**Instructions for Use**

# ACL reconstruction system

## Quadriceps tendon patella bone plug graft (QTB) for femoral press-fit fixation.

*An implant and bone-debris free technique*

## Intended use

The ‘ACL reconstruction system’ is a surgical instrument system intended to facilitate ACL repair. It provides guidance to the operating surgeon in performing the required bone and quadriceps tendon preparation and to create fixation space for the replacement of the broken native anterior cruciate ligament by a native quadriceps tendon segment including patella bone plug. This ensures appropriate restoration of the joint functionality of the knee of the patient and so protects cartilage and menisci from secondary injuries

The ‘ACL reconstruction system’ in combination with other supporting standard instrumentation provides the surgeon a logical and guided surgical procedure, to replace the anterior cruciate ligament with patient native materials, minimalizing the use of artificial implants and minimizing bone loss.

## Indications, contra-indications, warnings and precautions

### Indications:

Complete or partial primary anterior cruciate ligament (ACL) rupture, requiring surgical reconstruction

Factors indicating the need of surgical ACL reconstruction in the ACL deficient knee:

- Anteroposterior and rotational laxity in the knee causing instability
- Objective or subjective instability of the knee
- Concomitant injuries necessitating the reconstruction. Damage to other intra-articular structures, requiring the need for protection of cartilage and menisci from secondary injuries.
- Impaired function and ability to participate in sports
- Demand of patients to actively participate in athletic activities

### Contraindications:

- Prior quadriceps tendon rupture
- Weak or small quadriceps tendon
- Chronic quadriceps tendinopathy
- Patella pain problems
- History of joint problems (for example, existing osteoarthritis)
- Insufficient bone substance or poor bone quality which might compromise stable anchorage and fusion of the bone graft
- Lack of compliance of the patient in appropriately limiting his/her activities or following medical instructions during convalescence
- Severe deformities around the knee
- Acute or chronic infections, local or systemic (or corresponding history)
- Immature osteogenesis
- Patients in whom conservative therapy is promising
- Advanced age of the patient, when compromising convalescence

## Warnings and Precautions

- Only use the device for its intended purpose (intended use).
- The ACL reconstruction system must be used by specifically trained personnel only. The surgeon must be familiar with ACL reconstruction using a patella bone with attached quadriceps tendon graft, the surgical technique and surgical procedure prior to performing surgery. The surgeon is responsible for ensuring that the operation is carried out properly.
- The instructions for use must be well understood.
- Effectum Medical is not responsible for any complications arising from incorrect diagnosis, choice of incorrect graft and graft preparation, incorrectly combined implant components and / or operating techniques.
- All instruments need to be regularly inspected for wear and disfigurement prior to use.
- Unless otherwise indicated, instruments are defined and provided as NOT STERILE. Before use they must be thoroughly cleaned and sterilized according to the Processing Instructions. Instruments that are not clean may not be effectively sterilized.

## Potential Side Effects:

Anterior cruciate ligament reconstruction surgery carries potential side effects of a knee surgery, such as bleeding and blood clots, continued knee pain, infection, knee stiffness or weakness, loss of range of motion.

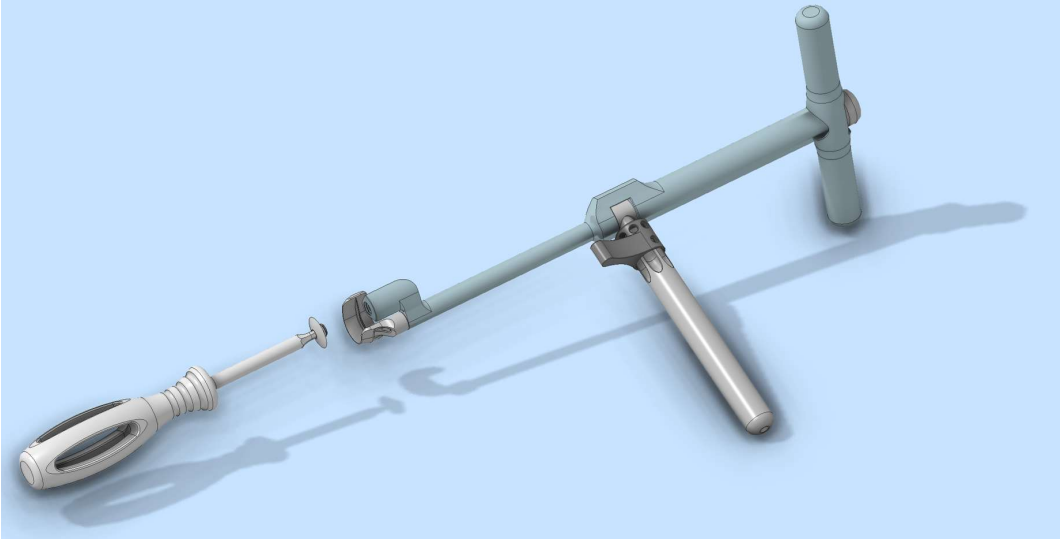
# Surgical technique:

## Assembly of the individual instruments

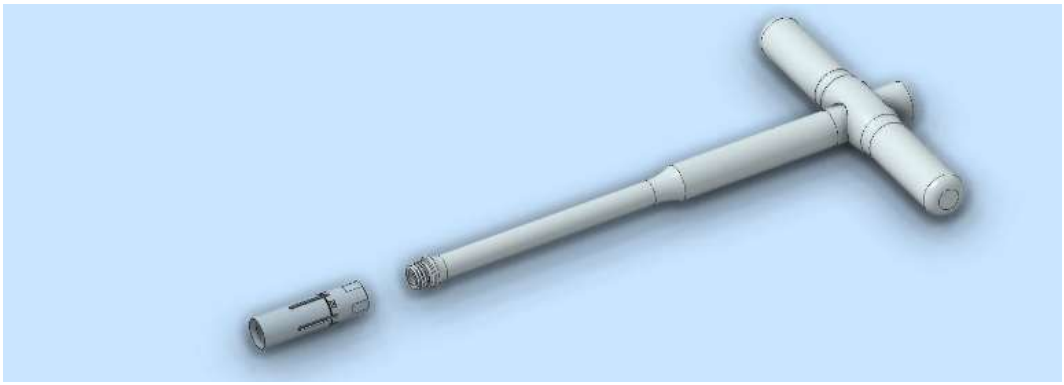
Assemble the blade to the graft cutter by use of the screwdriver

**Alternative instrument:**

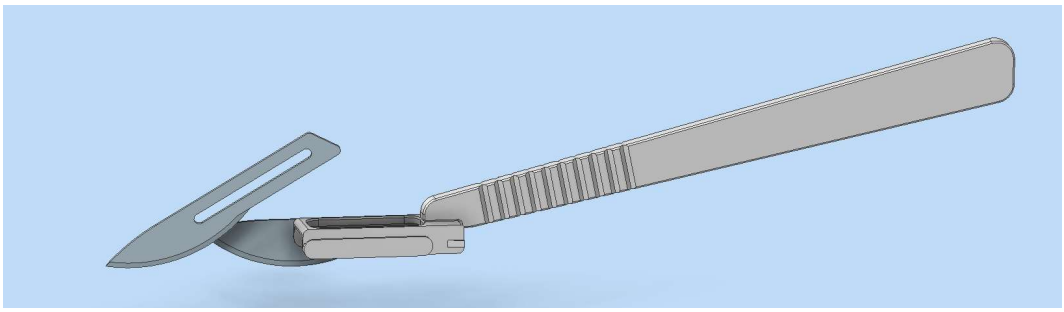
Assemble the blade to the tendon cutter by use of the screwdriver



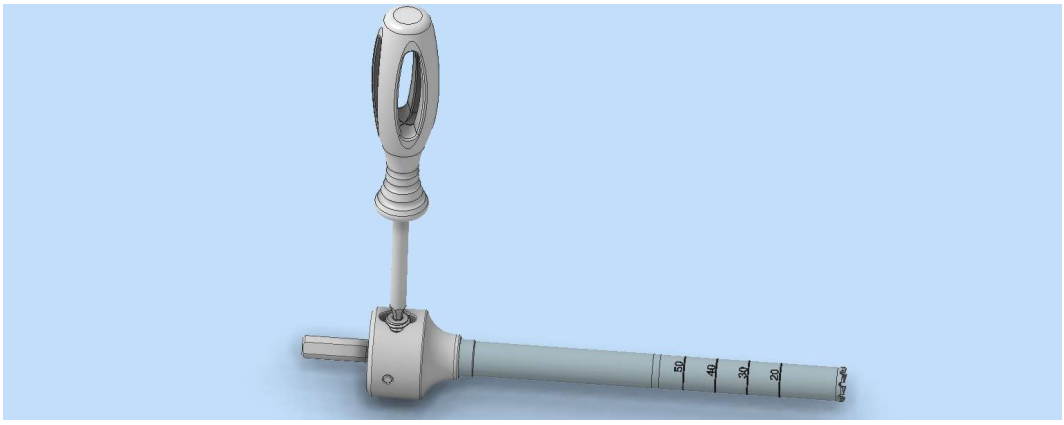
Screw the femoral punch onto the T-handle. Ensure the punch is well tightened. The bone plug removal aid can be used as a key to apply the necessary torque.



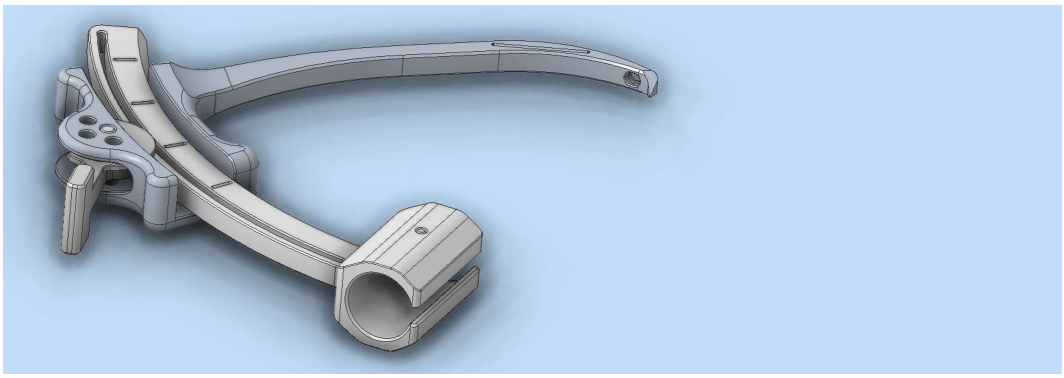
Assemble the scalpel blades to the parallel scalpel handle. The parallel scalpel handle is compatible with standard ISO 27740 blades. Size number 20 is the recommended size.



Assemble the hollow drill into the chuck for hollow drill. The hollow drill self-centers into the chuck. Secure the hollow drill upon tightening of the locking bolt by use of the screwdriver




Assemble the tibia aiming device and the tibia aiming device arc. By tilting of the lever the arc is locked into the desired orientation.



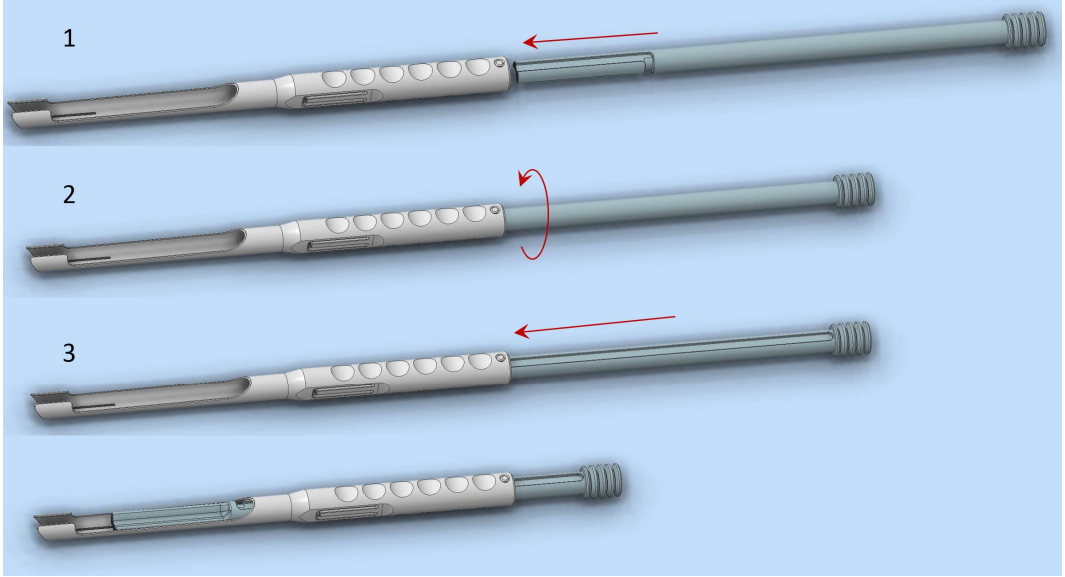
Screw the patella drill-guide handle into the patella drill-guide

By insertion of the bone plug inserter into the bone plug inserter handle the bone plug inserter assembly instrument is prepared for use.

1: Align the groove at the bottom side of the inserter with the guide pin of the handle

2: Advance the inserter forward till the seat, and turn the inserter 180° within the housing

3: Advance the inserter forward to its end position



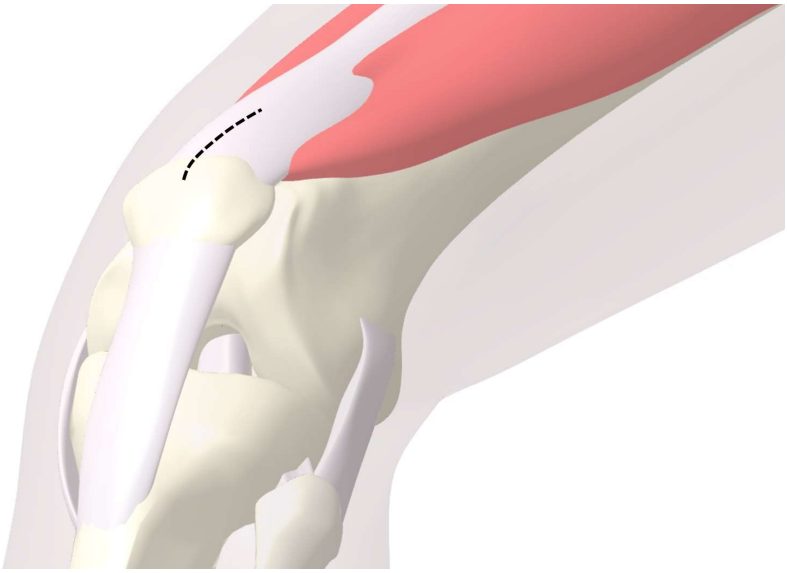
## Quadriceps and patella bone plug graft retrieval

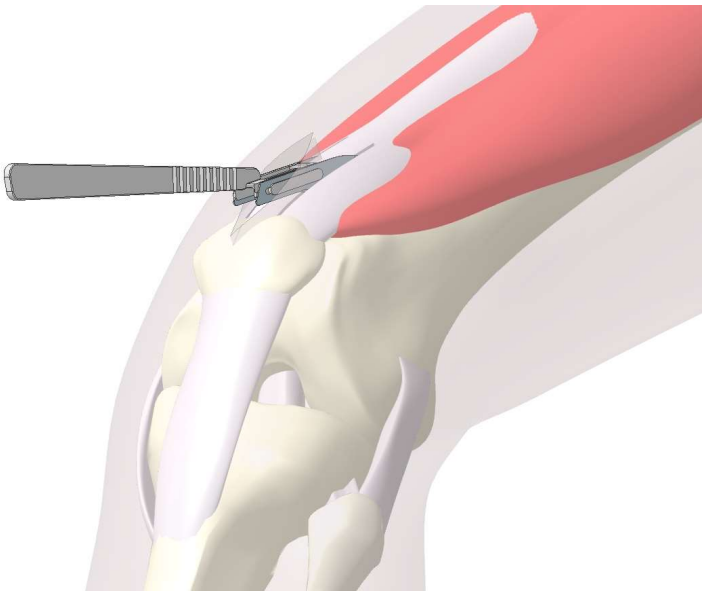
### Patient positioning and skin incision

Put the patient in a supine position with a leg holder in approximately 30° of flexion. Create a 3-4 cm longitudinal skin incision starting at the proximal one-third of the patella, directed towards and centered in relation to the quadriceps tendon. Use small retractors to visualize the quadriceps tendon.

### Parallel quadriceps tendon incision

Take the parallel scalpel handle with attached scalpel blades and create the parallel incision of approximately 5 cm length into the quadriceps tendon. Start the incision at the proximal end of the patella. Ensure that the incision is directed parallel to the quadriceps tissue fibers.

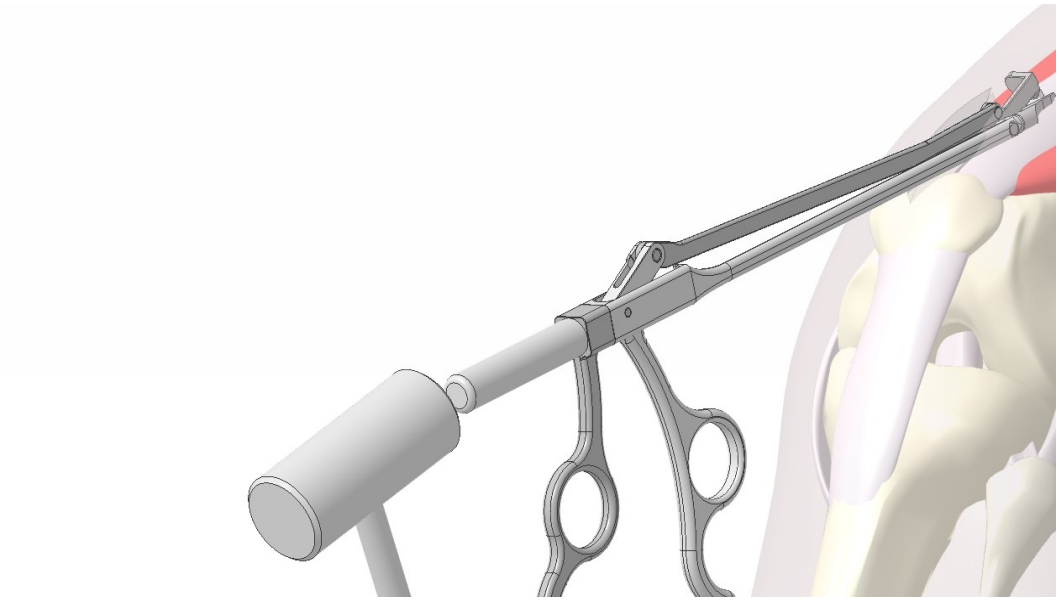


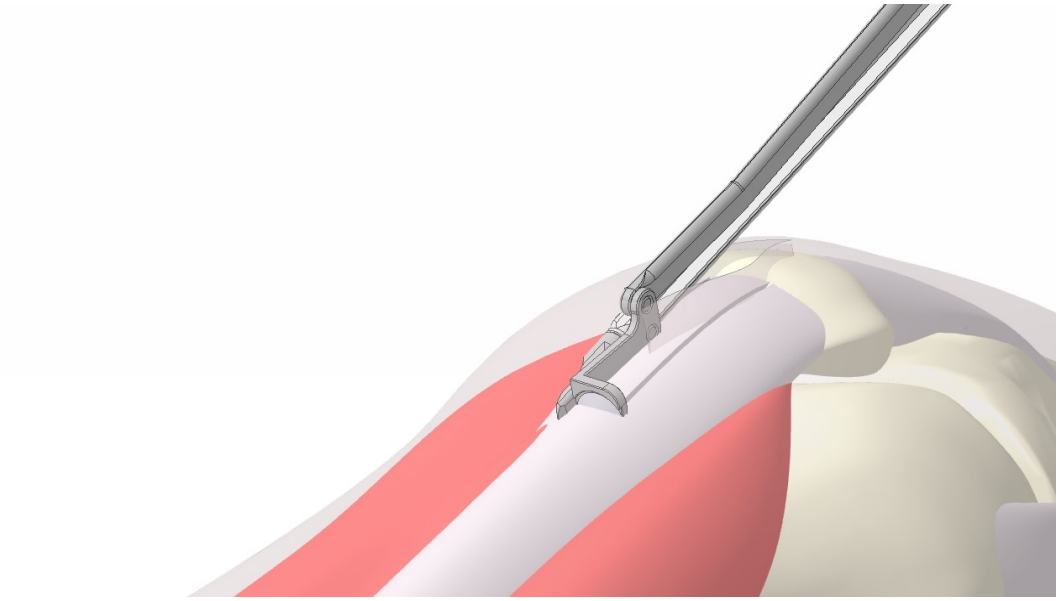


**Proximal tendon separation using the graft cutter**

Take the graft cutter with attached blade. The graft cutter U-shaped tip is hooked under the fibers of the quadriceps tendon at a depth of approximately 8-9 mm. The U-shaped tip connects the first parallel incision with the second parallel incision. By tapping on the impaction-end of the graft cutter, the graft cutter is advanced forwards to the end of the incision to a depth of approximately 5 cm.

By activation of the plier cutting mechanism, the graft is cut off. A 10 mm wide and 5 cm long strip of tendon is excised.

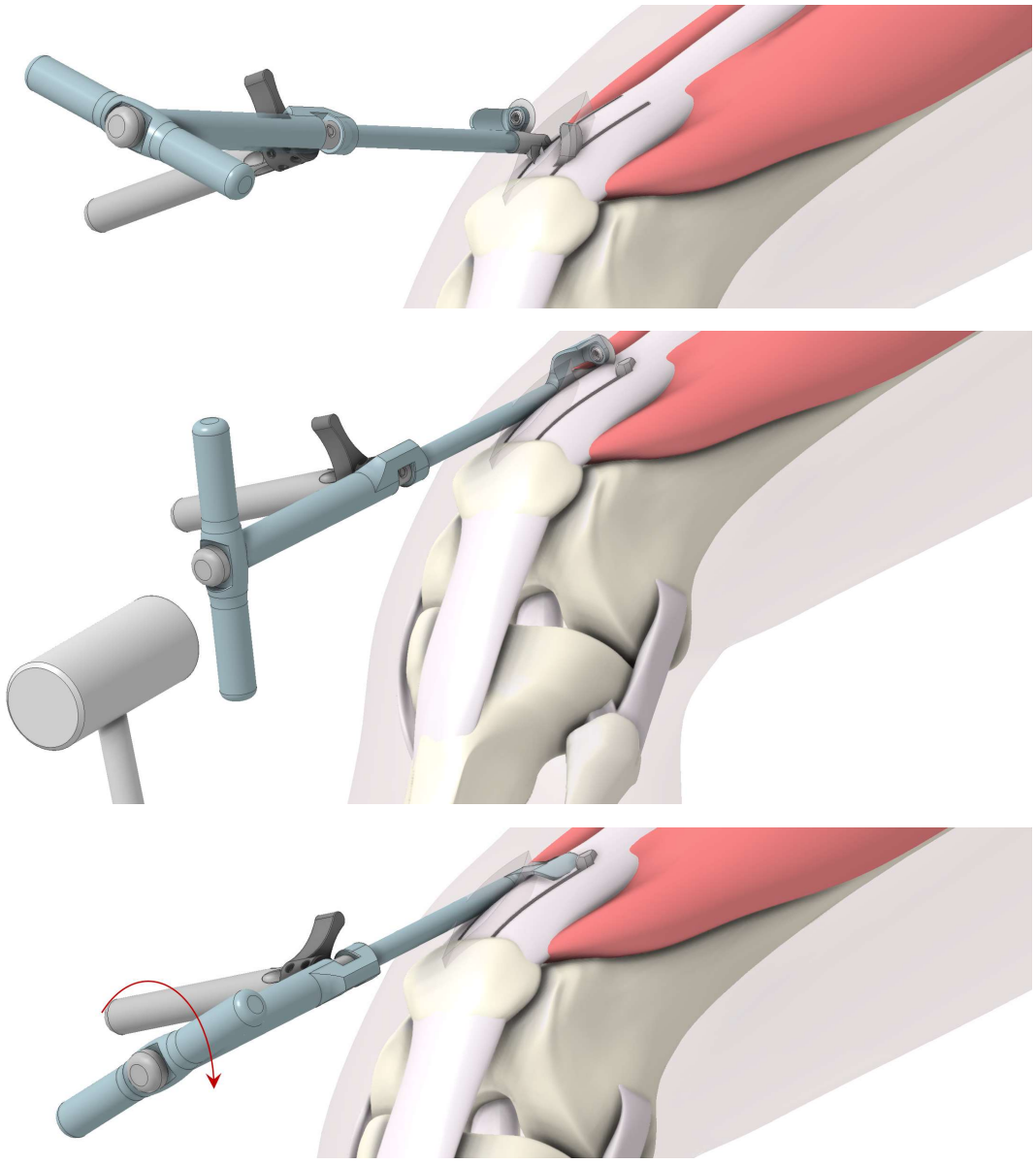




**Alternative instrument: Proximal tendon separation using the tendon cutter**

Take the tendon cutter with attached blade. The tendon cutter U-shaped tip is hooked under the fibers of the quadriceps tendon at a depth of approximately 8-9 mm. The U-shaped tip connects the first parallel incision with the second parallel incision. By tapping on the impaction-end of the tendon cutter, the graft cutter is advanced forwards to the end of the incision to a depth of approximately 5 cm.

By activation of the cutting mechanism, the graft is cut off. A 10 mm wide and 5 cm long strip of tendon is excised.



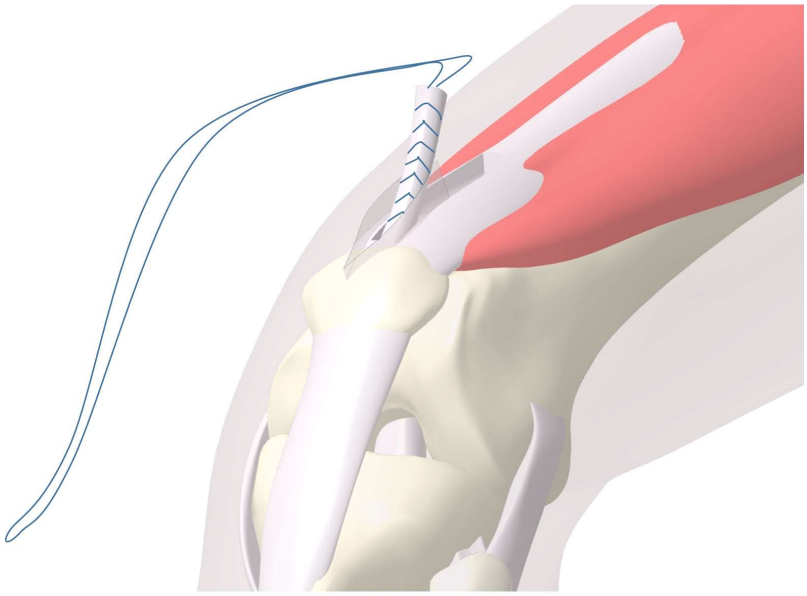
**Graft reinforcement**

Pull-up the quadriceps tendon graft  through the skin incision. Reinforce the quadriceps tendon graft by means of stitching. Start at the end which is attached to the patella. A whipstitch stich pattern with a USP 2-0 to USP 5-0 braid suture thickness is recommended. The reinforcement enhances the strength of the graft. Use a 90-100 cm suture strand.

***Remark***

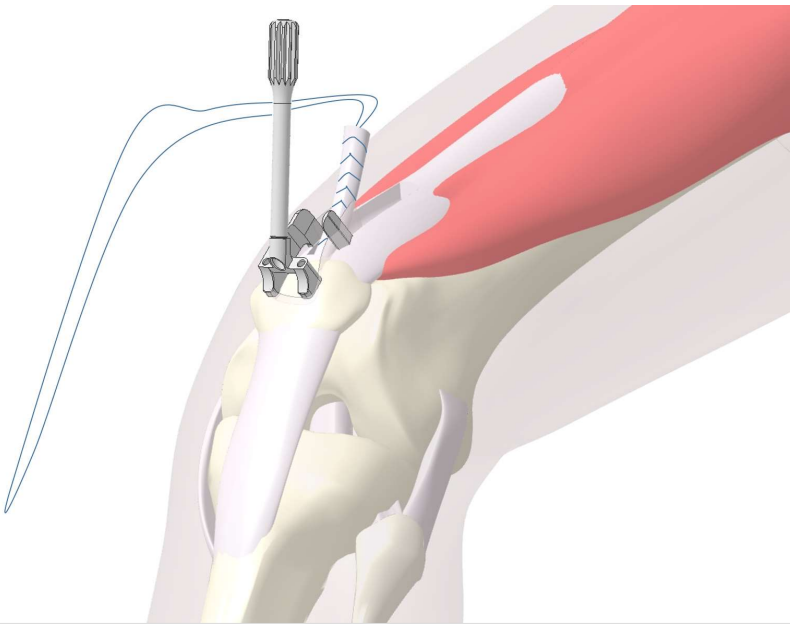
*In a following step, the remaining suture strands are used to pull the graft through the powertool with attached drill to keep tension on the quadriceps tendon graft during the preparation of the patella bone plug.*

*In a later step, the remaining suture strands are used to pull the graft into the tibia tunnel, and to fixate the graft to the tibial bone bridge.*

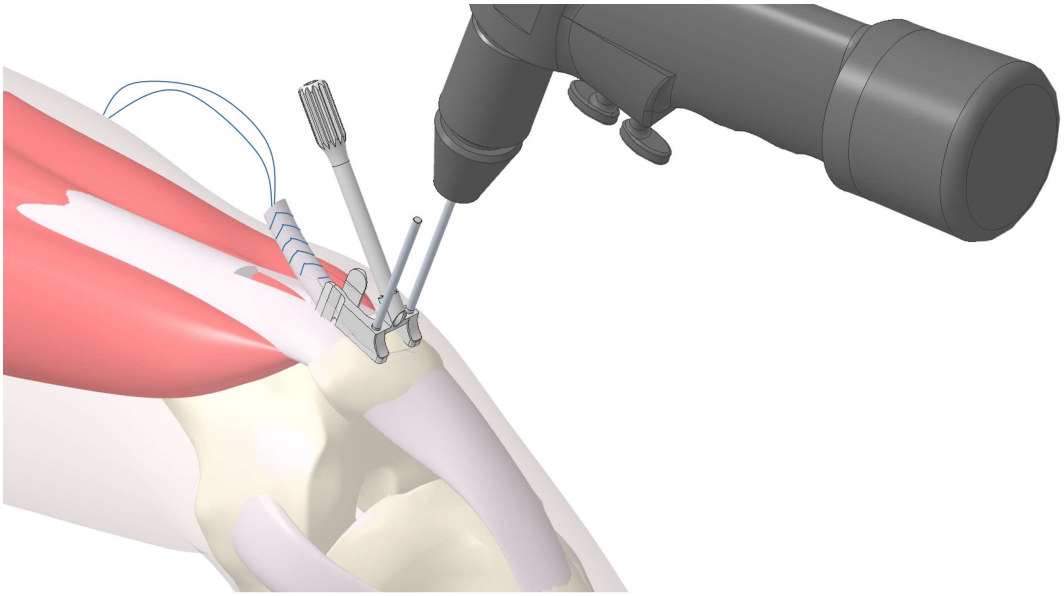


**Patella bone plug preparation and separation**

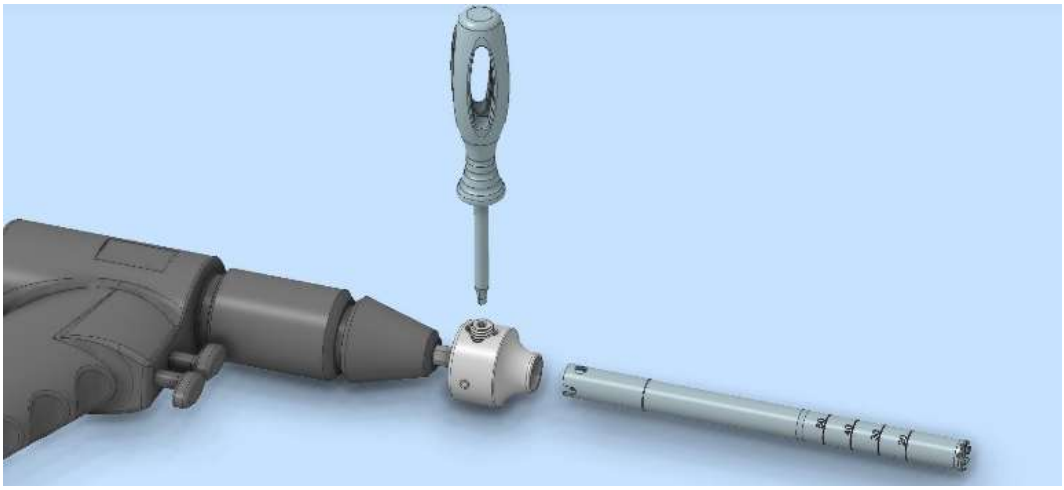
Hook the patella drill guide with attached handle around the quadriceps tendon graft. Ensure the drill guide is aligned with the graft and the sagittal plane of the patella. Engage the U-shaped guide against the proximal end of the patella bone. Engage the bottom side of the patella drill guide against the top surface of the patella bone.



Fixate the patella drill guide to the patella bone by use of the two pins with stop. First place the short pin through one of the fixation holes. Secondly place the long pin with stop. Drill the pin into the patella until the seat of the pin with stop is engaged against the patella drill guide.

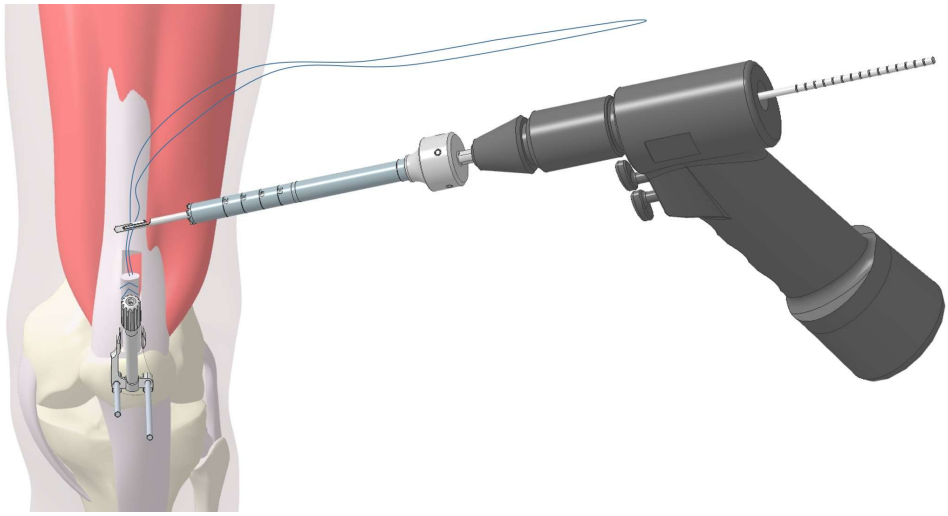


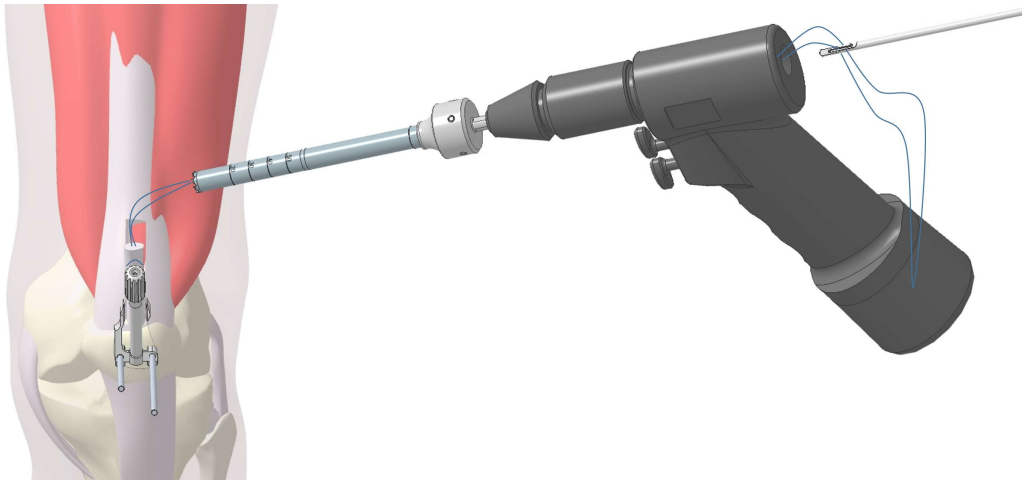
Assemble the chuck including hollow drill into the powertool.



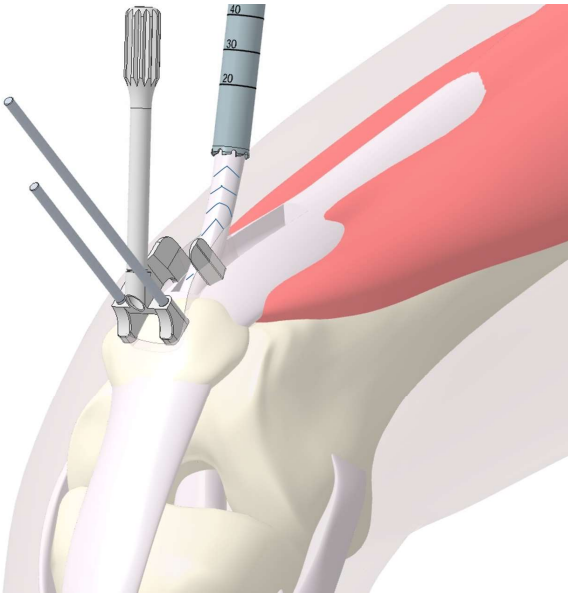
Insert the suture hook through the central cannulation of the powertool, chuck and hollow drill.

Hook the end(s) of the graft reinforcing suture strand into the suture hook. Pull the suture hook including suture strands through the powertool and unhook the suture from the suture hook.





Pull at the suture strands while arranging the tendon graft into the hollow drill. Arrange the hollow drill is into the patella drill guide. Ensure that the suture strands are kept under tension.

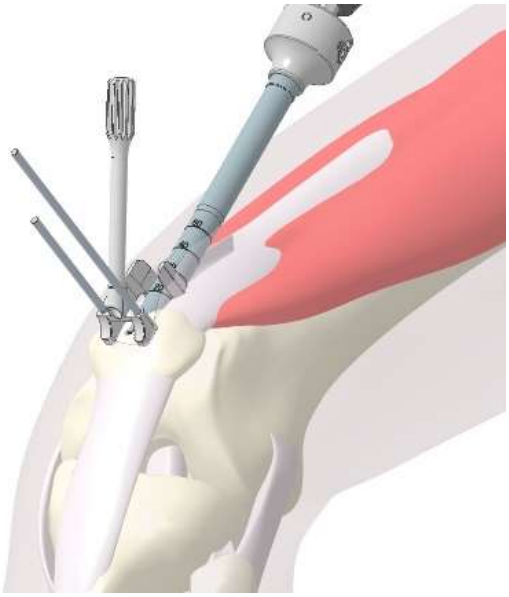



Keep tension on the suture strands and slowly drill the hollow drill into the patella bone. Drill to a depth of approximately 20 mm.

***Remark***

Ensure that the patella bone plug is harvested at the top surface of the patella bone. Too deep drilling may compromise the residual strength of the patella. Too shallow drilling may create an incomplete bone plug and can compromise the press fit in the femoral bone.

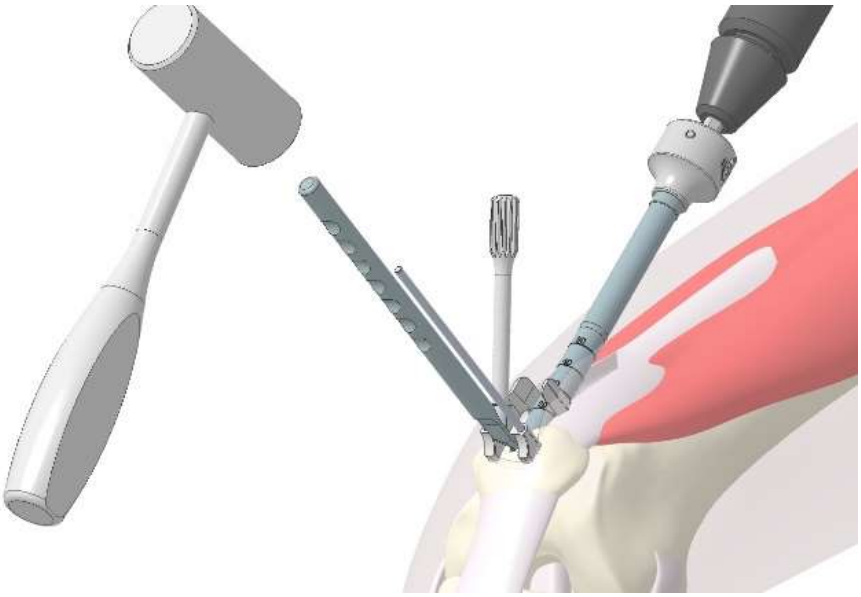
Advance the hollow drill forward into the patellar bone to a target depth of 20 mm. Markings on the hollow drill provide feedback on the drilling depth.



Separate the patellar bone plug including attached quadriceps tendon from the patella. Place the chisel in front of the hollow drill and cut the end by gently tapping on the chisel.

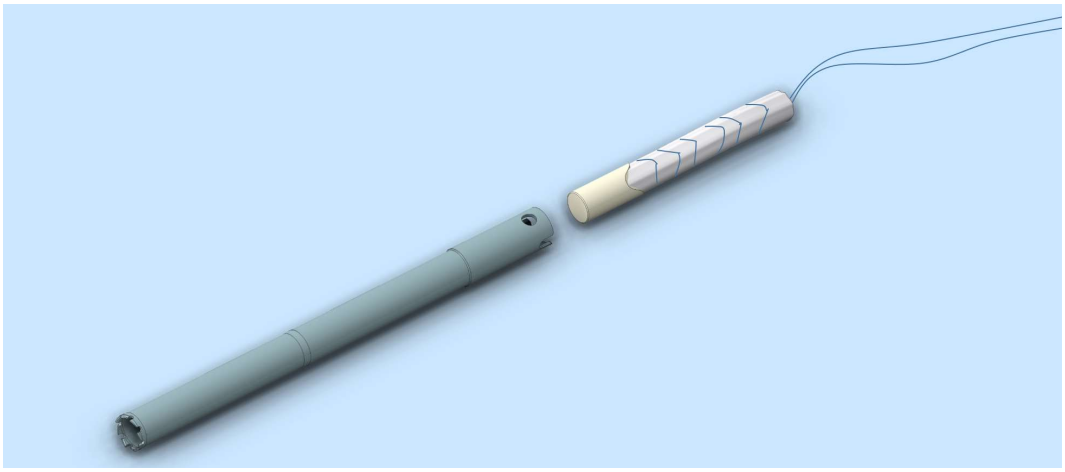
***Remark***

*The hollow drill may be released from the powertool before the final separation of the patella bone plug.*



Remove the graft from the hollow drill by pulling at the suture strand ends. Put the graft aside and cover the graft with a wet cover.

Remove all instruments from the patella.



## Tibial tunnel preparation

### Patient positioning and skin incision

Change the angle of the leg in approximately 90-100° of flexion. Create anterolateral and anteromedial portal.

### Diagnostic arthroscopy:

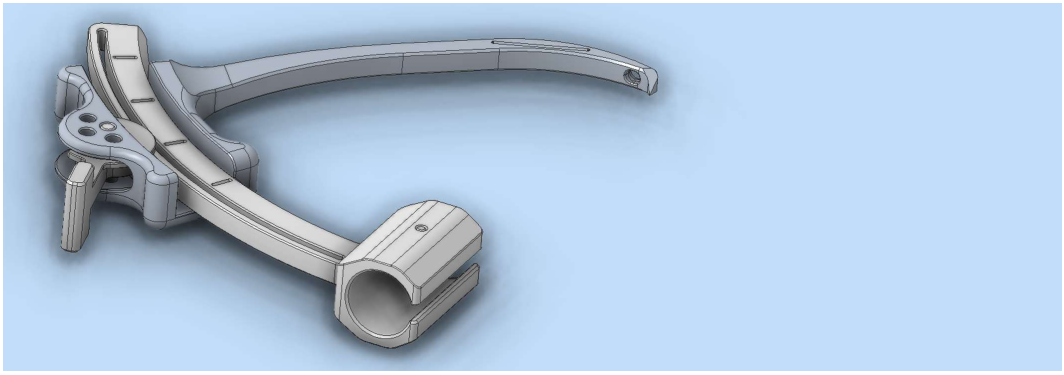
Comprehensive examination of the knee joint. Diagnosis and treatment of concomitant injuries as well as evaluation of the morphology of the ACL rupture.

Gentle reduction of the infrapatellar fat pad in order to ensure a clear view of the ruptured cruciate ligament and the tibial insertion point.

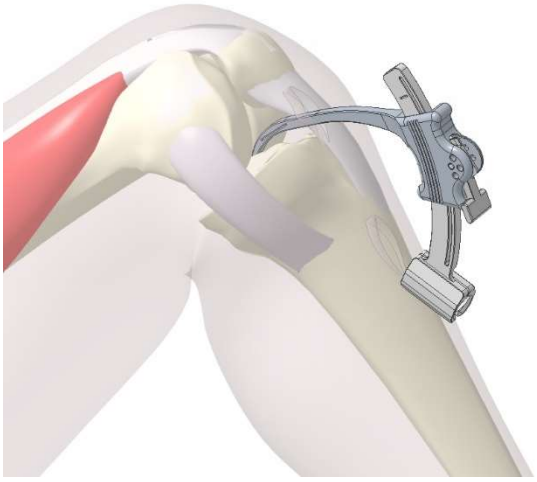
***Remark***

*Meniscal injuries should be treated first.*

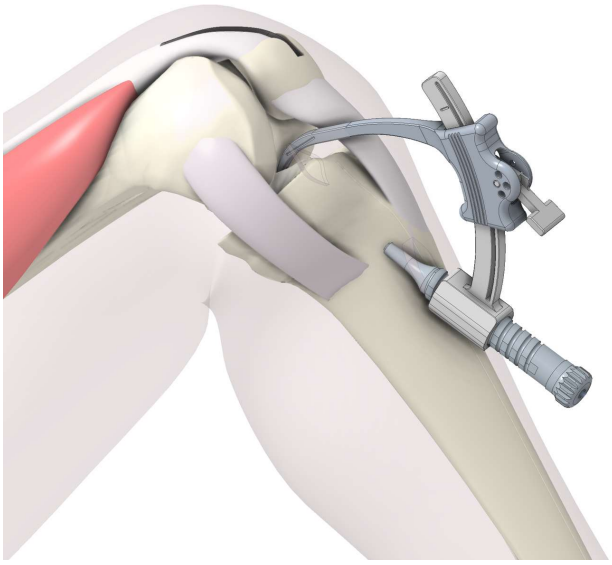
Arrange the tibia aiming device in the desired angular orientation and lock the construct by turning of the lever.



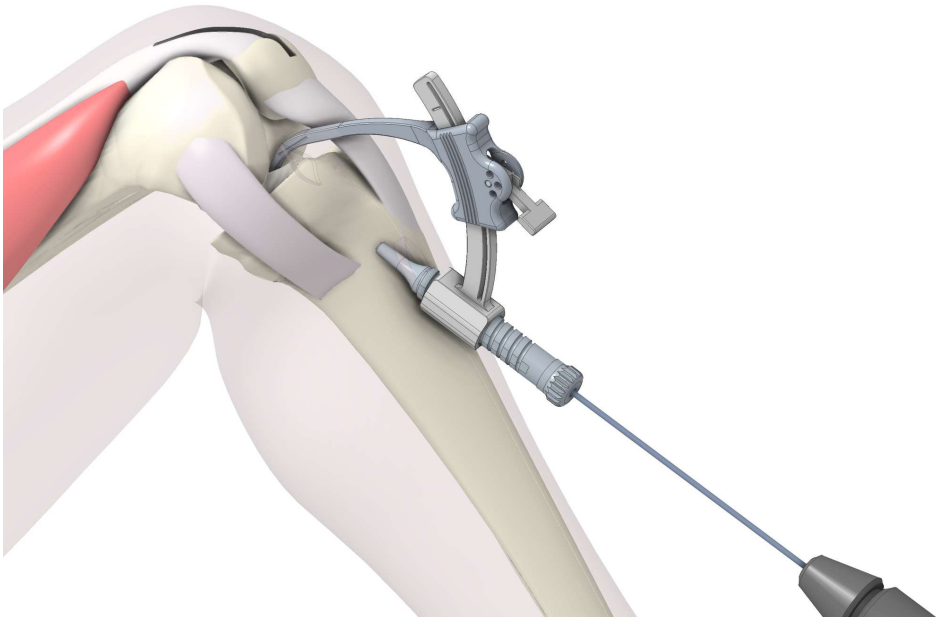
Hook the tibia aiming device assembly into the footprint of the ruptured ACL. The hook defines the central exit point of the tibial tunnel. Make a skin an antero medial skin incision to expose the anterior cortex of the tibia at the location of the desired start point of the tunnel.



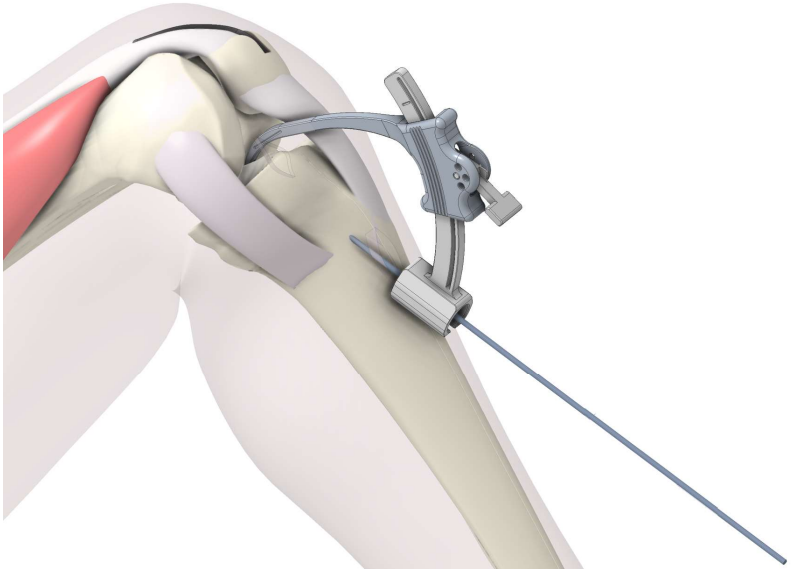
Insert the tibia drill bushing into the aiming device assembly and turn the drill bushing clockwise to engage against the anterior cortex. The tip of the drill busing defines the entry point of the tibia tunnel.



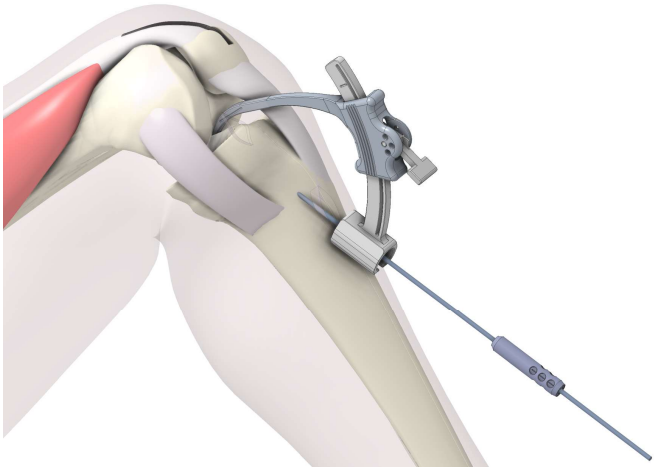
Assemble the Kirscher-wire (∅2.5 mm, length 300 mm) into the powertool. Drill the Kirscher-wire through the drill bushing until it exits into the hole at the end of the arm of the tibial aiming device.

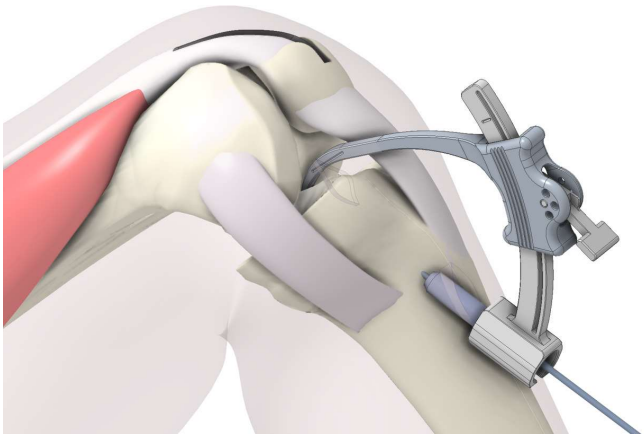


Turn the tibial dill bushing counter-clockwise for disassembly of the tibia aiming device

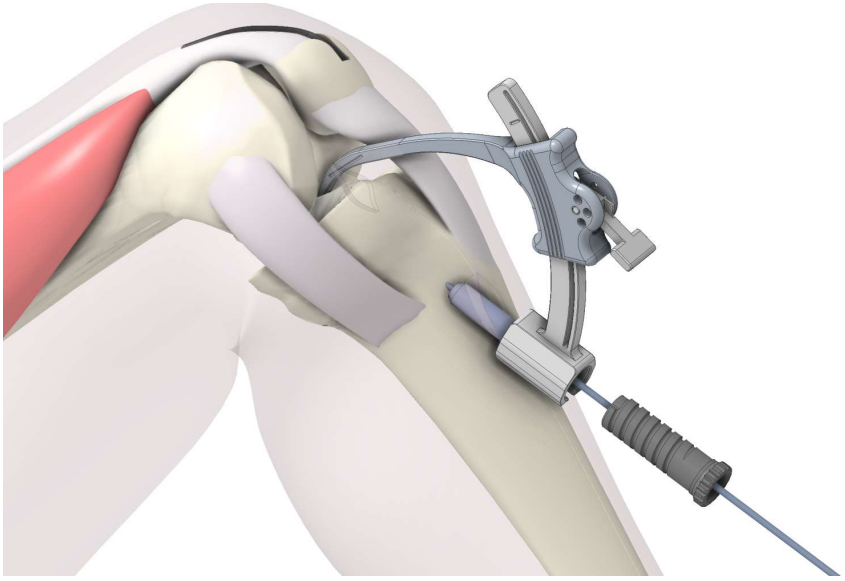


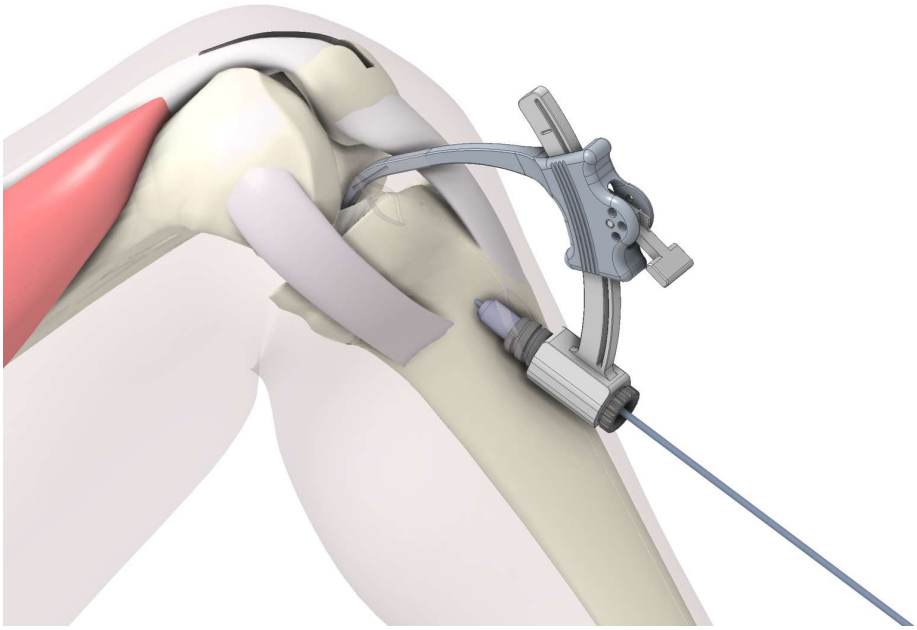
Place the hollow drill centralization aid over the Kirschner-wire. Advance the centralization aid forward end make it to engage with the tibial anterior cortex. The bullet-nose must be facing the tibia.



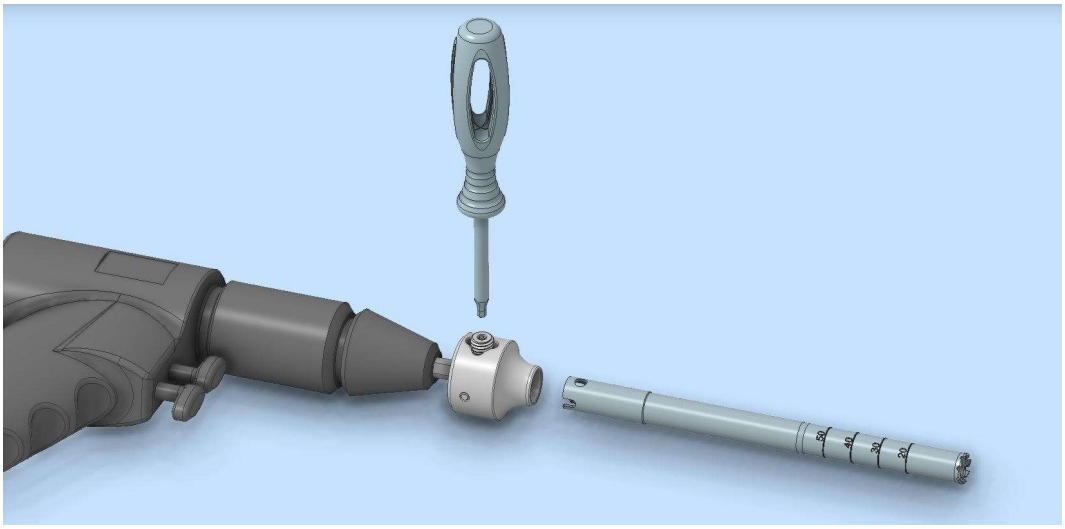


Insert the tibia drill sleeve into the aiming device assembly and turn the drill sleeve clockwise until it engages with the tibia aiming device arc.



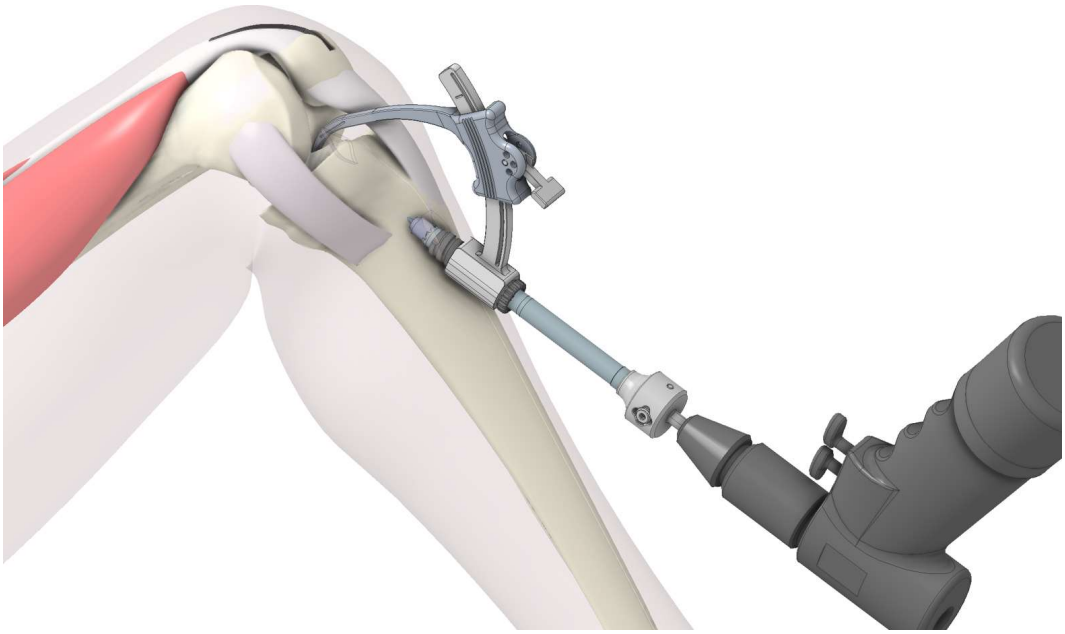


Assemble the hollow drill and the chuck to the powertool.

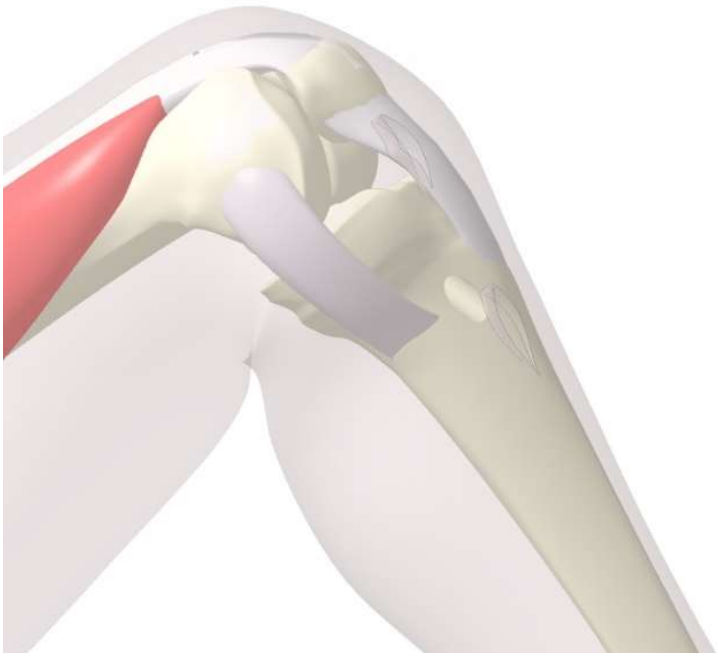


Engage the hollow drill into the tibia aiming device and over the hollow drill centralization aid. Advance the hollow drill towards the tibial bone. Ensure no tissue is captured between the drill tip and the bone.

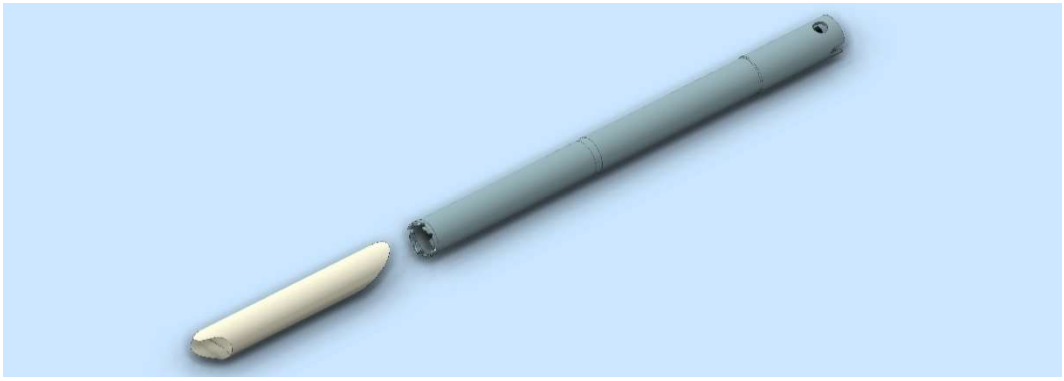
Drill the tibial tunnel.



Remove all instruments.



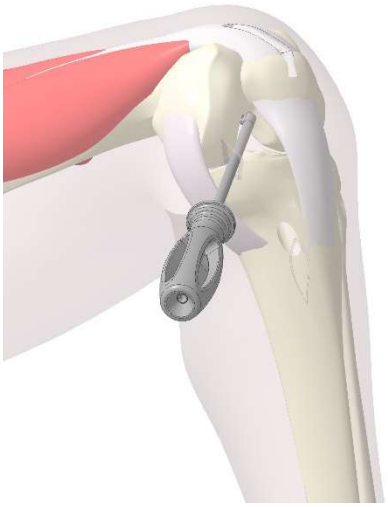
Remove the tibial bone plug



## Femoral tunnel preparation

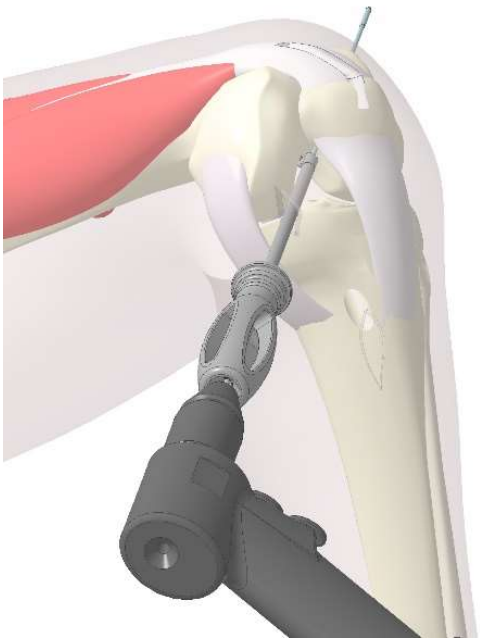
Place the leg in deep-flexion.

Insert the femoral aiming device into the joint space through the antero-medial portal. The 7 mm offset hook is referencing from the posterior end of the intra-condylar notch. The instrument shaft defines the tunnel start point and the tunnel direction.

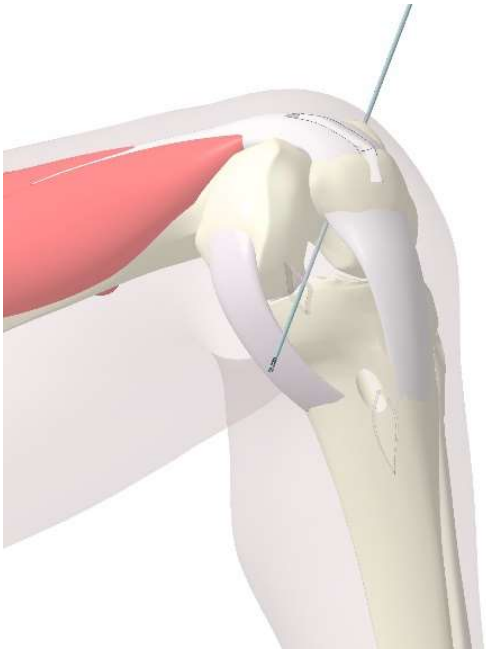


Assemble the guide wire with eyelet into the powertool. Drill the guidewire through the femoral aiming device until it exits at the lateral side through the skin.

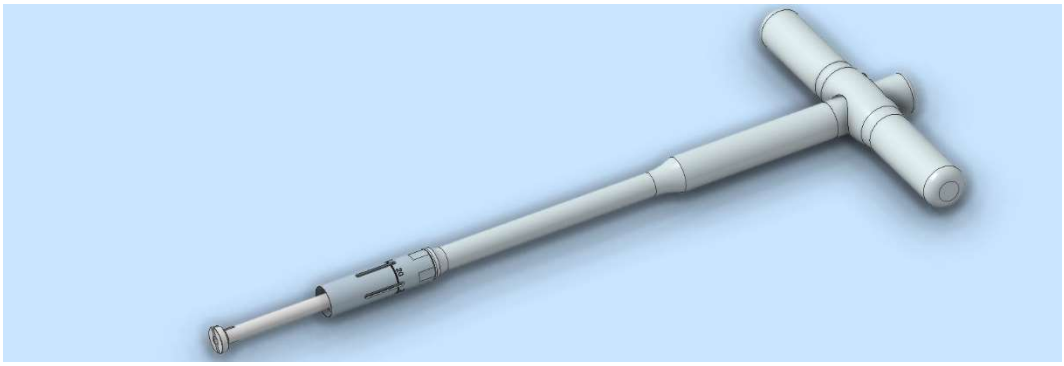
Disassemble the guide wire from the powertool and remove the femoral aiming device.



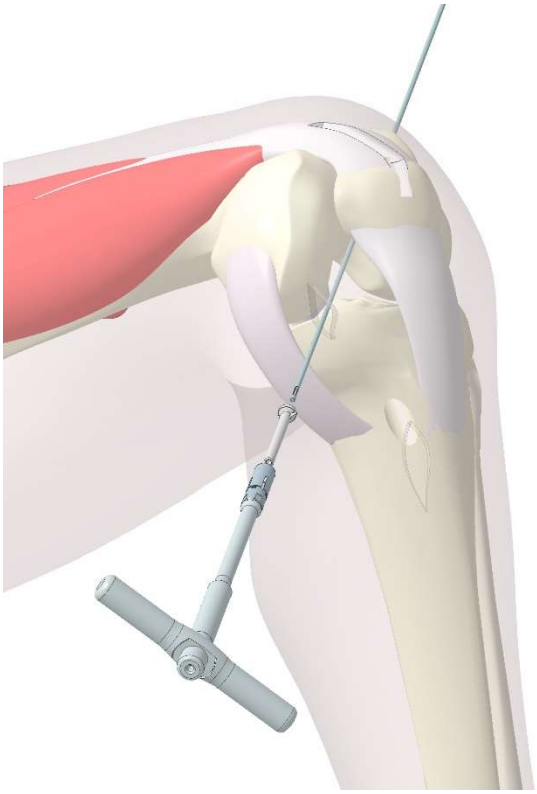
Translate the guide-wire through the knee until approximately 5-10 cm length is extending out of the anterior medial portal.



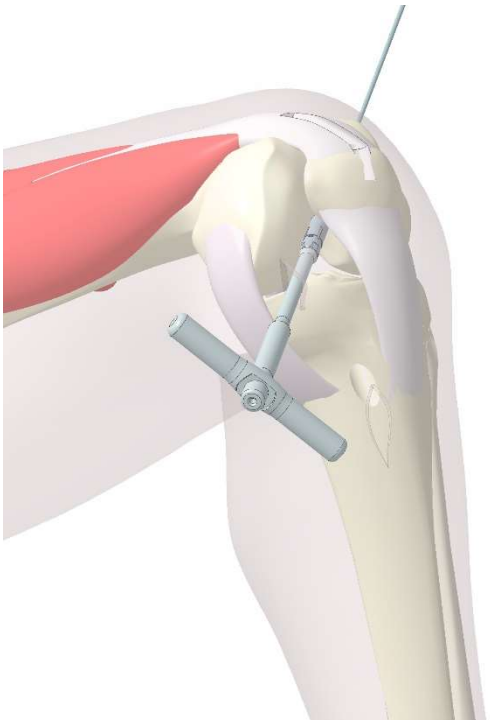
Assemble the guide for the femoral punch into the femoral punch. The thick end of the guide for femoral punch is seating flush with the cutting edge of the femoral punch.



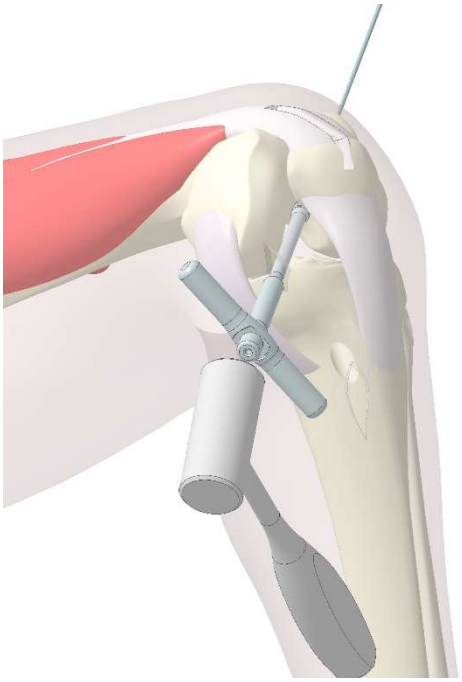
Slide the T-handle with attached punch and guide for the femoral punch over the guide-wire.



Advance the punch forward until it engages with the lateral femoral condyle



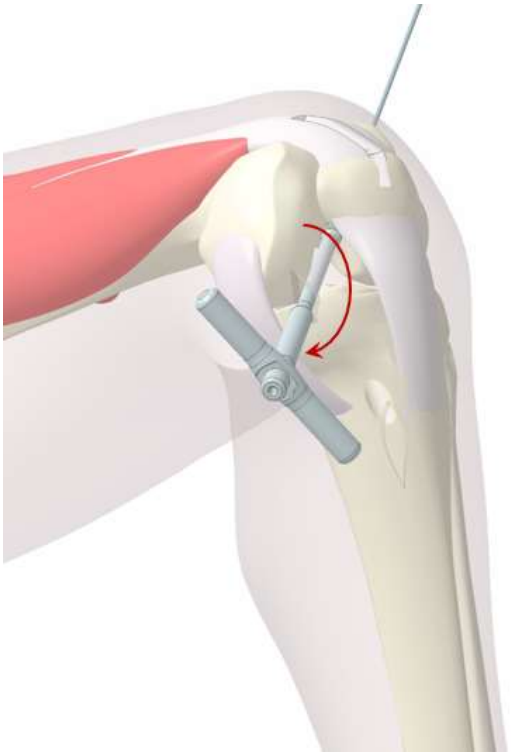
Tap the punch into the bone until the 20 mm marking is flush with the bone.



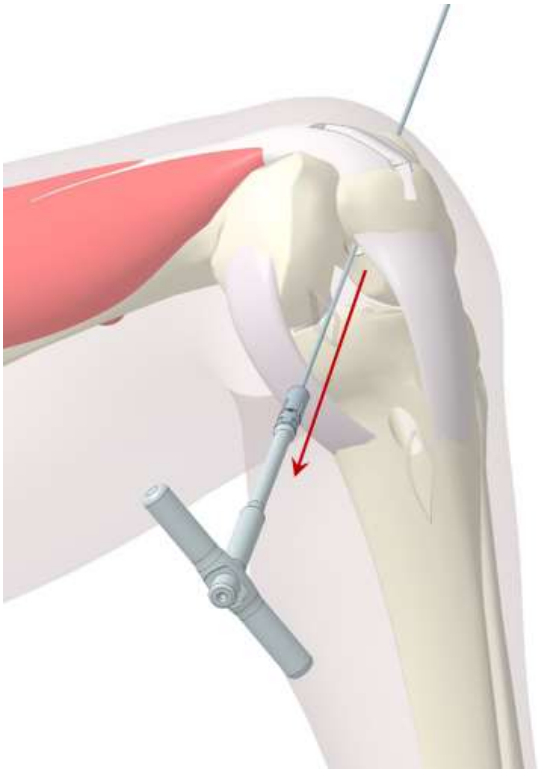
Turn the T-handle clockwise. By turning, the femoral bone plug is broken off.

***Attention:***

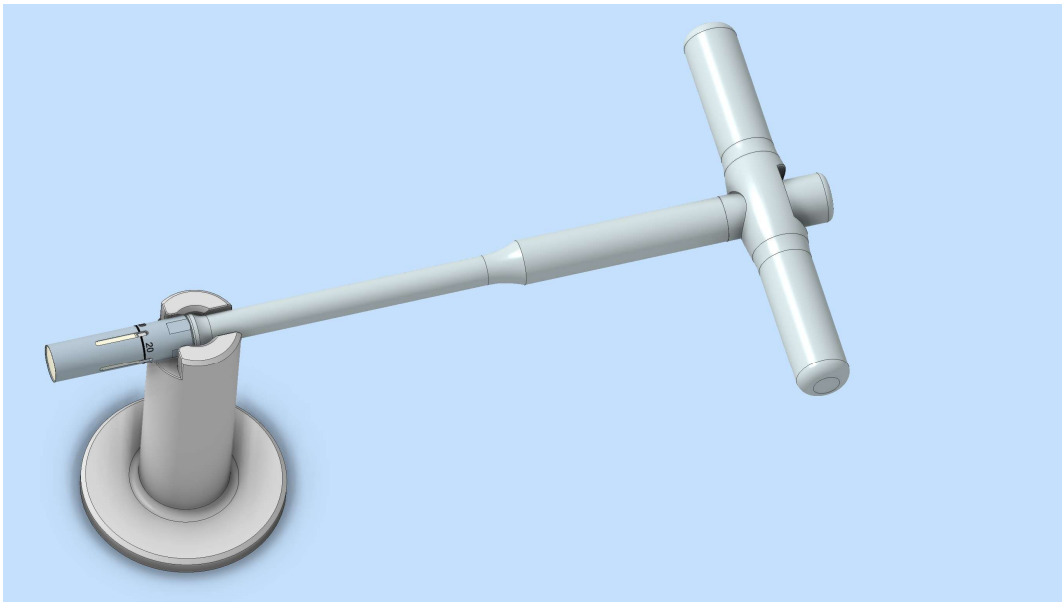
*turning counter clockwise can disengage the punch from the T-handle*



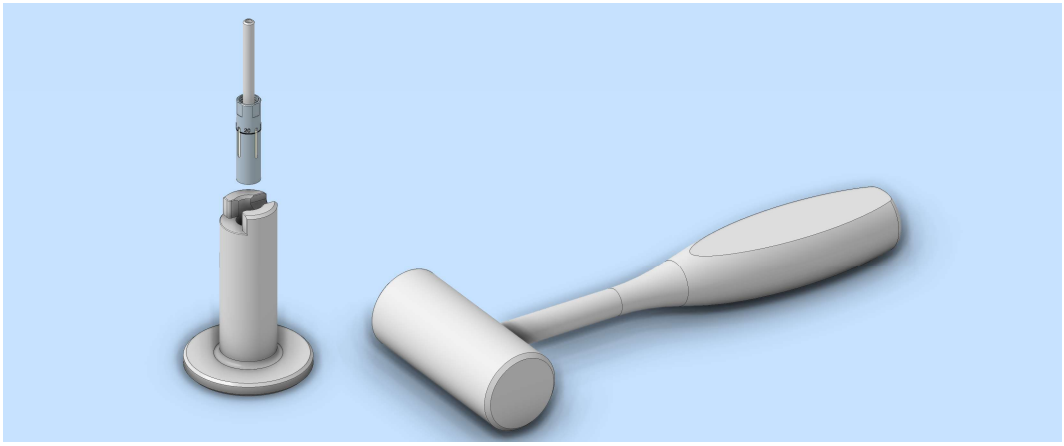
Pull the T-handle out of the knee joint. The guide wire with eyelet may be held to ensure that the guide wire remains in the femoral bone.



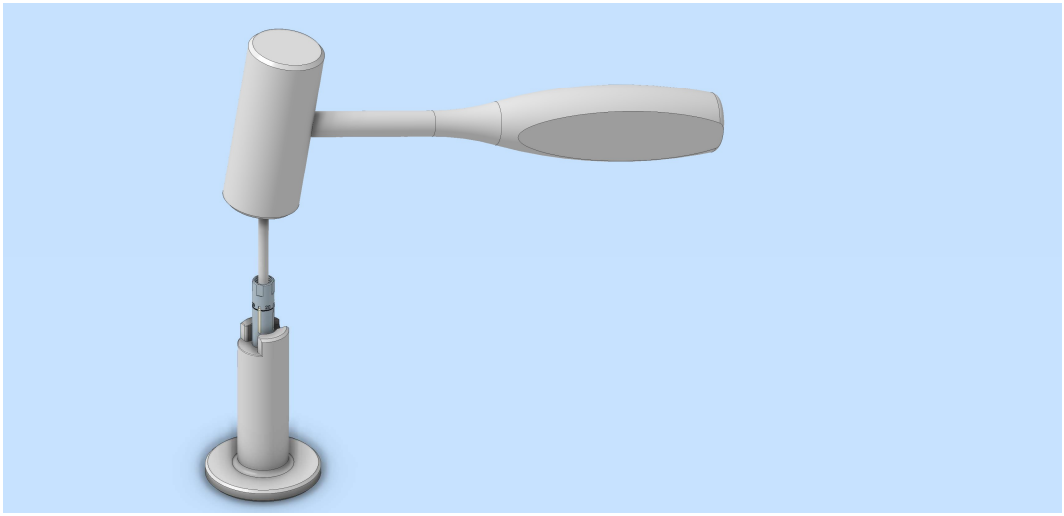
Engage the punch with attached T-handle in the bone plug removal aid. Turn the handle counter clockwise to release the punch from the T-handle.

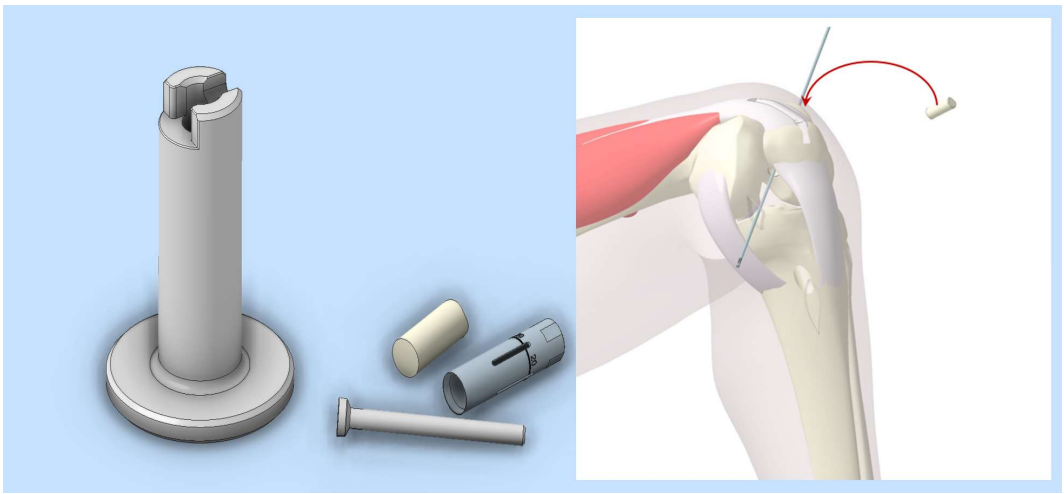


Place the punch in the bone plug removal aid.



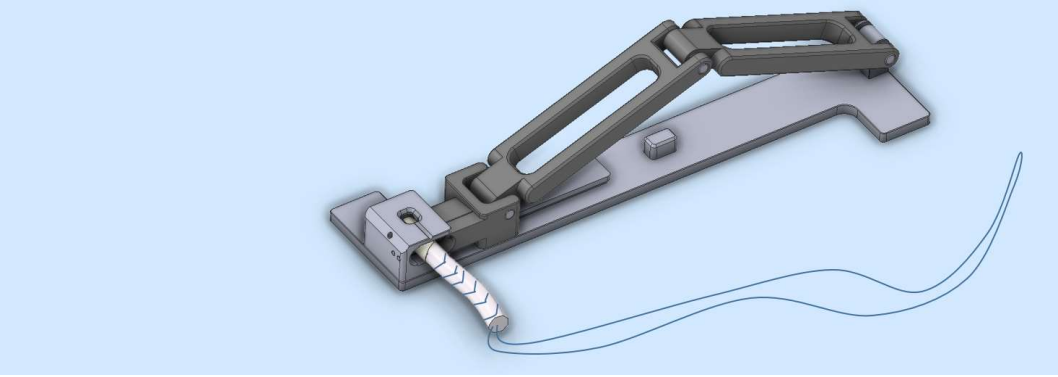
Tap the protruding guide for femoral punch downward. The femoral bone plug is pressed out of the punch. Place the femoral bone plug into the patella donor site.



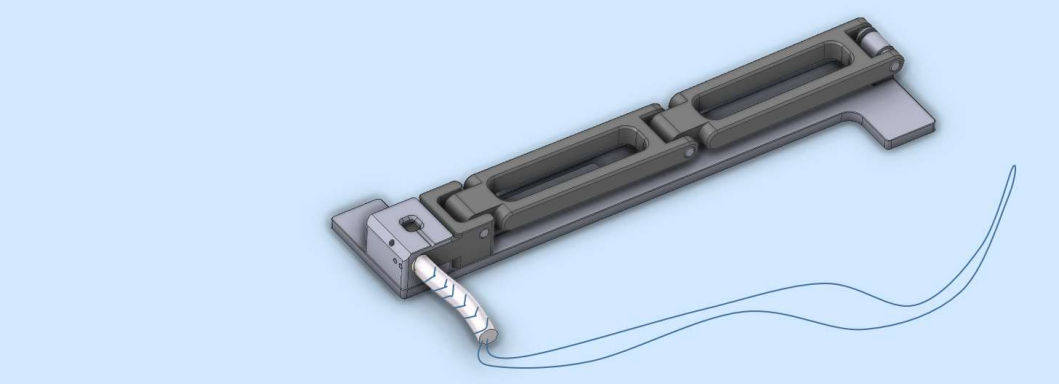


## Final patella bone plug graft preparation

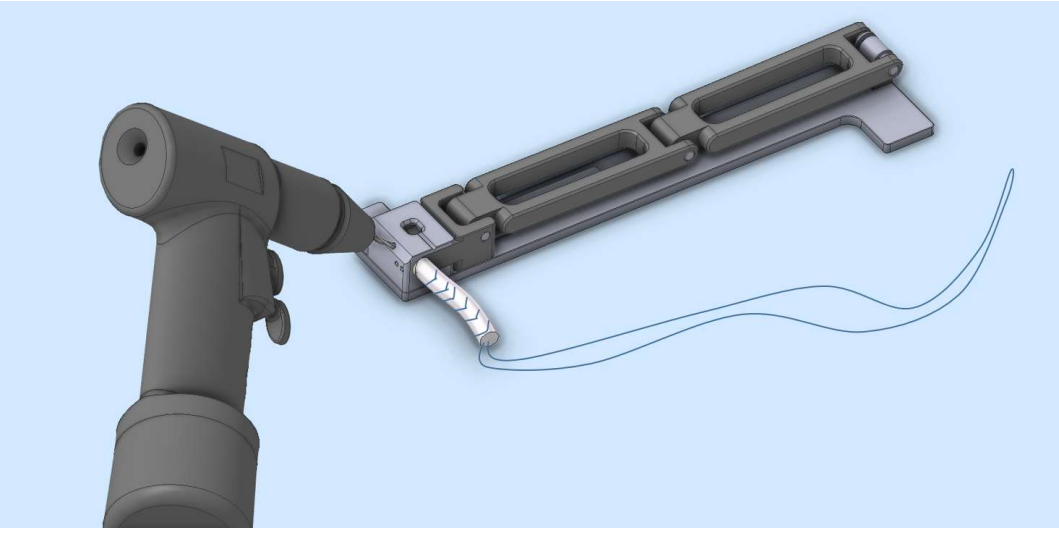
Open the bone plug compression instrument. Place the patella bone plug in the mold. The window with central marking indicates the insertion location. Ensure that the patella bone plug is seating against the back wall of the mold.



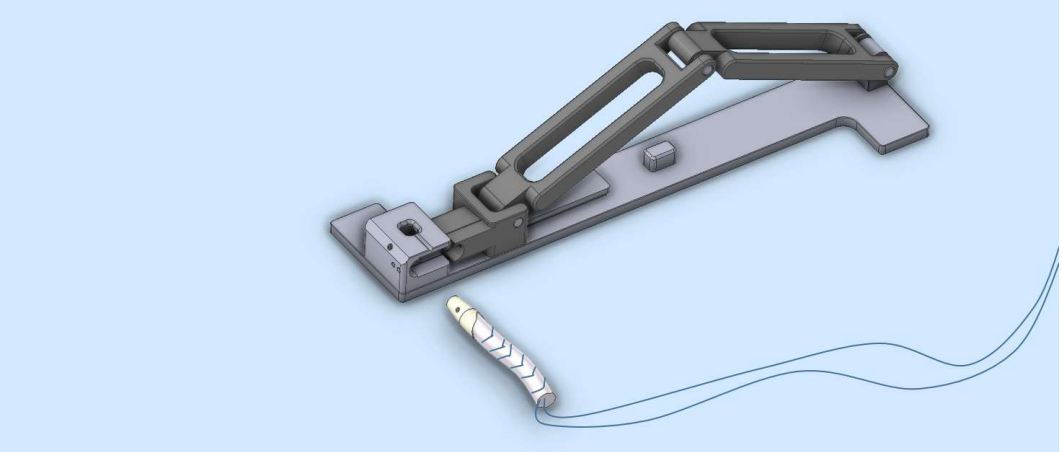
Press the levers down. The bone plug is reshaped.



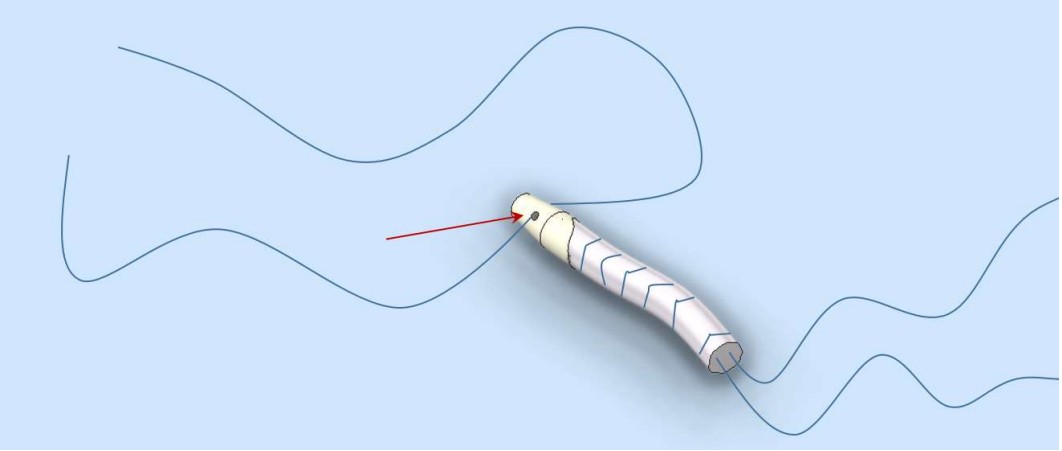
Assemble a diameter 2 mm drill in the powertool. Drill a hole through the integrated drill guide into the patella bone plug.



Open the bone plug compression instrument by pulling up of the levers. Remove the patella bone plug.

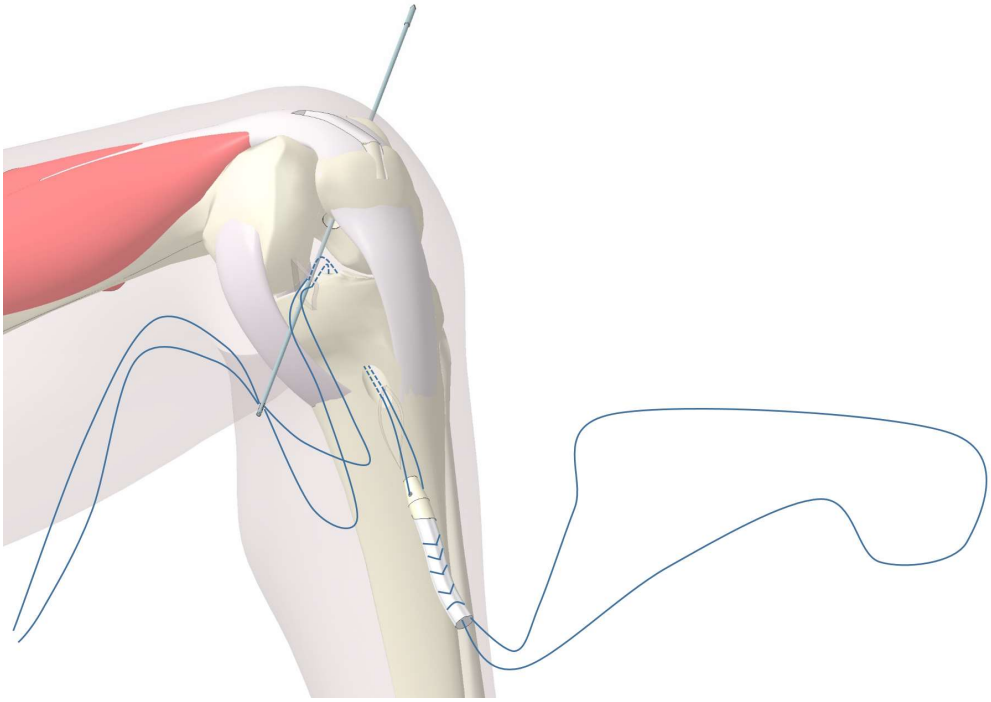


Pass a USP 3 suture through the hole in the patella bone plug

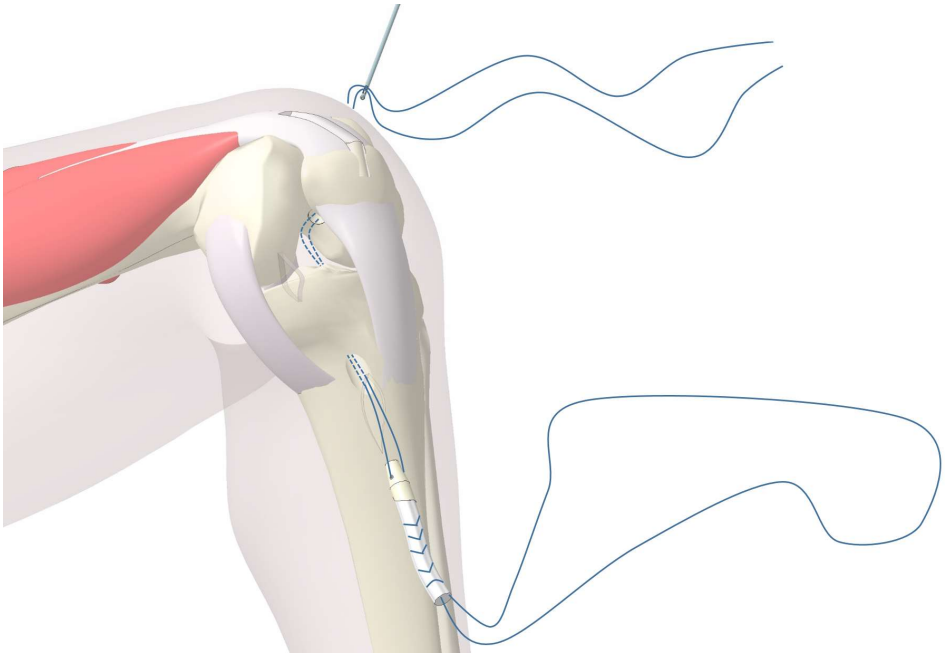


## Graft implantation: tibia tunnel approach

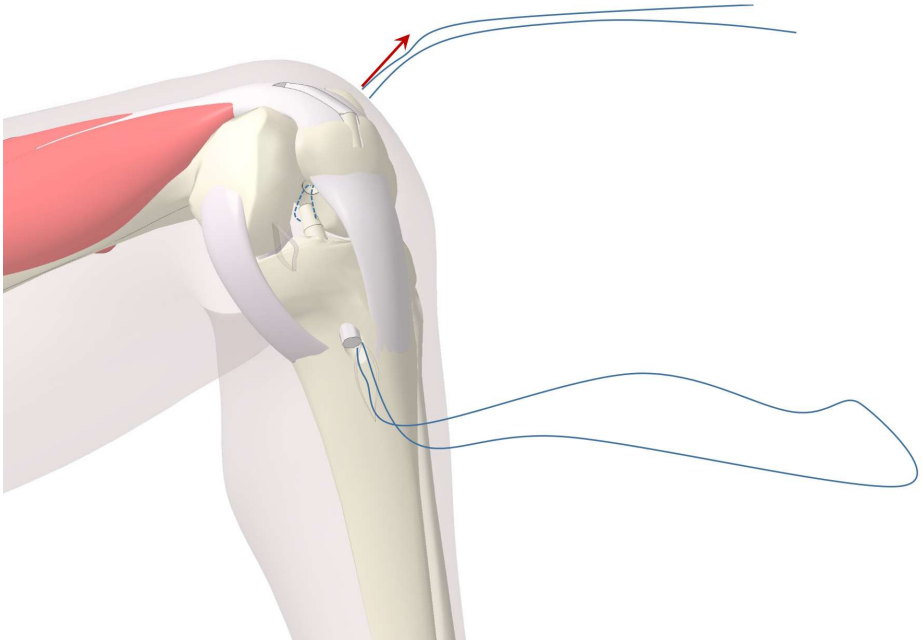
Loop the suture strands which are attached to the patella bone plug through the tibia tunnel and through the eyelet of the guide-wire with eyelet.



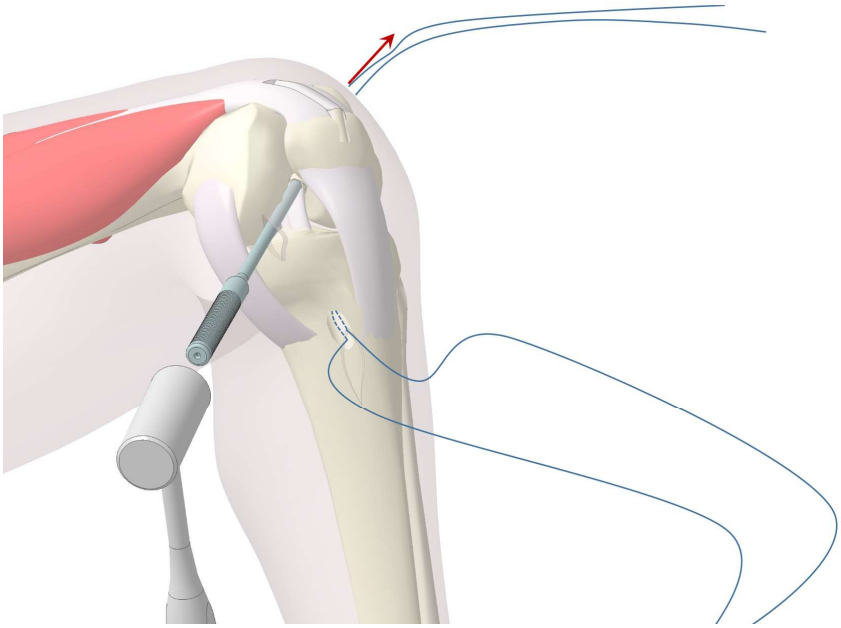
Pull the guide-wire through the femoral bone. The sutures are exiting the leg at the lateral side. Remove the guide-wire with eyelet.



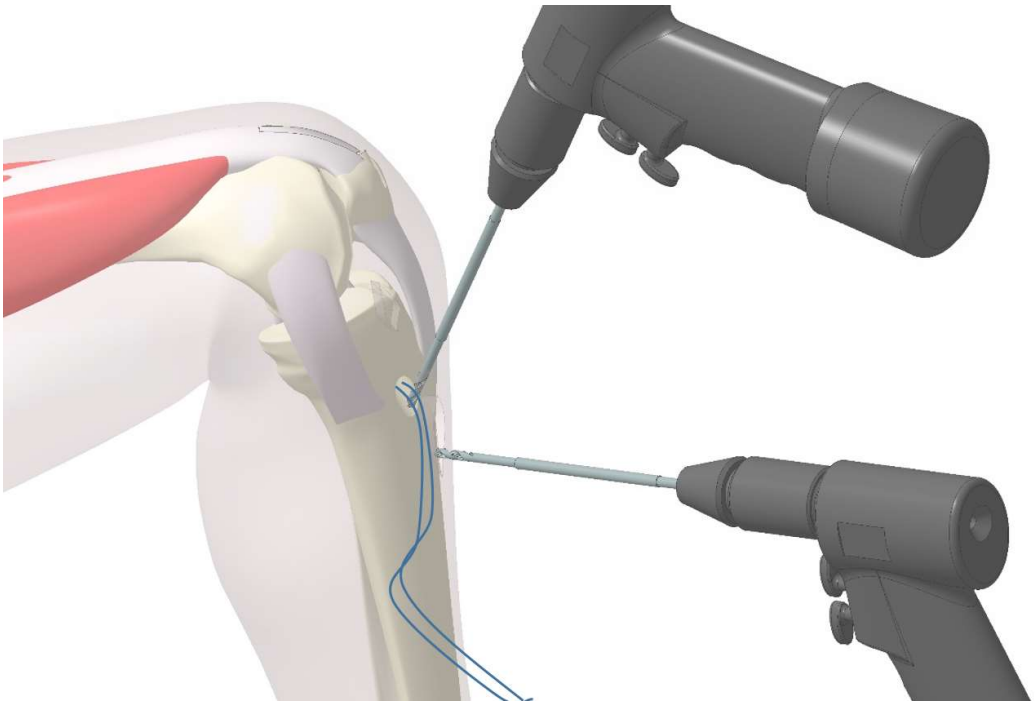
Pull the graft through the tibial tunnel. Center the graft in front of the femoral tunnel.



Take the bone plug pusher and a mallet. Apply tension to the sutures that exit the knee at the lateral side and simultaneously gently tap the bone plug into the femoral tunnel. Ensure the bone plug end is flush with the femoral bone.



Assemble the ∅4 mm drill with stop in the powertool. Drill the bone bridge into the tibia in a free hand manner. One hole starts in the tibial tunnel, the second holes starts at the anterior cortex. The holes connect below the cortex and form the bone bridge.

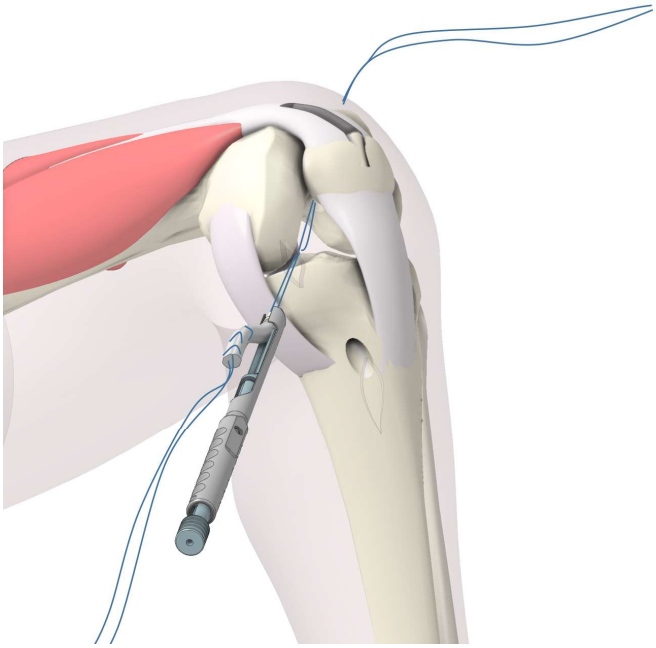


## Graft implantation: antero medial tunnel approach

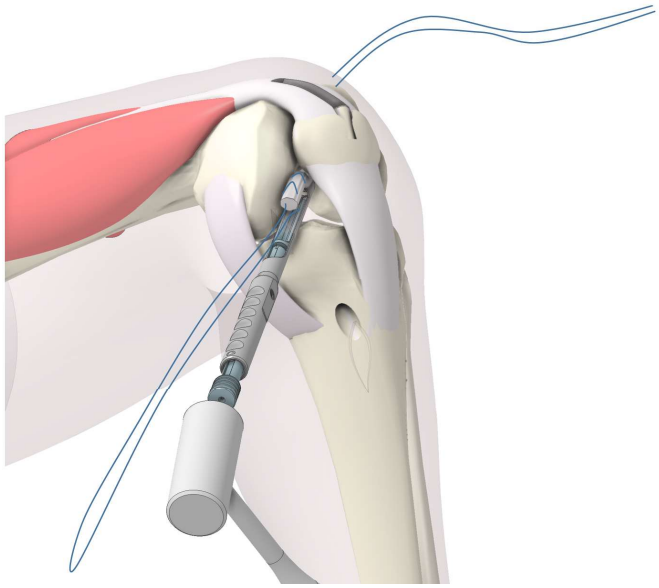
Loop the suture strands which are attached to the patella bone plug through the eyelet of the guide-wire with eyelet. Pull the guide-wire through the femoral bone. The sutures are exiting the leg at the lateral side. Remove the guide-wire with eyelet.

Engage the bone plug into the bone plug inserter assembly. Ensure the tip of the bone plug is projecting approximately 5 mm over the end of the bone plug inserter handle.

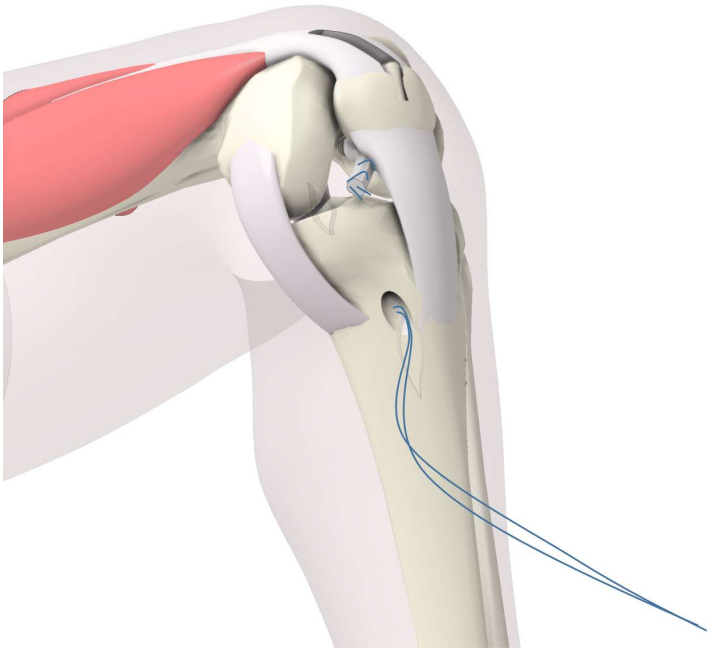
Slide the bone plug inserter (core) against the bone plug.



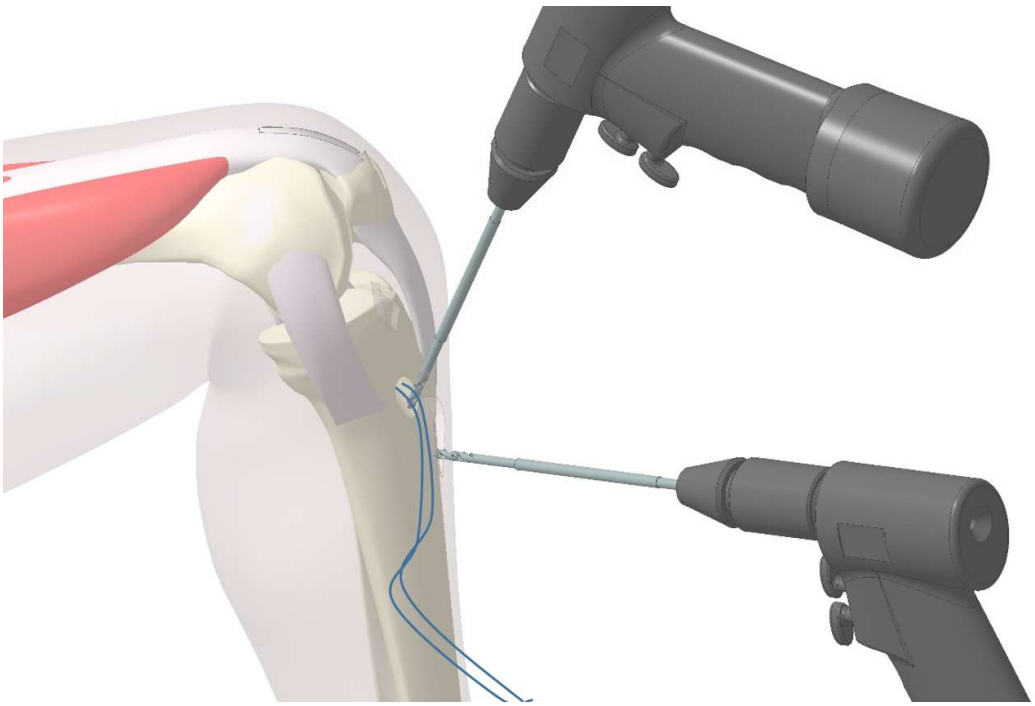
Advance the bone plug inserter assembly through the tibial tunnel towards the femoral tunnel and gently impact the patella bone plug into the femoral tunnel.



Pass the suture strands which are attached to the tendon portion of the graft through the tibia tunnel and pull the tendon graft into the tunnel



Assemble the ∅4 mm drill with stop in the powertool. Drill the bone bridge into the tibia in a free hand manner. One hole starts in the tibial tunnel, the second holes starts at the anterior cortex. The holes connect below the cortex and form the bone bridge.

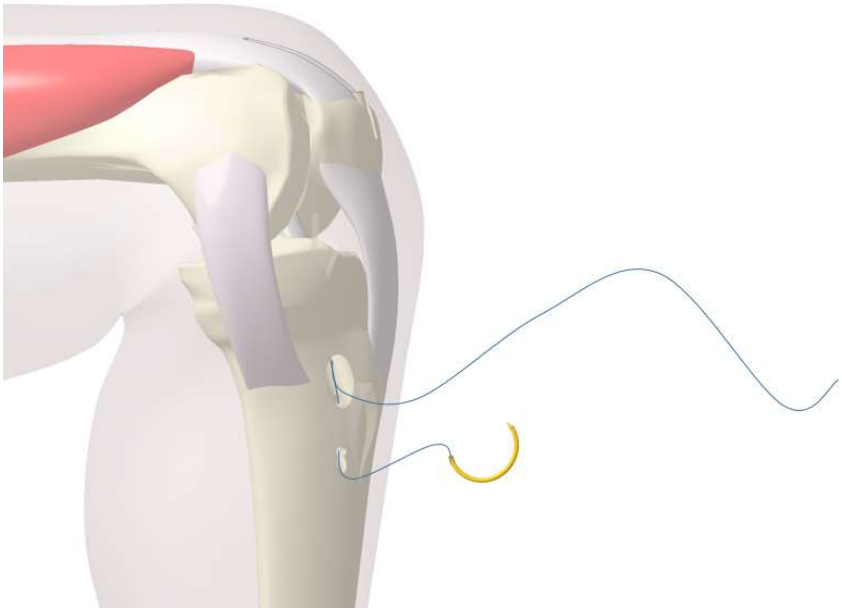


## Tibial fixation of the graft

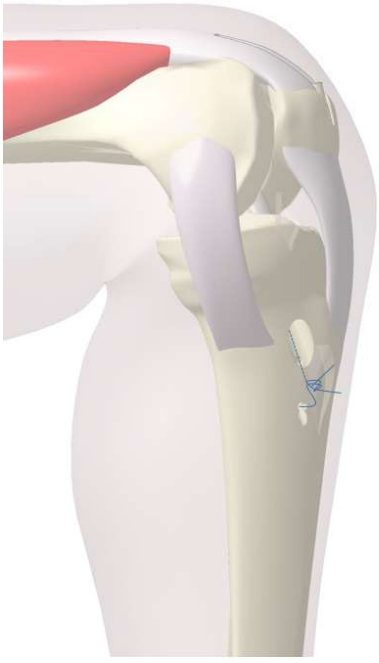
Ensure there are two suture strands. If necessary split the suture loop. Attach a needle to one suture strand and loop the suture strand through the tibial bone bridge.

***Remark***

*Alternatively, standard suture passers or nitinol wires may be used for this step*



Tension the graft into the tunnel and knot the suture strand together.



Take the tibial bone plug and manually reshape the bone plug to fill the tibial tunnel. An oscillating saw or bone forceps may be used for this step.

Take the bone plug pusher and a mallet and tap the bone plug into the tibia tunnel.

# Instruments:

| | |
|---|---|
| REF 02.001.025<br>Hollow drill |  |
| REF 02.001.026<br>Chuck for hollow drill |  |
| REF 02.001.027<br>Patella drillguide |  |
| REF 02.001.028<br>Pin with stop, short |  |
| REF 2.001.029<br>Graft cutter |  |
| REF 02.001.030<br>Graft cutter blade |  |

| | |
|---|---|
| REF 02.001.031<br>Screwdriver HEX 2.5 |  |
| REF 2.001.032<br>Patella drillguide handle |  |
| REF 02.001.033<br>Chisel |  |
| REF 02.001.034<br>Guide-wire with eyelet, D2.5, L400 |  |
| REF 02.001.035<br>Tibia aiming device |  |
| REF 02.001.036<br>Tibia drill bushing |  |

| | |
|---|---|
| REF 02.001.037<br>Guide for femoral punch |  |
| REF 02.001.038<br>T-handle for femoral punch |  |
| REF 02.001.039<br>Femoral punch D 8.6 mm, short |  |
| REF 02.001.040<br>Femoral aiming device, Offset 7 mm |  |
| REF 02.001.041<br>Bone plug pusher |  |
| REF 02.001.042<br>Bone plug compression instrument |  |

| | |
|---|---|
| REF 02.001.044<br>Tibia drill sleeve |  |
| REF 02.001.045<br>Drill D4.0 with stop |  |
| REF 02.001.046<br>Bone plug removal aid |  |
| REF 02.001.047<br>Tibia aiming device arc |  |
| REF 02.001.048<br>Hollow drill centralization aid |  |
| REF 02.001.049<br>Suture hook |  |

| | |
|---|---|
| REF 33.0225.300<br>K-wire D 2.5, L300 |  |
| REF 02.001.051<br>Pin with stop, long |  |
| REF 02.001.052<br>Parallel scalpel handle |  |
| REF 02.001.055<br>Tendon cutter |  |
| REF 02.001.056<br>Bone plug inserter handle |  |
| REF 02.001.057<br>Bone plug inserter |  |

## Cleaning and Sterilization of Instruments:

All instruments are provided non-sterile and must be sterilized before use. Please refer to the following processing instructions.

## Processing (Cleaning, Disinfection and Sterilization) Instructions

### A. PURPOSE

This document contains recommendations for the safe handling, effective care, cleaning, disinfection and sterilization of Effectum Medical reusable surgical instruments, instrument trays and cases. The information provided does not apply to Effectum Medical implants.

### B. INTRODUCTION

All instruments are to be cleaned, disinfected and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD (Washer-Disinfector), Sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Please pay attention to avoid a higher contamination of the complete sterilization tray during application by separate collection of contaminated instruments (without laying back into the sterilization tray). Pre-clean the contaminated instruments, clean, disinfect, then sort them back into the sterilization tray and sterilize the completely equipped sterilization tray.

Instruments shall to be cleaned separate from instruments trays and cases, also lids shall be removed from cases prior to cleaning.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions.

ATTENTION: In case additional or deviating procedures are required for specific instruments, see chapter SPECIFIC ASPECTS.

### C. CLEANING AND DISINFECTION

#### C.1. BASICS

If possible, an automated procedure (WD) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered[1].

The pre-treatment step is to be performed in both cases.

## C.2. PRE-TREATMENT

Body fluids and tissue should not be allowed to dry on instruments, please remove any impurities after application but within a maximum of 2 hours. To avoid contamination, soiled devices should be separated from non-contaminated devices.

Pay attention to the following points during selection of the cleaning detergent [2]:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see chapter C9 MATERIAL RESISTANCE)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

**PROCEDURE**

a. Disassemble the instruments as far as possible (see chapter E DISSASSEMBLY INSTRUCTION).
b. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F). Actuate movable parts at least three times during pre-rinsing if applicable (see chapter D SPECIFIC ASPECTS).
c. Rinse all lumen of the instruments at least three times at the beginning of the soaking time.
d. Soak the disassembled instruments for the given soaking time (but not less than 5 min) in the pre-cleaning solution[2] (ultrasonic bath, ultrasound not activated) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at beginning of soaking, aids see chapter D SPECIFIC ASPECTS). Actuate movable parts at least three times during pre-cleaning if applicable (see chapter D SPECIFIC ASPECTS).
e. Rinse all lumen of the instruments at least three times at the end of the soaking time.
f. Activate ultrasound for an additional soaking time (but not less than 5 min).
g. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Actuate movable parts at least three times during post-rinsing, if applicable (see chapter D SPECIFIC ASPECTS). Rinse all lumen of the instruments at least three times during post-rinsing.

## C.3. AUTOMATED CLEANING / DISINFECTION

Pay attention to the following points during selection of the washer-disinfector (WD):

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection – danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program

- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to the following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter C.9. Material Resistance)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

**PROCEDURE:**

a. Disassemble the instruments as far as possible (see chapter E DISSASSEMBLY INSTRUCTION)
b. Transfer the disassembled instruments in the WD (pay attention that the instruments have no contact).
c. Connect the instruments to the rinsing port of the WD if applicable (see chapter D SPECIFIC ASPECTS)
d. Start the program.
e. Disconnect from rinsing port if applicable and remove the instruments of the WD after end of the program.
f. Check and pack the instruments immediately after the removal ((see chapter C.4 VISUAL INSPECTION / FUNCTION TESTING, chapter E. DISSASSEMBLY INSTRUCTION, chapter C.6. PACKAGING and chapter F. PLACEMENT SPECIFICATION FOR STERILIZATION), if necessary after additional post-drying at a clean place).

### C.4. VISUAL INSPECTION / FUNCTION TESTING

Reusable instruments shall be visually inspected carefully prior to sterilization for the following characteristics:

| | |
|---|---|
| Cleanliness: | Ensure that all visible blood or other impurities have been removed. |
| Damage or wear: | Visually inspect for damage, including but not limited to, corrosion, damaged surfaces cracks or wear. |
| Functionality: | Including but not limited to sharpness of cutting devices, movement of joints and couplings (see chapter D. SPECIFIC ASPECTS) |

Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter C.10. REUSABILITY).

Still dirty instruments are to be cleaned and disinfected again.

## C.5. MAINTENANCE

Assemble disassembled instruments again (see chapter E. DISSASSEMBLY INSTRUCTION).

Lubricate hinges, threads and other moving parts according to chapter E. DISSASSEMBLY INSTRUCTION. Use only instrument oils (white oil) admitted to steam sterilization, considering the maximum possible sterilization temperature and with approved biocompatibility. DOnly apply a small amount to the relevant location (no sprayingof the complete instrument!).

For several instruments, the use of instrument oils must not be performed (see chapter D. SPECIFIC ASPECTS).

## C.6. PACKAGING

Insert the cleaned and disinfected instruments in standard sterilization trays (see chapter F. PLACEMENT SPECIFICATION FOR STERILIZATION) and pack them in sterilization containers, which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

A maximum weight of 7.2kg per content of the sterilization container must not be exceeded.

## C.7. STERILIZATION

Please use for sterilization of Effectum Medical devices only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure[3, 4], (with sufficient product drying[5])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus, tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature)

The following parameters are to be used for the sterilization of Effectum Medical devices with fractionated vacuum and dynamic air removal:

| Area | Minimum Sterilization Exposure Time (minutes) | Minimum Sterilization Exposure Temperature | Minimum Drying Time (minutes) |
|---|---|---|---|
| USA | 4 | 132°C (270°F) | 20[5] |
| Germany | 5[6] | 134°C (273°F) | |
| Other countries | 4 | 132°C (270°F) / 134°C (273°F) | |

The sterilizer manufacturer's operating instructions shall be followed. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the maximum sterilization load is not exceeded. Drying times will vary according to load size and should be increased for larger loads.

The sterilizer must be properly installed, calibrated, validated and maintained.

**ATTENTION:** Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, flash/immediate use sterilization as well as plasma sterilization!

### C.8. STORAGE

Packaged products should be stored in a dry, dust-free environment, protected from direct sunlight, pests and extremes of temperature and humidity.

### C.9. MATERIAL RESISTANCE

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral or oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 10.1, neutral/enzymatic or weak alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons
- oil (only silicone parts)

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.

Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments and sterilization trays by use of metal brushes or steel wool.

Please do not expose any instruments and sterilization trays to temperatures higher than 142 °C (288 °F)!

### C.10. REUSABILITY

The instruments can be reused (according to the labeling in the instrument overview above) – in case of adequate care and if they are undamaged and clean – for 100 reprocessing cycles,

unless otherwise indicated in chapter D. SPECIFIC ASPECTS. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

The single use only instruments are marked accordingly in the overview in this document and on the instrument itself. Single use instruments cannot be reused.

## D. SPECIFIC ASPECTS

The central cannulation of the longer and thin cannulated instruments need to be manually brushed before automated cleaning. This applies to the following instruments:

- REF 02.001.040 Femoral aiming device, offset 7 mm
- REF 02.001.036 Tibia Drill Bushing

## E. DISSASSEMBLY INSTRUCTION

In general all instruments must be separated before reprocessing.

Some instrument combinations are an assembly out of reusable instruments and single-use instruments. The single-use instruments need to be disassembled and disposed. This applies to the following instruments:

- REF 02.001.029 Graft cutter & REF 02.001.030 Blade for graft cutter (SINGLE USE)
- REF 02.001.052 Parallel scalpel handle & standard scalpel blade (SINGLE USE)

Some instruments combinations are an assembly of reusable instruments. These instruments must be disassembled in their individual parts. This applies to the following instruments:

- REF 02.001.027 Patella drillguide & REF 02.001.032 Patella drillguide handle
- REF 02.001.035 Tibia aiming device & REF 02.001.047 Tibia aiming device arc

All other assemblies are disassembled when following the surgical technique as described in this document.

## F. PLACEMENT SPECIFICATION FOR STERILIZATION

REF 02.001.042, the bone plug compression instrument comprises a processing and sterilization configuration. The molds and levers can be brought in an stretched configuration, which opens the surfaces of the sliding mechanism.

## G. SPARE PARTS
n/a

## H. ADDITIONAL INFORMATION
The instructions provided above have been validated as being capable of preparing reusable surgical instruments.

An independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory demonstrated the fundamental suitability of the instruments for an

- EFFECTIVE AUTOMATED CLEANING AND DISINFECTION by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher Mediclean (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.
- EFFECTIVE STEAM STERILIZATION by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure.

For this, typical conditions in clinic as well as the specified procedure were considered.

It is the responsibility of the processor to ensure that reprocessing is performed using the appropriate equipment and materials and that personnel in the reprocessing facility has been adequately trained in order to achieve the desired results. This normally requires validation and routine monitoring of the process. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Please ensure latest revision of Care & Maintenance Instruction available at Effectum Medical.

## I. CUSTOMER SERVICE INFORMATION
For further information, please contact:

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1 In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under sole responsibility of the user is required.
2 In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel's safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see chapter C.9. Material Resistance). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel's safety, but cannot replace the disinfection step later to be performed after cleaning.
3 At least three vacuum steps
4 The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure and requires a sterilizer, program, parameter, and product specific validation under sole responsibility of the user.
5 The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...)

and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied. 6 respectively 18 min (inactivation of prions, not relevant for USA)

**Key to Symbols:**


„Conformité Européenne“

Catalogue number


Date of Manufacture

Lot Number


Manufacturer


Consult instructions for use


Single use only

**Manufacturer:**

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CE 0297