

Your life. *In motion.*

Hyalofast[®]
One-step Cartilage Repair

Product information

Unique characteristics put Hyalofast Cartilage Repair one step ahead.

Hyalofast is One-Step Cartilage Repair made from a 3D non-woven scaffold composed of Hyaff® (benzyl ester of Hyaluronic acid - HA). In combination with mesenchymal stem cells (MSCs), Hyalofast supports the regeneration of hyaline-like cartilage.



Versatile

Acts as a scaffold for bone marrow aspirate or as a chondroprotective coverage after bone marrow stimulation procedures. Hyalofast can be used with or without fibrin sealant.



Fast

No fixation is required in most cases. It is easily adaptable to any lesion shape.



Effective

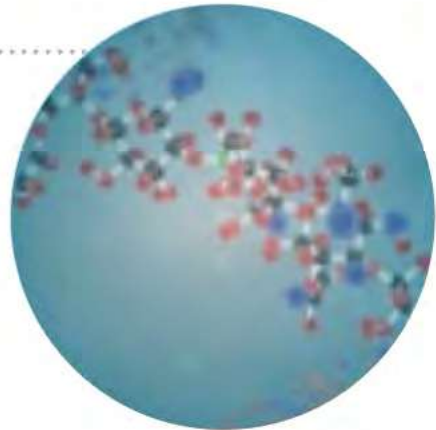
Excellent clinical and MRI results in the treatment of osteochondral defects of ankle and knee.¹⁻⁶ Hyaline-like cartilage confirmed by MRI T2 mapping.^{1,2,5}

Hyalofast-the only 100% hyaluronic acid-based scaffold for hyaline-like cartilage regeneration.

Unique composition makes Hyalofast a safe step to regeneration

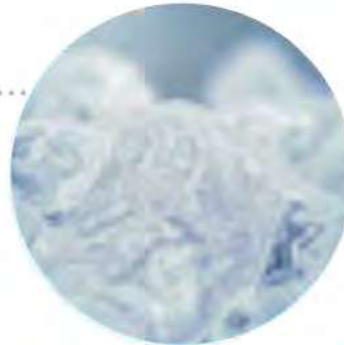
Safe and bioresorbable

Hyaff has been used in the tissue regeneration field for over 15 years, with an excellent safety profile.⁷ Once the Hyaff degrades releasing HA, it is naturally resorbed into the body. HA is a natural and major component of human cartilage and is highly biocompatible.



Regenerative environment

As HA is released into the lesion, this creates an embryonic-like micro-environment favourable to regeneration.



Non-woven 3D matrix

Hyalofast supports mesenchymal stem cell (MSC) adhesion and 3D organization, thus facilitating the recovery of the original tissue anatomy.



Unique handling properties

Hyalofast cartilage repair is a step up for repair of chondral and osteochondral lesions.

- Hyalofast can be easily and quickly implanted via arthroscopy or mini-arthrotomy
- The soft texture allows it to conform easily to any lesion shape
- It readily adheres to the site of application without requiring additional fixation in most cases
- The scaffold can be applied in any orientation or stacked due to its uniform single-layer 3D structure
- Two available sizes allow large lesions to be easily covered: 2x2 cm and 5x5 cm

Hyalofast goes the distance

Hyalofast in combination with MSCs has shown:

- Hyaline-like cartilage regeneration confirmed by T2 mapping¹
- Clinical results equivalent or superior to matrix-induced ACI^{4,5}
- When used with microfracture, good clinical and MRI outcomes at short-term follow-up that are superior to microfracture alone⁸
- Clinical results at medium-term follow-up superior to microfracture alone and to nanofracture^{8,9}
- Excellent short-term results the treatment of chondral injuries in FAI surgery, with a significant improvement in Hip Outcome Score and an ICRS cartilage assessment score for all lesions of "B" - nearly normal cartilage¹¹
- Excellent clinical and MRI results stable up to medium-term follow-up in the treatment of osteochondral lesions of the ankle⁵ and knee,^{3,8} including young OCD patients²
- To provide good to excellent clinical outcomes at long-term follow-up in the repair of full-thickness cartilage injuries (range 6-10 years)¹²
- To be an effective treatment for large chondral defects of the knee, including patients ≥ 45 years old⁶
- To be an effective treatment for large patello-femoral chondral defects with results stable up to medium-term follow-up (4.5 years)⁴

Clinical case

Hyalofast cartilage repair in the **knee**

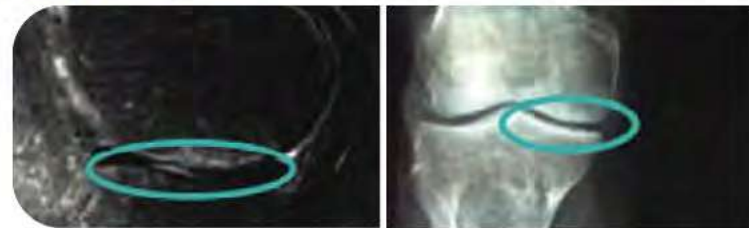
Hyalofast improved IKDC clinical score from 40 pre-op to 83 post-op.

- Male
- 64 years old
- Lawyer and jogger
- Grade IV medial femoral condyle
- *Implanted via open surgery with high tibial osteotomy.* Mesenchymal stem cells loaded onto Hyalofast scaffold via bone marrow aspirate concentrate (BMAC).

Pre-op MRI



Case Conclusion



Clinical case

Hyalofast cartilage repair in the **ankle**

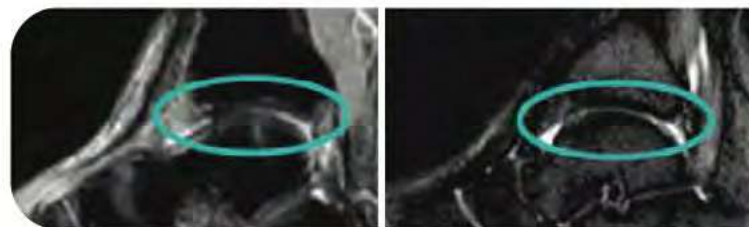
Hyalofast improved AOFAS clinical score from 65 pre-op to 95 post-op.

- Male
- 37 years old
- Military service and runner
- Grade IV osteochondral lesion on posteromedial aspect of talar dome (20mm x 7mm)
- *Arthroscopic implantation.* Mesenchymal stem cells loaded onto Hyalofast scaffold via bone marrow aspirate concentrate (BMAC).

Pre-op MRI



Case Conclusion



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 mobilization due to microfracture or perforation procedures.

What kind of chondral lesions?

ICRS Grade III and IV

Single or multiple lesions

Caused by:

- Acute trauma
- Repeated micro-trauma
- Instability and/or malalignment (in association with reconstructive and/or corrective surgery)
- Osteochondritis Dissecans (OCD)

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

References

1. Battaglia M, et al. Validity of T2 mapping in characterization of the regeneration tissue by bone marrow derived cell transplantation in osteochondral lesions of the ankle. *Eur J Radiol*. 2010 Aug.
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7. Data on file.
8. Gobbi A, et al. One-Stage Cartilage Repair Using a Hyaluronic Acid-Based Scaffold With Activated Bone Marrow-Derived Mesenchymal Stem Cells Compared With Microfracture: Five-Year Follow-up. *Am J Sports Med*. 2016 Nov.
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Preclinical data is available upon request.



GMP-Artwork-0693/07/2020

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