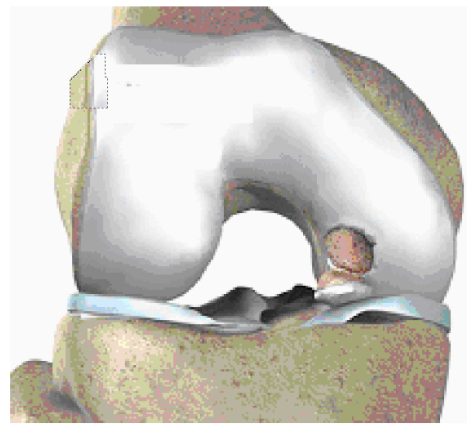
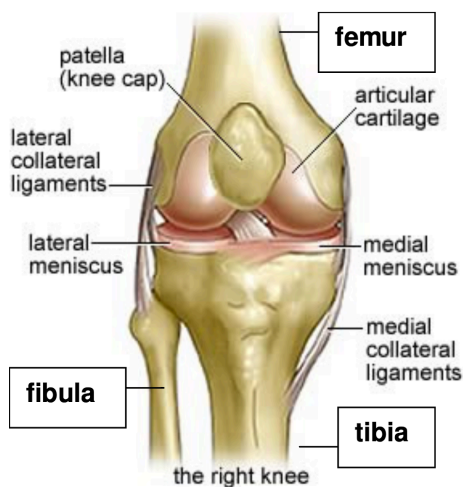


# Patient Information on Autologous Chondrocyte Implantation for Articular Cartilage Lesion

This booklet gives you information on autologous chondrocyte implantation for articular cartilage lesion.

## Anatomy



The knee is a complicated joint between the femur (thigh bone) and tibia (shin bone). The ends of these two bones are covered with a layer of articular cartilage.

This is similar to the cartilage that you will have seen at the end of a chicken bone. This smooth, shiny surface ensures that when two bone ends meet they glide and slide over each other without rubbing.

This reduces wear and tear stresses across the joint surfaces. This layer of articular cartilage can wear away over time; commonly known as osteoarthritis.

It can also be damaged through injury in a more localised area (known as a lesion or defect) and can give symptoms such as pain, swelling or giving way of the knee.

If you have injured this cartilage layer you will have a roughened area in the normally smooth surface. This occurs most commonly on the ends of the femur (thigh bone) but can occur behind the patella (knee cap) and on the top surface of the tibia (shin bone) as these areas all have articular cartilage covering them.

## Autologous Chondrocyte Implantation – ChondroCelect

ChondroCelect is a cell-based medicinal product for use in autologous chondrocyte implantation in which cells are taken from the patient's own knee, multiplied to reach a large quantity, and then re-implanted at the site of the defect. ChondroCelect is indicated for the repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society grades III or IV) in adults.

Treatment with ChondroCelect comprises a two-step surgical procedure. In the first step, a cartilage biopsy is obtained arthroscopically from healthy articular cartilage from a lesser-weight bearing area of the patient's knee. Chondrocytes, the cells that produce and maintain the cartilage matrix, are isolated from the biopsy, expanded in vitro through a process based on cell characterisation, and delivered as a suspension for implantation in the same patient. ChondroCelect can be delivered nine weeks from the day of biopsy.

ChondroCelect was the first cell-based product approved in Europe that successfully completed the entire development track from research through clinical development to European approval and received European Marketing Authorization in October 2009 as the first Advanced Therapy Medicinal Product. ChondroCelect currently benefits from national reimbursement in the Netherlands and Spain. Effective 1 June 2014, the company has entered into a distribution agreement with Sobi (Swedish Orphan Biovitrum AB) for the exclusive marketing and distribution rights with respect to ChondroCelect in Europe (excluding Finland, where TiGenix has a pre-existing distribution agreement with Finnish Red Cross Blood Services), the Middle East and North Africa.

The following images demonstrate the development of ACI treatment for a cartilage injury:



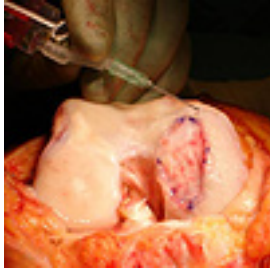
The chondral defect is debrided to remove all unstable cartilage.

Close examination of the trimmed chondral defect reveals evidence of the previous unsuccessful microfracture.



**First generation technique:**

The periosteal membrane is harvested and then sutured to the edges of the chondral defect.



**Second generation technique:**

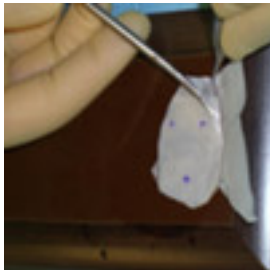
Stitching the patch is completed.

This image illustrates a periosteal patch, but a porcine origin membrane would be used in an identical manner.



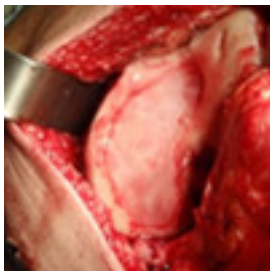
The sutured patch is now sealed with fibrin glue

Once sealed the patch is tested for water-tightness and the patient's own cells are injected beneath it.



**Third generation technique:**

The porcine membrane with the patient's own cells implanted in its deep surface being cut to fit the defect perfectly.

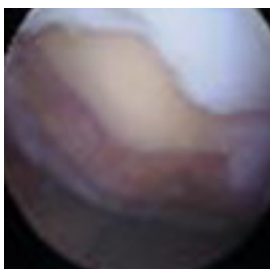


By using fibrin sealant instead of suturing, although this is a larger cartilage defect it has been repaired with using a much smaller approach.

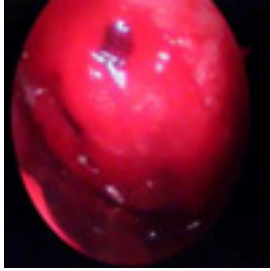


**Arthroscopic technique:**

It is now possible for some cartilage defects to insert and fix the membrane by keyhole surgery.



A cartilage defect on the medial femoral condyle after removing a failed microfracture showing a central osteophyte (bony bump).



The MACI membrane fixed in place with fibrin sealant arthroscopically, after the central osteophyte had been removed.



Arthroscopic appearance of a MACI graft at four months

For further information please visit:

<http://www.tigenix.com/en/page/150/chondroselect>

<http://www.kneeclinic.info/download/CKCGHCFTCCIR rehabGuide040612.pdf>

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