

Chondro-Gide®

AMIC® Talus

Autologous Matrix Induced Chondrogenesis



CARTILAGE REGENERATION

Cartilage Lesions of the Talus

Cartilage lesions of the talus are focal injuries of the articular cartilage, where the subchondral plate and the subjacent subchondral bone may also be damaged [1]. These osteochondral defects primarily occur as a result of acute and chronic ankle sprains, of repeated microtrauma resulting from chronic instability or of axial malalignment of the hindfoot [2–5]. Persistent load-dependent pain in the ankle joint severely restricts patients in their work and in their leisure activities. The treatment depends on the extent and classification of the defect as well as on the age of the patient [6–8].

Microfracturing as a first-line treatment is only recommended up to a defect size of 1.5 cm² [6, 9, 10]. AMIC® is a surgical treatment option for larger, symptomatic chondral (Outerbridge grade III to IV) or osteochondral lesions (Berndt & Harty grade III to V) [11, 12].

Common Defect Localisation in Osteochondral Lesions [4]



AMIC® – Autologous Matrix Induced Chondrogenesis

Autologous Matrix Induced Chondrogenesis, AMIC®, is an innovative biological surgical procedure developed by Geistlich Surgery for the treatment of traumatic chondral and osteochondral lesions. This unique single-step procedure combines the microfracturing method, which is an established first-line treatment, with the application of Chondro-Gide®, a porcine collagen type I/III matrix.

The functional principle of microfracturing is based on the release of multipotent mesenchymal progenitor cells, cytokines and growth factors from the subchondral bone. The super clot formed as a result of haemorrhage is covered and hence stabilised by the Chondro-Gide® matrix and fibrin glue. Chondro-Gide® is a suitable scaffold [13] that enhances the chondrogenic differentiation of mesenchymal stem cells and, in combination with fibrin glue, stimulates chondrocytes to enhance proteoglycan deposition [14].

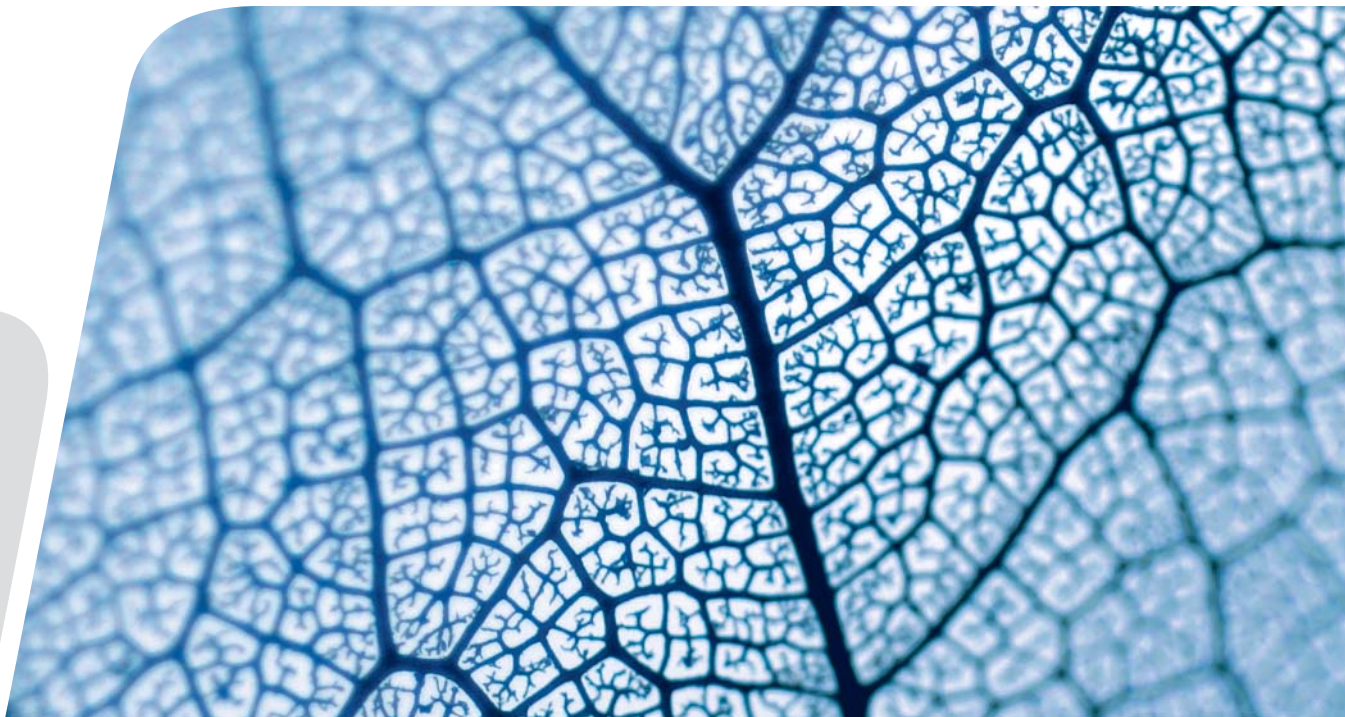
For osteochondral lesions, an osseous reconstruction is necessary after the removal of sclerotic bone in order to re-create vital bone tissue and a sustainable joint. Both at the knee and at the talus, the AMIC® method shows clinically comparable results to autologous chondrocyte implantation and supports the body in the formation of functional cartilaginous repair tissues.

AMIC® – Advantages

- › A minimally invasive, one-step surgical technique for the treatment of chondral and osteochondral lesions larger than 1 cm²
- › Based on microfracturing, the established first-line treatment
- › Natural protection of the super clot resulting from Chondro-Gide®'s unique bilayer structure
- › Marked reduction in discomfort, even after resumption of sports activities
- › Promising clinical results
- › Straightforward, cost-efficient surgical technique

Chondro-Gide® – Advantages

- › The leading natural collagen matrix for cartilage regeneration
- › Unique bilayer matrix protects and stabilises the super clot
- › Excellent defect filling capacity
- › High form stability
- › Prevents intra-articular haemorrhage
- › Promotes migration and adhesion of progenitor cells
- › Chondro-Gide® positively influences chondrogenesis of progenitor cells
- › Easy handling
- › Ready for use and can be applied ad hoc



Chondro-Gide® – Bilayer Collagen Matrix

Specifications of Chondro-Gide®

Collagen is the main structural protein of connective tissue and an important component of articular cartilage. Chondro-Gide® is comprised of collagen type I and III. It is manufactured in a patented process which results in a unique bilayer matrix (Fig. 1) with a compact and a porous side.

The compact layer (Fig. 2) consists of a compact, cell-occlusive surface, preventing the mesenchymal stem cells from diffusing into the joint space and protecting them from mechanical stress. The porous layer (Fig. 3) of the matrix is composed of loose collagen fibres that support cell invasion and attachment. The arrangement of the fibres provides high tensile strength and resistance to tearing. Chondro-Gide® can therefore be held in position by glue or sutures.

Chondro-Gide® is produced from porcine collagen, which is naturally resorbed. Collagenases, gelatinases and proteinases are responsible for its breakdown into oligopeptides and finally single amino acids.

Safety and Quality

The proprietary manufacturing process of Chondro-Gide® involves several steps before the unique bilayer design is achieved. Standardised processes under clean room conditions, rigorous in-process and end control guarantee a high quality natural product. Thorough biocompatibility safety testing according to international standards proves that all elements possibly causing an undesirable local or systemic response are removed during the manufacturing process. The immunogenic potential of the matrix is reduced to a minimum.

Chondro-Gide® is a CE-marked product to cover articular cartilage defects that are either treated with autologous chondrocyte implantation (ACI) or with bone marrow stimulation techniques (AMIC®).

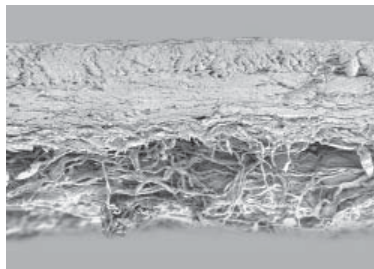


Fig. 1: Unique bilayer structure of Chondro-Gide® (100x)

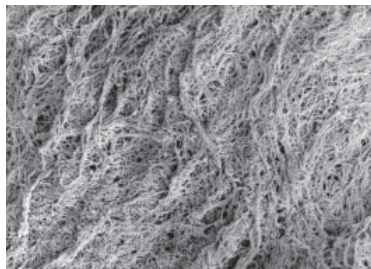


Fig. 2: Compact, cell-occlusive surface (SEM 1500x)

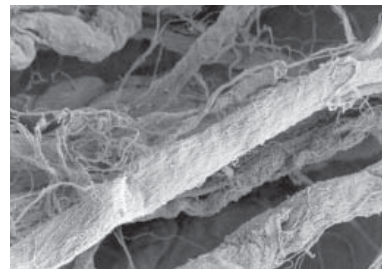


Fig. 3: Porous, cell-adhesive surface (SEM 1500x)

AMIC® Talus Surgical Technique

The following surgical technique uses a posteromedial osteochondral lesion as an example.
Clinical case of Prof. Dr. med. Dr. phil. Victor Valderrabano, University Hospital, Basle, Switzerland.

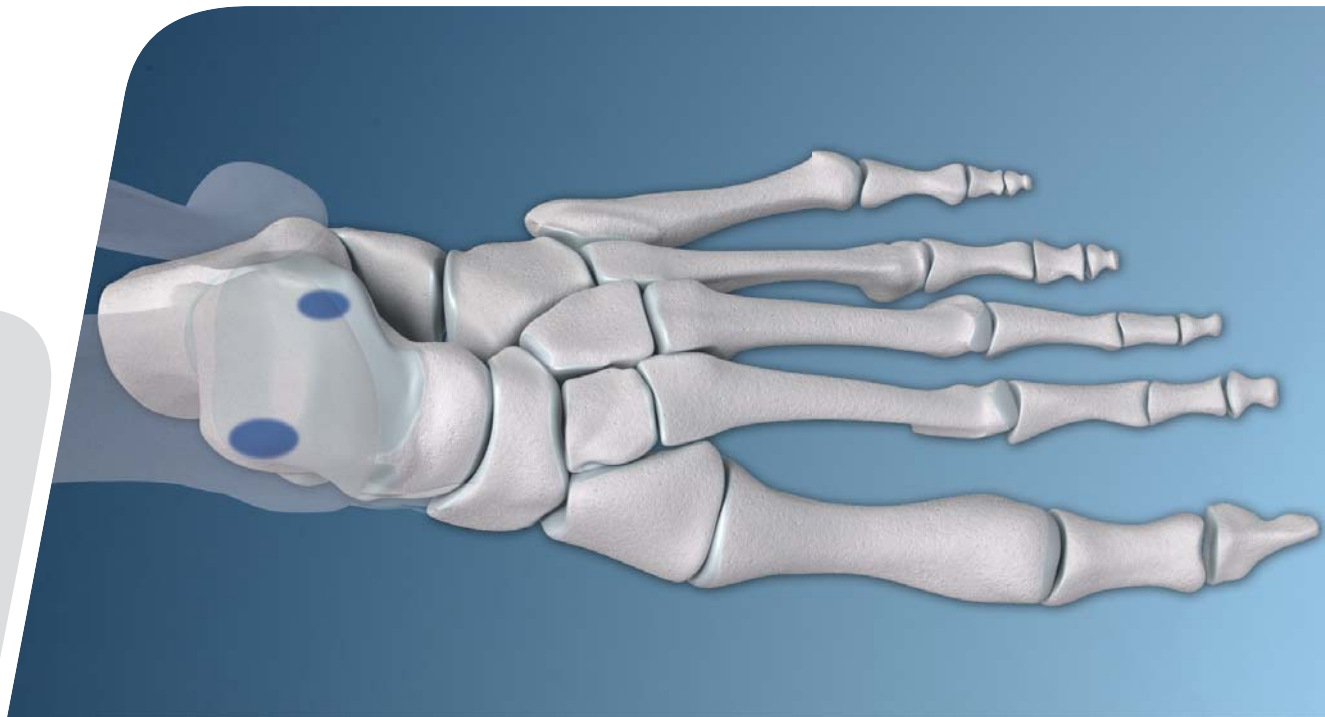
Indication

- > Chondral & osteochondral lesions
- > Focal, traumatic defects
- > Intact surrounding cartilage
- > Lesion > 1.0 cm²
- > Patients aged from 18 to 55
- > Osteochondral lesions in association with osseous reconstruction
- > Correction of associated pathologies: axial malalignment and ligament instabilities
- > Primary and revision procedure

Note: It is important to correct attendant pathologies, such as an instability of the joint or an osseous malalignment, as well as the osseous and chondral reconstruction.

Exclusion Criteria

- > Metabolic arthropathies
- > Kissing lesions
- > Major, non-reconstructable defects
- > Non-correctable axial malalignments
- > Chronic inflammatory systemic disorders
- > Obesity (BMI > 30)



Diagnostic Imaging

Radiographic imaging and magnetic resonance imaging (MRT) are essential for the diagnostic imaging investigation. Optionally, SPECT/CT may be performed.

Radiograph

Conventional standing radiography in two planes is performed to assess skeletal deformations.

Note: Depending on the projection, the osteochondral lesion is commonly not observable on non-contrast radiographs.



Left ankle joint with valgus and slightly abducted forefoot with distinct talonavicular subluxation. This was corrected by performing a lengthening osteotomy of the calcaneus.

MRI

The MRI examination assists in showing the chondral or osteochondral defect and in diagnosing attendant soft-tissue pathologies.

Note: The extent of the lesion can be overestimated in the MRI where there is attendant osseous oedema.



Sagittal T2 sequence with severe accumulation and bone bruise in the region of the osteochondral lesion.



Coronal T1 sequence to confirm the instability of the medial and lateral ligaments. A medial and lateral ligament reconstruction was performed to correct the rotational instability.

SPECT/CT

Optional SPECT/CT shows the size of the osseous lesion with more precision than MRI. Additionally, the extent of the scintigraphic activity and the anatomically correct position can be ascertained.



Osteochondral lesion on the posteroomedial talus and extent of the osseous lesion.

Surgical Treatment

Position

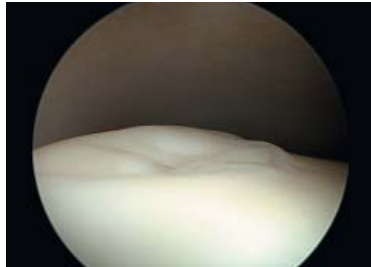
AMIC® is performed under a general or spinal anaesthetic in a supine position with a thigh tourniquet and the leg freely moveable and covered. The leg is positioned hanging for the diagnostic arthroscopy.



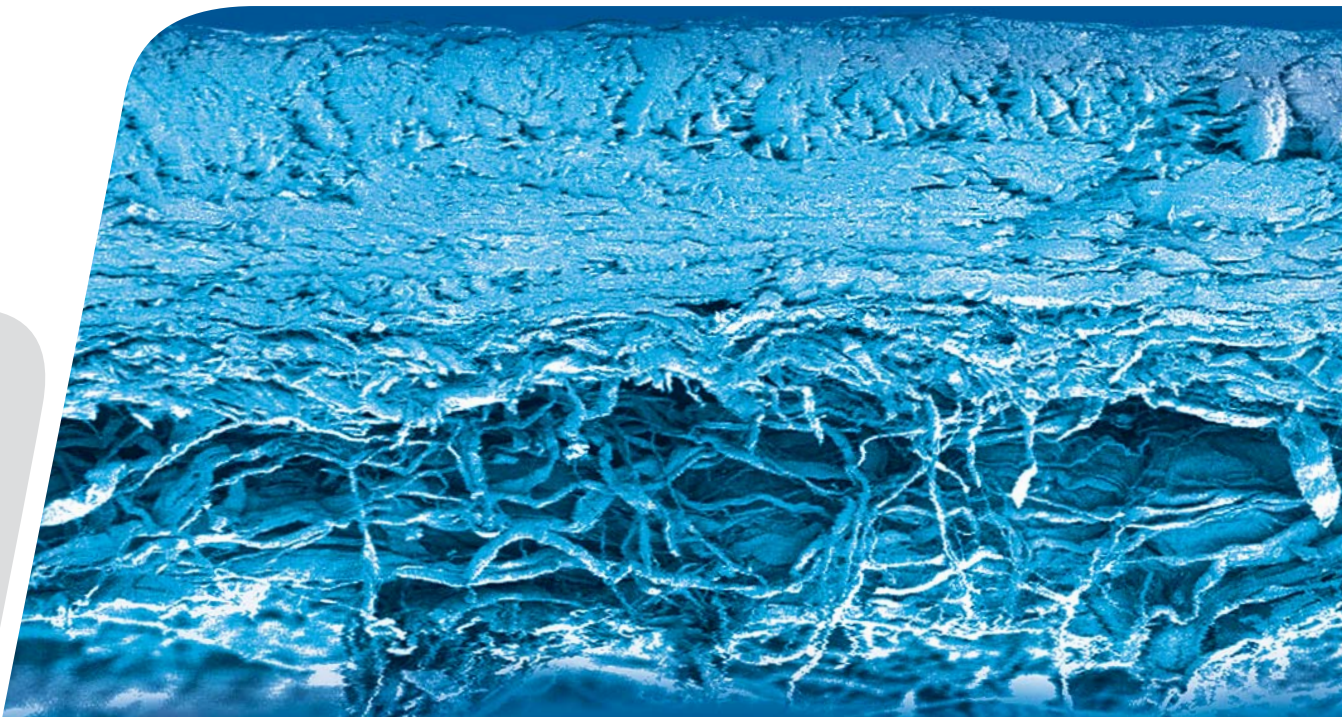
Arthroscopy

The initial diagnostic arthroscopy is performed to assess ligament instability and to locate and determine the size of the osteochondral lesions.

Note: A standard Ø 2.7 mm arthroscope with a 30° lens and isotonic electrolyte solution as the arthroscopy medium is recommended.



Posteroomedial chondral defect shown via a standard anterocentral approach.



Approach

An anteromedial or anterolateral approach is used depending on the location of the defect.

Note: An oblique medial malleolus osteotomy approach is recommended for better access to postero-medial lesions.



Anteromedial arthrotomy with osteotomy of the medial malleolus.

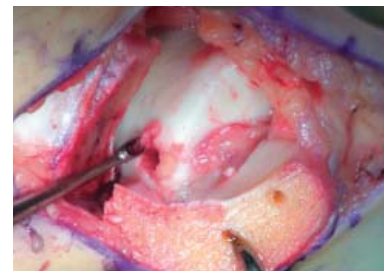


Debridement of the osteochondral lesion

Damaged and instable cartilage and sclerotic bone beneath the chondral defect are removed using a scalpel and curettes. Any osseous cysts are curetted and the mucoid fibrous contents are completely removed. The cartilage edges of the healthy cartilage must be stable and upright.



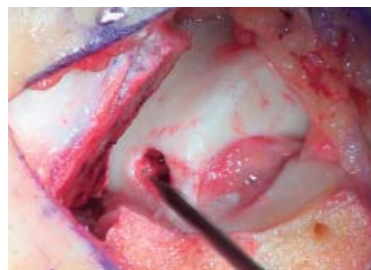
Damaged and instable cartilage.



Curettage of sclerotic bone.

Microfracturing

The sclerotic area at the base of the lesion is perforated using a sharp awl from the periphery of the lesion towards the centre at intervals of 2–4 mm. The residual tissue is carefully removed and the adequacy of the subchondral bleeding is verified.



Microfracturing with a sharp awl.



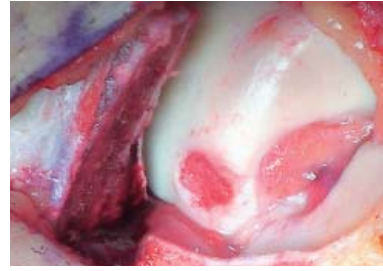
Perforated subchondral bone.

Note: The perforation of the sclerotic area can be performed by way of antegrade drilling with adequate cooling.

Osseous Reconstruction

The osseous defect is reconstructed up to the subchondral bone lamella using autologous bone from the iliac crest.

Note: Alternatively, Orthoss® can be used as a natural bone graft substitute.



Reconstruction of the osseous defect using autologous bone.

Preparation of the Chondro-Gide®

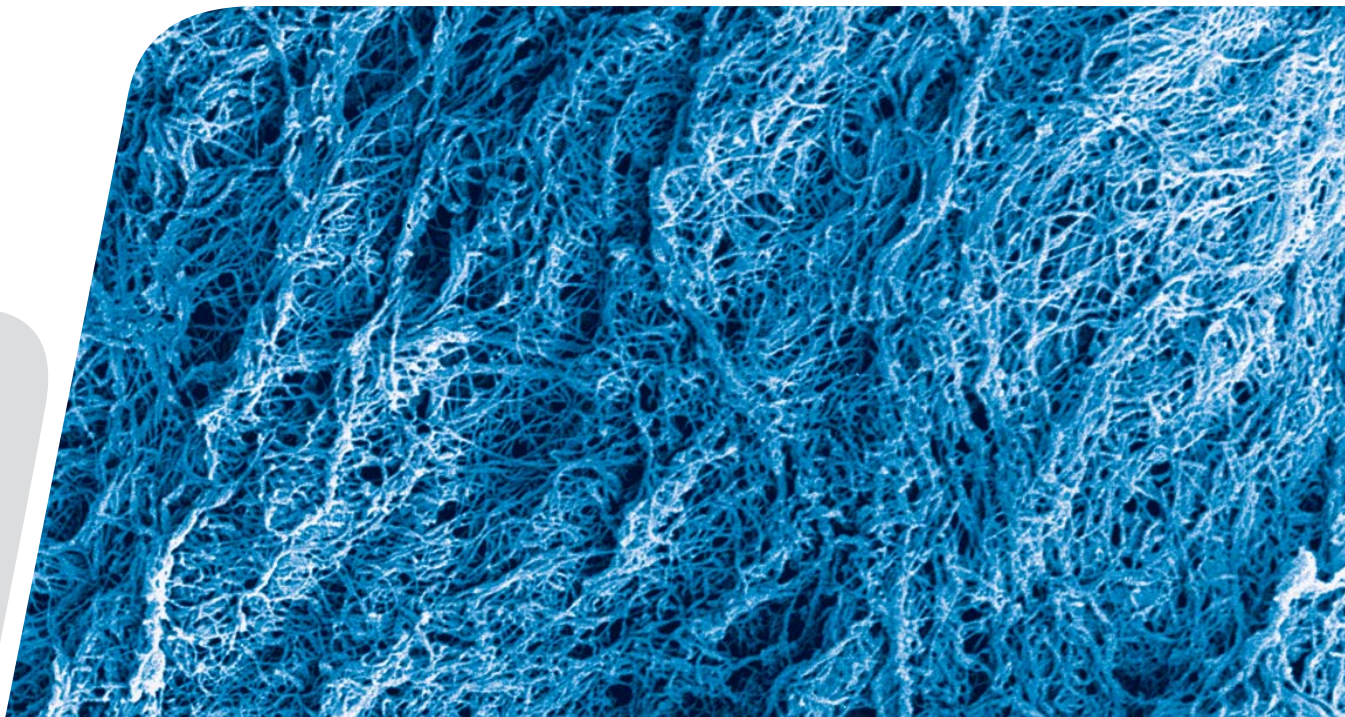
An exact impression of the defect is made using the sterile aluminium template. Because of the precision required in the ankle joint, it is recommended that the matrix is trimmed in a moistened condition, as the material will increase in size by approximately 10 – 15% after moistening.



Make an exact impression of the defect.



Trimming the Chondro-Gide® matrix.



Fixing the Chondro-Gide®

Commercially available fibrin glue (preferably Tissucol, Baxter) is applied directly to the bone reconstruction and the Chondro-Gide® is glued in with the porous surface facing the bone.

The stable position of the matrix is checked by moving the joint 10 times between plantar extension and dorsal flexion.

Note: In order to avoid delamination, care should be taken that the matrix does not overlap the edge of the adjacent cartilage.



Application of fibrin glue onto the bone reconstruction.



Glued-in Chondro-Gide®.

Osteosynthesis

After treating the osteochondral lesion, the divided medial malleolus is precisely repositioned with two 3.5 mm screws and the incision is sutured layer by layer.



Precise osteosynthesis with two 3.5 mm screws.



**Correction of the
biomechanical factors**

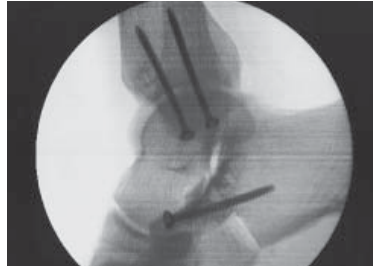
It is recommended that associated pathobiomechanical factors are corrected subsequent to the AMIC® procedure:

Chronic instability:

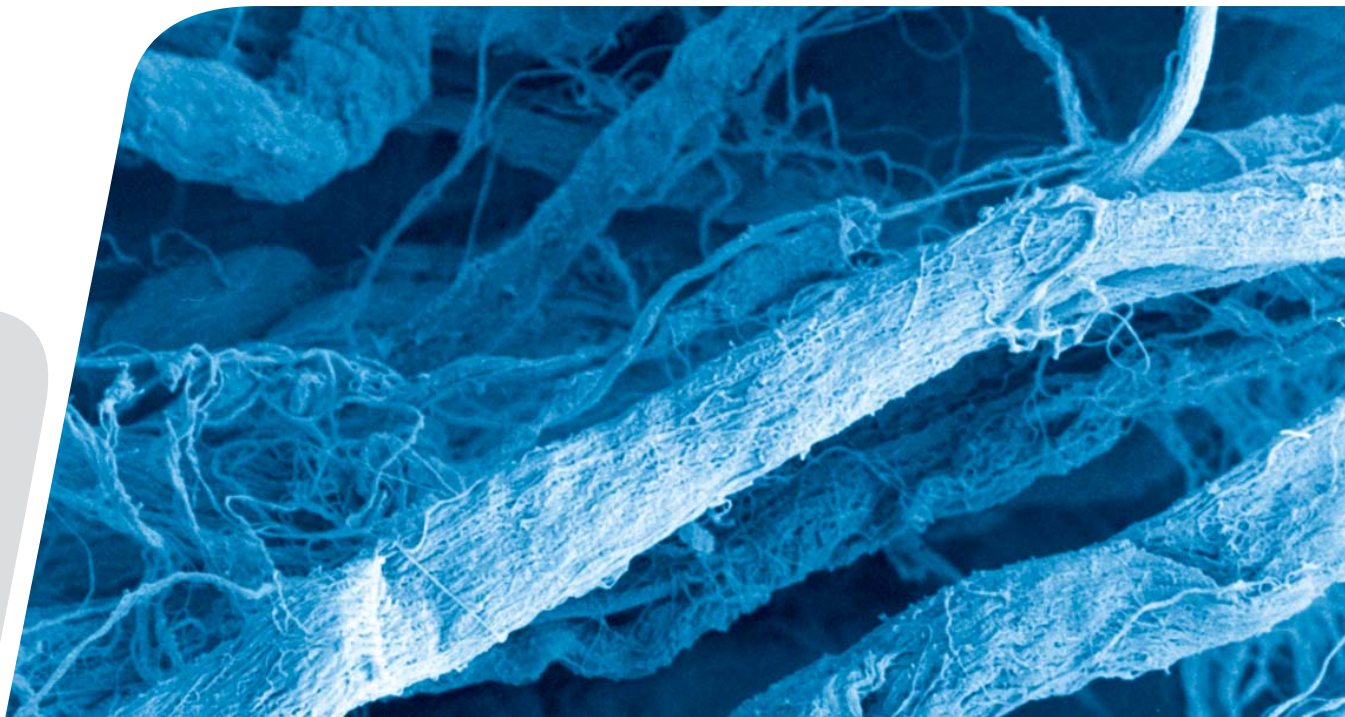
reconstruction of the ligaments
(e.g. medial, lateral or combined)

Axial malalignment:

corrective osteotomy
(e.g. supramalleolar, talar or
calcaneal)



Radiographic monitoring with image converter.



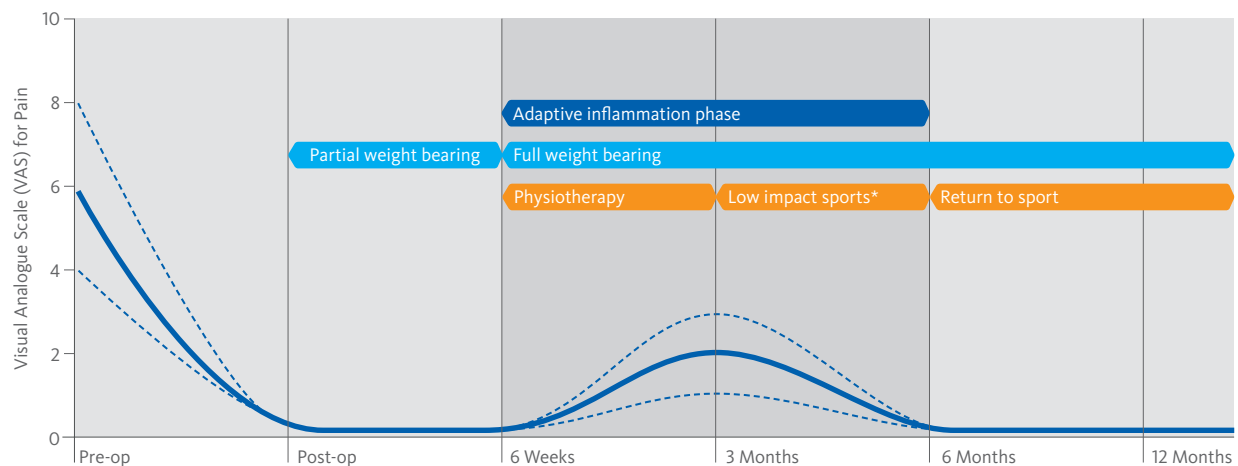
Follow-up Treatment

Thrombosis prophylaxis with low molecular weight heparin until full weight-bearing is recommended. Non-steroidal anti-inflammatory drugs can be administered as analgesics. Sufficient elevation and cryotherapy is important. Additional physical therapy (muscle stimulation or electrotherapy) may be used for postoperative treatment as required.

Postoperatively, the foot is stabilised using a functional orthosis. Movement is restricted to 20° with partial load-bearing of a maximum of 20 kg for 6 weeks or for 8 to 10 weeks in concomitant ligament reconstruction.

Appropriate cartilage therapy within the permitted range of movement can be commenced subsequently by trained physiotherapists. In the course of this, the load is progressively increased up to full load-bearing.

Physiotherapy includes isometric muscle activation and closed kinetic chain exercises to strengthen and stabilise the ankle joint and the lower leg muscles. The increased load brings about an adaptive inflammation phase where patients often report an initial increase in the level of pain.



* For example, swimming and cycling [source: V. Valderrabano]

Light sports activities (e.g. cycling, swimming) can be introduced after three months. The ability to engage in a complete range of sports is achieved after six months at the earliest. Transition to the next load stage should only be made if the previous stage has been managed without problems.

A balanced diet over the entire period is recommended. Cartilage regeneration is enhanced by adequate intake of fluids (min. 3 litres per day) and vitamin C and by abstaining from alcohol and smoking.

	Post-op to 6 weeks *	6 weeks to 3 months	3 to 6 months	After 6 months
Load bearing	Max. 20 kg	Progressive increase in load bearing to 100%	Full	Full
Mobilisation	Orthesis with 20° restriction Passive → Assistive → Active	No restriction Full range of movement Cartilage therapy	No restriction	No restriction
Physiotherapy and Sport	No Sport Immobilisation Manual lymphatic drainage Electrotherapy	No Sport Physiotherapy	Light sporting activities (e.g. swimming, cycling)	Full return to sports

* 8 to 10 weeks in concomitant ligament reconstruction



Product Range



Item No. Description

- 30890.3 Chondro-Gide® Bilayer Collagen Matrix 20 x 30 mm
- 30915.5 Chondro-Gide® Bilayer Collagen Matrix 30 x 40 mm
- 30939.9 Chondro-Gide® Bilayer Collagen Matrix 40 x 50 mm



A sterile aluminium template is supplied with Chondro-Gide®



Item No. Description

- 30869.1 Orthoss® 3 g
Spongy granules 2 – 4 mm
Volume approx 8 cm³
- 30865.1 Orthoss® 5 g
Spongy granules 1 – 2 mm
Volume approx 13 cm³
- 30870.7 Orthoss® 7 g
Spongy granules 2 – 4 mm
Volume approx 20 cm³

References

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France

Geistlich Pharma France SA
Parc des Nations – Paris Nord II
385 rue de la Belle Etoile
BP 43073 Roissy en France
FR-95913 Roissy CDG Cedex
Phone +33 1 48 63 90 26
Fax +33 1 48 63 90 27
surgery@geistlich.com
www.geistlich.fr

Germany

Geistlich Biomaterials
Vertriebsgesellschaft GmbH
Schneidweg 5
D-76534 Baden-Baden
Phone +49 7223 96 24 0
Fax +49 7223 96 24 10
surgery@geistlich.de
www.geistlich.de

Italy

Geistlich Biomaterials Italia S.r.l
Via A. Fogazzaro 13
I-36016 Thiene VI
Phone +39 0445 370 890
Fax +39 0445 370 433
surgery@geistlich.com
www.geistlich.it

United Kingdom

Geistlich Sons Ltd.
Long Lane
GB-Chester CH2 2PF
Phone +44 1244 347 534
Fax +44 1244 319 327
surgery@geistlich.com
www.geistlich.co.uk

Headquarters Switzerland

Geistlich Pharma AG
Business Unit Surgery
Bahnhofstrasse 40
CH-6110 Wolhusen
Phone +41 41 492 55 55
Fax +41 41 492 56 39
surgery@geistlich.com
www.geistlich-pharma.com