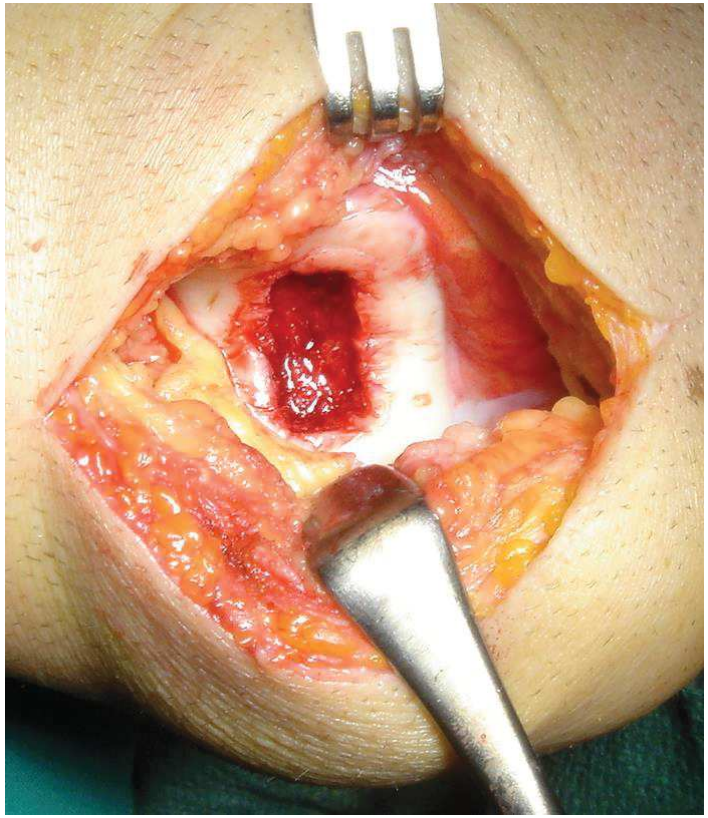
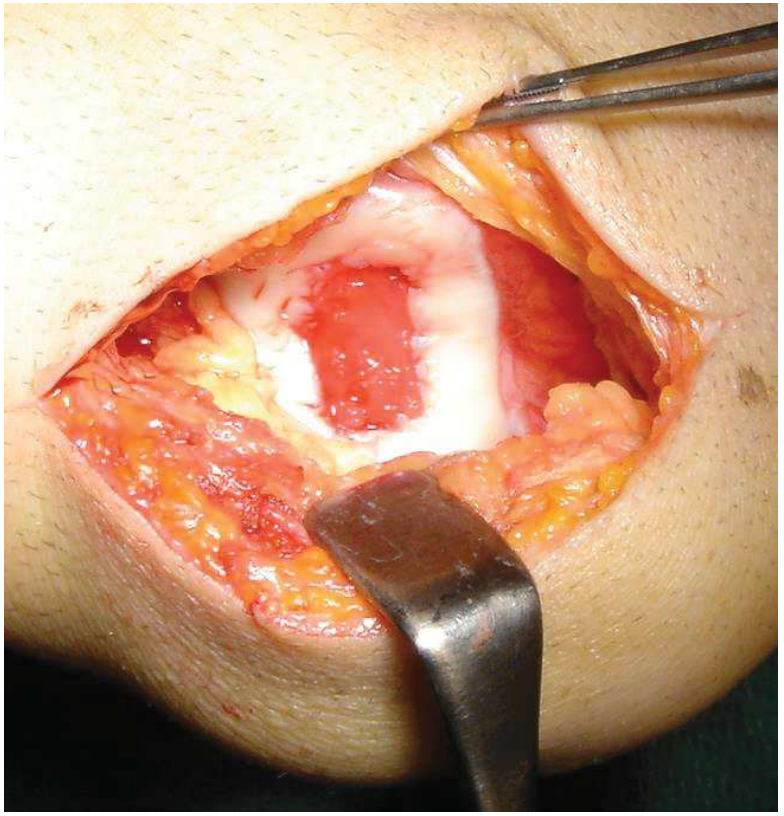
MaioRegen

Biojoint System

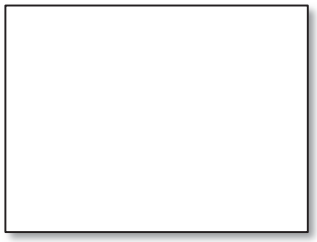
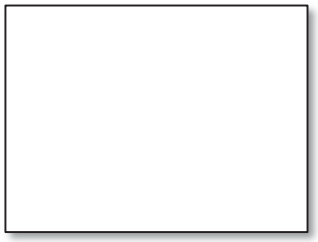
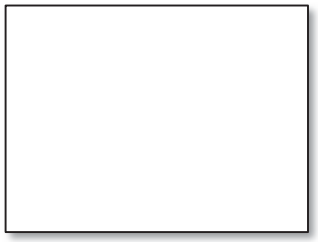
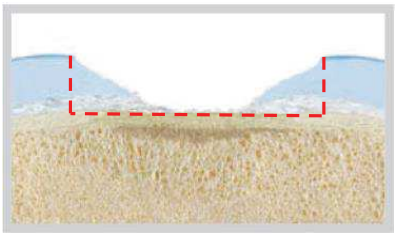
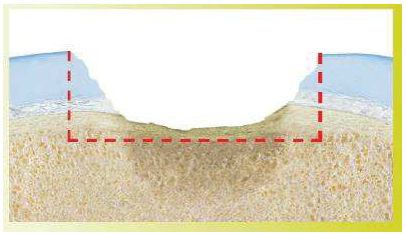
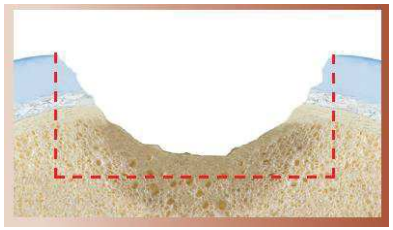
Surgical Technique

Open Surgery of the Knee





Open Surgery: Available Sizes

	MaioRegen Biojoint System Chondro+	MaioRegen Biojoint System Slim	MaioRegen Biojoint System Prime
2 x 3 cm			
3 x 4 cm			
	Cartilage lesions	Osteochondral lesions with moderate bone involvement	Osteochondral lesions with severe bone involvement
			

Surgical Technique

Steps 1 - 4

Lodging preparation

MaioRegen Biojoint System Slim MaioRegen Biojoint System Prime

Remove the damaged tissue and create a squared, regular-shaped lodging through the use of an osteotome.

Create the lodging according to the device to be implanted (approx. **4 - 5 mm** deep for **Maioregen Slim** or approx. **7 - 8 mm** deep for **Maioregen Prime**).

Make sure the bottom is flat and regular. Evaluate the need for marrow stimulation (e.g. drilling).

Accurately measure the lodging size.

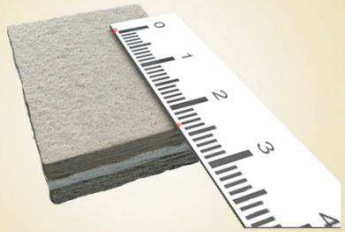
Surgical Technique

MaioRegen BioJoint System Slim
MaioRegen BioJoint System Prime

Steps 5 - 8

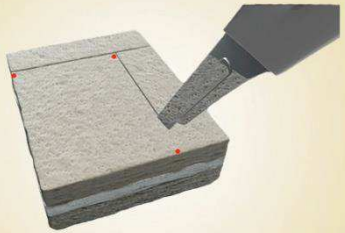
Scaffold preparation

5



Prepare the scaffold according to the site dimension.

6



Use a scalpel to cut the smooth cartilage-like layer of the scaffold.

7

Use surgical scissors to cut the deeper layer(s).

8

Apply few drops of fibrin glue on the scaffold borders to ensure mechanical stability of the implant once in situ.

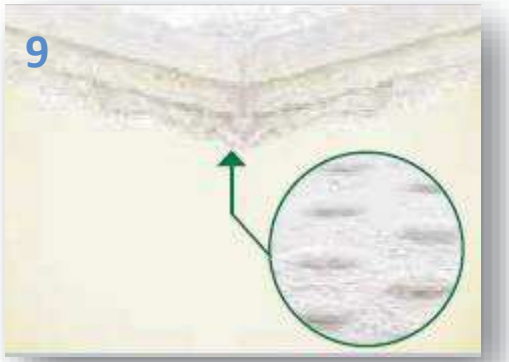
Surgical Technique

Steps 9 - 12

Implantation

MaioRegen Biojoint System Slim

MaioRegen Biojoint System Prime



Identify the bottom layer, characterized by the presence of “bumps”, for the correct orientation of the product.

Insert the scaffold by gentle press-fit, making sure that the bottom layer (“bumps”) gets in contact with the bone floor.

Application of fibrin glue on the upper perimeter is suggested for ensuring adequate mechanical stability.

Perform three flexion/extension cycles in order to verify the stability of the scaffold.

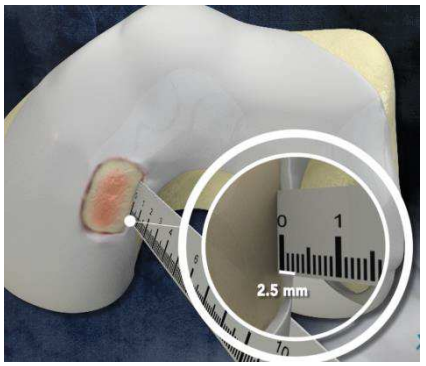
Surgical Technique

MaioRegen Biojoint System Chondro+

Steps 1-4

Lodging Preparation

Use a curette or similar instrument to clean the lesion and to create a lodging for MaioRegen Chondro+.



Lodging depth for MaioRegen Chondro+ must be **2.5 mm deep**.

Perform the appropriate bone marrow stimulation technique (e.g. microfractures).

Accurately measure the lodging size.

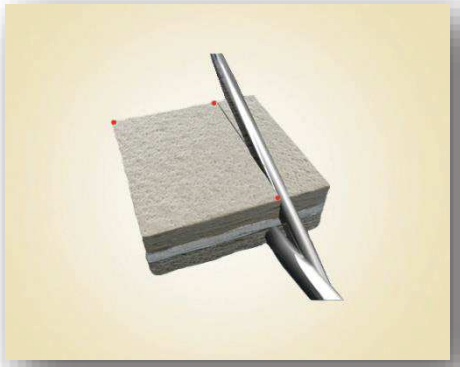
Surgical Technique

MaioRegen
Biojoint System
Chondro+

Steps 5-8

Scaffold preparation and Implantation

Prepare the scaffold according to the site dimension.



Cut the scaffold accordingly

Insert the scaffold by gentle press-fit, making sure that the bottom layer (“bumps”) gets in contact with the bone floor.

Application of fibrin glue on the upper perimeter is suggested for ensuring adequate mechanical stability.

Rehabilitation Protocol

Post-Operative Rehabilitation Program Following Osteochondral Lesion Treatment with MaioRegen.

The objectives of osteochondral lesion treatments are to help tissues reach biological maturity and facilitate the functional recovery of joints.

Biological maturation of tissues can take a long time and will continue for up to two years after treatment. **Functional recovery** is shorter in time and typically achieved a year after treatment. Functional recovery itself is indispensable in reaching the tissue's biological maturation, which is in turn the definitive base for recovery.
Step-by-step rehabilitation with **criteria-based progression rather than fixed time lines** is recommended in order to reach complete functional recovery. Rehabilitation is conducted in the following suitable environments: gym, swimming pool and sports field.

In the **gym**, where the majority of rehabilitation exercises are performed, patients undergo physical therapies and are guided through a range of functional exercises. Once the patient's stitches have been removed, rehabilitation then moves to the **swimming pool**. Reduced effects of gravity allow patients to re-establish their correct gait and to completely recover range of motion and joint flexibility.

Rehabilitation on the **sports field** corresponds to the last phase of our rehabilitation program and is recommended for all types of patients willing to lead an active life. This part of the rehabilitation programme consists of exercises designed for the progressive recovery of walking, articular fluidity, running and sport-specific skills. This last phase is important for physical fitness and the prevention of re-injuries.

Rehabilitation protocol is divided into phases. In order to safely proceed from one stage of the rehabilitation program to another, patients should pass established clinical and functional requirements (green lights). It is worth noting that it is better to remain in one phase for longer than to over-exert yourself and fall back a stage.

How to proceed with rehabilitation.

When is full weight bearing allowed?

- ✓ After their Orthopaedic surgeon's approval
- ✓ Extension is the same in each limb
- ✓ Absence of, or minimal, pain and swelling
- ✓ Recovery of the correct gait

When can patients run on a treadmill?

- ✓ No pain experienced while walking
- ✓ Knee Flexion > 120°
- ✓ Appropriate muscular strength in the thigh and leg

When can patients start rehabilitation on the field?

- ✓ Less than 20% strength deficit found between the quadriceps and hamstrings during isokinetic testing
- ✓ Patient able to run on a treadmill at 8 km/h for 10 mins

When can the patient return to playing sport?

- ✓ Following their orthopaedic surgeon's approval
- ✓ No strength deficit between quadriceps and hamstrings during isokinetic testing
- ✓ Recovery of endurance (threshold test to evaluate aerobic and anaerobic thresholds)
- ✓ After completing their rehabilitation on the field

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MaioRegen

Finceramica
Regenerative surgery

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Rehabilitation Protocol

1st Phase Objectives
Control of pain and swelling
Initial recovery of range of motion
Full load bearing

Weight bearing
- Walking allowed with 2 crutches, no weight bearing, leg locked in extension with a brace
  - for 4 weeks ▲ - for 6 weeks ▲ - for 8 weeks ▲
- Progressive increase of full weight bearing until the complete recovery of correct gait

Pain and swelling
- Physical therapies
- Lymphatic drainage massage
- Use of ice therapy (20 mins 3 times/day)
- Active mobilisation of the ankle

Range of motion
- CPM from the 3rd- 4th day post-op for about 2 weeks
- Self assisted mobilisation of the knee between 0° and 90°
- Passive mobilisation of the patella ▲
- Pendulum exercises
- Stretching program for the posterior muscular chain

Strength
- Co-contractions of the quadriceps
- Isometric contractions of the quadriceps
- Electrostimulation of the quadriceps
- Eccentric strengthening of the triceps muscle

In this phase, therapies will be performed in the gym before the swimming pool once stitches are removed.

Criteria for progression to the 2nd phase
- ✓ Surgeon's approval
- ✓ Absence of, or minimal pain and swelling
- ✓ Full knee extension
- ✓ Knee flexion at 90°
- ✓ Recovery of the correct gait cycle

2st Phase Objectives
Progressive recovery of range of motion
Progressive recovery of activities for daily life
Progressive recovery of strength

Weight bearing
- Full weight bearing
  If the knee begins to swell, reduce daily activity

Pain and swelling
- Physical therapies
- Lymphatic drainage massage
- Use of ice therapy (20 mins, 3 times/day)

Range of motion
- Mobilisation of the patella
- Maintaining of extension
- Active mobilisation with heel reaching the buttock
- Stretching program for the posterior muscular chain

Strength
- Reinforce quadricep muscles in the hip
- Eccentric leg press
- Eccentric strengthening of the triceps in eccentrica

Proprioception
- Proprioceptive exercises with bipodalic load

Aerobic conditioning
- Cycling
- Walking on the treadmill
- Swimming (no breaststroke)

In this phase, therapies are alternatively performed in the gym and swimming pool.

Criteria for progression to the 3nd phase
- ✓ No pain or swelling
- ✓ Complete range of motion
- ✓ Knee flexion at 120°
- ✓ Patient is able to walk on a treadmill for 10 mins without pain or swelling

3st Phase Objectives
Complete recovery of range of motion
Progressive strength recovery
Initial recovery of proprioceptive abilities

Range of motion
- Maintain extension
- Active and passive mobilisation with heel reaching the buttock
- Stretching program for the posterior muscular chain

Strength
- Open kinetic chain strengthening of the quadriceps muscle ▲
- Open kinetic chain strengthening of the quadriceps muscle ▲
- Eccentric strengthening of the triceps muscle
- High speed isokinetic training

Proprioception
- Proprioceptive exercises with monopodalic load

Aerobic conditioning
- Cycling
- Elliptical devices
- Running on a treadmill

In this phase, therapies are performed in the gym.

Criteria for progression to the 4nd phase
- ✓ No pain or swelling
- ✓ Complete range of motion
- ✓ Less than a 20% deficit between the two quadriceps and hamstrings in the isokinetic test
- ✓ Patient able to run on a treadmill at 8km/h for 10mins without pain or swelling

4st Phase Objectives
Progressive recovery of proprioceptive abilities
Complete recovery of strength
Recovery of sport-specific skills

Strength
- Muscular strengthening

Proprioception
- Advanced proprioceptive exercises (uneven ground and trampoline)
- Core stability exercizes

Aerobic conditioning
- Cycling
- Elliptical device
- Running on a treadmill

In this phase therapies are performed alternatively in the gym, and on the field.

Criteria for returning to sport
- ✓ Surgeon's approval
- ✓ No pain or swelling
- ✓ Complete range of motion
- ✓ No difference between the two limbs in isokinetic tests
- ✓ Good endurance, supported by a threshold test

LEGEND: exercises marked with symbols are specific for that condition

▲ Patello-femoral lesions ▲ Osteochondritis Dissecans ▲ Complex lesion (with associated surgery such as an osteotomy)

Pre- & Intra-op recommendations

Make sure that patient adequately fits with indications of MaioRegen or MaioRegen Slim.
Inform the patient about possible surgery outcomes and post-operative rehabilitation and progress.

i. Be sure that lodging is squared, with parallel walls, flat floor and adequate depth (see points 1, 2 and 3)

ii. Use scalpel first and scissors in a second step to cut the scaffold (see points 6 and 7)

iii. Application of fibrin glue on scaffold edges and upper perimeter is suggested to guarantee an adequate primary stability (see points 7 and 11)

iv. Make sure to insert the scaffold with the “bumps” facing the blone floor (see point 9)

v. Once in its lodging, scaffold must be completely below the adjacent cartilage surface. Make sure that corners and edges are not outside the lodging, in order to gurantee the stability of the scaffold

Post-op recommendations

i. Apply drainage (if necessary, i.e. in large lesions with extensive bleeding) on the opposite side of the knee (e.g. contro-lateral condyle).

ii. Strictly follow the suggested post-operative rehabilitation protocol

iii. Do not perform any inspectional arthroscopy for 1-2 months after surgery. Arthroscopies are in any case not recommended for 6 months after surgery.

iv. In case of persistent swelling or other adverse events related to MaioRegen implantation, contact Fin-ceramica to get in contact with a consultant surgeon for clinical suggestions.

MaioRegen

Biojoint System

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regenerative surgery

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