ANIKA

Hyalofast®

Chondral and osteochondral ankle lesions

Surgical Technique Guide



Chondral & Osteochondral Ankle Lesions

Arthroscopic Implantation

INTRODUCTION

Osteochondral lesions of the talus (OLT): understanding the clinical need

Osteochondral lesions of the talus (OLT) remain a difficult problem for orthopaedic surgeons. At the heart of the challenge is cartilage itself - it has very limited capacity to heal, and even when it does, restoring its original biomechanical function is far from straightforward.

These lesions often affect younger, active patients and can lead to persistent pain and functional limitation. Left untreated, they frequently progress, with reported rates of degeneration into ankle osteoarthritis ranging from 17% to 50%.[1–4]

Conservative management is an option, but outcomes are inconsistent and often disappointing. There is ongoing debate about its role, particularly given the risk that symptoms may persist while underlying cartilage damage continues to worsen.[5, 6]

As a result, surgical treatments to restore articular cartilage have been developed and evolved significantly over time from reconstructive techniques to the more recent regenerative strategies.[7] Among these, autologous chondrocyte implantation (ACI) has shown the ability to produce tissue that more closely resembles native hyaline cartilage[8, 9], but its use is limited by cost, complexity and regulatory constraints.

This has driven increasing interest in alternative regenerative approaches. Bone marrow, for example, provides a rich source of growth factors and mesenchymal stem cells (MSCs), which can differentiate into cartilage and bone while also supporting tissue repair through the release of bioactive signals. When combined with an appropriate scaffold - such as **Hyalofast®** - these cells can be delivered in a single-step procedure, offering a more practical and accessible option for the treatment of challenging osteochondral lesions.[10, 11]

The evolution of scaffold technology

Scaffold-based strategies have emerged to address this gap, providing a three-dimensional structure that helps contain and support cells within the defect.

Hyalofast is a non-woven, biodegradable scaffold composed of HYAFF® - a semi-synthetic derivative of hyaluronic acid. It is designed to support the entrapment and organization of mesenchymal stem cells (MSCs), helping to facilitate the regeneration of hyaline-like cartilage in a single-stage procedure. By avoiding the need for a second surgery, it offers a more streamlined approach compared with cell-based techniques such as ACI, while still supporting the biological processes involved in cartilage repair. As the scaffold gradually degrades, it contributes to an environment that supports new cartilage formation for long-term joint preservation.[12]



In clinical practice, Hyalofast can be used in combination with bone marrow aspirate concentrate (BMAC) or alongside bone marrow stimulation techniques such as microfracture, microdrilling or abrasion arthroplasty. These approaches aim to enhance the biological environment at the defect site by introducing autologous MSCs and growth factors, while the scaffold helps to retain and organise these elements where they are needed.

Chondral & Osteochondral Ankle Lesions

Arthroscopic Implantation

Why Hyalofast? A surgeon's perspective

When treating osteochondral lesions in the ankle, the challenge is rarely just what to use - it's how easily it fits into the procedure, and whether it works in the realities of the operating theatre.

Hyalofast is designed with that in mind. It's not just a scaffold in theory, but something that behaves in a practical, predictable way once you're in the joint.



One of its immediate advantages is handling

The material is soft and highly conformable, which means it can be easily trimmed to match the defect and introduced arthroscopically, even in the constrained space of the ankle. That simplicity matters - particularly when access is limited and precision is key.



Stability is another important factor

Once placed, the scaffold adheres to the prepared lesion bed through its natural self-adherent properties. In many contained defects, this removes the need for additional fixation such as fibrin glue or sutures, helping to keep the procedure more streamlined and controlled.



In terms of versatility

Hyalofast can be used in different ways depending on the surgical approach. It can act as a matrix to capture mesenchymal stem cells following bone marrow stimulation techniques such as microfracture or it can be combined with bone marrow aspirate concentrate (BMAC) to enhance the biological environment within the defect. This flexibility allows the surgeon to tailor the approach based on the lesion and the patient, rather than applying a single fixed strategy.



Practical considerations

Hyalofast is typically used in the treatment of chondral and osteochondral lesions of the talus, particularly where there is a need to support and organise a biological repair response within the defect. As with all cartilage procedures, appropriate patient selection and lesion characteristics remain key considerations in achieving good outcomes.

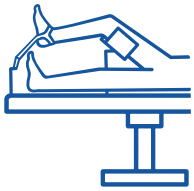
The technique described in this guide focuses on an arthroscopic approach, which allows for a minimally invasive treatment while maintaining visual control of the lesion. However, access is not always straightforward in the ankle. In cases where visualisation or placement is limited, a mini-open approach may be required. This is usually achieved by extending the existing arthroscopic portal on the affected side, without the need for a malleolar osteotomy.

Chondral & Osteochondral Ankle Lesions

Arthroscopic Implantation

PATIENT PREPARATION

1



Positioning

The patient is in supine position with foot distraction (mechanical or manual) to access the anterior or posterior talar dome.

2



Tourniquet Application

Apply a tourniquet with 280-mm Hg pressure at the proximal thigh of the affected limb to minimise intraoperative bleeding and maintain a clear visual field.

3



Portal Placement

Establish anterolateral and anteromedial arthroscopic portals to access the ankle joint. Posterolateral approach can also be considered.

4



Lesion Visualisation

Perform diagnostic arthroscopy - identify the cartilage lesion and affected subchondral bone.

5

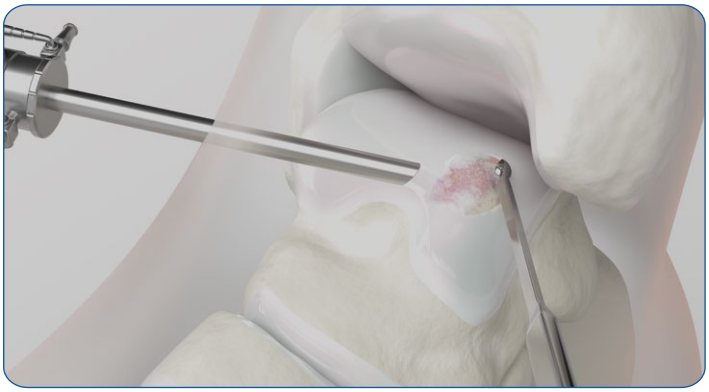


Procedure Sequencing

Complete all other surgical planned procedures prior to the implantation of Hyalofast.

NOTE: Hyalofast implantation should be the final step of the surgical procedure, as it should be performed in a dry environment to ensure optimal adherence and placement.

DEFECT CLEANING



Debride the chondral lesion, removing any loose or damaged cartilage and subchondral bone until healthy, stable bone is reached.

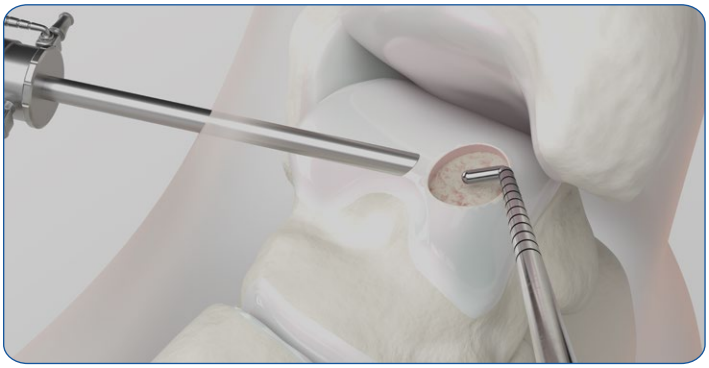


Establish a stable and well-defined border with vertical margins around the defect to ensure proper containment of Hyalofast.

Chondral & Osteochondral Ankle Lesions

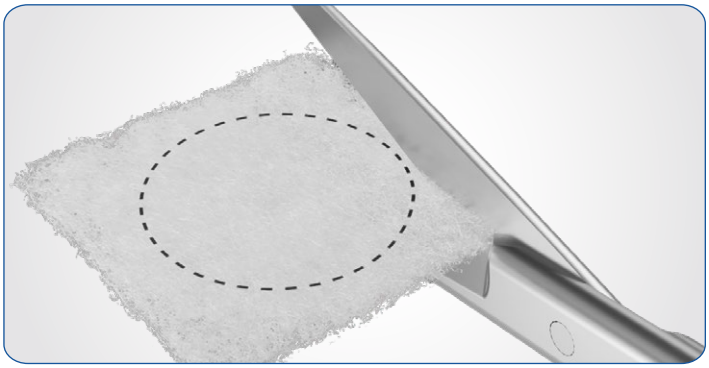
Arthroscopic Implantation

DEFECT MEASUREMENT



After achieving a well-contained defect, measure its dimensions using a calibrated probe or sterile template to determine the appropriate Hyalofast size.

PREPARE HYALOFAST

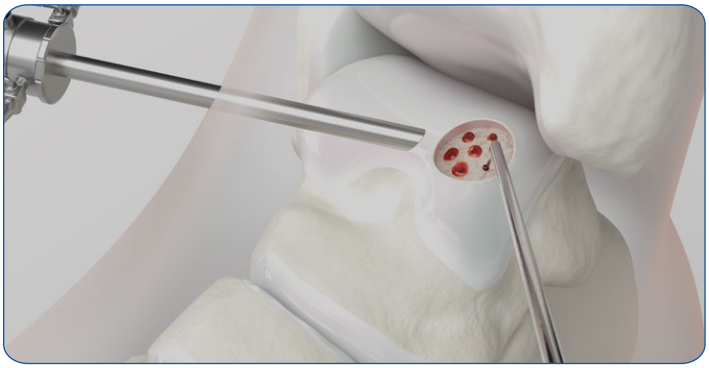


Using sterile scissors, trim Hyalofast to match the shape and size of the prepared defect.

NOTE: Precise cutting is not critical due to Hyalofast's conformability.

BIOLOGIC AUGMENTATION

Bone Marrow Stimulation or BMAC (Bone Marrow Aspirate Concentrate)



Bone Marrow Stimulation and Hyalofast

Perform bone marrow stimulation in healthy bone tissue at the base of the lesion

NOTE: The image shown depicts the microfracture technique. Alternative bone marrow stimulation methods include drilling or abrasion arthroplasty.



Hyalofast and Bone Marrow Aspirate Concentrated (BMAC)

Harvest sufficient autologous bone marrow aspirate (BMA) from the patient, typically from the iliac crest, as per the instructions for use of the harvesting device. Process the BMA according to the concentration device-specific instructions to obtain the BMAC for Hyalofast application.

Load BMAC onto Hyalofast

Load the BMAC directly onto Hyalofast positioned in the product tray, or in any sterile container available in the surgical theatre. Hyalofast's non-woven structure enables rapid and uniform absorption of the BMAC, ensuring even distribution throughout.

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Chondral & Osteochondral Ankle Lesions

Arthroscopic Implantation

HYALOFAST APPLICATION



Defect drying

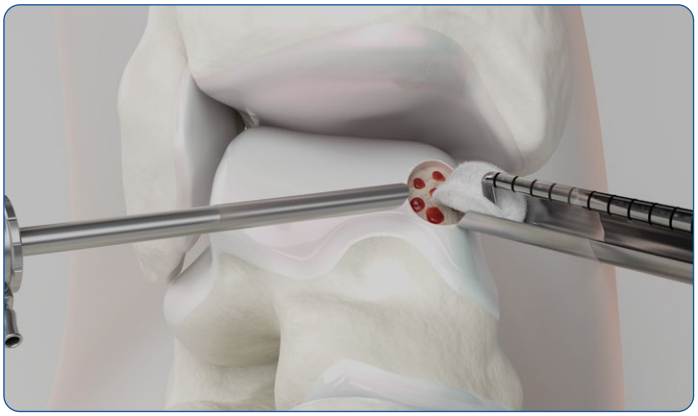
Switch off the fluid management system and drain the ankle joint of any fluid. Thoroughly dry the surface of the defect, before inserting Hyalofast.

Hyalofast Implantation

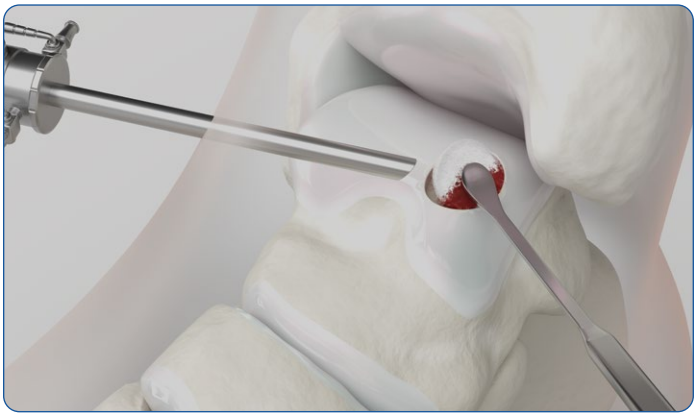
Gently deliver Hyalofast into the joint space and position it in the prepared defect using the preferred instruments and delivery technique. If a suitable slotted cannula is available, Hyalofast can be introduced into the joint passing through the cannula as follows:



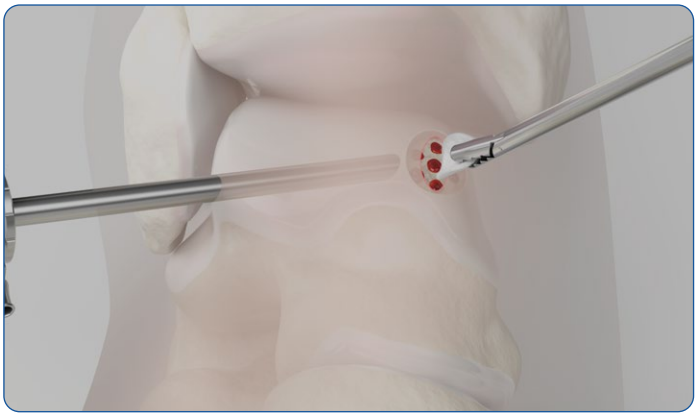
Insert the cannula into the arthroscopic portal closest to the defect



Use a probe to slide Hyalofast into the joint and onto the defect, and then to position it more accurately within the margins of the defect



Remove the cannula, and make any final positioning adjustments to Hyalofast using a flat probe

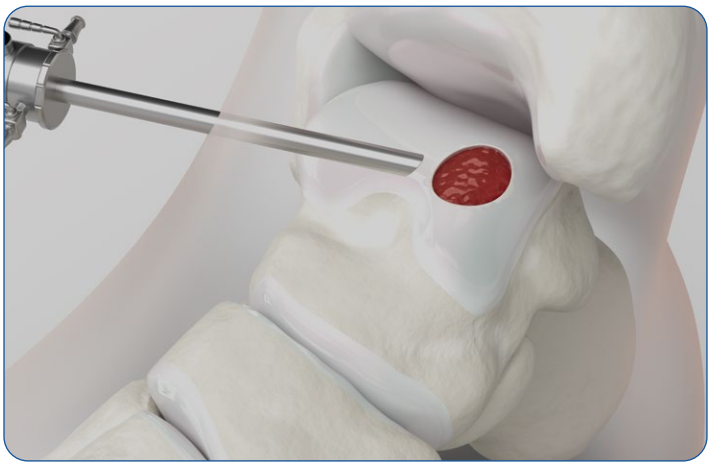


If preferred, Hyalofast can be applied via direct access using an atraumatic grasper

Chondral & Osteochondral Ankle Lesions

Arthroscopic Implantation

HYALOFAST APPLICATION *CONTINUED*

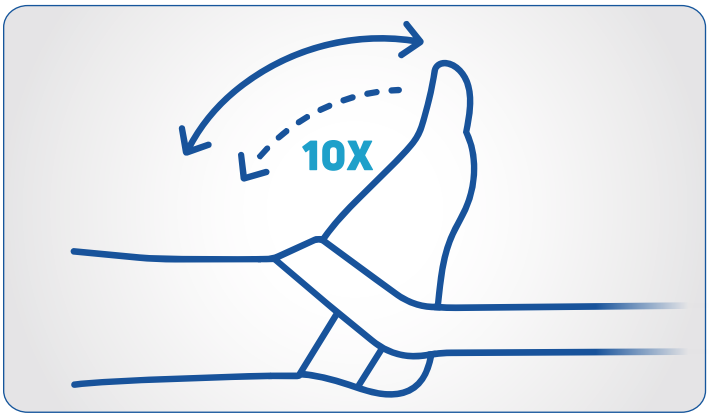


Final Positioning

Use the preferred instrument to make final adjustments, ensuring Hyalofast:

- Sits below the level of the surrounding cartilage
- Is fully contained within the defect margins
- Does not overlap onto adjacent healthy cartilage

NOTE: After Hyalofast placement, do not reintroduce arthroscopic fluid into the joint.



Implant Stability Check

To confirm Hyalofast adherence and stability, mobilise the ankle joint with multiple flexion-extension movements under arthroscopic control, then proceed with the standard closure of the surgical incision.

APPLICATION TIPS

- **Orientation:** Hyalofast structure is non-directional; either surface may face the defect.
- **Osteochondral defects:**
  - *< 5 mm in depth* - Hyalofast can be stacked to fill the defect, if needed.
  - *≥ 5 mm in depth*, a bone graft, e.g. bone chips mixed with fibrin glue should be used to reconstruct the bone bed, followed by the application of Hyalofast on top to complete the defect filling.
- **Thinning:** Hyalofast can be pulled apart or halved; fibers may be packed into the defect as needed.

Fixation considerations

- For small, well-contained defects, no additional fixation is typically required.
- If enhanced fixation is needed, fibrin glue can be applied around the Hyalofast margins.
- If used, remove any excess fibrin glue, ensuring final construct does not protrude above the level of the surrounding cartilage.

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POST-OPERATIVE REHABILITATION PROTOCOL

This protocol is a general guideline. The rehabilitation protocol should be customised to meet each patient's needs and circumstances.

Phase	Timeline	Primary Goals	Weight-Bearing & Activity
Phase I: Protection	Weeks 0–2	Wound healing; reduce oedema; protect the graft.	**Non-weight bearing** with crutches. Passive Range of Motion (ROM) exercises allowed.
Phase II: Transition	Weeks 2–6	Restore ankle mobility; initiate muscle activation.	**Partial weight bearing** as tolerated (25-50%). Stationary cycling (low resistance).
Phase III: Loading	Weeks 6–12	Full ROM; gait normalisation; strength building.	**Full weight bearing.** Progress to proprioceptive training (balance board).
Phase IV: Impact	Months 4–6	Return to functional activities; agility.	**Low-impact sports** (swimming, cycling)
Phase V: Return to sport	Months 6–9+	Return to high impact sports.	**Full sports clearance**, including high impact sports (jogging, football, etc...) based on functional testing and pain-free performance.

Indications

Hyalofast is CE-marked as a biodegradable support for the entrapment of mesenchymal stem cells for the repair of chondral and osteochondral lesions.

It acts as a support for bone marrow aspirate or as a chondroprotective coverage, which favors in situ residence of mesenchymal stem cells after their mobilisation due to bone marrow stimulation procedures.

For complete product information including indications, contraindications, warnings, precautions, possible complications and product storage, please refer to the product IFU. https://www.anikaifu.com

Part #	Description
144714F	Hyalofast 2x2
144722F	Hyalofast 5x5

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1. Barbier O, Amouyel T, de l'Escalopier N, Cordier G, Baudrier N, Benoist J et al (2021) Osteochondral lesion of the talus: what are we talking about? Orthop Traumatol Surg Res 107:103068 **2.** Buckwalter JA, Mow VC, Ratcliffe A (1994) Restoration of injured or degenerated articular cartilage. J Am Acad Orthop Surg 2:192–201 **3.** Canale ST, Belding RH (1980) Osteochondral lesions of the talus. J Bone Joint Surg Am 62:97–102 **4.** Walther M, Gottschalk O, Madry H, Muller PE, Steinwachs M, Niemeyer P et al (2023) Etiology, Classification, Diagnostics, and Conservative Management of Osteochondral Lesions of the Talus. 2023 Recommendations of the Working Group "Clinical Tissue Regeneration" of the German Society of Orthopedics and Traumatology. Cartilage. https://doi.org/10.1177/19476035231161806 **5.** Anwander H, Vetter P, Kurze C, Farn CJ, Krause FG (2022) Evidence for operative treatment of talar osteochondral lesions: a systematic review. EFORT Open Rev 7:460–469 **6.** Buck TMF, Lauf K, Dahmen J, Altink JN, Stufkens SAS, Kerkhoffs G (2023) Non-operative management for osteochondral lesions of the talus: a systematic review of treatment modalities, clinical- and radiological outcomes. Knee Surg Sports Traumatol Arthrosc. https://doi.org/10.1007/s00167-023-07408-w **7.** Moran ME, Kim HK, Salter RB (1992) Biological resurfacing of full-thickness defects in patellar articular cartilage of the rabbit. Investigation of autogenous periosteal grafts subjected to continuous passive motion. J Bone Joint Surg Br 74:659–667 **8.** Basad E, Ishaque B, Bachmann G, Sturz H, Steinmeyer J (2010) Matrix-induced autologous chondrocyte implantation versus microfracture in the treatment of cartilage defects of the knee: a 2-year randomised study. Knee Surg Sports Traumatol Arthrosc 18:519–527 **9.** Brittberg M (1999) Autologous chondrocyte transplantation. Clin Orthop Relat Res. 367:S147-55. https://doi.org/10.1097/00003086-199910001-00016 **10.** Gugjoo MB, Amarpal SGT, Aithal HP, Kinjavdekar P (2016) Cartilage tissue engineering: role of mesenchymal stem cells along with growth factors & scaffolds. Indian J Med Res 144:339–347 **11.** Le H, Xu W, Zhuang X, Chang F, Wang Y, Ding J (2020) Mesenchymal stem cells for cartilage regeneration. J Tissue Eng 11:2041731420943839 **12.** Vannini F, Berveglieri L, Boffa A, Filardo G,·Viglione V, Buda R, Giannini S, Faldini C. Hyaluronic scaffold transplantation with bone marrow concentrate for the treatment of osteochondral lesions of the talus: durable results up to a minimum of 10 years. Knee Surg Sports Traumatol Arthrosc. 2023 Jun 17.

Anika Therapeutics S.r.l.
Corso Stati Uniti 4/U - 35127 Padova, Italy
+39-049-295-8311 | salessupportitaly@anika.com
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