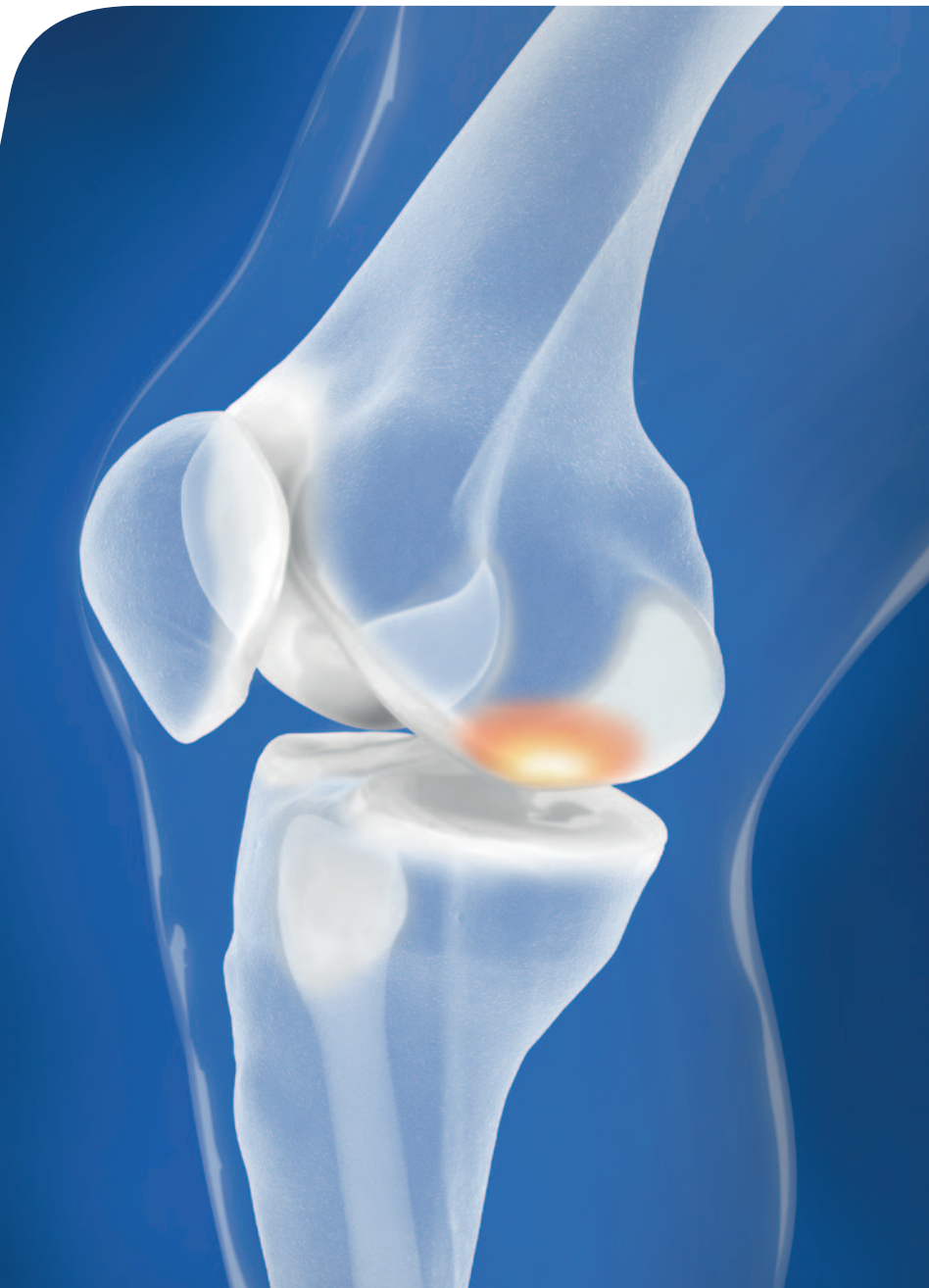


Chondro-Gide®

AMIC® Knee

Autologous Matrix-Induced Chondrogenesis



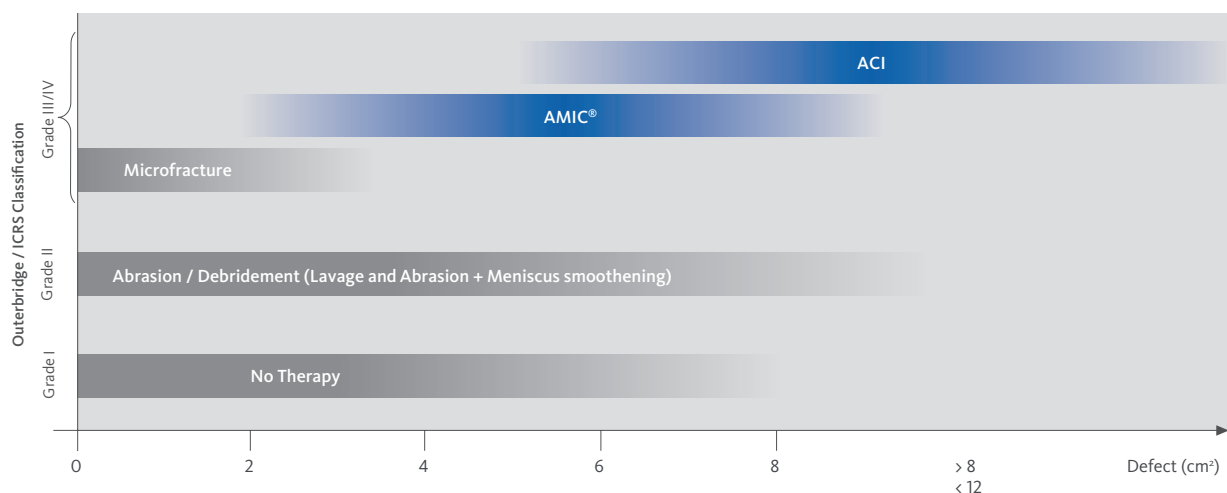
AMIC[®] – Autologous Matrix-Induced Chondrogenesis

Autologous Matrix-Induced Chondrogenesis, AMIC[®], is an innovative biological surgical procedure developed by Geistlich Surgery for the treatment of traumatic chondral and osteochondral lesions which are larger than 1–2 cm². 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 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 [5] that enhances the chondrogenic differentiation of mesenchymal stem cells and, in combination with fibrin glue, stimulates chondrocytes to enhance proteoglycan deposition [6].

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 tissue.

Treatment algorithm



Indications

- > Chondral & osteochondral lesions Grade III–IV (Outerbridge classification)
- > Focal, traumatic defects
- > Defect size approx. 1.0 – 8.0 cm²
- > Patients aged from 18 to 55

Exclusion Criteria

- > More than two or corresponding cartilage defects
- > Systemic, immune mediated disease or infection of the knee including osteoarthritis
- > Inflammatory joint reactions
- > Instable knee, meniscectomy
- > varus/valgus (concomitant realignment procedure required)
- > Hemophilia A/B
- > Allergy to porcine collagen

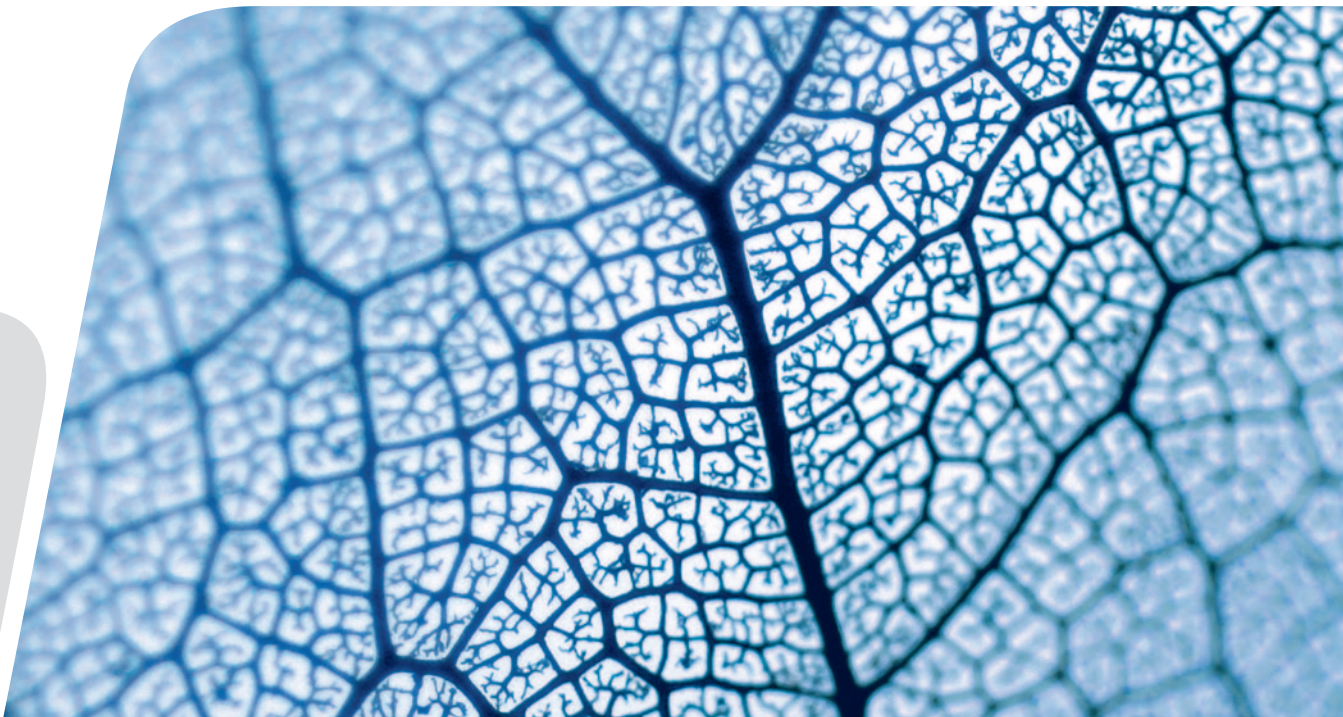
Microfracturing in combination with Chondro-Gide (AMIC[®]) is a minimally invasive, effective technique for the repair of focal cartilage defects of the knee joint [1]. Multipotent mesenchymal progenitor cells from the subchondral bone have a high chondrogenic differentiation potential and can be guided directly into the cartilage defect using Chondro-Gide[®] [2, 3].

AMIC® – Advantages

- › A minimally invasive, one-step surgical technique for the treatment of chondral and osteochondral lesions
- › Based on microfracturing, the established first-line treatment
- › Natural protection of the super clot resulting from Chondro-Gide®'s unique bilayer structure
- › Verified improvement of clinical function, patient satisfaction and pain reduction
- › Over 7 years clinical experience
- › Straightforward, cost-efficient surgical technique

Chondro-Gide® – Advantages

- › The leading natural collagen matrix in 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 natural collagen. It is manufactured in a patented process which results in a unique bilayer matrix (Image 1) with a compact and a porous side.

The compact layer (Image 2) consists of a dense, cell occlusive surface, preventing the mesenchymal stem cells from diffusing into the joint space and protecting them from mechanical stress. The porous layer (Image 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®).

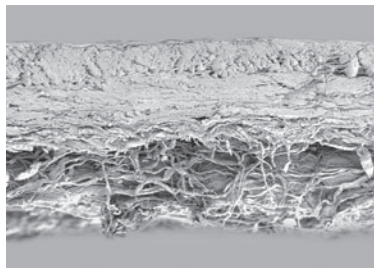


Image 1: Unique bilayer structure of Chondro-Gide® (100x)

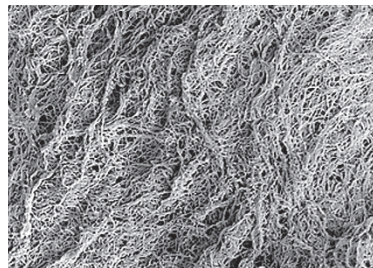


Image 2: Compact, cell occlusive surface (SEM 1500x)

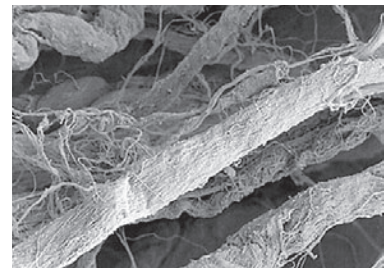
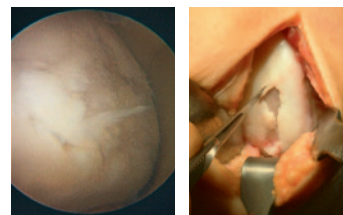


Image 3: Porous, cell adhesive surface (SEM 1500x)

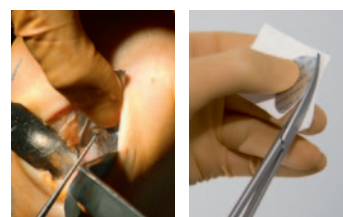
The AMIC® procedure is an easy to handle, cost effective method with good clinical results [3] and is particularly suitable for treating osteochondral and retropatellar defects [4].

Surgical Technique

Arthroscopy/mini-arthrotomy During arthroscopy the size and classification of the defect is carefully assessed. If necessary, concomitant interventions, e.g. partial meniscus resection, are carried out. Afterwards the knee joint is opened, using a standard minimal invasive anterior approach. Destroyed and unstable cartilage is removed using a scalpel, curette and spoon to achieve a well-contained defect.

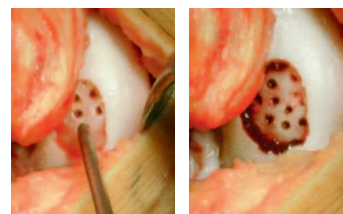


Preparation of Chondro-Gide® An exact impression of the defect is made using the sterile aluminium template. The imprint is cut out and transferred onto the Chondro-Gide®. The side of the template which was facing the defect is transferred onto the smooth surface of the matrix. When trimming a dry Chondro-Gide®, the matrix is cut smaller to compensate for an increase in matrix size of around 10 – 15 % once moistened with physiological saline solution.

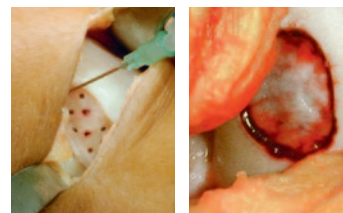


Microfracturing The subchondral bone at the base of the lesion is perforated using a sharp awl from the periphery of the lesion towards the centre at intervals of 4–5 mm [4]. The residual tissue is carefully removed and the adequacy of the subchondral bleeding is verified.

Note: The perforation of the subchondral bone can be performed by antegrade drilling with adequate cooling.



Fixation of the Chondro-Gide® Commercially available fibrin glue (preferably Tissucol, Baxter) is administered directly to the subchondral bone plate around the perforations. The moistened Chondro-Gide® is glued into the defect with the porous layer facing the bone surface. Chondro-Gide® can also be attached using Vicryl or PDS 6/0 sutures with a TF-plus needle (inside out technique, single stitches every 5 mm).



Flexion of knee and closure Once set, after approx. 5 minutes, excess fibrin glue is cut away cautiously with a sharp scalpel. To prevent delamination, an overlapping of the matrix over the rim of the adjacent cartilage should be avoided. The stable position of the matrix can be checked by bending and extending the knee 10 times. Insertion of an intra-articular drain without suction, careful haemostasis and suturing of the wound complete the surgery.

Clinical Case: Dr. med. S. Anders
Dept. of Orthopedics
University of Regensburg, Germany



Follow-up Treatment

The following illustrations show the recommended post-operative care for femoral and tibial defects as well as for trochlear and patellar defects.

Thrombosis prophylaxis with low molecular weight heparin until full weight-bearing is recommended. Non-steroidal antirheumatic drugs can be administered as analgesics. Cryotherapy, elevation and muscle stimulation or electrotherapy may be used for post-operative treatment as appropriate. The intra-articular drainage may be removed after 24 h with commencement of functional treatment. Physiotherapy includes isometric muscle activation and closed kinetic chain exercises.

Femoral and tibial defects

	week 1	week 2–6	after week 6
Weight bearing	Light foot contact 3-point-walking with crutches	Light foot contact 3-point-walking with crutches	Building-up to full weight bearing over a period of 2 weeks. Intensive muscle and coordinative training
Mobilisation	Orthesis: First 48h: 0/0/0° Afterwards: 0/0/60°	CPM with restrictions: Week 2: 0/0/60° Week 3–4: 0/0/90° Week 5–6: 0/0/120° 2–6 hours of CPM daily	Free movement (restricted by pain)
Physiotherapy and Sport	No sport Mobilisation Manual lymphatic drainage Electrotherapy	No sport Physiotherapy Swimming	Aqua jogging After 8 weeks: biking After 6 months: jogging, skating After 6–12 months: skiing After 12–18 months: contact sports

Patellar and trochlear defects

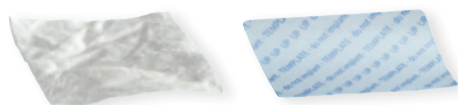
	week 1	week 2–6	after week 6
Weight bearing	Light foot contact 3-point-walking with crutches	Light foot contact 3-point-walking with crutches	Building-up full weight bearing over a period of 2 weeks. Intensive muscle and coordinative training
Mobilisation	Orthesis: first 48h: 0/0/0° Afterwards: 0/0/30°	CPM with restrictions: Week 2: 0/0/30° Week 3–4: 0/0/60° Week 5–6: 0/0/90° 2–6 hours of CPM daily	Free movement (restricted by pain)
Physiotherapy and Sport	Analogous to femoral and tibial defects		

Chondro-Gide® provides a suitable cell carrier [5], positively influences chondrogenic differentiation of mesenchymal stem cells and stimulates chondrocytes to enhance proteoglycan deposition in combination with fibrin glue [6].

Product Portfolio



Art.-Nr.	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®

Products may not be available in all markets. Product availability is subject to the regulatory or medical demands that govern individual markets. Please contact Geistlich Pharma AG if you have questions about the availability of Geistlich Pharma AG products in your area.

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Chondro-Gide® Bilayer Collagen Matrix 30 x 40 mm

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