



Hyalofast[®]

The Scaffold for Cartilage Regeneration in the Ankle

Product Brochure



100% hyaluronic acid based scaffold. Backed by 10+ years of clinical outcomes in ankle in cartilage repair ¹

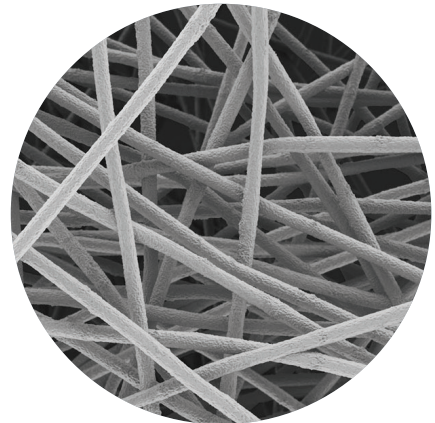
Hyalofast: The Simple, Adaptable and Proven Cartilage Repair Solution for the Ankle

Hyalofast is a biodegradable scaffold designed to support the repair of cartilage injuries, including chondral and osteochondral lesions of the ankle. Made entirely from Hyaff®, a benzyl ester of hyaluronic acid (HA), Hyalofast is a natural derived, non-animal biomaterial designed to support safe and effective cartilage repair for every patient.²

It is designed to entrap mesenchymal stem cells (MSCs) from bone marrow aspirate concentrate (BMAC) for the repair of cartilage defects, specifically chondral and osteochondral lesions.^{1,3} It can also act as a chondroprotective layer, helping retain MSCs at the site following bone marrow stimulation (BMS) procedures.

The scaffold's fibrous structure promotes cell adhesion, proliferation, and differentiation, allowing MSCs to organise within its three-dimensional structure to support the creation of functional cartilage.²

As Hyalofast gradually degrades, it enriches the site with hyaluronic acid, a key component of the extracellular matrix, and supports cartilage regeneration.²



Hyalofast Has Two Roles

Structural Role

3D structure of Hyalofast facilitates the entrapment of mesenchymal stem cells (MSCs) and cell adhesion, supporting their multi-dimensional development²

Biological Role

As Hyalofast degrades, it creates an HA-rich environment that favours chondrogenesis (the biological process of cartilage formation)^{2,4}

The Process



MSCs recruited by bone marrow stimulation (BMS) procedures or from BMAC



Hyalofast initially fills the defect, temporarily substituting the chondral and osteochondral tissue



Facilitates cartilage repair by guiding the formation of new tissue that mimics native cartilage⁵

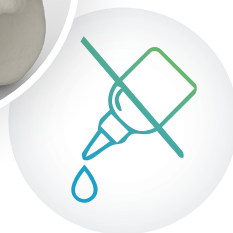
Designed for Ease of Use and Surgical Handling

Quickly and easily implantable via arthroscopy or mini-arthrotomy



Soft texture allows it to conform easily to the defect anatomy

Can be applied in any orientation, stacked or laid side by side



Adheres to the site of application with no additional fixation in most cases



Enduring Patient Outcomes Backed by Long-Term Data

01

Medium Term Follow up

Clinical results equivalent to matrix-induced ACI (MACI) at medium term follow-up^{6,7}

02

Long Term Outcomes

Durable results up to a minimum of 10 years in osteochondral lesions of the talus¹

03

Quality and Durability of Repair

MRI T2 mapping demonstrated hyaline-like cartilage regeneration in 85% of patients at 4-year follow-up⁷

Durable Clinical Outcomes at 10+ years¹

Hyalofast® demonstrated durable improvements in pain relief, ankle function and patient satisfaction at a minimum 10-year follow-up. Patients experienced substantial reductions in pain, significant functional recovery ($p < 0.0005$), and 85% reported a satisfactory health status at long-term follow-up.

Fig.1 NRS Pain from baseline to final mean follow-up (12.6 years)

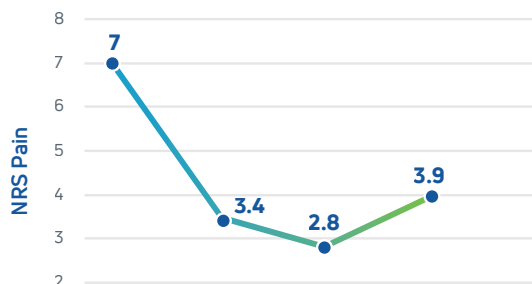
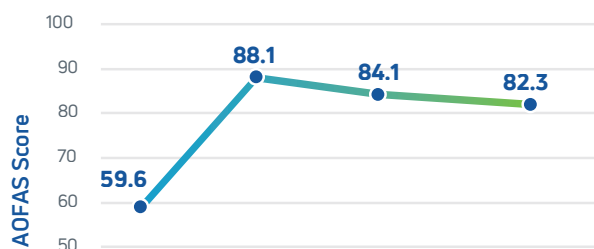


Fig.2 AOFAS Score from baseline to final mean follow-up (12.6 years)

AOFAS Score from baseline to ≥ 10 years



Hyalofast: 85% Patient Satisfaction at 10+ Years

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 microfracture or perforation procedures.

For complete product information including indications, contraindications, warnings, precautions, possible complications and product storage, please refer to the product IFU.

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

References

1. Vannini F, et al. 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 Oct;31(10):4551-4558
2. Hyalofast IFU
3. Pasquinelli G, Orrico C, Foroni L, Bonafè F, Carboni M, Guarnieri C, Raimondo S, Penna C, Geuna S, Pagliaro P, Freyrie A, Stella A, Calderera CM, Muscari C. Mesenchymal stem cell interaction with a nonwoven hyaluronan-based scaffold suitable for tissue repair. *J Anat.* 2008 Nov;213(5):520-30.
4. Whyte GP, Bizzoco L, Gobbi A. One-Step Cartilage Repair of Full-Thickness Knee Chondral Lesions Using a Hyaluronic Acid-Based Scaffold Embedded With Bone Marrow Aspirate Concentrate: Long-term Outcomes After Mean Follow-up Duration of 14 Years. *Am J Sports Med.* 2024 Dec;52(14):3561-3568. Epub 2024 Nov
5. Cavallo C, Desando G, Columbaro M, Ferrari A, Zini N, Facchini A, Grigolo B. 2012. Chondrogenic differentiation of bone marrow concentrate grown onto a hyaluronan scaffold: Rationale for its use in the treatment of cartilage lesions.
6. Giannini S, et al. Cartilage repair evolution in post-traumatic osteochondral lesions of the talus: From open field autologous chondrocyte to bone-marrow-derived cells transplantation. *Injury.* 2010 Nov;41(11):1196-203
7. Buda R., et al. Regenerative treatment in osteochondral lesions of the talus: autologous chondrocyte implantation versus onestep bone marrow derived cells transplantation. *Int Orthop.* 2015 May;39(5):893-900

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