



Ligamys

Preservation of the freshly ruptured anterior cruciate ligament

Cruciate ligament rupture – what next?

A tear (rupture) of the anterior cruciate ligament is the most frequent ligament injury of the knee joint. Nearly three quarters of all cruciate ligament ruptures happen during athletic activities.¹

This injury occurs when the knee is twisted while in a flexed position and is thus overstretched. Cruciate ligament rupture frequently occurs e.g. during football, when the knee of the supporting leg undergoes such a rotational movement during a kick.²

In the past, ruptured cruciate ligaments could be preserved and healed only in individual cases. In most cases, they were replaced through reconstruction with a graft. On the following pages, we present to you a treatment method leading to the healing of the injured ligament structure.

A ruptured anterior cruciate ligament that requires surgery has good chances of being healed if it is treated immediately after the injury using the Ligamys implant.³

¹ Riss des vorderen Kreuzbandes: Operative oder konservative Behandlung? Merkblatt Schweiz. Akademie der Medizinischen Wissenschaften 2015

² See Gesundheitsdirektion des Kantons Zürich (2009): Die Ruptur des vorderen Kreuzbandes

³ Henle et al., Dynamic Intraligamentary Stabilization (DIS) for treatment of acute anterior cruciate ligament ruptures: case series experience of the first three years. BMC Musculoskeletal Disorders (2015) Feb 13;16:27

Sports with a high risk of cruciate ligament ruptures



Fig. Rupture of the anterior cruciate ligament

The anterior cruciate ligament

Together with the posterior cruciate ligament, the collateral ligaments and the thigh muscles, the anterior cruciate ligament stabilises the knee joint. It limits rotational movements, protects the knee from hyperextension, and during flexion it prevents the lower leg from shifting forward with respect to the thigh.

Nerve fibres inside the cruciate ligament constantly signal the joint position and the forces acting on the ligament. Due to its sensitivity, the cruciate ligament actively supports control of motion in the knee joint.

Therefore, a cruciate ligament rupture impairs the precise control of knee movements in addition to the mechanical stability of the knee.

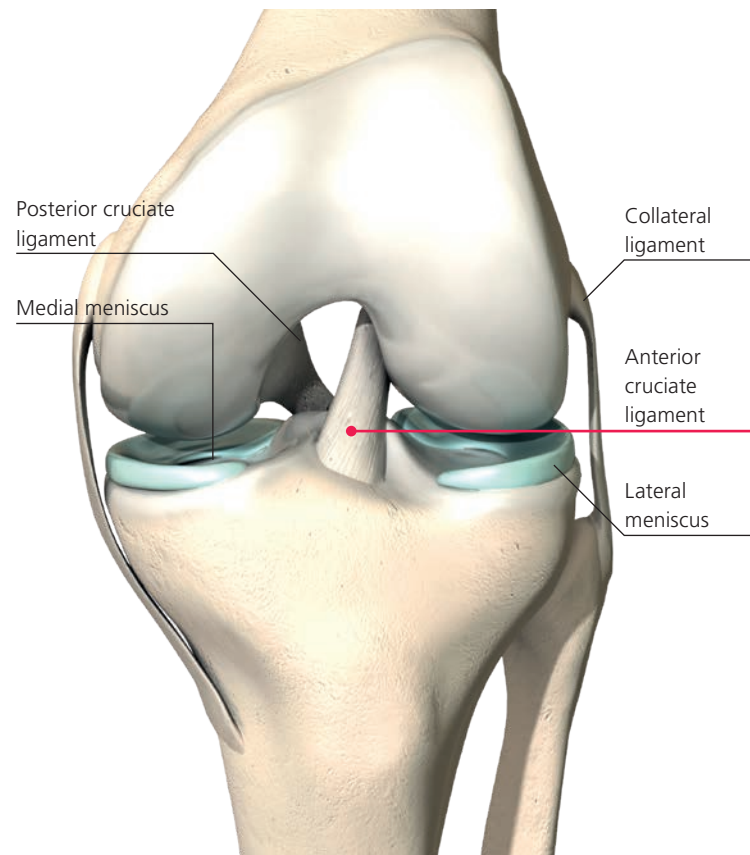


Fig. Schematic illustration of the knee joint

Conventional treatment methods

Two standard treatment options are primarily used to treat a cruciate ligament rupture.

Conservative treatment (without surgery)

In cruciate ligament patients with little loss of stability and limited sporting activities, surgery can generally be avoided initially. Instead, specific training of the thigh muscles is used in an attempt to achieve sufficient stability for the affected knee.

Cruciate ligament reconstruction

During arthroscopic surgery, the ruptured cruciate ligament is removed and replaced by a tendon from the patient's own body or a foreign tendon. In this process, surgery is performed at two sites: on the knee and at the site from which the tendon is taken.

Cruciate ligament reconstruction, also known as ligamentoplasty, restores the stability of the knee joint, but rarely restores full sensitivity. Therefore, knee function and the feel of the joint may consequently be perceived by patients as altered.

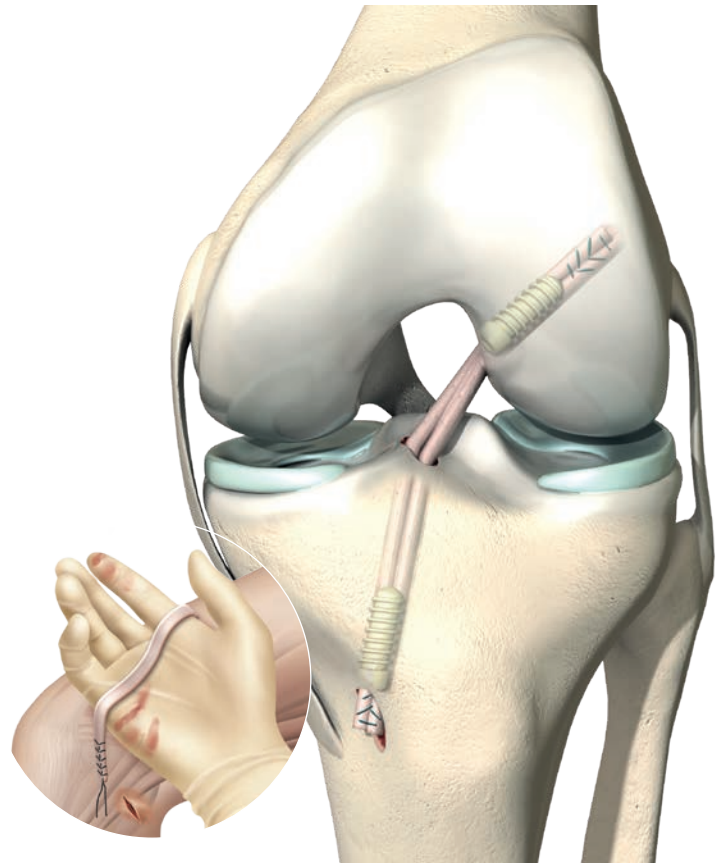


Fig. Surgically removed cruciate ligament graft and subsequent fixation with screws

Ligamys – Preservation of the freshly ruptured anterior cruciate ligament

Ligamys is a surgical implant for the treatment of fresh ruptures of the anterior cruciate ligament. It relieves and stabilises the knee directly and allows healing of the ruptured ligament, which is returned to its biological origin using bioresorbable threads.

The Ligamys implant consists of a thin polyethylene thread, a metal plate and a metal sleeve with a spring element, and at the end of the surgery it is anchored in the tibia under defined pre-tensioning.

Immediately after insertion, the Ligamys implant ensures mechanical stability throughout the entire range of motion of the knee. As a result, the injured cruciate ligament, which is precisely aligned once again, is appropriately relieved so that it can grow back together stably.

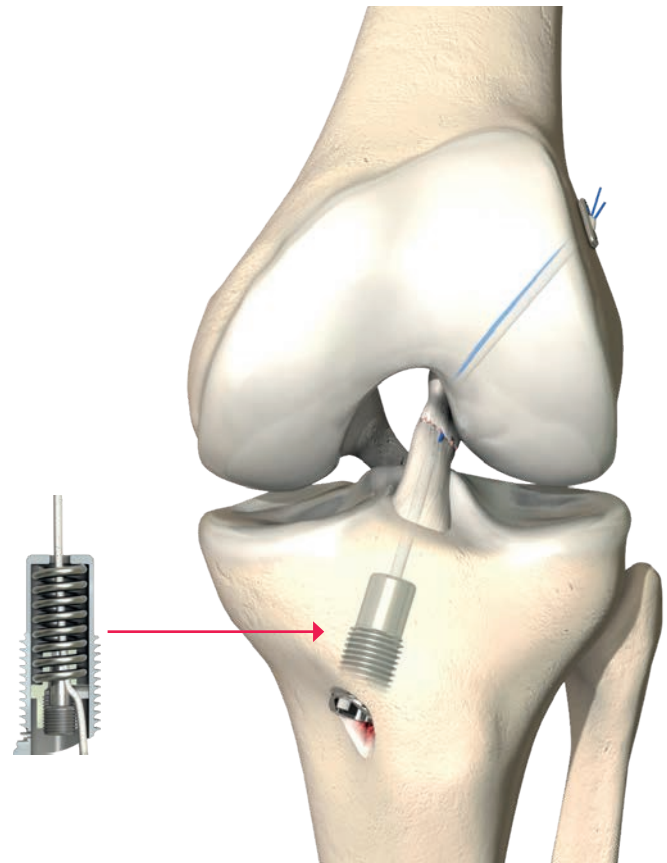


Fig. Dynamic stabilisation with a Ligamys implant

Ligamys

In addition, the need to remove a graft from the patient's own body in the case of cruciate ligament reconstructions is eliminated. The surgical procedure in the case of Ligamys is thus less extensive.

Studies demonstrate that rehabilitation with a Ligamys implant is rapid; it lasts six months on average. The original functionality of the knee joint is nearly completely restored – an aspect which is particularly important for ambitious athletes.⁴

Ligamys is authorised for the treatment of fresh ruptures of the anterior cruciate ligament which are maximally 21 days old. A current list of hospitals that implant Ligamys can be found on the website: **www.ligamys.com**



Fig. Ligamys implant

⁴ Back to Sports 6 Monate nach biologischer Selbstheilung der vorderen Kreuzbandruptur. Bieri, 2014 AGA-Poster.

Surgical procedure with Ligamys

Ligamys is inserted at the start of a brief inpatient hospitalisation which generally does not exceed two days. The surgery is performed using a special camera and fine instruments, so only small scars remain.

During the procedure the metal component incorporating a spring mechanism is inserted into the upper part of the tibia. Then the polyethylene thread is anchored in the femur, guided through a 2.4-mm drill hole to the tibia and secured with specified tension in the spring system. The femur and tibia can now no longer shift relative to one another, even during movements of the knee joint. The knee is stable again – an important precondition for self-healing of the cruciate ligament.

The two cruciate ligament stumps are not sutured but instead only brought together so that they can grow back together without any tensile strain. In addition, small perforations in the non-weight-bearing area of the femur promote healing.

The surgery takes about 45 minutes and can be performed under regional or general anaesthesia. The metal sleeve can be removed from the tibia about six months after the surgery (see illustration on page 9).

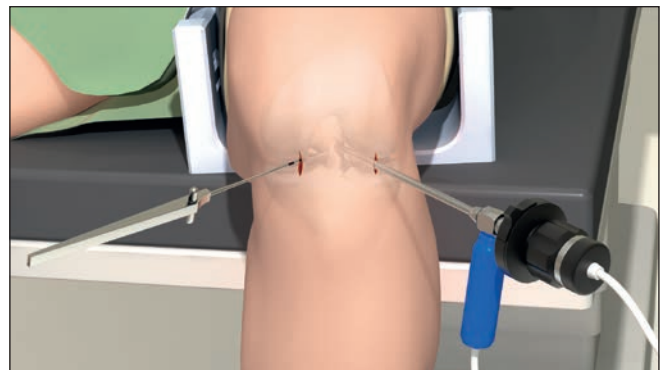


Fig. Instrument (left) and arthroscopy camera (right)

When can a Ligamys implant be used?

Ligamys can be used for a first-time rupture of the anterior cruciate ligament. **However, the surgery must be performed within the first three weeks after the accident, since a patient's biological healing potential decreases from day to day.** The decision regarding treatment with Ligamys should therefore be made directly after the accident.

The healing process

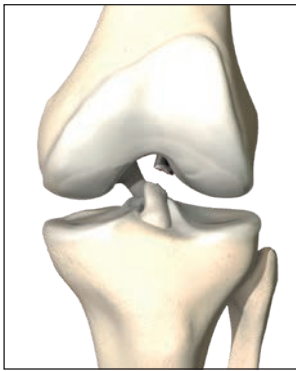


Fig. Cruciate ligament rupture

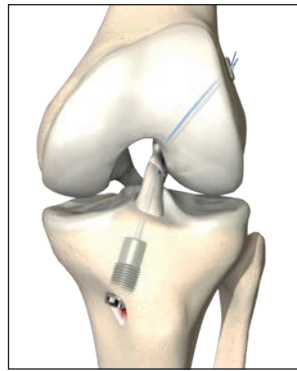


Fig. Treatment and preservation of the anterior cruciate ligament

Post-treatment/rehabilitation

The surgery is only the first step in the treatment of a cruciate ligament rupture. The second step consists of comprehensive rehabilitation, which normally takes six months.

After four days in a traction splint, training starts on the 5th day. By this time, the knee joint may already be moved over its full range of motion again. The training focuses on building up strength and muscular guidance of the movements in the knee joint. Strong musculature protects the cruciate ligament during the healing phase and beyond.

Special exercises, e.g. on the trampoline, help train proprioception, the unconscious internal perception of position and load bearing of the joint. The exercises should stimulate the nerves of the cruciate ligament to bridge the torn area and resume their original function for precise control of the knee joint muscles.

The rehabilitation phase takes about six to twelve months. During this time, the knee can be reintroduced to athletic stress. Inner healing takes time, and the healing process is individually different. After you have passed the Back to Sports test, you can return to your normal training routine. The test consists of four exercises that assess the strength and mobility of the knee.

All times indicated in this brochure are merely orientation values, for the individual healing process depends on the severity of the injury, the training condition prior to the cruciate ligament rupture, as well as the patient's athletic goals. The doctor's or physical therapist's specifications are always authoritative.

A separate brochure with a detailed rehabilitation programme – as a recommendation for physical therapists – can be obtained from the attending doctor or from the manufacturer.

Frequently asked questions

What symptoms are indicative of a rupture of the anterior cruciate ligament?

A rupture of the anterior cruciate ligament can often cause a sound similar to the crack of a whip. Typical symptoms of the injury are knee swelling, bruising in the joint, pain and instability.

How is a cruciate ligament rupture diagnosed?

Along with the symptoms of pain, swelling, bruising and instability, possible shifting of the lower leg in relation to the thigh indicates a cruciate ligament rupture. This shifting is investigated by the doctor using the «drawer test». X-ray and magnetic resonance imaging (MRI) help confirm the diagnosis.

When can Ligamys be used in my case?

Within 21 days after a first-time rupture of the anterior cruciate ligament and according to additional assessment by the doctor.

Can the Ligamys implant be felt in the tibial bone?

In most patients, the metal component in the tibia (mono-

block) does not cause any significant impairments. In individual cases, a small bump on the anterior edge of the tibia can be felt. This is not problematic and is completely normal.

Does the Ligamys implant remain in the joint over the long term?

All components of the implant may be left in the body. The metal component can be removed in a minor procedure after healing has completed. The polyethylene thread is left in place. The regenerated cruciate ligament generally fuses with this thread.

What materials is Ligamys made of?

Ligamys is made of materials which have been proven for years in orthopaedics. The thread is made of polyethylene, and the plate at the upper end of titanium. The metal component for the tibia is made of medical implant steel. In individual cases, hypersensitive reactions to metal materials may occur. Please inform your attending doctor if you know you have a metal allergy.

Can MRI examinations be performed in the future on patients with a Ligamys implant?

Yes, MRI examinations are possible under defined conditions. These are described in the instructions for use of the product, which can be downloaded from the website www.ligamys.com.

What should be borne in mind in the case of Ligamys, in comparison to conventional cruciate ligament reconstruction?

In contrast to conventional cruciate ligament reconstruction, which can still be performed at a later time, the Ligamys implant must be inserted no later than three weeks after a cruciate ligament rupture. If the treatment with Ligamys does not lead to the desired healing of the cruciate ligament in the individual case, conventional cruciate ligament reconstruction with a graft can be performed in a subsequent procedure.

Can Ligamys be used for other ligament ruptures as well?

No. At present, the Ligamys treatment method is limited to the anterior cruciate ligament.

Is the ruptured cruciate ligament sutured together?

No. The knee is dynamically stabilised solely through the Ligamys implant. The ruptured ends of the cruciate ligament are brought together through bioresorbable support threads, so that self-healing can occur at the correct site.

What happens during the surgery?

The surgery is performed during an arthroscopy using a small camera and fine instruments. The procedure can be performed under regional or general anaesthesia and takes about 45 minutes. The length of the inpatient hospital stay depends on the extent of the injury and the healing process. In general, Ligamys patients spend two days in the hospital.

How large will the knee scars be?

A total of four small incisions are made. Both of the access incisions on the knee joint are each approx. 1.5 cm long. For the implantation of the metal spring component (monoblock) in the tibia, an approx. 4-cm long incision is required. A small incision is made in the thigh to retract the Ligamys thread. In general, the scars are hardly visible after healing has completed.

How long does it take for the cruciate ligament to grow back together?

This varies from patient to patient. Normally the ligament heals sufficiently within six months to allow full participation in sports again.

Will I be able to play football or go skiing again afterwards?

Ideally yes. The vast majority of patients who were treated with a Ligamys implant were able to resume their original athletic activity in full³.

In which hospital and by which doctor will Ligamys be implanted?

Ligamys is applied only by experienced doctors who have undergone training in the special surgical technique. Ruptures of the anterior cruciate ligament can be treated with Ligamys at hospitals specialising in this technique. The current list of surgical centres can be found at:

www.ligamys.com

³ Henle et al., Dynamic Intraligamentary Stabilization (DIS) for treatment of acute anterior cruciate ligament ruptures: case series experience of the first three years. BMC Musculoskeletal Disorders (2015) Feb 13;16:27

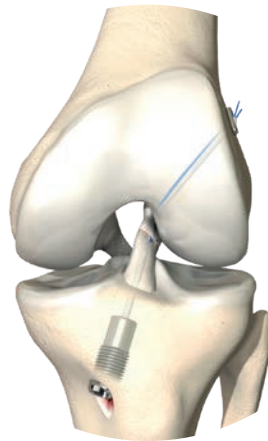
Ligamys – Advancement in cruciate ligament surgery

The Ligamys method for the treatment of fresh ruptures of the anterior cruciate ligament was developed under the direction of Prof. Dr. med. Stefan Egli and Dr. med. Sandro Kohl in collaboration with the Swiss company Mathys Ltd Bettlach.

The technology to preserve the anterior cruciate ligament was awarded the renowned German Innovation Prize of the German Association for Orthopaedics and Trauma Surgery in 2011.



Cruciate ligament rupture



Implantation



Preservation



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