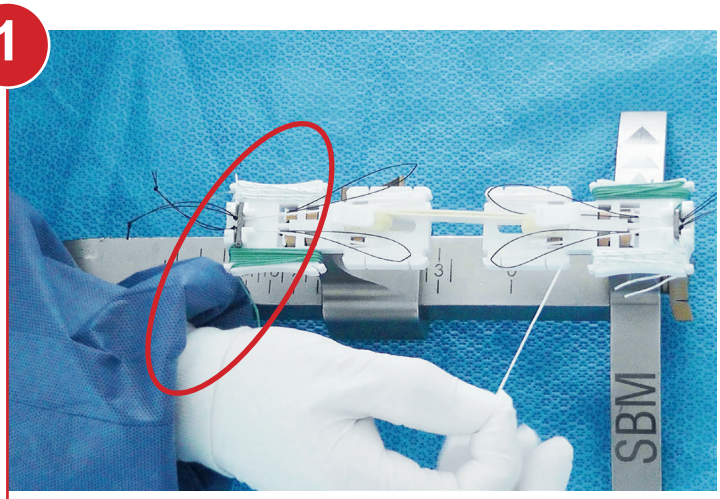


Insert the patellar bone plug flush against the holder clip.
The drill holes must be parallel to the holder.
Then use the same method to fix the tibial bone plug.

5. PREPARATION OF THE PLUGS

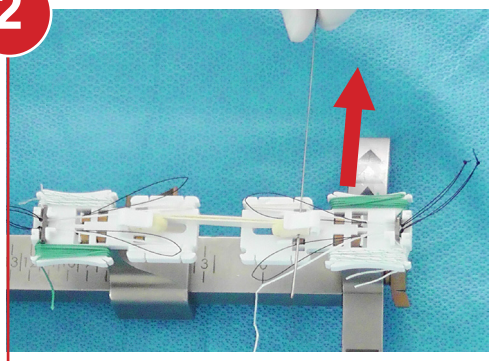
The BTloop and BTloop XL graft assembly methods are strictly identical. Strictly follow the assembly steps described below. The devices must be assembled one after the other.

1



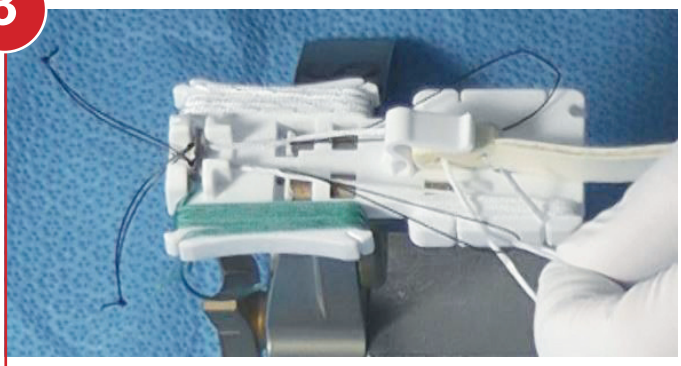
Completely unravel one of the two white braided sutures.

2



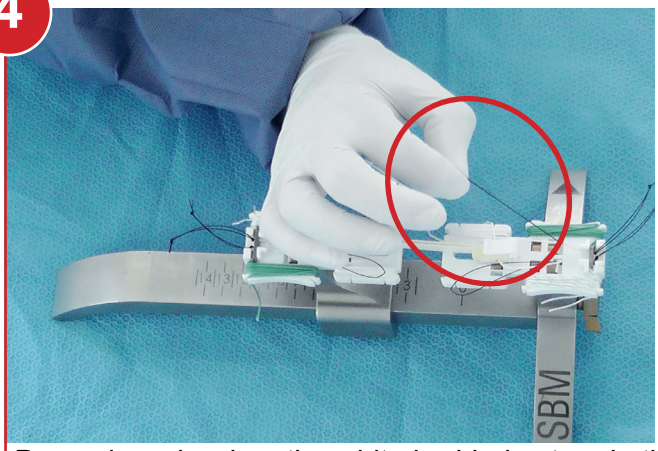
Using the suture-passer pin, pass the white braided suture through the proximal bone plug hole and the **opposing** temporary black loop.

3



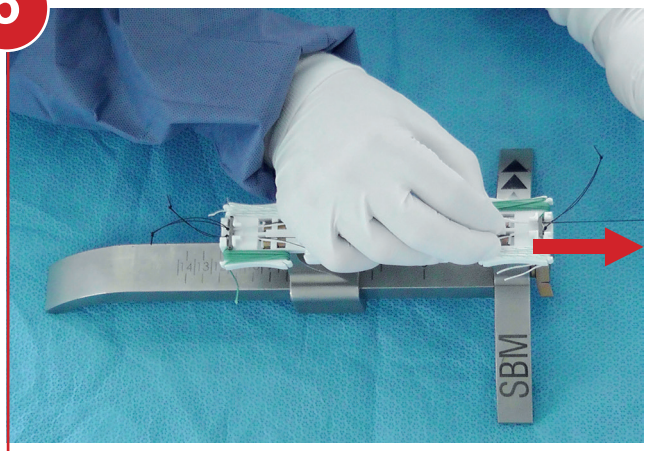
The length of the braided suture traversing the temporary black loop must be less than 10 cm

4



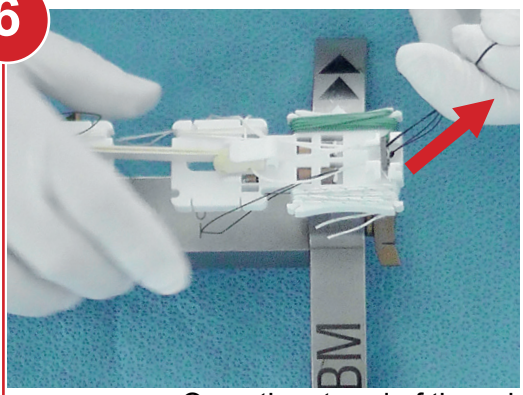
Press down hard on the white braided suture in the traction zone of the temporary black loop to facilitate its insertion into the splice.

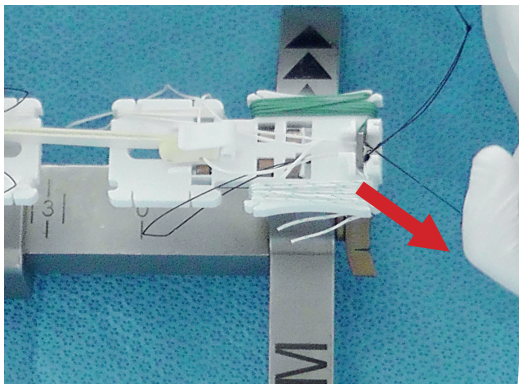
5



Pull gently, in line with the splices, on the end of the corresponding temporary black loop.

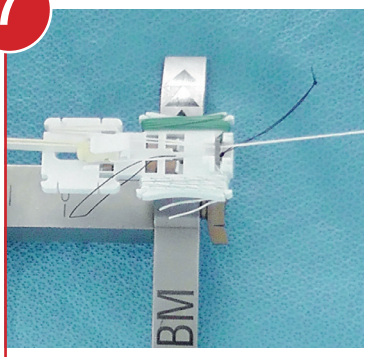
6

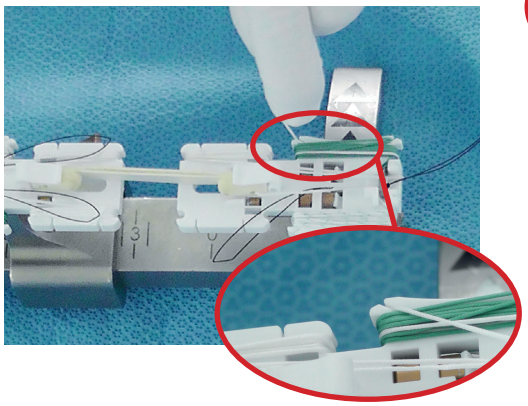




Once the strand of thread has entered the splice, exercise lateral movements on the end of the temporary black loop, continuing to pull gently, in order to facilitate its progress, until the strand of thread has fully exited the splice.

7





Reduce the white thread loop by applying light tension and wind the strand of thread around the winder before wedging it inside the free notch.

8

Repeat the different steps with the other strand of white thread through the drill hole at the tendon/bone plug junction by passing it through it in the opposite direction from the first strand.

Wrap the graft in a sterile wet compress to prevent it drying during the tunnel drilling phase.

6. ARTHROSCOPIC USE (assessment and cleaning)

Meniscus inspection.
Notch preparation.
Test the remainder of the anterior cruciate ligament by trying to preserve the anteromedial and posterolateral bundle if it is conserved.

7. TIBIAL TUNNEL



Position the tibial aiming device.
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 tibia, the superior branch of the aiming device must be parallel with the tibial plateau).
Next, mount the drill guide on the aiming device and insert the ø 2.5mm Kirchner pin into the motor. The articular surface can be protected by a curette. The pin is removed under arthroscopic control.



Drilling of the tibial tunnel
Remove the aiming device by keeping the guide pin in place, then drill the tibial tunnel on the pin, first with the Ø 6mm drill bit and then with the drill bit of the definitive diameter (gauged tibial plug Ø). Between these two drillings, the 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.

8. FEMORAL TUNNEL

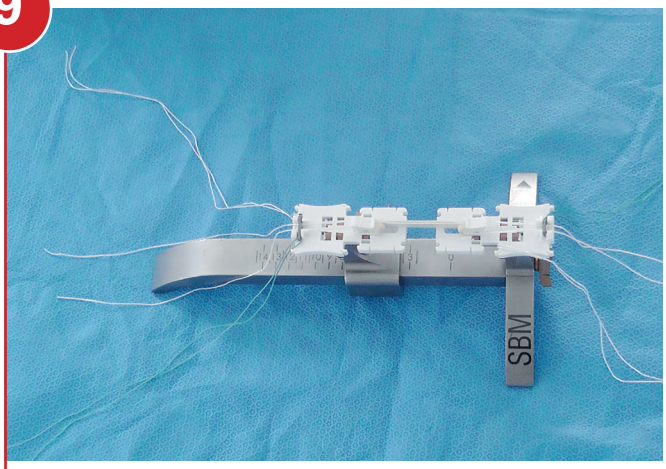


Position of the femoral aiming device
With the knee in hyperflexion at approx. 120 degrees, pass the femoral aiming device through the anteromedial portal and position the hook of the aiming device against the posterior border of the lateral condyle.
The gap between the hook of the aiming device and the axis of the pin depends on the diameter of the tunnel: gap of 6.4 mm with the ø 9 mm aiming device, and of 6.9 mm with the ø 10 mm aiming device.

Drilling of the femoral tunnel
The knee in hyperflex position, insert the ø 2.5 mm eyelet pin into the femoral aiming device and push it until it is visible under the skin. Make an incision at the exit point.
Under arthroscopic control, drill the femoral tunnel on the eyelet pin to a depth matching the length of the transplant bone plug, with the graduated drill or router bit matching the gauged diameter of the plug.
To guarantee optimal centring, always drill on the same eyelet pin with the Ø 4.5 mm cannulated drill bit until the external cortex is reached.
Depending on the pin's exit point in the femur, which can make the tunnel longer, extend the BTloop® loops to favour the flipping of the implant onto the cortex.
N.B.: By default, following the assembly of the BTloop®, the distance between the plate and the end of the bone plug is 40 mm.

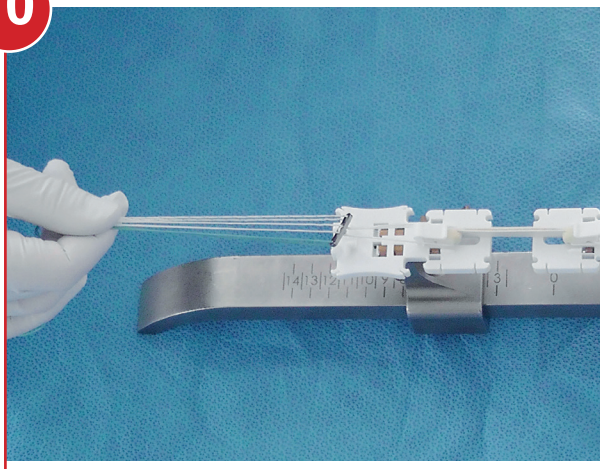
9. REMOVING THE IMPLANT AND THE HOLDER FROM THE GRAFTECH

9



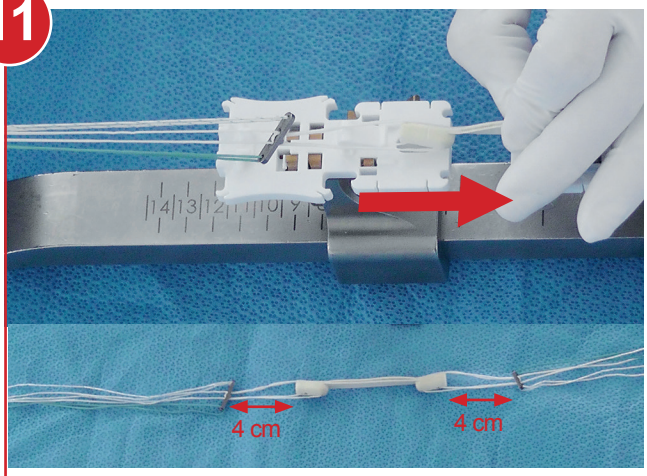
Remove the protective compress from the graft. Unwind all the sutures.

10



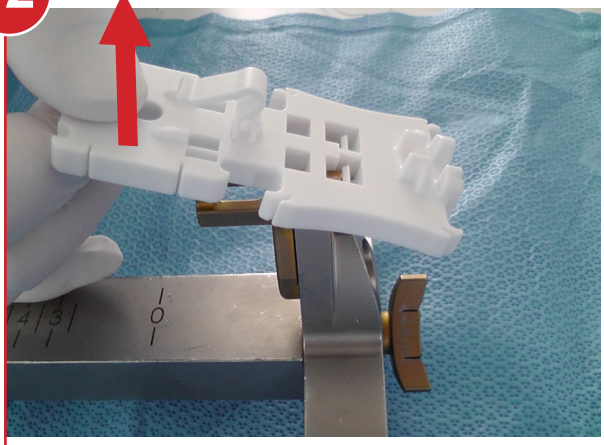
Remove the plates from their housing by lifting up all the threads.

11



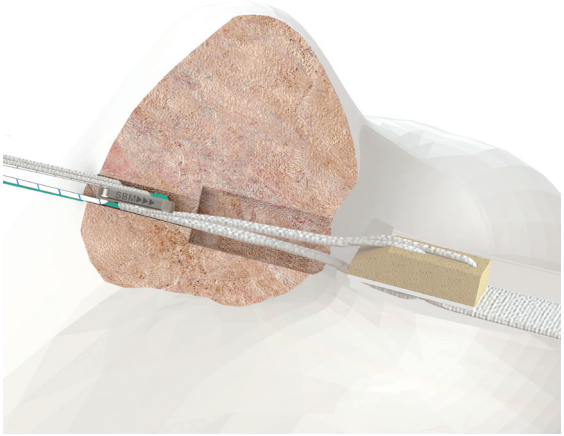
Pull on the bone plug to remove it from the holder. Make sure that the distance between the bone plug and the plate is at least 4 cm.

12



Remove the BTloop® holder from the GraftTech®.

10. PASSING THE TRANSPLANT THROUGH THE TUNNELS



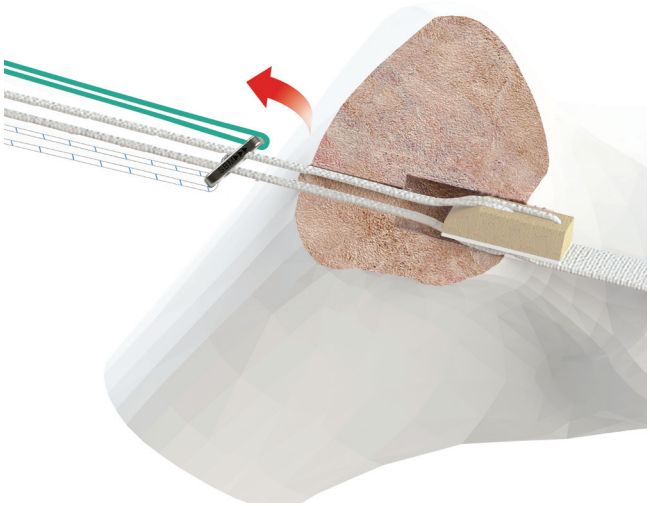
The traction thread, previously passed through the eye of the Ø 2.5 pin, is pulled with the pin via the arthroscopic anteromedial portal through the femoral tunnel, and then retrieved in the tibial tunnel with Kelly's pliers.
All the threads of the BTloop® implant are passed through the relay suture loop.

Using the relay suture, pull all the BTloop® threads from the tibia towards the femur.

Position the BTloop® in line with the tibial tunnel, pulling lightly on the white/blue thread, then grasp all the BTloop® threads and pull them all until the plate exits the femoral tunnel.

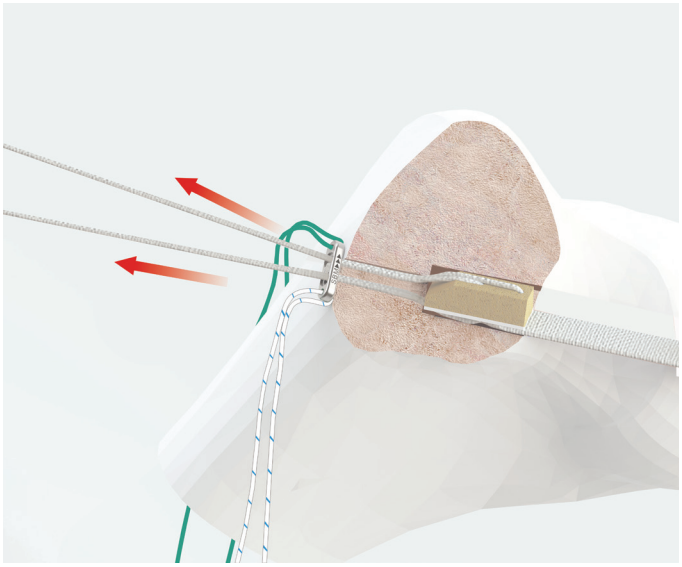
11. FEMORAL AND TIBIAL FIXATION

Flipping of the implant



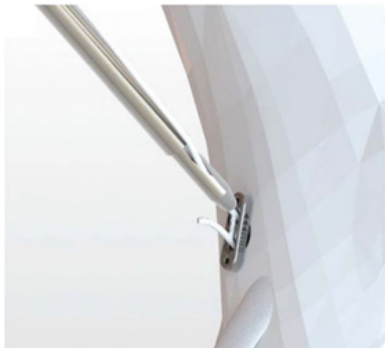
Flip the plate using the green thread.
Alternately pull on the green and white/blue threads to check whether the plate has reached the external cortex and that it has been successfully flipped.

Locking of the femoral fixation



Alternately pull on the white threads of the BTloop® implant until they are locked and the plate makes contact with the cortex.
Check the stability of the assembly by pulling on the graft.
Check for proper kinematics of the transplant before tibial fixation.
Follow the same steps for the tibial fixation.

12. FINAL CHECKING AND CUTTING OF THE THREADS



Under arthroscopic control, check the tension of the graft.
Remove the green and white/blue threads by pulling on one of their ends.
Use the cutting pliers to sever the implant's white threads.

REFERENCES

BTloop® - Adjustable fixation system for KJ-technique ligament reconstruction

References	*Designation*	*Quantity*
BTB0001709	BTloop® - Adjustable fixation system for KJ-technique ligament reconstruction in cortical tunnel ø 4.5 mm	1
BTBXL01709	BTloop® XL- Adjustable fixation system for KJ-technique ligament reconstruction in cortical tunnel ø 5 to 10 mm	1

GraftTech® preparation station for ligament reconstruction

References	*Designation*	*Quantity*
PULL000217	GraftTech® preparation station mounted with brackets	1
NC2410	GraftTech® preparation station stainless steel basket with silicones	1
ND2425	GraftTech® preparation station stainless steel basket lid	1

BTloop® suture-passer pin

References	*Designation*	*Quantity*
PUL9000303	BTloop® suture-passer pin	1

Implant for patellar filling

References	*Designation*	*Quantity*
P822694220	BIO 1® implant for patellar filling - 10 x 10 x 6 mm	1

About SBM

SBM (Science & Bio Materials) has been specialized in the design, manufacture and distribution of biomaterials for bone reconstruction since 1991. The company's priority is the development and optimization of medical devices which promote bone healing and human tissue replacement. By completely controlling its manufacturing techniques, the company elaborates a range of innovative, 100% synthetic and absorbable material-based systems along with specific ancillary instrumentation.

SBM's environmental commitment

Driven by a strong desire to protect the Planet, SBM has placed the development of an environmentally-friendly economy at the heart of its concerns.
The three pillars of its strategy are:

- An ISO 14001 : 2015-certified environmental management system, implemented across the entire business and by its partners.
  - Reducing the environmental impacts of its business activities
  - Cutting its CO2 emissions by 30% by 2030 (Paris COP 21 Agreements)
  - Managing its energy consumption (photovoltaic production of 15% of its electricity)
  - Managing its waste and emissions
- The desire to develop its business activities in accordance with the principles of sustainable development

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Carefully read the instructions for use that comes with the medical device or labelling provided to medical professionals. Device featured on the list of additional refundable products; for further information, please refer to the price lists.
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S.B.M. SAS
ZI du Monge
65100 LOURDES FRANCE
FRANCE
Tél. : (+33) 5 62 42 32 12
Fax : (+33) 5 62 42 32 52
www.sbm-france.fr

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