

# + Repair cartilage restore bone

FDA-approved for use in cartilage  
and osteochondral defects

**Smith+Nephew**

CARTIHEAL<sup>®</sup>  
AGILI-C<sup>®</sup> Cartilage Repair Implant



The CARTIHEAL<sup>◇</sup> AGILI-C<sup>◇</sup> Implant is a porous biomaterial that is biphasic and is derived from naturally occurring calcium carbonate (aragonite).

**+ Effective**

Twice the pain reduction compared to microfracture or debridement<sup>1</sup>

**+ Versatile**

Small to large lesions, with and without the presence of osteoarthritis<sup>2</sup>

**+ Convenient**

Simple single surgery and no donor tissue required

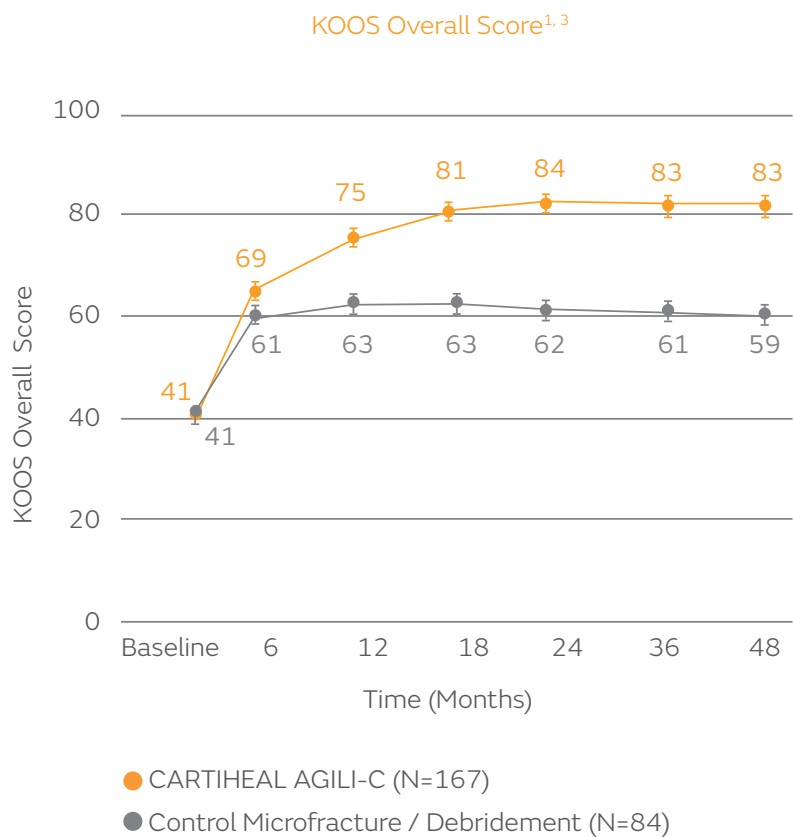
CARTIHEAL AGILI-C  
Implant delivered  
clinically meaningful  
improvements in  
pain, function and  
quality of life.<sup>1</sup>

## Effective

### Pivotal IDE clinical study results

The superiority of the CARTIHEAL<sup>®</sup> AGILI-C<sup>®</sup> Implant over the surgical standard of care was confirmed in the following areas\*<sup>1</sup>:

- KOOS and IKDC
- MRI defect fill
- Response rate
  - Subgroups:
    - Age ≥ 50yo
    - BMI ≥ 30
    - Mild to moderate OA (KL 2-3)
    - Large and multiple lesions (>3cm<sup>2</sup>)
- Post-partial meniscectomy

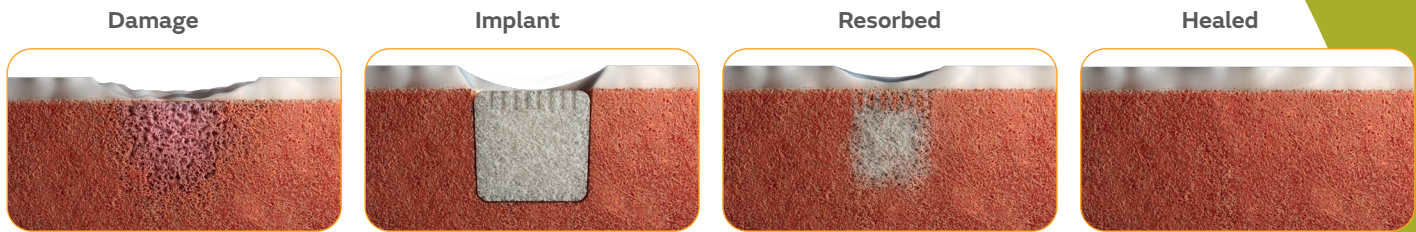


\*As compared to the surgical standard of care (microfracture or debridement)  
IKDC: International Knee Documentation Committee  
KOOS: Knee injury and Osteoarthritis Outcome Score

## Mechanism of action\*

After implantation, the CARTIHEAL<sup>®</sup> AGILI-C<sup>®</sup> implant is infiltrated by bone marrow which contains mesenchymal stem cells. The implant is biphasic and works through two mechanisms combining simultaneous processes:

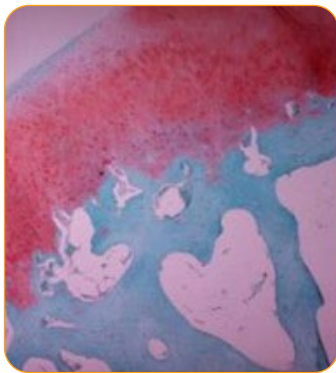
- 1 Bone Phase** – In this phase, the implant has a natural porosity that mimics the physical and chemical structure of bone. The stem cells adhere and differentiate into osteogenic cells which form new bone.
- 2 Cartilage Phase** – In this phase, the implant has a modified porosity created by drill channels in which stem cells adhere and differentiate into chondrocytes. On the surface, chondrocytes cells also migrate from the surrounding native cartilage and, together with the cells from the channels, they form new cartilage.<sup>4,5</sup>



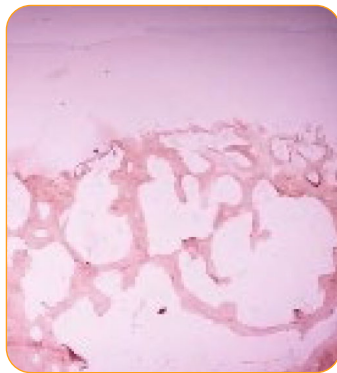
## Repair Cartilage

The cartilage lesion is fully repaired with high-quality tissue abundant in proteoglycan content and collagen type II, resembling that in native hyaline cartilage, with minimal to no fibrous cartilage formation.<sup>5</sup>

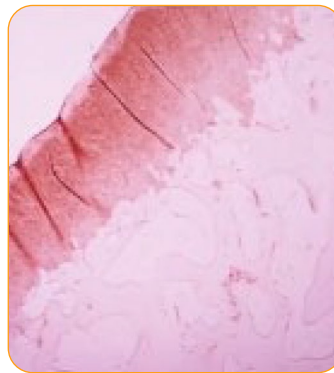
## Histology at 6 months in animal models



Safranin-O Cartilage and Bone stains



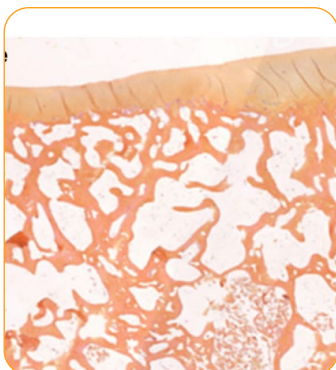
Collagen type 1 Fibrous tissue and bone marker



Collagen type II Hyaline cartilage maker

## Restore Bone

The regenerated subchondral bone shows normal bone trabecular structure throughout with substantial remodeling at 6 months and little coral implant left.<sup>6</sup>



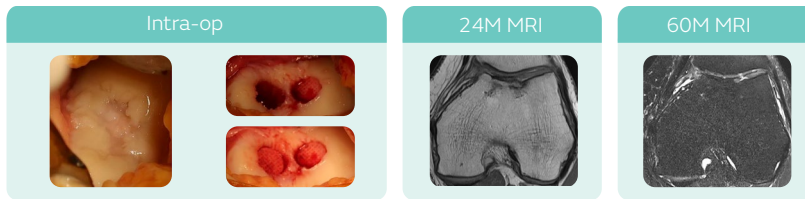
Histology stains of chondrocytes within newly formed articular hyaline cartilage in animal bone

## Versatile

Cases from a multicenter randomized controlled trial provide level 1 evidence.<sup>7</sup>

### Trochlea: “Butterfly” lesion, young patient

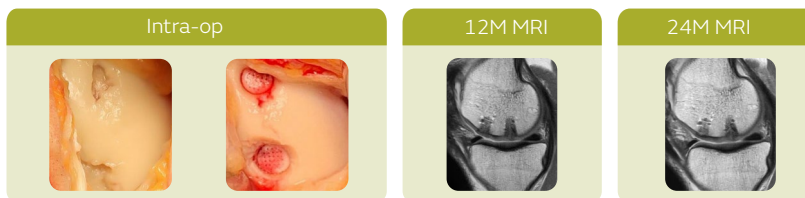
37-year-old male, 6.3cm<sup>2</sup> lesion on left trochlea, ICRS Grade III, Lateral meniscus – small posterior tear; ACL – partial tear\*



	Baseline	24M	60M
IKDC	44.83	93.10	98.85
KOOS	43.44	93.98	100

### Multi-lesion MFC: ICRS grade IV, mid-40s patient

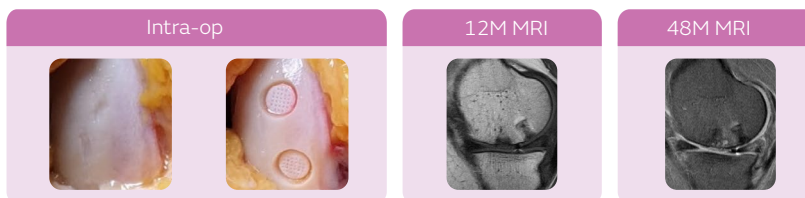
46-year-old male, 3cm<sup>2</sup> lesion on right MFC, ICRS grade IV\*



	Baseline	12M	24M
IKDC	47.13	85.06	89.66
KOOS	58.76	87.61	93.22

### Osteoarthritic: KL 3, mid-50s patient

54-year-old female, 3.8cm<sup>2</sup> lesion on center MFC, ICRS grade IV, KL score 3, concomitant treatment of medial meniscectomy.\*



	Baseline	12M	48M
IKDC	48.28	78.16	81.61
KOOS	43.94	89.42	87.08

\*Individual patient responses may vary  
 ACL: Anterior Cruciate Ligament  
 ICRS: International Cartilage Repair Society  
 KL: Kellgren Lawrence  
 MFC: Medial Femoral Condyle

CARTIHEAL<sup>◊</sup> AGILI-C<sup>◊</sup>  
 Implant treats a broad  
 group of patients  
 across age, lesion  
 size and presence of  
 OA while delivering  
 clinically meaningful  
 results.<sup>1</sup>

## Convenient

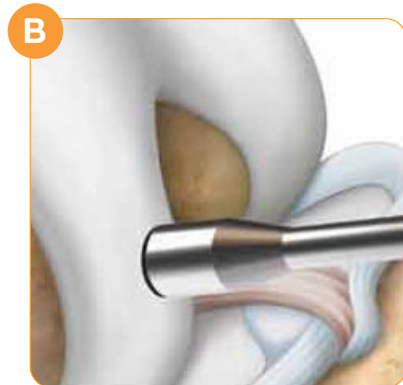
### Simple Single Surgery

The CARTIHEAL<sup>®</sup> AGILI-C<sup>®</sup> Implant is an off-the-shelf solution implanted in one simple surgery, avoiding the need for donor matching or cell harvesting.

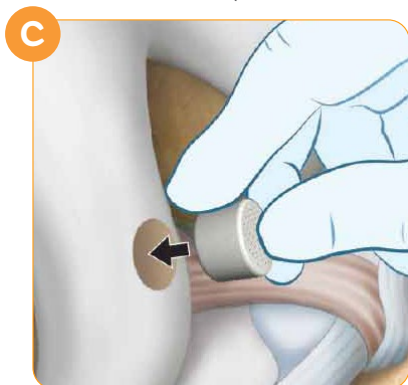
Off-the-shelf



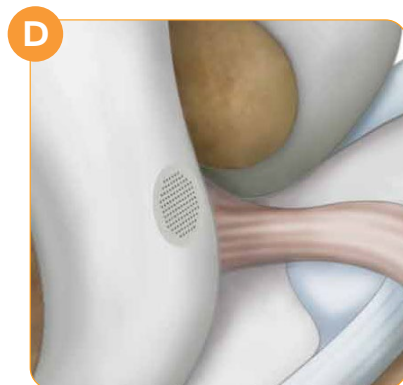
Drill



Manually insert



Press fit



### Watch



- Implantation Procedure: Large osteochondral defect, medial femoral condyle feature Prof. Peter Verdonk and Prof. Elizaveta Kon

### Learn



- CARTIHEAL AGILI-C Cartilage Repair Implant Surgical Technique

# Ordering information

CARTIHEAL <sup>°</sup> AGILI-C <sup>°</sup> Cartilage Repair Implant	
Reference #	Description
CH-075	CARTIHEAL AGILI-C Implant Pack, 7.5mm, single pack
CHP0752	CARTIHEAL AGILI-C Implant Pack, 7.5mm, two per pack
CHP0753	CARTIHEAL AGILI-C Implant Pack, 7.5mm, three per pack
CHP0755	CARTIHEAL AGILI-C Implant Pack, 7.5mm, five per pack
CH-100	CARTIHEAL AGILI-C Implant, 10mm, single pack (rescue only)
CH-125	CARTIHEAL AGILI-C Implant, 12.5mm, single pack (rescue only)
MINI-DS	Mini-Disposable Tools set (K-wire, Tamper)
RU-TRAY-F	Instrument Tray, reusable

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use. Individual patient responses may vary.

To order the instruments used in this technique, call +1 800 343 5717 in the U.S. or contact an authorized Smith+Nephew representative. Prior to performing this technique, consult the Instructions for Use documentation provided with individual components – including indications, contraindications, warnings, cautions and instructions.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

## Learn more at [smith-nephew.com](https://www.smith-nephew.com)

Smith & Nephew, Inc.  
150 Minuteman Road  
Andover, MA 01810  
USA

[www.smith-nephew.com](https://www.smith-nephew.com)  
T +978 749 1000  
US Customer Service:  
+1 800 343 5717

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### References

**1.** Altschuler N, Zaslav KR, Di Matteo B, et al. Aragonite-based scaffold versus microfracture and debridement for the treatment of knee chondral and osteochondral lesions: results of a multicenter randomized controlled trial. *AJSM*. 2023;51(4):957-967. **2.** CartiHeal. (2009). Indications for use: Agili-C™ implant. **3.** Agili-C [package insert]. Kfar Saba, Israel: CartiHeal: 2021. **4.** Chubinskaya S, Di Matteo B, Lavato L, Iacono F, Robinson D, Kon E. Agili-C Implant promotes the regenerative capacity of articular cartilage defects in an ex vivo mode. *Knee Surg Sports Traumatol Arthrosc*. 2018;27(6):1953-1964. **5.** Kon E, Filardo G, Shani J, Altschuler N, Levy A, Zaslav K, Eisman JE, Robinson D. Osteochondral regeneration with a novel aragonite-hyaluronate biphasic scaffold: up to 12-month follow-up study in a goat model. *J Orthop Surg Res*. 2015;10(1). **6.** Kon E, Filardo G, Robinson D, et al. Osteochondral regeneration using a novel aragonite-hyaluronate bi-phasic scaffold in a goat model. *Knee Surg Sports Traumatol Arthrosc*. 2014;22:1452-1464. **7.** CLN-0000035 CartiHeal AGILI-C Pivotal IDE Study. Rehabilitation Recommendations (CLN0021). **8.** CartiHeal (2023). 48-M PAS Report PMA P210034 (2023).