

**5-
YEAR
DATA**

**1
STEP**

**Proven results
in cartilage repair**

Supporting healthcare professionals for over 150 years

 **smith&nephew**
CARGEL[®]
Bioscaffold



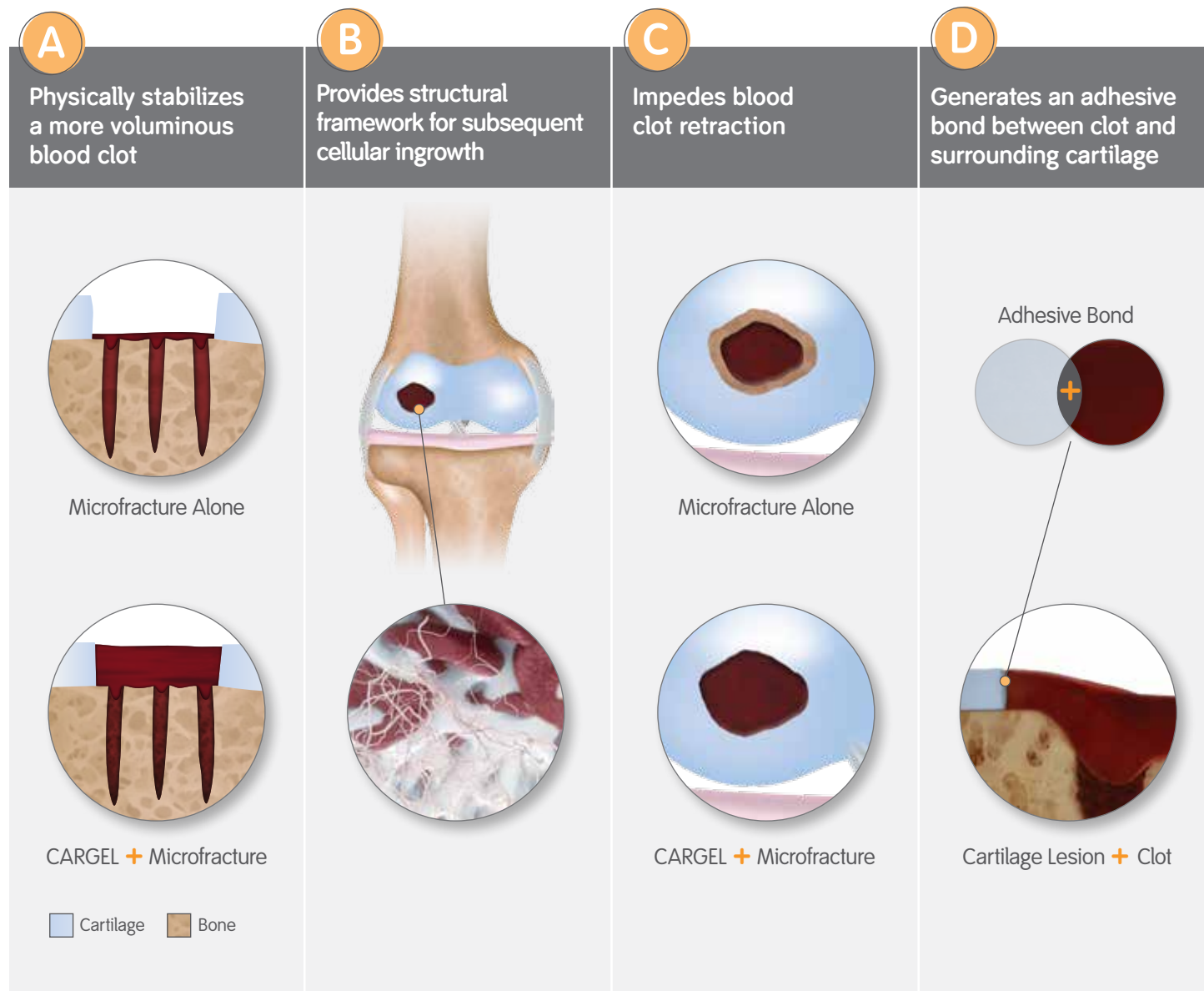
A close-up, low-angle shot of a surgeon in a sterile operating room. The surgeon is wearing a light blue surgical cap, a matching face mask, and a blue surgical gown. Their hands, wearing white gloves, are visible at the bottom right, holding a surgical instrument. The background is a soft, out-of-focus blue, suggesting a clinical environment. The overall tone is professional and clinical.

Proven Performance | Simplicity | Versatility

What is CARGEL[◇] Bioscaffold?

CARGEL Bioscaffold is an easy, ready-to-use product applied during a single-step bone marrow stimulation procedure. It is easily prepared by mixing a buffer, a chitosan solution and the patient's whole blood to create a liquid bioscaffold, resulting in superior cartilage repair.^{1,2}

How does CARGEL Bioscaffold work?



The above images are provided for illustrative purposes only.

Why choose CARGEL[◇] Bioscaffold?

Proven Performance

- Superiority to microfracture in lesion fill and quality of repair tissue at 1 and 5 years¹
- Clinical improvement versus baseline¹



Versatility

- Arthroscopic or mini-open
- Suited for most cartilage lesions in the knee joint*

Simplicity

- Single-step system²
- Liquid scaffold conforms to any lesion shape

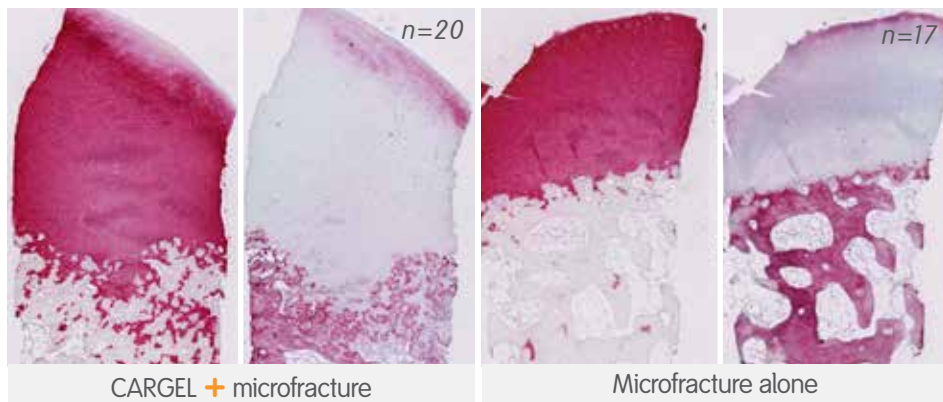


Proven Performance

CARGEL Bioscaffold has the highest standard of proven evidence in cartilage repair, as shown through Level I, randomized, controlled clinical trials at 1 and 5 years.¹

Improvement in cellular and structural tissue quality

CARGEL Bioscaffold treatment improves repair-tissue structure at 13 months by ICRS histological scoring of biopsies. The results also showed improved tissue cellularity and a smoother articulating surface.³



CARGEL VS MICROFRACTURE

Number of Improved ICRS Parameters

ICRS I, 4 of 6
ICRS II, 10 of 14

Superior Structure Parameters

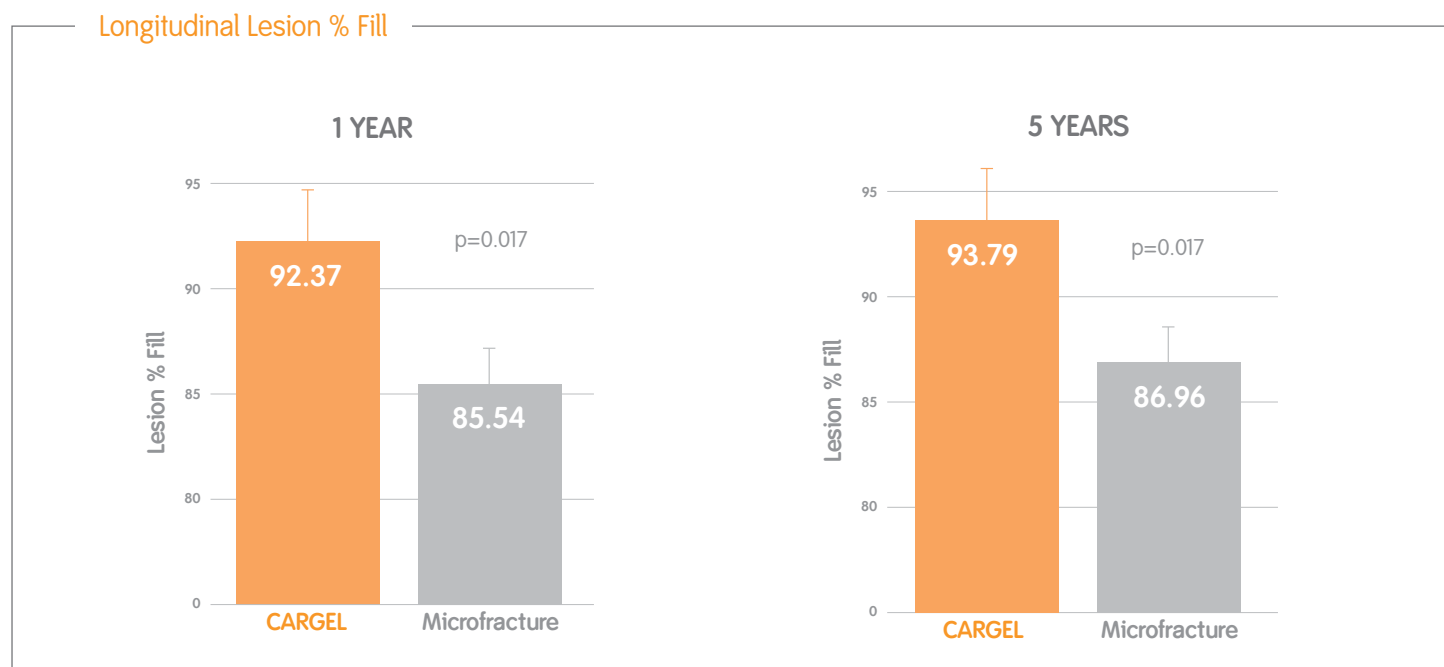
Surface Architecture
Superficial Zone
Basal Integration
Overall Assessment

The biopsy images above represent the best of both groups. Results will vary.

**Please refer to the Instructions for Use (IFU) for a complete list of indications and contraindications.*

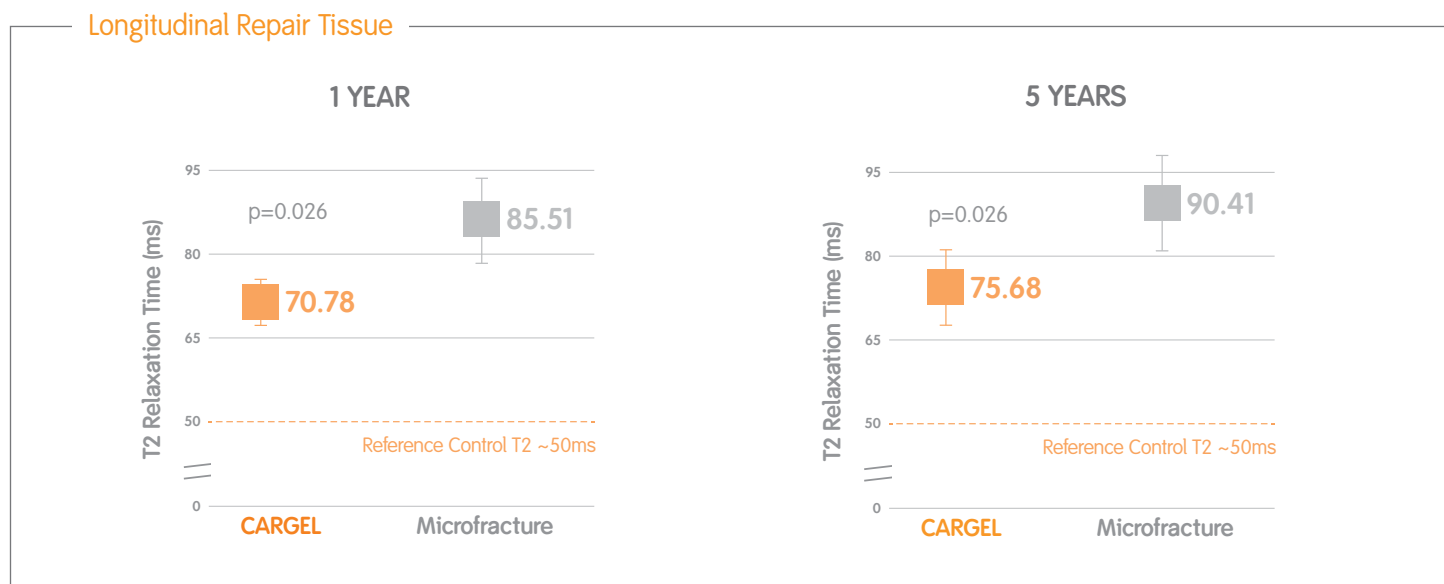
Greater quantity of repair tissue¹

Statistically significant difference in % fill over 5 years with CARGEL[®] Bioscaffold compared to microfracture alone.



Better quality of repair tissue¹

Statistically significant difference in T2 relaxation time* over 5 years with CARGEL Bioscaffold compared to microfracture alone.



* Lower scores for T2 indicate superior quality, with ~50 ms considered the average value for a control posterior region on the same condyle.

Significant modifications in healing sequence

Animal studies have shown increased bone remodeling, increased vascularization, and increased stromal cell recruitment with CARGEL Bioscaffold versus microfracture alone.⁴

Simplicity

CARGEL® Bioscaffold is easy to use and is applied as a liquid, allowing it to conform to any lesion shape. CARGEL Bioscaffold eliminates the need for sizing, shaping, cutting, gluing and suturing, which are common with solid scaffolding technologies.



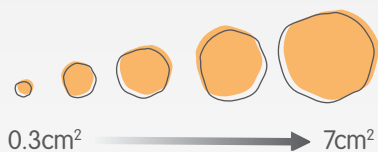
PREPARE. The lesion area is surgically prepared by standard bone marrow stimulation.

MIX. These steps can be done by a non-sterile nurse while the lesion is being surgically prepared.

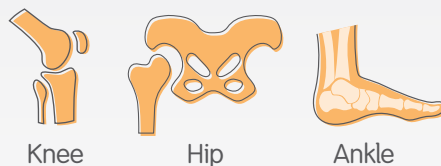
DELIVER. Administer the CARGEL Bioscaffold/blood mixture to the lesion.

Versatility

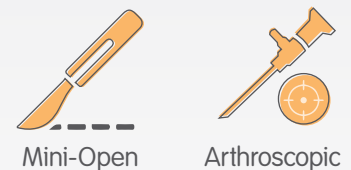
Available for use arthroscopically or through a mini-open technique, and applicable in a broad range of lesions in all synovial joints, CARGEL Bioscaffold is highly versatile and adaptable.



SIZE. CARGEL Bioscaffold can be used in a variety of lesion shapes and sizes.



INDICATIONS. CARGEL Bioscaffold is indicated for use in all synovial joints.*



PROCEDURES. CARGEL Bioscaffold can be applied arthroscopically or through mini-open procedures.

*Please refer to the Instructions for Use (IFU) for a complete list of indications and contraindications.

Case report

Pre and post images of a repair using CARGEL® Bioscaffold with 13-month follow-up

41-year-old male, BMI: 27 | Chronic chondral lesion | Lesion size: 3.85cm²



Cartilage lesion



After debridement



After microfracture



Second look at 13 months

QUANTITATIVE MRI RESULTS

Lesion % Fill: **97%**

Average Repair
Tissue T2: **58 ms**

Courtesy of Dr. Manuel Leyes, Spain

Results may not represent typical outcomes. Results will vary.



Proven Performance | Simplicity | Versatility

Ordering Information

CARGEL® Bioscaffold

Reference #	Description
72204980	CARGEL Bioscaffold

B. Braun Dispensing Pin™

Reference #	Description
72204937	Dispensing Pin

Microfracture Pick

Reference #	Description
72202119	Microfracture Pick XL, 30°
72202120	Microfracture Pick XL, 45°
72202210	Microfracture Pick XL, 60°

Open Ring Curette

Reference #	Description
72202584	Open Curette XL, reverse cut 6.0mm

SPIDER2 Limb Positioner

Reference #	Description
72203299	SPIDER2 Limb Positioner
72203300	Switch Drape (case of 20)
72203301	SPIDER2 Battery Pack
72203840	SPIDER2 Battery Charger
7210570	Piggy Back Connector (2 per box, required for all sterile procedures)

Leg Accessories

72203235	SPIDER Leg Accessory (left)
72203236	SPIDER Leg Accessory (right)
72203239	3D SPIDER Connector (one required for each Leg Accessory)
72203238	SPIDER Leg Stabilization Kit (case of 10)

In all approved countries (with the exception of Canada) CARGEL Bioscaffold is indicated for all synovial joints. In Canada, CARGEL Bioscaffold is indicated for the repair of Grade 3 or 4 cartilage lesions of the femoral condyles with areas of $\geq 2\text{cm}^2$.

CARGEL Bioscaffold is not available in the United States and its territories.

1. Shive M, Stanish W, McCormack R, et al. "BST-CarGel® Treatment Maintains Cartilage Repair Superiority over Microfracture at 5 Years in a Multicenter Randomized Clinical Trial," *Cartilage*. 2015; 6(2):62-72.
2. Steinwachs M. "Arthroscopic Treatment of Cartilage Lesions With Microfracture and BST-CarGel," *Arthroscopy Techniques*. 2014; 3(3):399-402
3. Méthot S, Changoor A, Tran-Khanh N, et al. "Osteochondral Biopsy Analysis Demonstrates that BST-CarGel Treatment Improves Structural and Cellular Characteristics of Cartilage Repair Tissue Compared With Microfracture," *Cartilage*. (2015):1-13.
4. Chevrier A, Hoemann CD, Sun J, et al. "Chitosan – Glycerol Phosphate/Blood Implants Increase Cell Recruitment, Transient Vascularization and Subchondral Bone Remodelling in Drilled Cartilage Defects," *Osteoarthritis and Cartilage*. 2007; 15:316-327. The results of animal studies have not been proven to predict clinical performance.