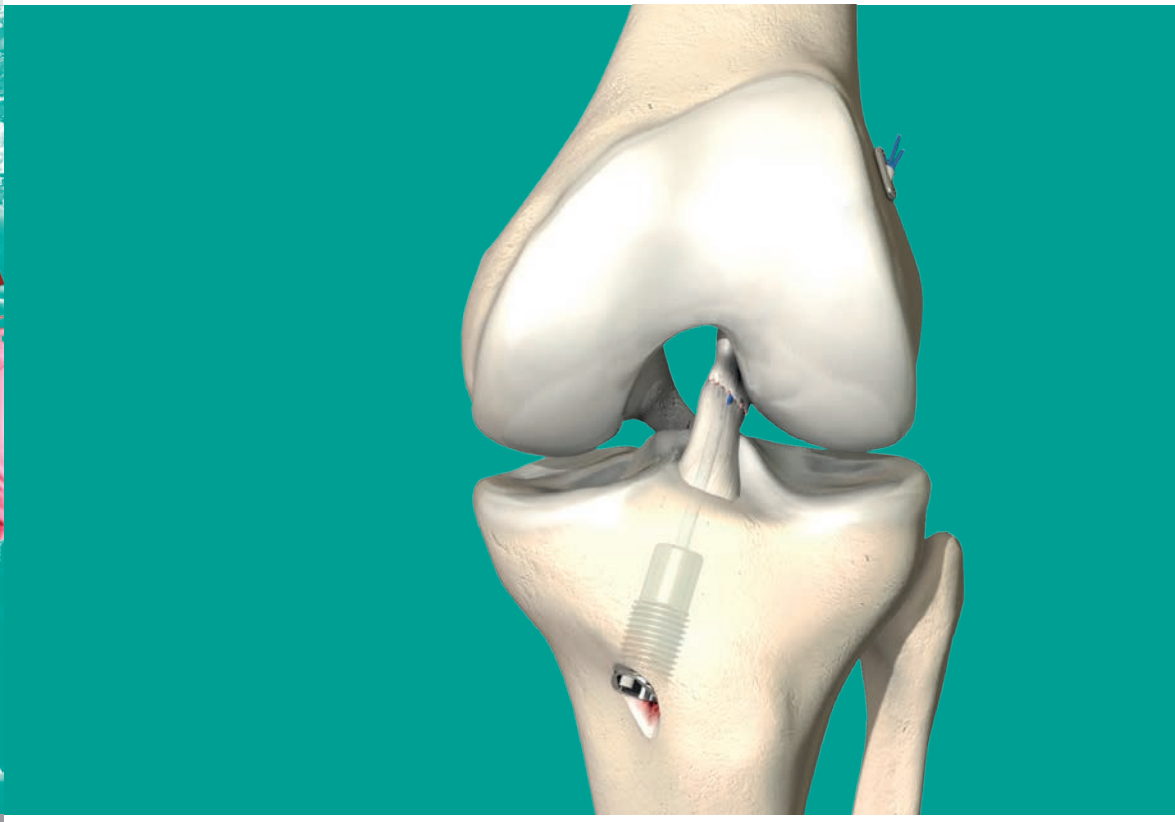
MATHYS
European Orthopaedics

Sporthopaedics

Ligamys® – Healing of the ruptured anterior cruciate ligament

Surgical technique



Ligamys

Table of contents

Note
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.

1. Introduction

Experience from the last 30 years in cruciate ligament surgery has taught us that only the native ligament can ensure the physiological kinematics and dynamic stabilisation of the knee. Guided by this insight, the technique of dynamic intraligamental stabilisation (DIS) after injury of the anterior cruciate ligament was developed. This technique is based on the following principle: the knee joint is temporarily stabilised with a dynamic spring system which provides the necessary rest needed for the native cruciate ligament to achieve stable cicatrisation. The authors are convinced that this healing procedure offers an additional option over the conventional replacement of the ligament. They see Ligamys as an extension of the conservative treatment because no tendon grafts need to be taken and all options of secondary reconstruction remain available in case of non-union of the ligament. If the ligament heals up successfully, the patient retains an almost fully resilient knee joint that has not been additionally damaged by the removal of tendon grafts.

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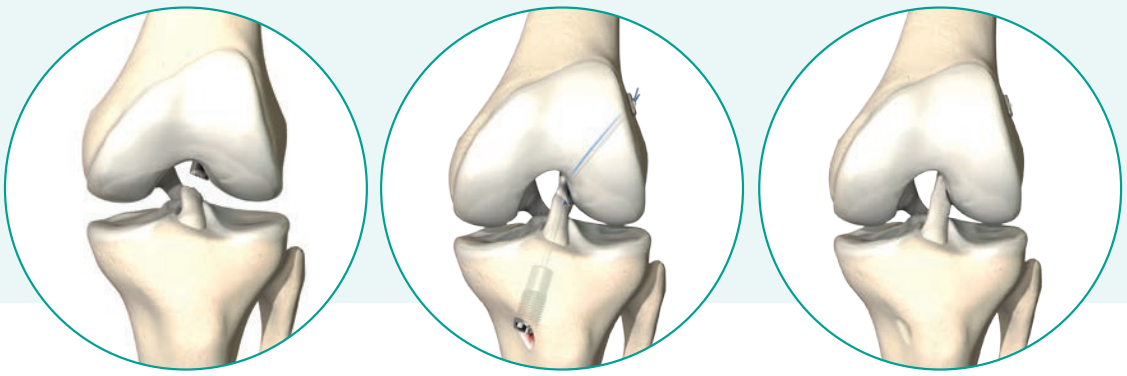


Rupture ***Implantation*** ***Healing***

2. Indications and contraindications

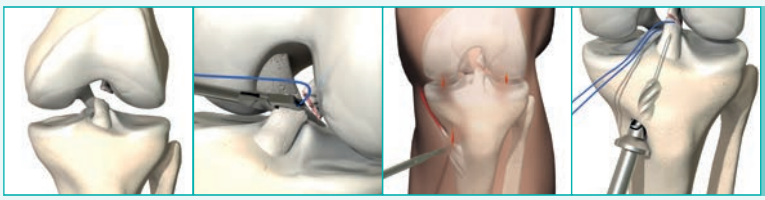
Indications

- Acute rupture of the anterior cruciate ligament (ACL) no older than 21 days

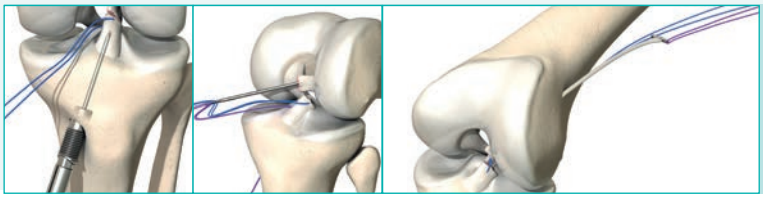
Contraindications

- ACL ruptures older than 21 days due to impaired healing potential of the cruciate ligament
- Acute or chronic infection, local or systemic (including a history of such infections)
- Arthrofibrosis
- Severe malalignment of the knee joint
- Severe muscular, neural or vascular diseases that may threaten the affected limb
- Oversensitivity to the materials involved (e. g. cobalt, chromium, nickel, etc.)
- Insufficient bone substance and poor bone quality that may compromise stable anchorage of the implant
- Open physis

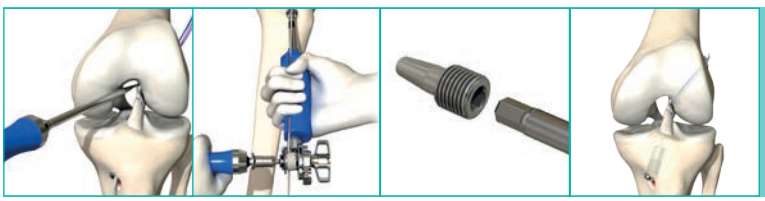
3. Overview of surgical technique



- Rupture of ACL
- Tibial tying
- Monobloc access
- Tibial drilling



- Placement of Ligamys monobloc
- Transfer of sutures
- Insertion of Ligamys thread



- Microfracturing
- Pre-tensioning of spring system
- Blocking with clamping cone

4. Surgical technique

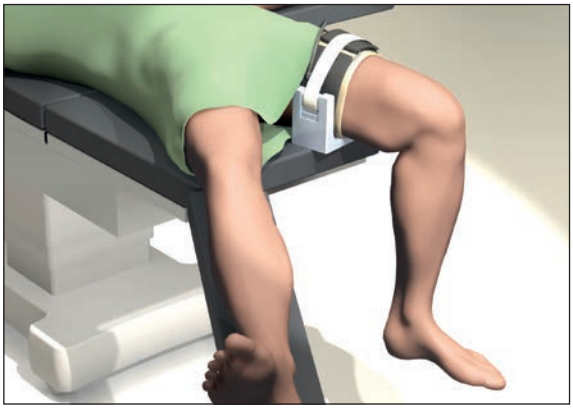


Fig. 1 Positioning of the leg

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

Use of a mobile leg holder and blood arrest.

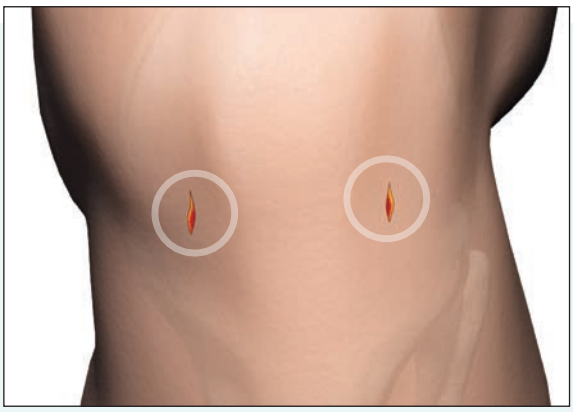


Fig. 2 Approaches on the knee

Establishment of anterolateral and anteromedial portal.

Important: Placement of the anteromedial portal should be far lateral to enable free access to the femoral insertion point of the anterior cruciate ligament.

Fig. 3 Ruptured anterior cruciate ligament

Diagnostic arthroscopy
Comprehensive examination of the knee joint.

Diagnosis and treatment of concomitant injuries and evaluation of ACL rupture morphology.

Sparing reduction of Hoffa's fat pad to enable unimpeded vision of the ruptured cruciate ligament and the tibial insertion point.

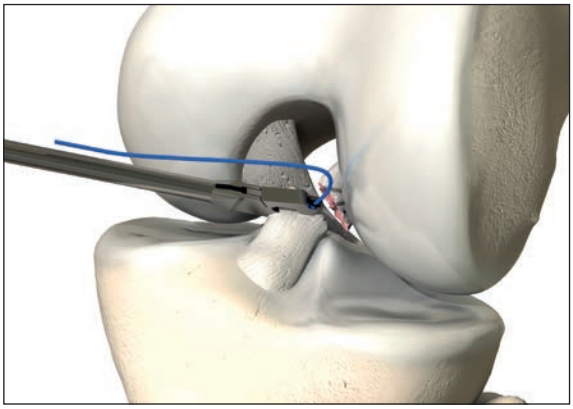


Fig. 4

Tying on the tibial cruciate ligament stump
Using a suturing forceps, the cruciate ligament stump is tied on with an absorbable retaining thread [blue] **(PDS 2-0)**.

The retaining thread [blue] is guided with both ends through the anteromedial portal to the outside.

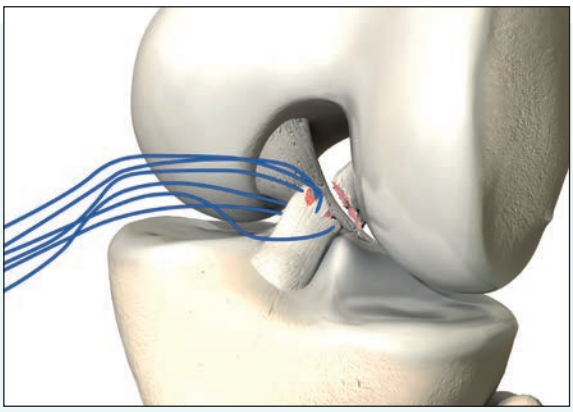


Fig. 5

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

The ends of the retaining thread [blue] should always have the same length.

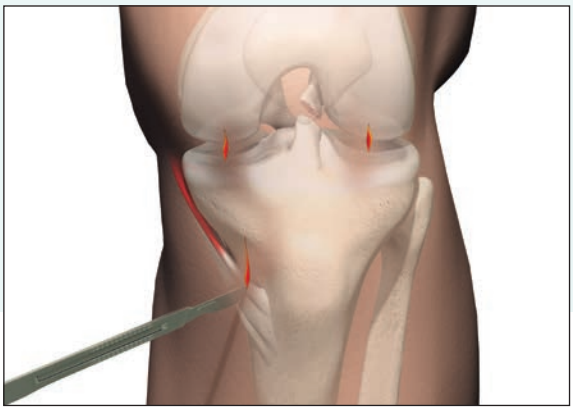


Fig. 6

Incision for preparation of the tibial drilling duct
Skin incision 2 – 3 cm medially of the tibial tuberosity

Length of incision: approx. 4 cm

Preparation to the periosteum of the tibia

Important: Avoid injury to the superficial pes anserinus.

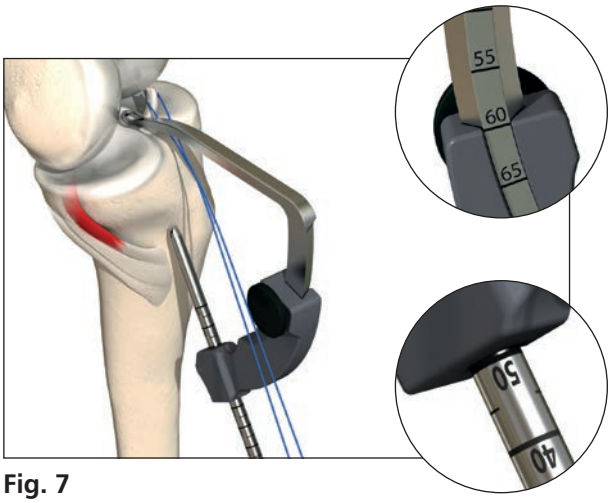


Fig. 7

Placement of the tibial guide wire
The tibial targeting device is used
Important: 60°–65° angle setting; min. distance setting **50 mm**

Palpation of the superficial pes anserinus: place the drilling sleeve of the targeting device directly above it and align the bracket in parallel with the tibial plateau.
Important: The position of the tibial entry point is lower than for conventional ACL reconstruction (monobloc length: 30 mm).

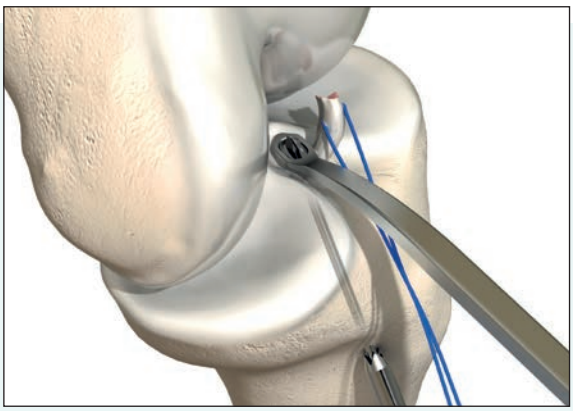


Fig. 8

The bracket tip of the targeting device is placed directly behind the tibial cruciate ligament stump.

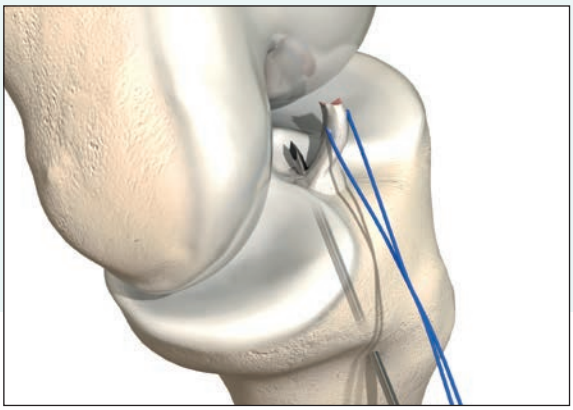


Fig. 9

Drill with a short guide wire [without lug] until the tip has securely reached the intra-articular space.

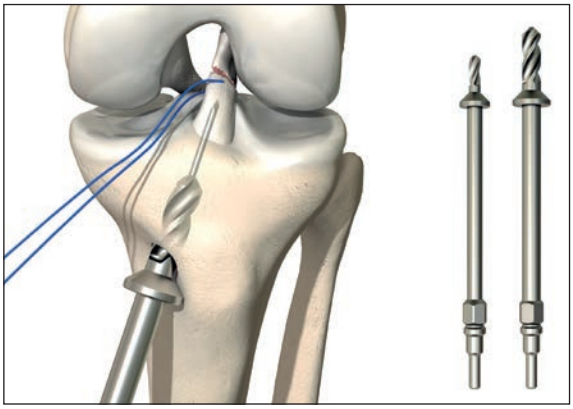


Fig. 10

Tibial drilling duct
Drilling over the guide wire with the two cannulated drills with depth limitation.

Important: Drill over in the axis of the guide wire must be ensured to avoid tilting.

Important: The cannulated drills must be replaced after **30 Ligamys operations.**

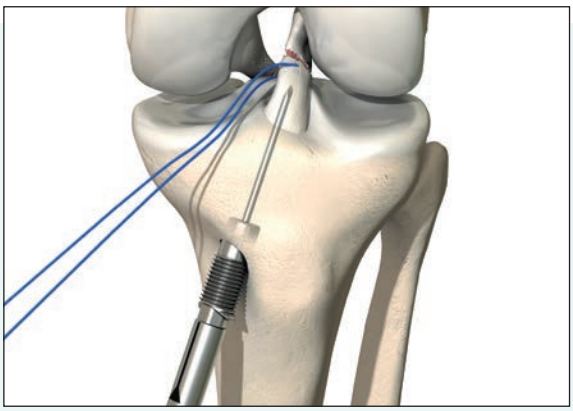


Fig. 11

Placement of the monobloc
Using the Ligamys screwdriver, the monobloc is turned clockwise – over the guide wire [without lug] – until it lines up precisely with the corticalis.

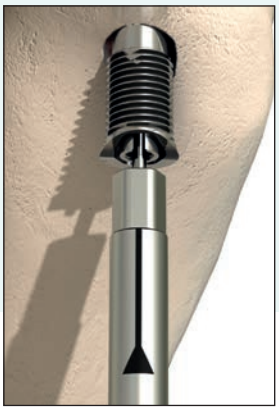


Fig. 12

Fig. 13

Important: It must be ensured that the Ligamys screwdriver is positioned correctly in the monobloc; the laser mark ▶ must point to the exit point of the thread.

The nose of the monobloc – in the corticalis – must reach a position at the distal pole of the drill hole.

Removal of the short tibial guide wire [without lug].

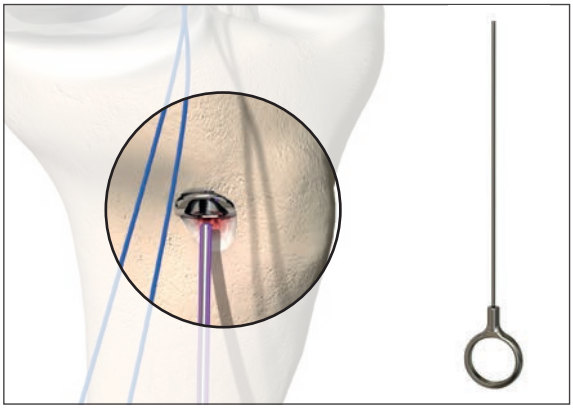


Fig. 14

Insertion of the shuttle thread
Using a thread passer, the loop of a strong shuttle thread [purple] is inserted through the monobloc into the joint (e.g. **MERSILENE 1** // 1.40 m length).

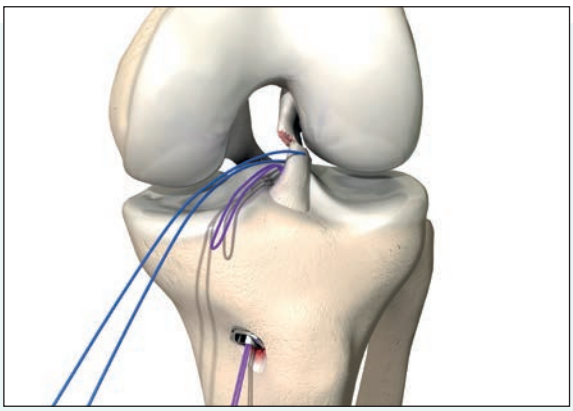


Fig. 15

Using a grasping forceps, this loop is pulled outward through the antero medial portal and fixated with a clamp.

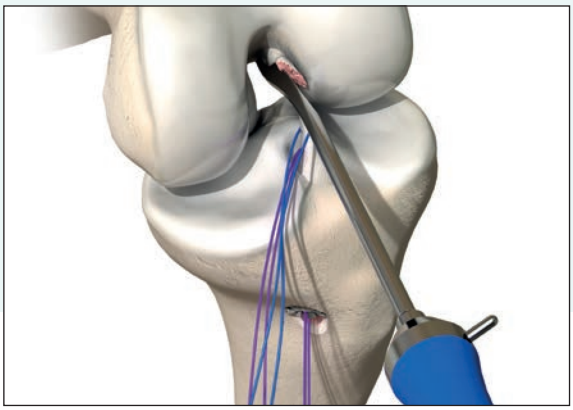


Fig. 16

Placement of the femoral targeting device in maximum possible flexion of the knee joint.

Placement of the long guide wire [**with** lug] immediately posterior to the femoral insertion point.

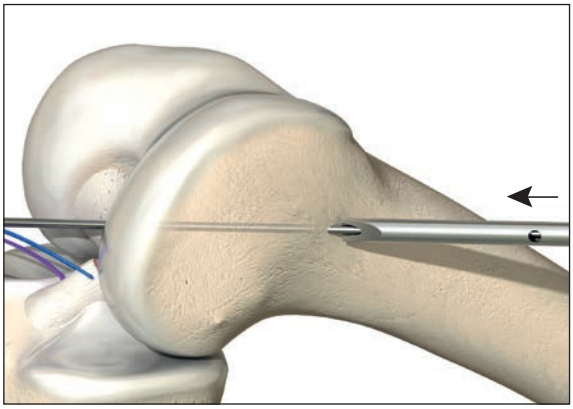


Fig. 17

Gentle spreading of the muscle tissue with a soft tissue dilatator over the guide wire.

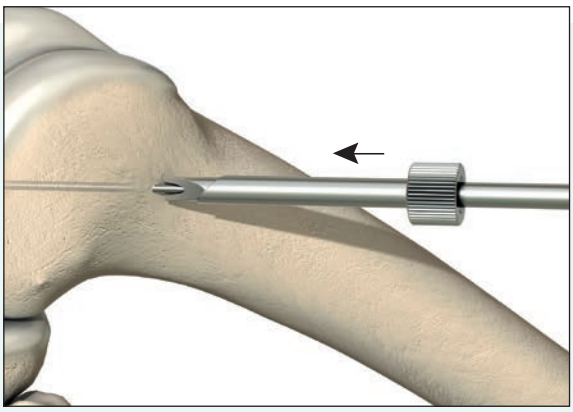


Fig. 18

Advancing the dilatator sleeve

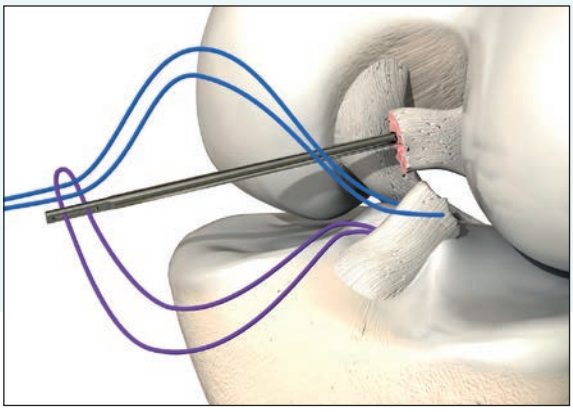


Fig. 19

Transfer of the threads
The shuttle thread [purple] is threaded into the lug of the long guide wire. The retaining threads [blue] are then placed in the loop of the shuttle thread [purple].

Important: The retaining threads [blue] should form a loop to avoid any traction on the tibial cruciate ligament stump when they are pulled proximally.

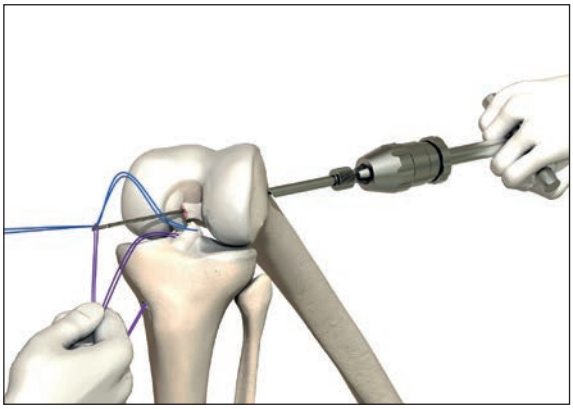


Fig. 20

The long guide wire [with lug] is then carefully pulled upward through the femur along with all threads.

Note: The chuck with T-handle is well-suited for this step.

Important: Hold the shuttle thread [purple] in place manually so that the retaining threads [blue] are fixated on the long guide wire [with lug].

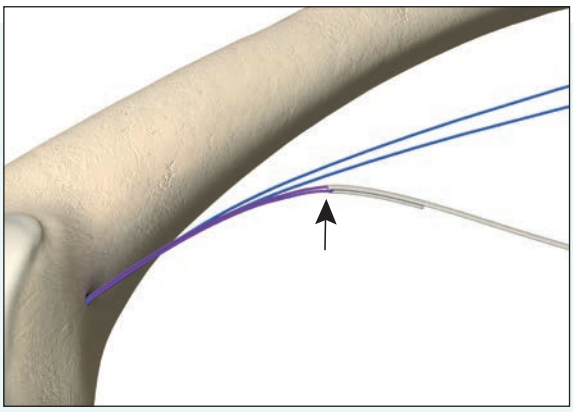


Fig. 21

Threading in the Ligamys braid
The thin part of the white implant braid is threaded into the loop of the shuttle thread [purple].

Important: Thread the thin part of the white implant braid up to maximally half its length into the shuttle thread [purple].

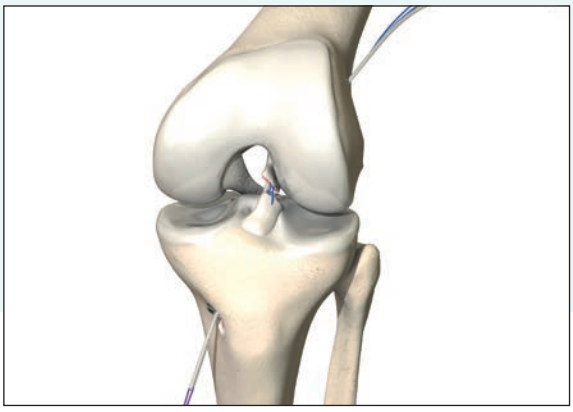


Fig. 22

Pulling through the Ligamys braid
The white implant braid is guided through the joint (transfemorally and transtibially) and through the monobloc to the outside.

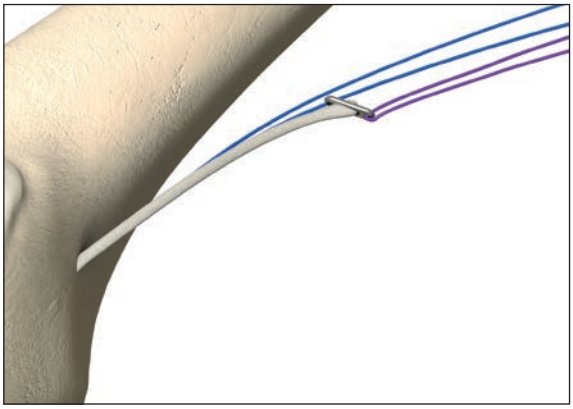


Fig. 23

Positioning the button
Threading in the shuttle thread [purple] on the button. **Important:** Remove only at the end of the operation!

If necessary, it can be used to pull back the Ligamys braid.

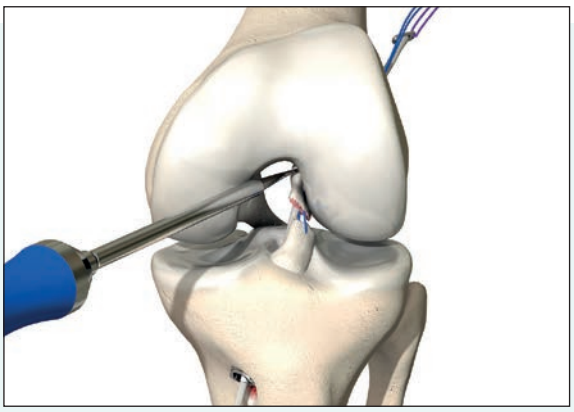


Fig. 24

Microfracturing in the notch
Using the microfracturing awl tiny fractures in the underlying bone are created at the cruciate ligament's femoral insertion point, releasing blood and bone marrow containing stems cells **(healing response)**.

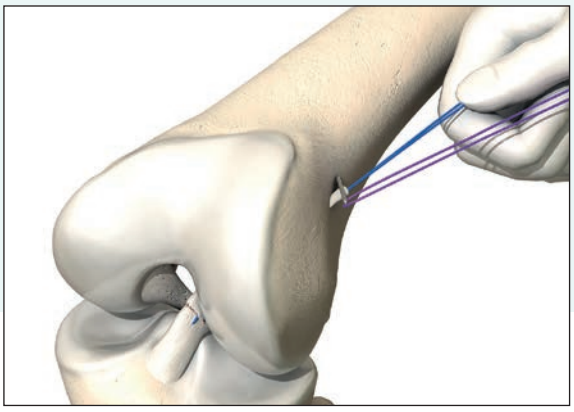


Fig. 25

Tighten the retaining threads [blue] by pulling them proximally while simultaneously pulling the Ligamys braid distally.

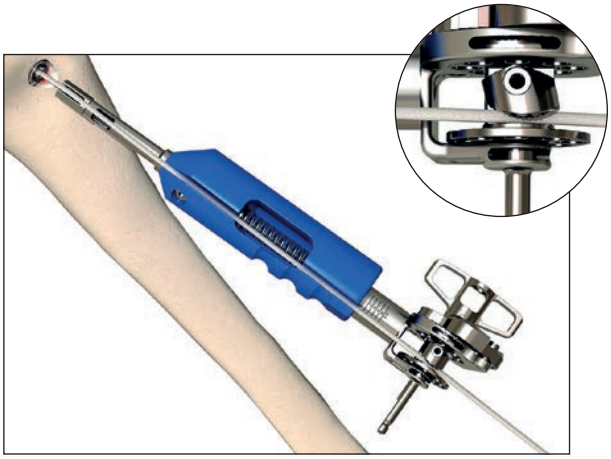


Fig. 26

The white Ligamys braid is placed in the lock of the tensioner and the tensioner is guided to the monobloc with the braid tensioned.

The tensioner must be guided in the longitudinal axis of the monobloc.

Fig. 27

Important: Correct positioning must be ensured. Incorrect positioning invariably leads to damage of the Ligamys braid.

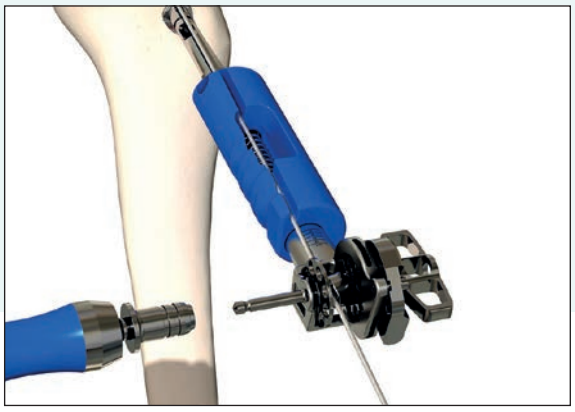


Fig. 28

Safe placement of the button on the femur
Slip the click handle (3,5 Nm) onto the AO coupling of the tensioner.

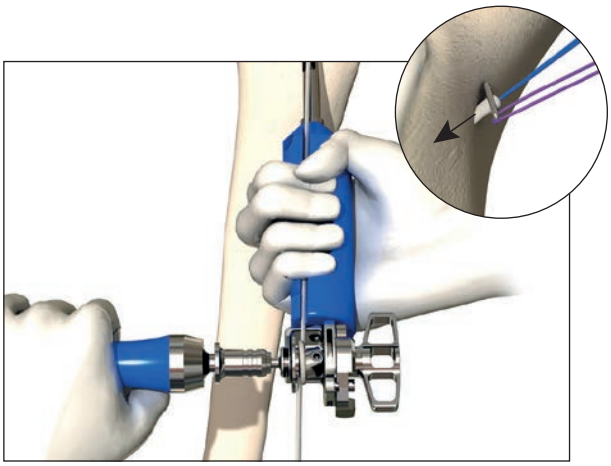


Fig. 29

Step-wise maximum pre-tensioning of the Ligamys braid by turning the click handle (**3 clicks**).

Important: The retaining threads [blue] must be well tightened in opposite direction of the Ligamys braid to keep the tibial stump tensioned (arthroscopic control).

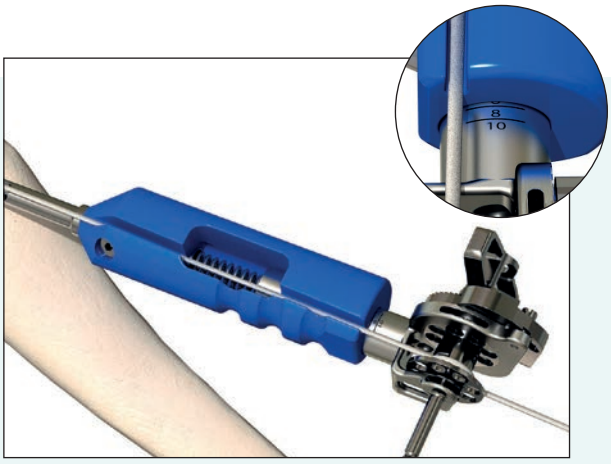


Fig. 30

Pre-tensioning the spring system
Disconnect the click handle

Completely release the tension on the tensioner.

Pre-tension again with the tensioner while the knee joint is in full extension until the desired value on the scale is attained.

Important: Reference value for pre-tensioning: 6 to 8 (this corresponds to an approximate tension of 60 to 80 N on the spring system).

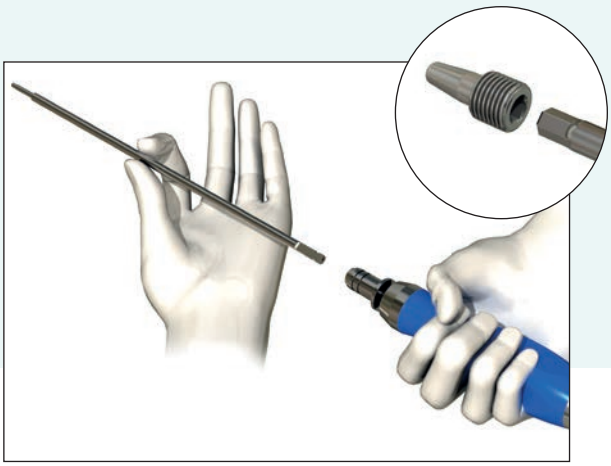


Fig. 31

Preparation for screwing in the clamping cone
Connect the AO hexagon head coupling into the click handle and place on the clamping cone.

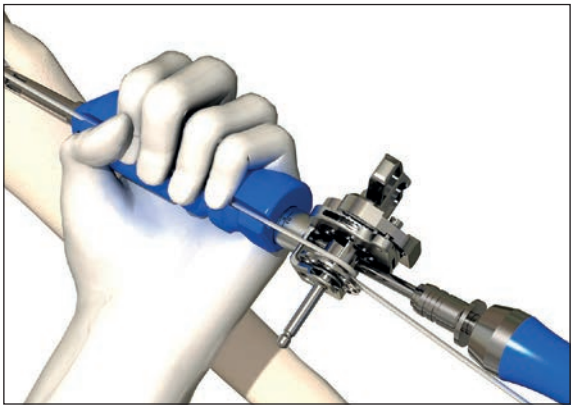


Fig. 32

Fixation of the Ligamys implant
The clamping cone is guided through the pretensioned tensioner and turned into the monobloc (3 clicks).

While turning in the clamping cone, the tensioner must be held against rotation to keep the monobloc from rotating along.

The Ligamys braid is now fixated in the dynamic spring system of the monobloc.

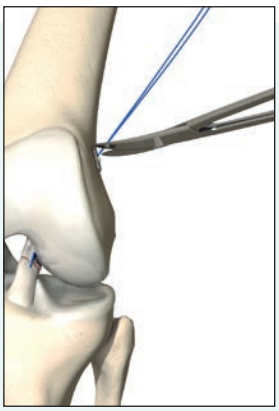


Fig. 33

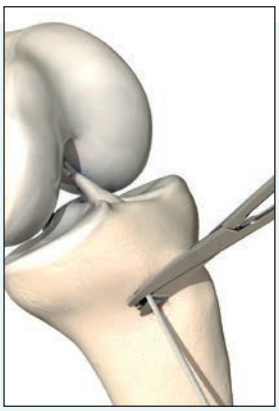


Fig. 34

Completion of the operation
Pull out the shuttle thread [purple] on the button and detach the holding braid [blue].

Cut off the white Ligamys braid on the monobloc.

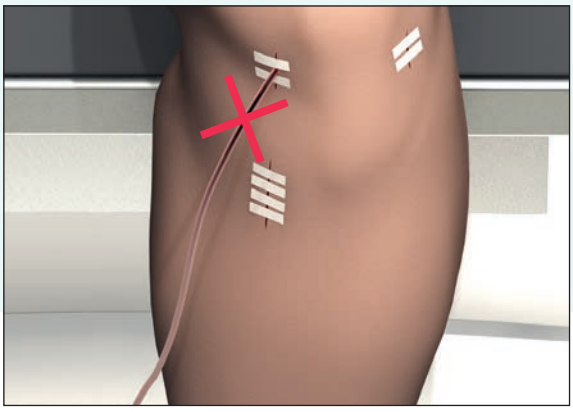


Fig. 35

Wound closure
Intracutaneous suture + steri-strips

Important: To make optimal use of the cell potential in the knee joint, no drainage should be applied.

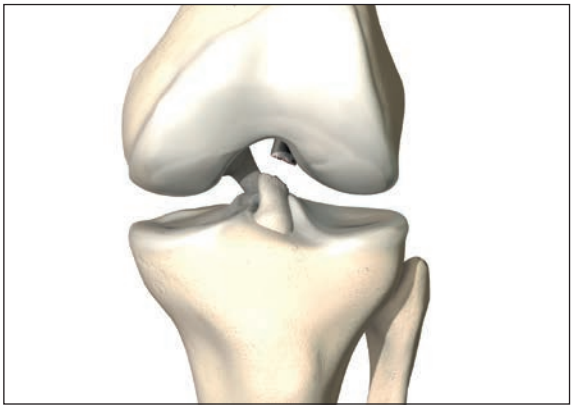


Fig. 36 Ruptured anterior cruciate ligament

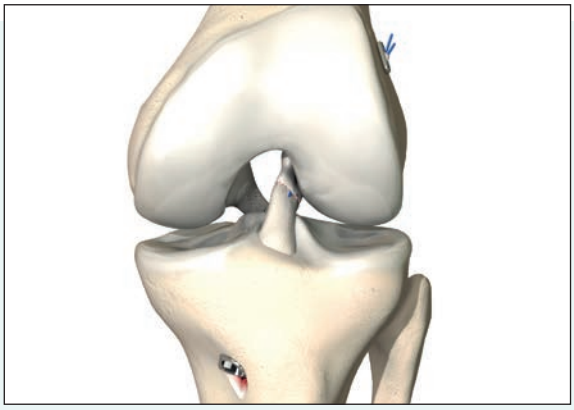


Fig. 37 Ligamys implantation

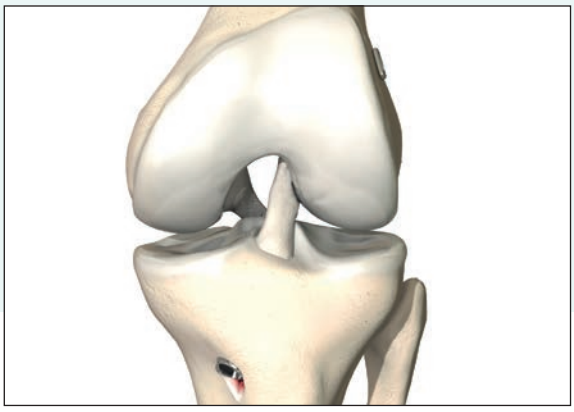


Fig. 38 Regeneration and stable cicatrisation

Preservation and regeneration of the ruptured cruciate ligament structure

If the recommended rehabilitation protocol is followed, the two stumps of the ruptured cruciate ligament will cicatrise naturally.

The monobloc may be removed, if necessary, no sooner than 6 months post surgery.

Important: For removal, the specially designed extraction instruments with red handles should be used.

5. Implants and instruments

Ligamys

Ligamys implant
Ligamys-Braid with button
Monobloc
Clamping Cone

Ligamys Backup-Set
Ligamys-Braid with button
Clamping Cone

Ligamys instrument set
Ligamys tray
Ligamys tray lid
Suturing forceps
Tibia targeting device
Ligamys Drill bit 6/7 mm cannulated [1)]
Ligamys Drill bit 10 mm cannulated [1)]
Ligamys screwdriver
Suture passer
Femur targeting device
Soft tissue dilatator
Dilatator sleeve
Chuck with T handle
Microfracturing awl
Tensioner
Click handle 3,5 Nm with AO connector [2)]
AO-coupling hexagonal bar

[1)] Replacement of the drill after 30 operations
[2)] Replacement of the click handle after 3 years

Medical disposables
Pack of 10 Ligamys guide wires 2.4 mm

Ligamys instruments for implant extraction
Ligamys monoblock extractor
Ligamys clamping cone extractor

6. Rehabilitation

Today, physical activity and sports play an important role in our daily lives. An intact cruciate ligament is one of the prerequisites for maintaining the long-lasting stability and proprioception required for such activity.

When a cruciate ligament is ruptured, patients wish to preserve the injured ligament if possible. Previously, the surgical treatment of cruciate ligament ruptures could not offer this option because the injured ligament was usually removed and replaced by an autologous graft.

In 2009 Swiss orthopaedists developed a new kind of treatment, which made it possible to preserve a ruptured cruciate ligament and enable it to grow back together.

Within 21 days of the rupture, the injured ligament structure is dynamically stabilised with a Ligamys implant. Subsequently, the ligament can regenerate and cicatrize whilst proprioception is preserved. With this innovative medical technology, it is no longer necessary to replace the injured cruciate ligament with a tendon graft.

Current experience shows that the Ligamys implant leads to faster rehabilitation than conventional cruciate ligament reconstruction. Immediate intraligamentary stabilisation makes it possible to load the knee sooner, as exemplified by the protocol described below. The period of rehabilitation varies depending on the patient's initial condition and desired future sporting activities.

A well-developed musculature and a high degree of muscle power act as natural protective factors for the anterior cruciate ligament; they protect this structure against overload in critical situations. The aim is to gradually re-establish this protective mechanism after an injury. A distinction should be made between isolated cruciate ligament ruptures and injuries that additionally involve damage and suturing of the meniscus.

In case of a concomitant treatment – for instance meniscus suture – a more restrictive rehab protocol may be advised.

Resuming the previous type of sports activity should be possible within 18–20 weeks after Ligamys implantation. However, clearance for such activity may be given only if the respective test battery (page 23) is successfully completed.

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Rehabilitation: With isolated ACL rupture

The following principles apply:

- weight bearing depending on the level of discomfort
- no training of the M. quadriceps (extensor) in the open muscle chain (2)(3)
- activation of the musculature from day 5 in order to preserve the protective function

- The indications below should be regarded as guidelines; time frames may vary depending on the case history and/or the presence of concomitant injuries
- Patients should inform the surgeon and the physiotherapist about their preferred types of sports so that the course of rehabilitation can be adjusted accordingly

Phase 1 from day 1

Priorities: reduction of swelling, pain control, learning independent mobilisation

Goals:

- reduction of activities to a minimum in order to enable adhesion of the cruciate ligament stumps
- control of swelling
- fixed orthesis in an extended position (1)(2)
- physiotherapy for independent mobilisation (4)
- learning safety precautions (avoiding anterior drawer movement, quadriceps/hamstring tension, co-contraction)
- walking and climbing stairs on crutches with weight bearing depending on level of discomfort (5)–(7)

Phase 2 from day 5

Priorities: start of active physiotherapy without orthesis

Goals:

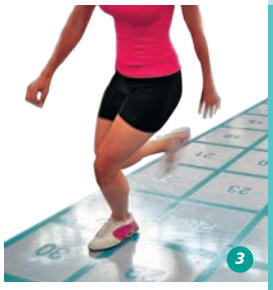
- knee joint mobility, free flexion, extension up to 0° **(caution: avoid overextension!)** (1)
- neuromuscular coordination (2)
- innervation training of extensors in a long-sitting position (3)
- prevention of major muscle atrophy, start of strength-endurance training for neural facilitation (complex method) (4)
- Promoting muscular elasticity (5)

Phase 3 from week 3

Priorities: muscle growth, sensomotoric control

Goals:

- mobility by end of week 6, free flexion/extension, at least 90°/0°/0° (1)
- muscle development training (hypertrophy) of the entire leg musculature, especially the quadriceps (in closed muscle chain) in an initially near-extended position, as well as the hamstrings and the calf and hip museles (2)–(3)
- active in-line axial stabilisation in a single-leg stance on a stable and later on an unstable surface (4)



Phase 4 from week 6

Priorities: unlimited control of movement, bilaterally equal strength

Goals:

- continued rehabilitation until capacity of unlimited movement is attained, including critical situations during normal everyday movements (1)
- maximum strength (2)
- optimal coordination and stabilisation, including when in moving (running) (3)

Phase 5 from week 10

Priorities: jumps, sports-specific training

Goals:

- jumping ABC (1)–(4)
- optimal stabilisation when changing direction and making quick movements
- build up to sports-specific training (5)–(7)
- vibration training now permitted (recommended: Zeptor)

Test battery Weeks 16 and 24

After completion of physiotherapeutic treatment

Goal: return to sport

Tests:

- Lysholm score (for subjective assessment)
- hop tests*
- range-of-motion measurement
- pain measurement (visual analogue scale VAS)
- strength test (on leg press: at least 90 % of the healthy leg)

* *Hop tests: single limb hop test, timed 6 m hop test, triple hop for distance, crossover hop for distance*

Calculation of lower limb symmetry:

Distance measurement = affected side / healthy side x 100 % ➔ *min. score 85 %*

Time measurement = affected side / healthy side x 100 % ➔ *min. score 85 %*

Sporting activities

With optimal rehabilitation and good muscular stabilisation of the knee, sporting activities may be started as follows:

Cycling (on roads)	from week 6
Jogging (with good quality footwear)	from week 10
Skiing/snowboarding	from month 5*
Stop-and-go sports such as tennis, squash etc.	
Contact sports such as soccer, handball, martial arts etc.	

* Previous results have shown that some patients may resume the desired sporting activity sooner (Important: successful hop test)

Summary of rehabilitation protocol

With isolated ACL rupture

Level of exercise	
	Exercise depending on level of discomfort
From day 1	Reduction of activities to a minimum
From day 5	Start of active physiotherapy, free flexion, extension up to 0°
From week 3	Mobility up to end of week 6: free flexion/extension, at least 90°/0°/0°
From week 6	Unlimited control of movement
From week 10	Sports-specific training, jumps
Orthesis	
From day 1	Fixed orthesis in an extended position
From day 5	Physiotherapy without orthesis
Crutches	
From day 1	Walking and climbing stairs with crutches with loads depending on level of discomfort
Resumption of sports	(after test battery in week 20 or 28, respectively)
From week 6	Cycling (on roads)
From week 10	Jogging (with good quality footwear)
From month 5	Skiing, snowboarding, stop-and-go sports (tennis, squash etc.), contact sports (soccer, handball, martial arts etc.)

In case of a concomitant treatment – for instance meniscus repair – a more restrictive rehab protocol may be advised.

Note

Note

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