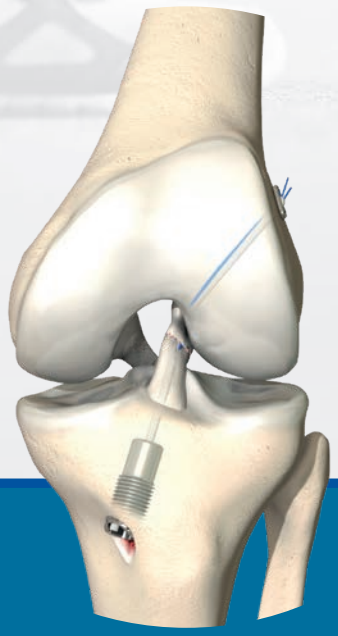
MATHYS
European Orthopaedics

Surgical technique

Ligamys



Preservation in motion

Building on our heritage
Moving technology forward
Step by step with our clinical partners
Towards a goal of preserving mobility

***Preservation** in motion*

As a Swiss company, Mathys is committed to this guiding principle and pursues a product portfolio with the goal of further developing traditional philosophies with respect to materials or design in order to address existing clinical challenges. This is reflected in our imagery: traditional Swiss activities in conjunction with continuously evolving sporting equipment.

Table of contents

Remark
Please make yourself familiar with the handling of the instruments, the product-related surgical technique and the warnings, the safety notes as well as the recommendations of the instruction leaflet before using an implant manufactured by Mathys Ltd Bettlach. Make use of the Mathys user training and proceed according to the recommended surgical technique.

Introduction

Experience from the past 30 years of cruciate ligament surgery has taught us that only the natural ligament can ensure the physiological kinematics and dynamic stabilization of the knee. In accordance with this guideline, the technique of dynamic intraligamentary stabilization (DIS) after injury to the anterior cruciate ligament was developed. This is based on the following principle: The knee joint is temporarily biomechanically stabilized with a dynamic spring system, providing the rest needed for the natural cruciate ligament to stably cicatrize.
The authors are convinced that this method provides an additional treatment option or a supplement to the current treatment methods for a primary rupture of the anterior cruciate ligament.
Upon successful cicatrization of the ligament, a knee joint in the patient results that is capable of full weight bearing and was not additionally weakened by the removal of tendon grafts.

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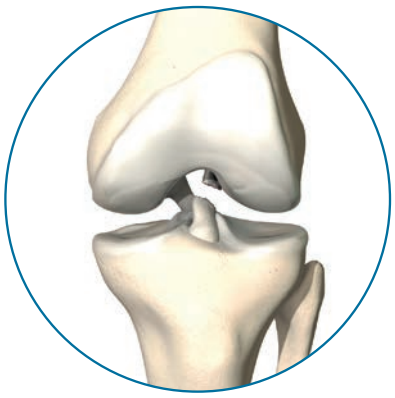
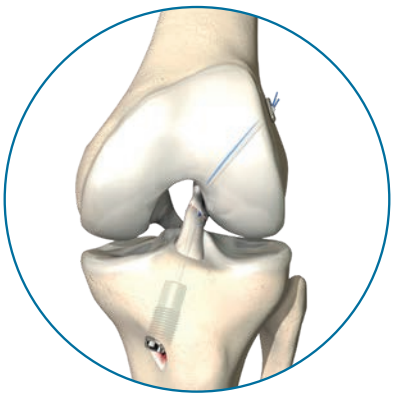
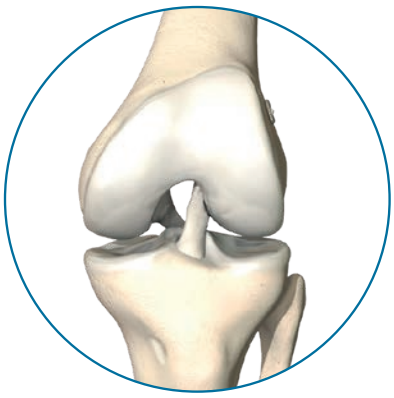


Cruciate ligament tear



Implantation



Preservation

1. Indications, contraindications and precautions

Indications

- Fresh primary rupture of the anterior cruciate ligament, not older than 21 days on the day of surgery

Contraindications

- Acute or chronic infections, local or systemic (or corresponding history)
- Severe muscular, neural or vascular diseases that may endanger the affected limb
- Insufficient bone substance or poor bone quality which might compromise stable anchorage of the implant
- Any circumstances that may prevent the patient from appropriately limiting his/her activities or following medical instructions during the healing phase
- Patients in whom conservative therapy is promising
- Hypersensitivity to the material to be implanted

Precautions

- This product may be unsuitable for patients with inadequate or immature osteogenesis. In this patient population, the placement of the implant must not affect the epiphyseal plate
- Lack of compliance
- Bone disease
- Severe deformities
- Infection or generally weakened immune system
- Drug or alcohol abuse
- Midsubstance and distal ACL tears may have an impaired healing potential
- Young age and high level of physical activity are factors generally associated with increased failure risk after ACL surgery

For further information, please refer to the instructions for use or ask your Mathys representative.

2. Surgical technique

2.1 Overview of the surgical technique

- Rupture of ACL
- Looping of the ACL stump
- Tibial drilling

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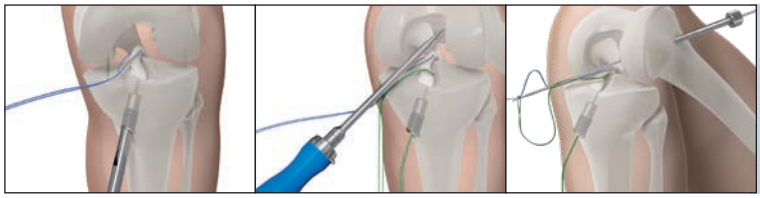

- Placement of Ligamys Monoblock
- Microfracturing
- Transfer of sutures

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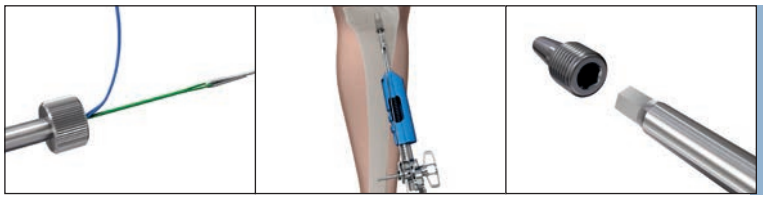

- Insertion of Ligamys Braid
- Pre-tensioning of spring system
- Fixation with clamping cone

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2.2 Implantation of Ligamys

The surgical technique for treating a primary anterior cruciate ligament rupture is described using a standard arthroscopic approach as an example.

Remark

The Ligamys surgical technique is based on system-specific instruments, which are mandatory for successful Ligamys implantation (p. 23–26). In addition, two to five PDS 2-0, as well as one non-resorbable 1-0 suture at least 90 cm in length, are needed.

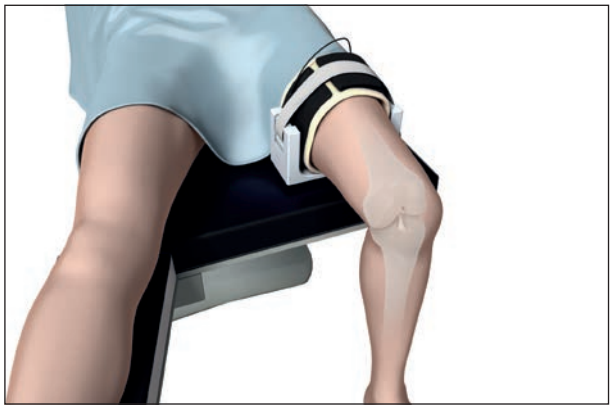


Fig. 1 Positioning of the leg

Patient positioning and arthroscopic approaches
Supine position with leg holder: Anteromedial portal technique, i. e. **130° flexion range**.

Use of a mobile leg holder and blood arrest.

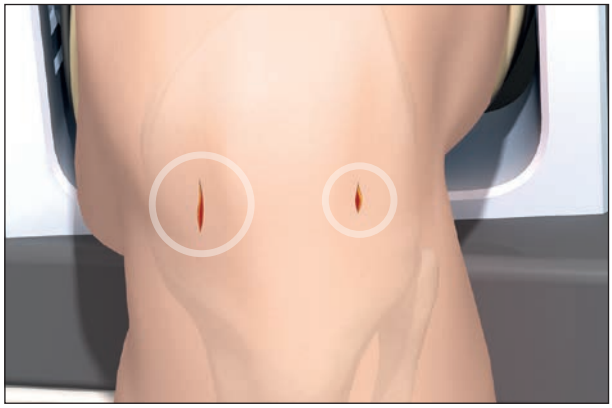


Fig. 2 Approaches on the knee

Create anterolateral and anteromedial portal.

Remark
Large medial incision to guide the opened suturing forceps outwards and prevent soft tissue bridging.

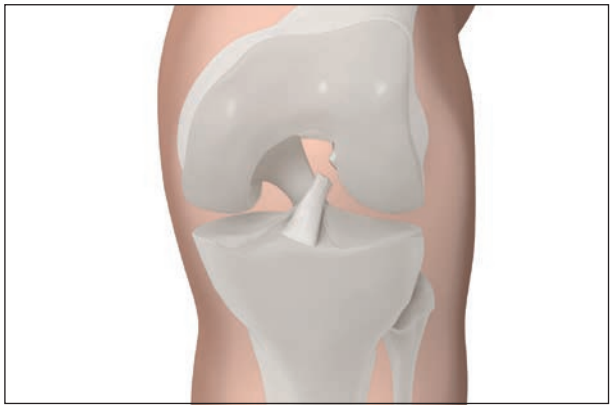


Fig. 3 Ruptured anterior cruciate ligament

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.

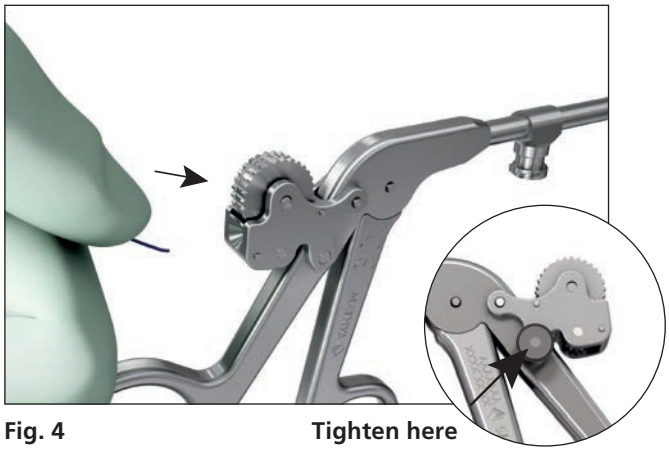


Fig. 4

Looping of the ACL stump
Thread absorbable PDS 2-0 retaining suture [blue] without needle into the Suturing Forceps.

Remark
The movable roller housing of the Suturing Forceps must be correctly locked in place with the knurled screw.

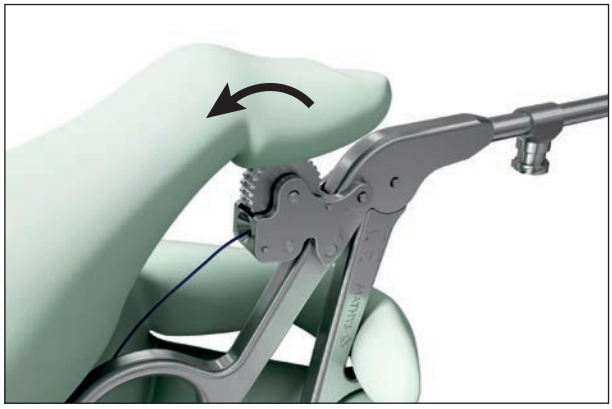


Fig. 5

Advance the retaining suture up to the level of the tip of the cannula by simultaneously rotating and pressing on the knurled metal knob.

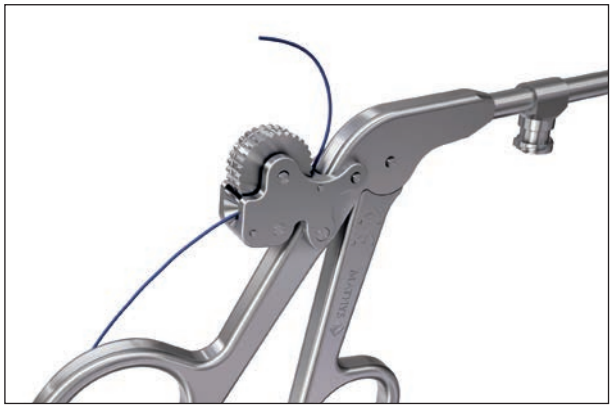


Fig. 6

Remark
If no pressure is applied to the knurled metal knob when threading in the retaining suture, the suture may escape from the roller housing.

In this case, the retaining suture must be manually withdrawn and the bent part must be detached.

Thread in the suture again. Simultaneously rotating and pressing on the knurled metal knob advances the retaining suture securely.

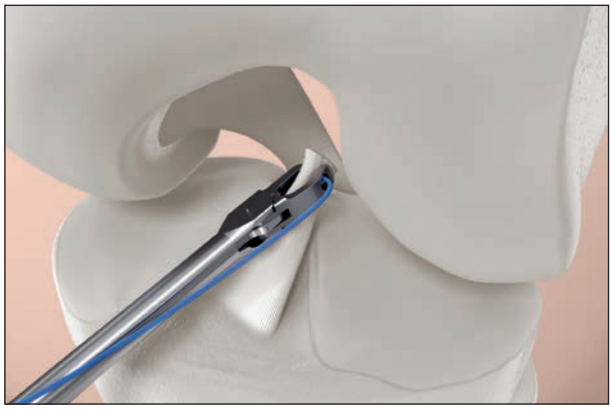


Fig. 7

Tying on the tibial cruciate ligament stump
Pierce the cruciate ligament stump with the Suturing Forceps and advance the absorbable retaining suture [blue] into the joint.

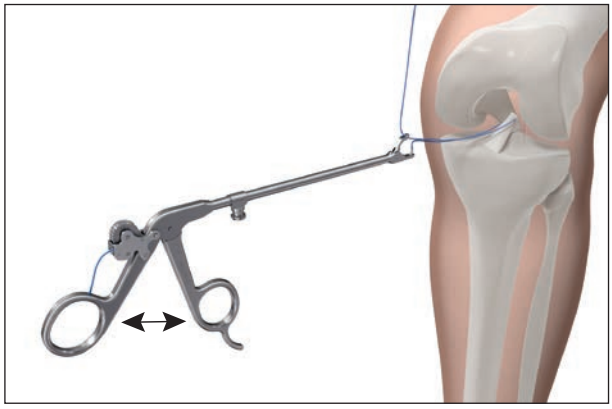


Fig. 8

Guide the ends of the retaining suture [blue] outwards with the opened Suturing Forceps.

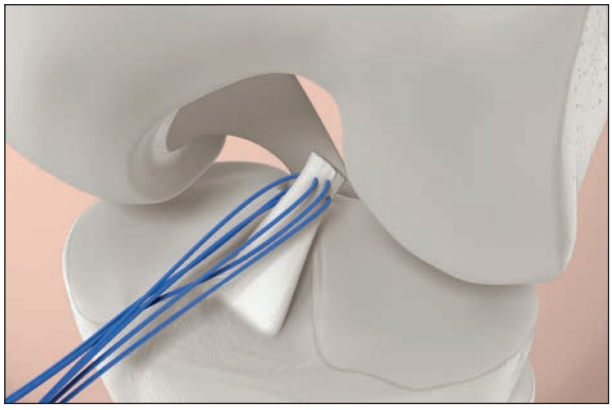


Fig. 9

Depending on the condition of the tibial stump, it may be necessary to tie on individual bundles using several retaining sutures [blue] (min. 2, max. 5).

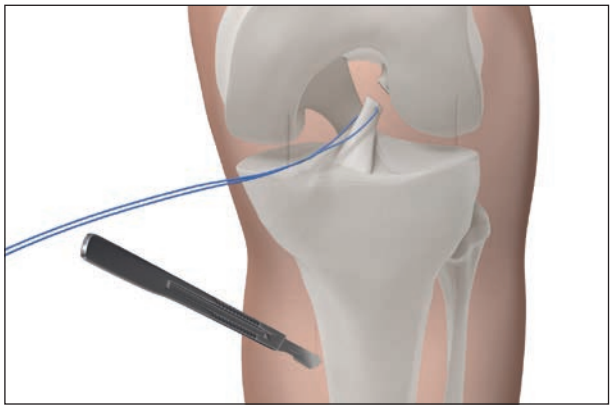


Fig. 10

Incision for implantation of the Monoblock

- Skin incision 2 – 3 cm medial to the tibial tuberosity
- Incision length: Approx. 4 cm
- Dissection up to the tibial periosteum

Avoid damaging the superficial pes anserinus.

Fig. 11

Placement of the Tibial Guide Wire

Place the tip of the bracket of the Tibial Targeting Device laterally directly behind the tibial cruciate ligament stump.

Advance drill sleeve up to the 50 mm marking and position it directly over the pes anserinus superficialis flush with the bone.

Remark

60° – 65° angle setting; min. 50 mm distance setting (wide laser marking).

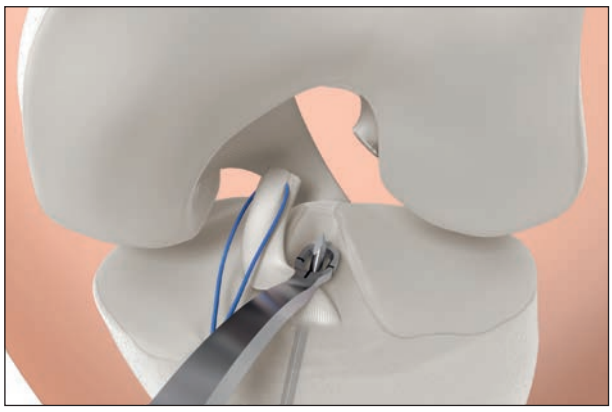


Fig. 12

Drill with a short Guide Wire (without lug) until its tip is securely in an intraarticular position, directly behind the tibial stump.

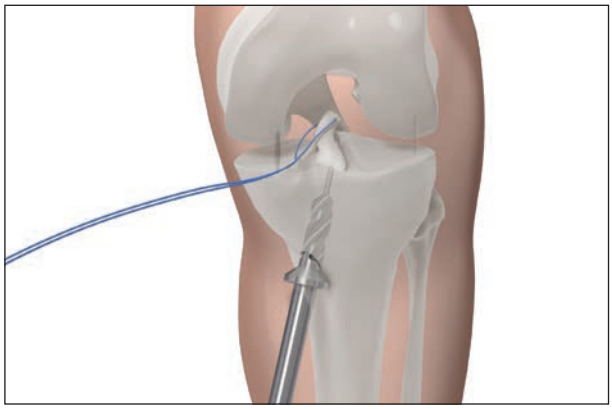


Fig. 13

Tibial drilling channel
Over-drilling of the Guide Wire until the collar of the Cannulated Drill Bit (diameter 10 mm) is at the cortical bone.

Remark
It should be ensured that overdrilling is performed along the axis of the Guide Wire to avoid tilting between the Drill Bit and the Guide Wire.

Fig. 14

Fig. 15

Attach the Ligamys Monoblock in the correct position onto the Ligamys Screwdriver.

Remark
The laser marking must point to the suture exit point.

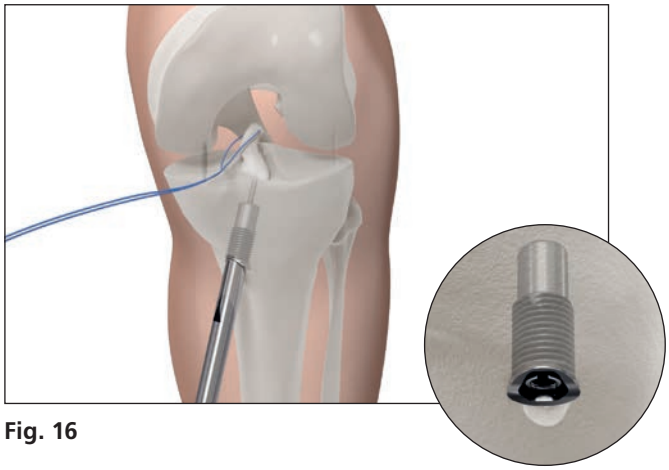


Fig. 16

Placement of the Monoblock
Screw in the Ligamys Monoblock clockwise using the Ligamys Screwdriver over the short Guide Wire (without lug) until the Ligamys Monoblock is flush with the cortical bone.

The Monoblock has a self-tapping thread and can therefore be screwed in without application of pressure.

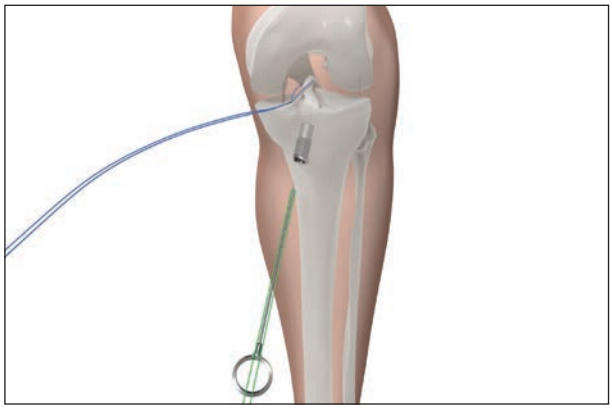


Fig. 17

Removal of the short Guide Wire (without lug) and insertion of a loop of the shuttle suture (non-absorbable suture 1-0 // min. 90 cm long), using the Thread Passer, through the Monoblock into the joint.

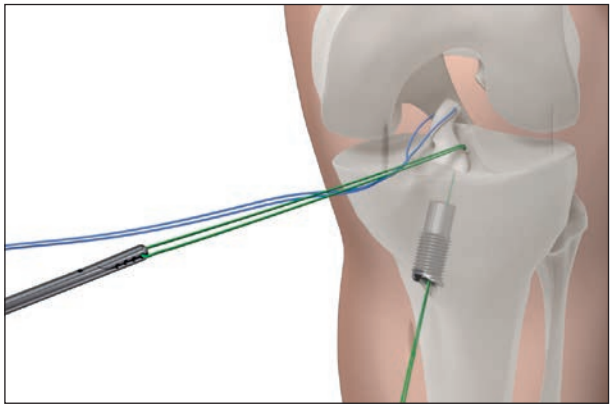


Fig. 18

Pull the suture loop outwards using Grasping Forceps through the anteromedial portal and secure with a Clamp.

Remark
Ensure clear lateral separation between the retaining suture [blue] and shuttle suture [green] outside of the anteromedial portal.

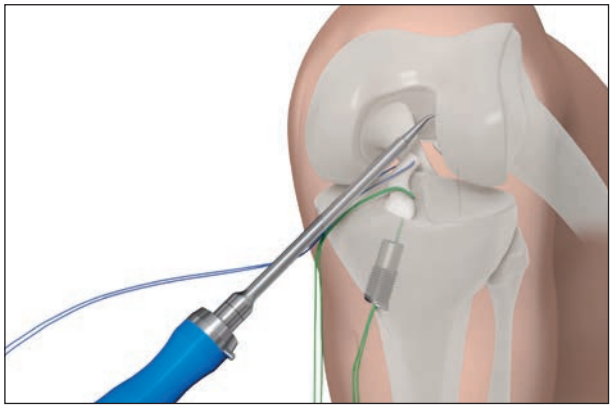


Fig. 19

Microfracturing in the notch
Using the Microfracturing Awl at the femoral base of the cruciate ligament, make several microfractures **(healing response)**.

The Ligamys Braid must not be damaged with the Microfracturing Awl.

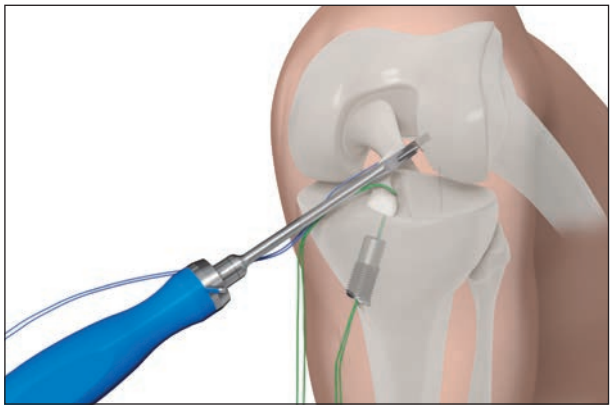


Fig. 20

Positioning of the Femur Targeting Device in **maximum flexion of the knee joint**.

Placement of the long Guide Wire (with lug) centrally through the femoral base and drilling through until the tip of the drill appears on the femoral side.

Remark
Guide the Femur Targeting Device above the emergent sutures through the anteromedial portal into the knee joint.

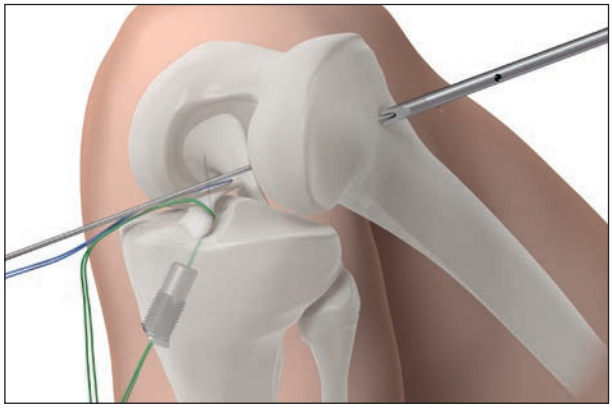


Fig. 21

Perform an incision at the emerging tip of the Guide Wire. Gently spread the muscle tissue using the Soft-tissue Dilatator over the Guide Wire.

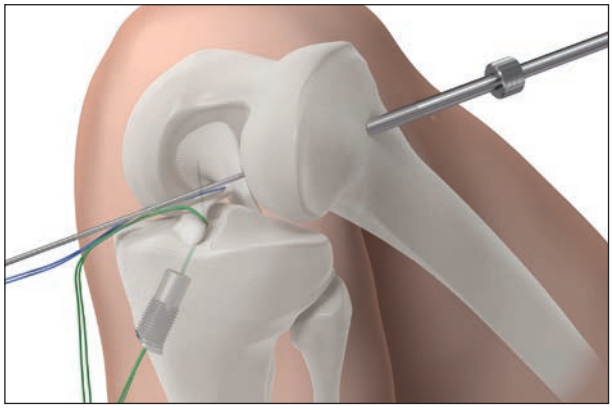


Fig. 22

Advance the Dilatator Sleeve up to the cortical bone and remove the Soft-tissue Dilatator.

Remark
The Dilatator Sleeve remains in place until the end of the surgery. The Ligamys Braid is also introduced through it.

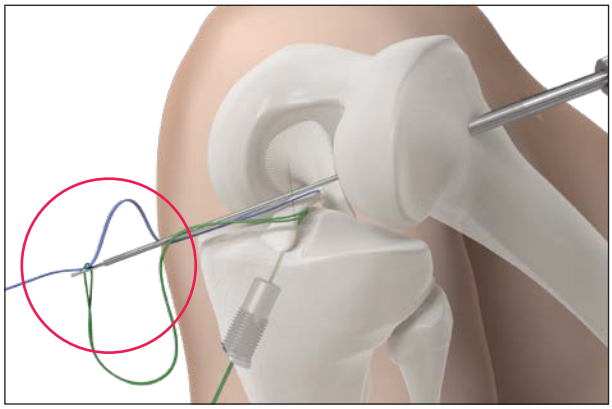


Fig. 23

Suture management
Thread the shuttle suture [green] through the lug of the long Guide Wire, and guide the retaining sutures [blue] into the loop of this shuttle suture [green].

Remark
The retaining sutures [blue] must form a loop so that they are not damaged when they are subsequently pulled proximal.

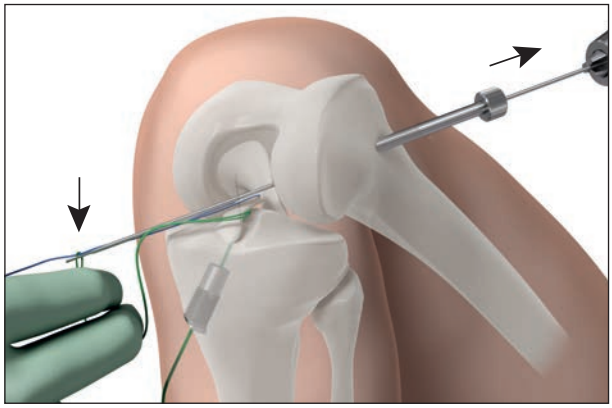


Fig. 24

Clamp the tip of the long Guide Wire (with lug) into the chuck with T-handle. Gradually transfer sutures carefully through the femur using a hammer.

Remark
Hold the shuttle suture [green] in place manually such that the retaining sutures [blue] remain secured on the long Guide Wire (with lug).

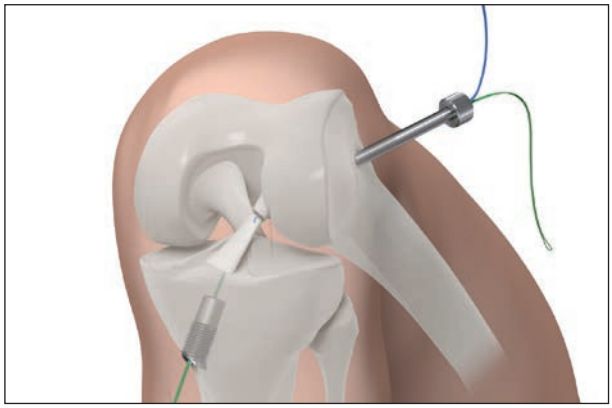


Fig. 25

On the femoral side, ensure clear lateral separation between the retaining sutures [blue] and shuttle sutures [green].

Remark
Tensioned PDS sutures can be secured femorally with a Clamp.

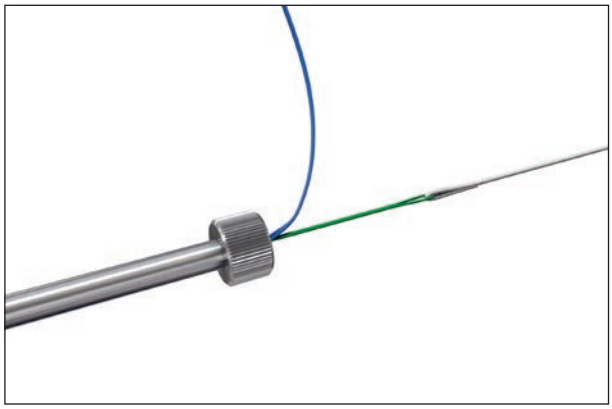


Fig. 26

Threading in the Ligamys Braid
Insert the thin part of the Ligamys Braid up to a maximum of halfway overlapping into the loop of the shuttle suture [green].

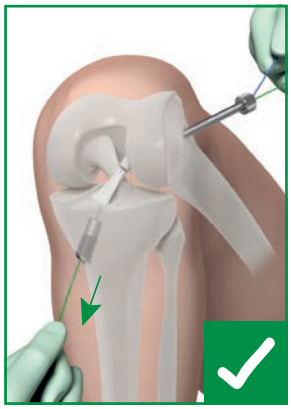


Fig. 27

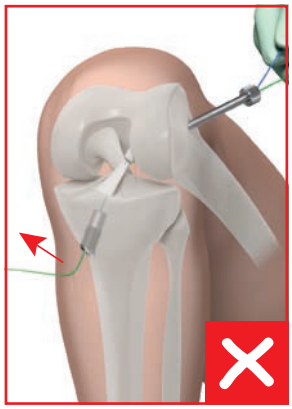


Fig. 28

Pulling the Ligamys Braid through
Using the shuttle suture, guide the Ligamys Braid tibially outwards through the joint and through the Monoblock.

Pull the Ligamys Braid downwards in the axis of the Ligamys Monoblock. In the event of a deviation of the axis, the Ligamys Braid can become damaged.

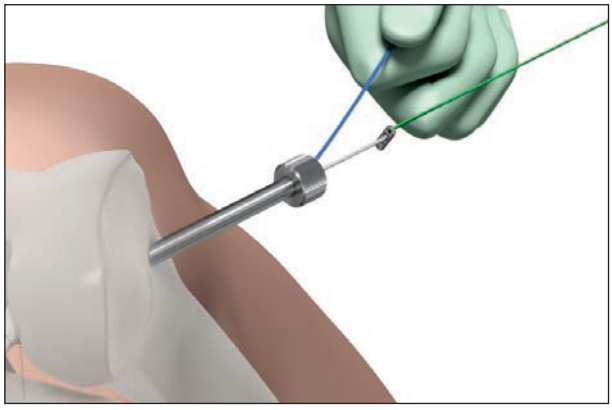


Fig. 28

Positioning the button
At the button, thread in the shuttle suture [green] already used.

Remark
This shuttle suture [green] is to be removed only at the end of the surgery! If necessary, it can be used to retract the Ligamys Braid.

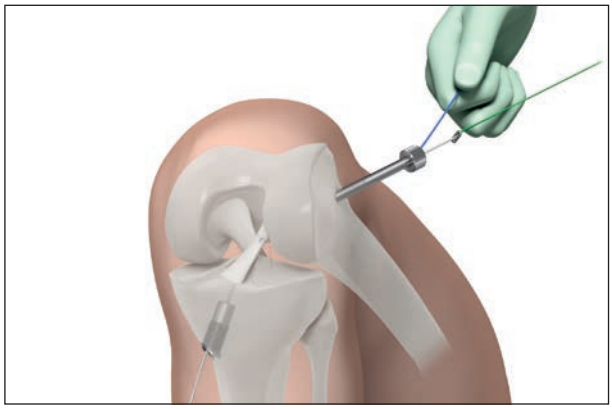


Fig. 30

Repositioning of the tibial stump

Tension the retaining sutures [blue] pairwise under arthroscopic view, then tighten and secure the Ligamys Braid distal.

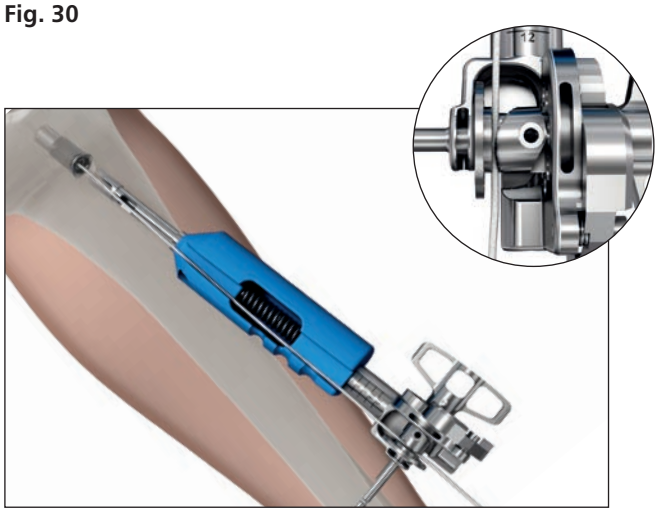


Fig. 31

Place the Tensioner correctly on the monoblock.

Place the Ligamys Braid into the lock of the Tensioner and pull it downwards (Fig. 32).

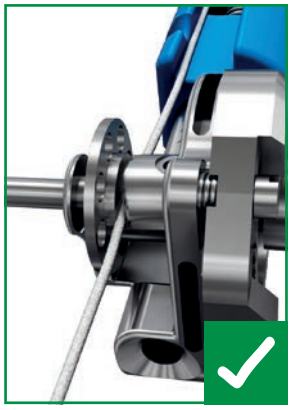


Fig. 32

Fig. 33

Ensure correct positioning of the Ligamys Braid in the Tensioner. In the event of incorrect positioning, the Ligamys Braid can become damaged.

Fig. 34

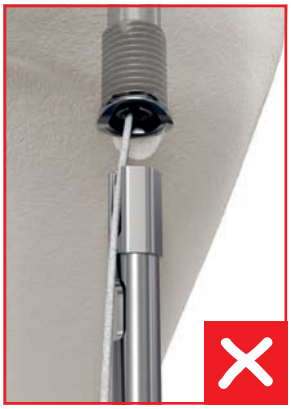


Fig. 35

Ensure correct positioning of the Tensioner in the Ligamys Monoblock. If the Tensioner is not correctly positioned on the Monoblock, the Ligamys Braid can become damaged.

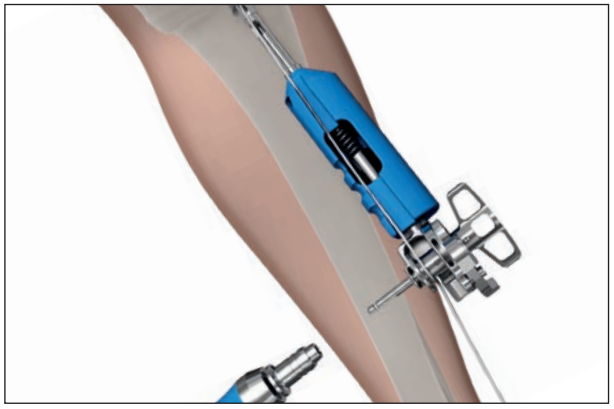


Fig. 36

Secure placement of the button on the femur
Rotate the wing handle until the scale on the Tensioner is no longer visible. Placement of the Click-fit handle (3.5 Nm) on the AO coupling of the Tensioner.

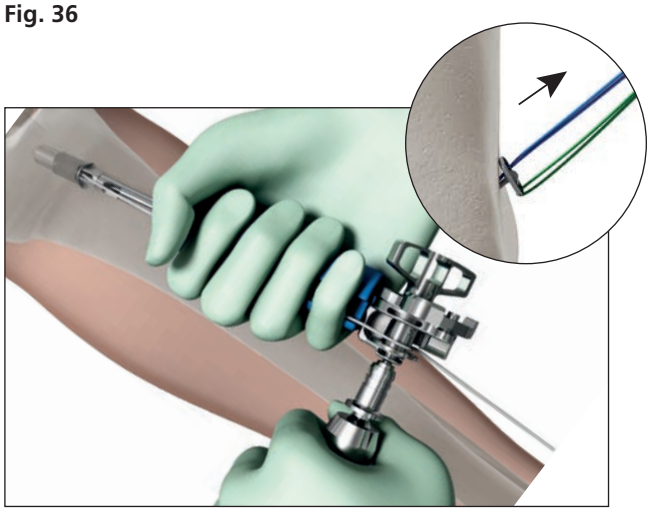


Fig. 37

Maximum tensioning of the Ligamys Braid and pulling the button by rotating the Click-fit Handle clockwise **until 3 clicks are heard**.

Remark
Under arthroscopic control, continue to hold the retaining sutures [blue] so that the tibial stump remains reduced.

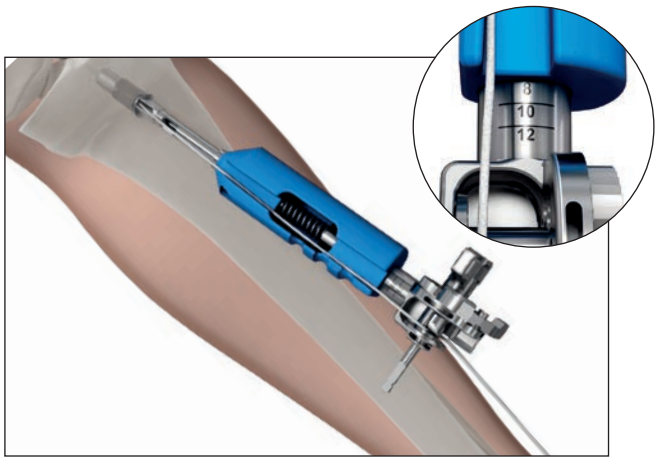


Fig. 38

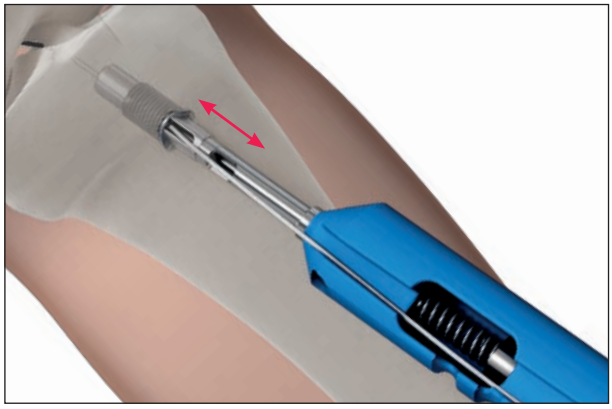


Fig. 39

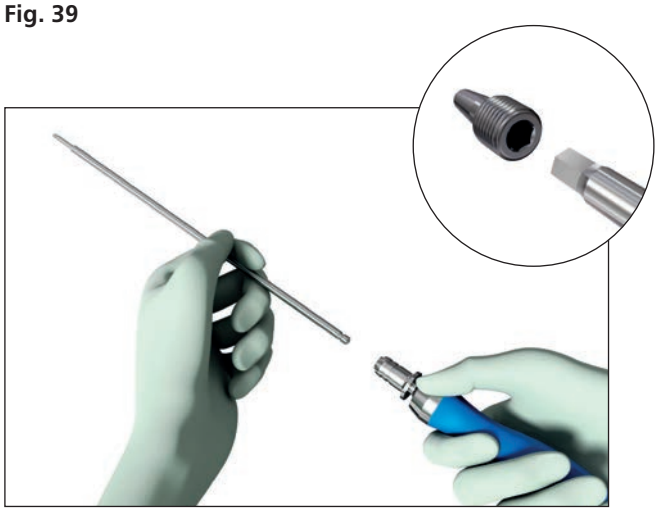


Fig. 40

Pre-tensioning the spring system in the Monoblock

- Disconnection of the Click-fit Handle
- Complete release of tension on the Tensioner
- Repeat pre-tensioning with the Tensioner with **the knee joint fully extended** by turning the wing handle anticlockwise until the pre-tensioning corresponds to the desired value on the scale

Reference values for pre-tensioning in the Monoblock

Between 6 and 8 (this corresponds to an approximate tension of 60 N to 80 N on the spring system).

Remark

The Tensioner must be guided in the longitudinal axis of the Monoblock when pre-tensioning.

Functional control after pre-tensioning in full extension

Move the preloaded tensioner in the monoblock back and forth to ensure the mobility of the clamping element inside. The top of the tensioner must be correctly positioned in the monoblock while the instrument is pushed into the monoblock and moved back. Bend the knee 2 – 5 times after tensioning the Ligamys braid to detect and, if necessary, correct for possible loss of tension. Check if there is a loss in tension during flexion and an increase in tension at full extension.

Preparation for screwing in the Clamping Cone

Insert the AO coupling piece hexagonal in the Click-fit Handle and attach the Clamping Cone.

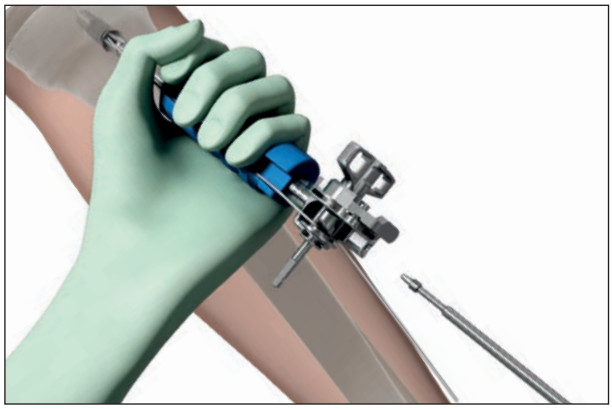


Fig. 41

Remark
Secure the Clamping Cone during introduction into the Tensioner so that it will not fall out.

Secure introduction of the Clamping Cone into the Tensioner.

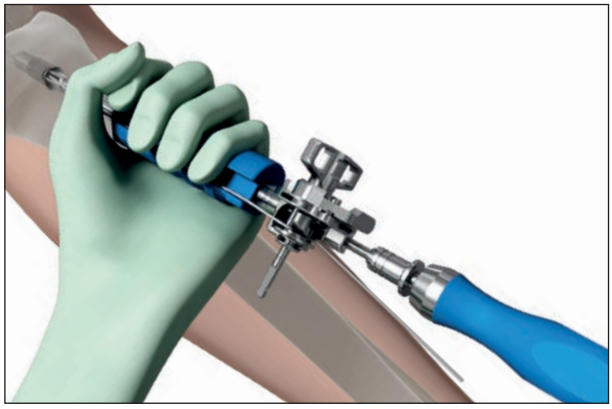


Fig. 42

Fixation of the Ligamys Braid in the Ligamys Monoblock
Guide Clamping Cone through the pre-tensioned Tensioner and screw into the Ligamys Monoblock clockwise **until 3 clicks are heard**.
The Ligamys Braid is now secured in the dynamic spring system of the Ligamys Monoblock.

Remark
When screwing in the Clamping Cone, the handle of the Tensioner must be held to prevent the Ligamys Monoblock from rotating as well.

Remark
When holding the handle of the Tensioner, ensure that the spring system is not over-tensioned due to additional manual pressure.

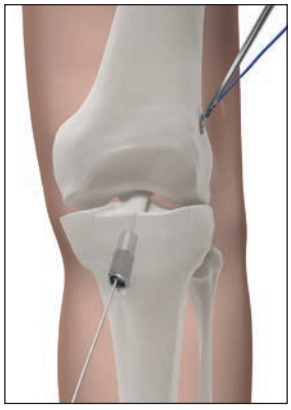


Fig. 43

Fig. 44

Conclusion of the surgery
Pull out the shuttle suture [green] at the button and cut off the retaining sutures [blue] at maximum possible depth.

Cut off the Ligamys Braid at the Ligamys Monoblock.

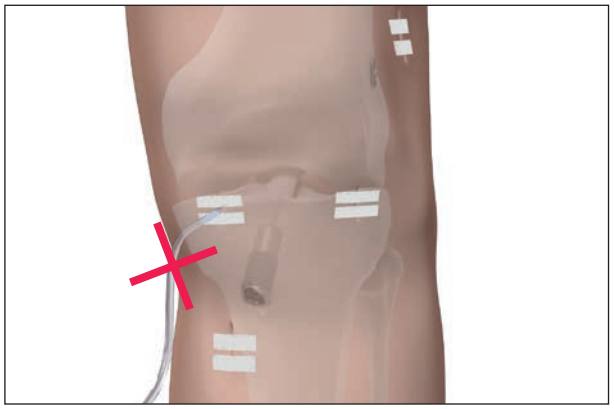


Fig. 45

Wound closure
Close portals in the standard fashion using sutures or Steri-Strips.

Remark
To be able to optimally utilise the cell potential in the knee joint, ***no*** *drainage should be used.*

Remark
The necessary post-operative treatment is described in the rehabilitation guidelines «Physiotherapy and return to sports» on www.ligamys.com.

2.3 Optional: Metal implant removal – Ligamys Monoblock (no earlier than 6 months after Ligamys implantation)

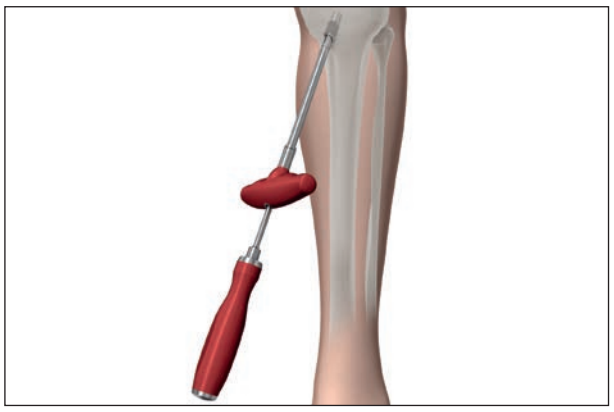


Fig. 46

Skin incision at the site where the Monoblock was implanted. Insert the Ligamys Clamping Cone Extractor in the Ligamys Monoblock Extractor. Attach the Ligamys Monoblock extractor to the Ligamys Monoblock.
Extract the Clamping Cone in an anticlockwise direction.

Remark
Before attaching the two instruments, the Ligamys Monoblock must be completely free of any hindering connective tissue.

The Ligamys Clamping Cone Extractor may only be used in combination with the Ligamys Monoblock Extractor since the instrument may otherwise break.

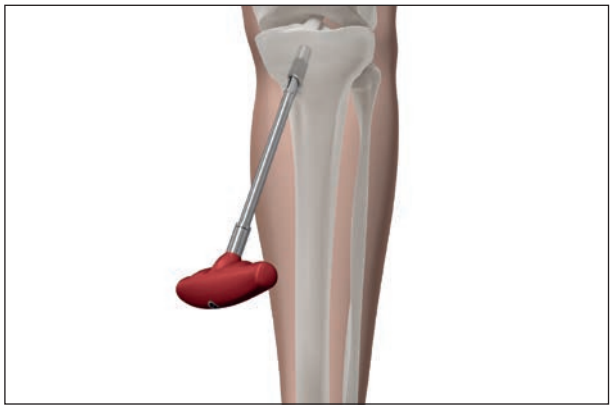


Fig. 47

Extraction of the Monoblock by rotating it in a counterclockwise direction.

Proper guidance of the Monoblock Extractor in the implant can be ensured only through adequate compression of the spring mechanism in the Monoblock. The defect can be left empty or filled with a bone substitute material.

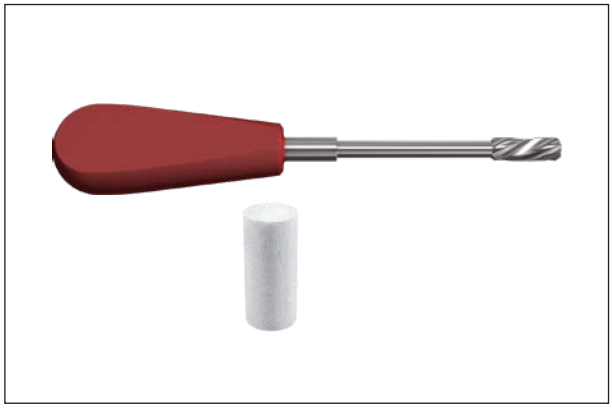


Fig. 48

Defect filling with bone substitute
To prepare the implant site, ream the entire length of the bone defect with the Reamer.

Fill the defect with an appropriate bone substitute material.

Optional
Fill the defect with a cyclOS cylinder of 11.3 x 25 mm diameter (Item no. 42.34.2201). Insert the press-fit bone substitute into the entire length of the bone defect.

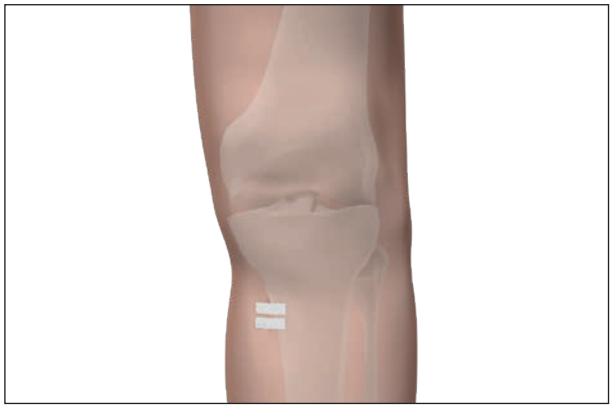


Fig. 49

Wound closure
Close portals by default using sutures or Steri-Strips.

3. Implants

Item no.	Description
82.34.0005	Ligamys braid with button

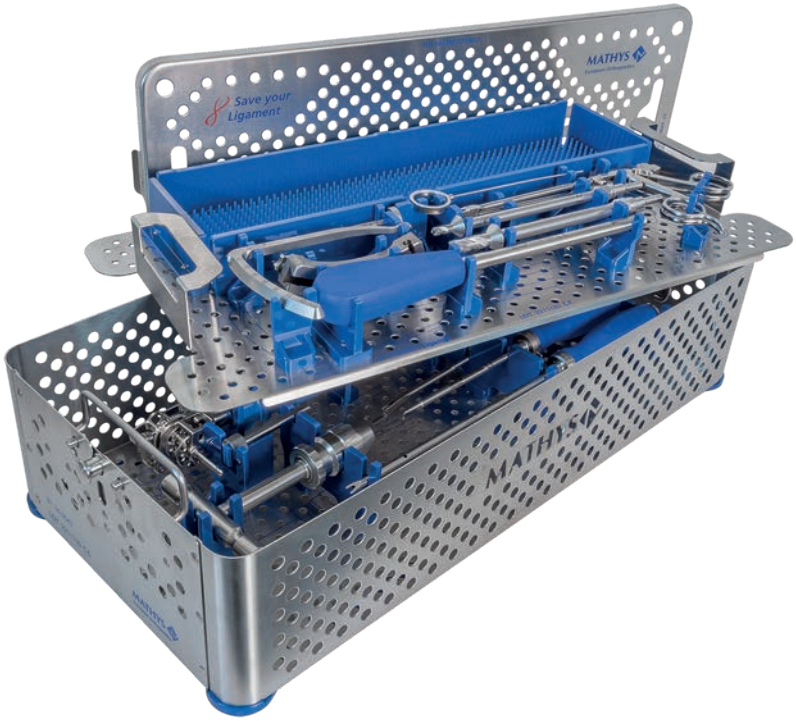
Material: TiAl6V4, UHMWPE

Item no.	Description
82.34.0013	Ligamys monoblock Gen. 2

Material: FeCrNiMoMn, CoCrNiMoFe

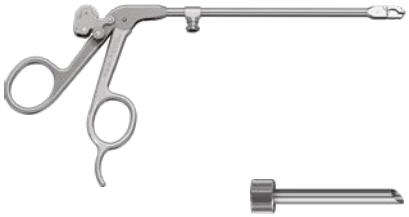
4. Instruments

4.1 Ligamys Instrumentation 81.34.0030A



Individual tray components

Item no.	Description
81.34.0047	Ligamys Tray 2nd gen.
81.34.0048	Ligamys Tray Insert
81.34.0022	Ligamys lid



Item no.	Description
81.34.0043	Ligamys suturing forceps

Item no.	Description
81.34.0002	Dilatator sleeve

Item no.	Description
81.34.0004	Ligamys Drill bit 6 mm cannulated

Item no.	Description
81.34.0005	Ligamys Drill bit 10 mm cannulated

Item no.	Description
81.34.0006	Ligamys screwdriver

Item no.	Description
81.34.0007	Suture passer

Item no.	Description
81.34.0008	Femur targeting device

Item no.	Description
81.34.0009	Soft tissue dilatator

Item no.	Description
81.34.0010	Chuck with T handle

Item no.	Description
81.34.0011	Ligamys Tensioner

Item no.	Description
81.34.0049	Microfracturing awl 30°

Item no.	Description
81.34.0020	Tibia targeting device

Item no.	Description
81.34.0044	Click-fit handle (AO coupling) [1]

Item no.	Description
81.34.0045	AO coupling piece hexagonal

[1] Replacement of the click handle after 3 years

To be able to ensure safe reprocessing of the Ligamys suturing forceps, Mathys Ltd Bettlach has created a guideline for reprocessing:

Item no.	Description
336.060.012	Processing Instructions for the Ligamys suturing forceps

Remark
The guideline for reprocessing must be additionally ordered when ordering the instrument set.

4.2 Consumables

Item no.	Description
81.34.0051	Ligamys pack of 10 guide wires tap.

Single use, sterile

4.3 Optional instruments

For removal of the Ligamys monoblock
(no earlier than 6 months after Ligamys implantation)

Item no.	Description
81.34.0024	Ligamys clamping cone extractor

Item no.	Description
81.34.0026	Ligamys monoblock extractor

Item no.	Description
81.34.0050	Reamer

5. Symbols

 Manufacturer

 Correct

 Incorrect

 Caution

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