



autologous cultured  
chondrocytes  
on porcine  
collagen membrane

Active cells help  
restore active patients



MACI.COM

**Indication:** MACI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product that is indicated for the repair of single or multiple symptomatic, full-thickness cartilage defects of the adult knee, with or without bone involvement.

**For more information, please see full Indication and Important Safety Information and full Prescribing Information.**



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# MACI REPAIRS KNEE CARTILAGE DEFECTS USING A PATIENT'S OWN CELLS

to help them return to an active lifestyle

MACI is for the repair of symptomatic, full-thickness cartilage defects of the knee

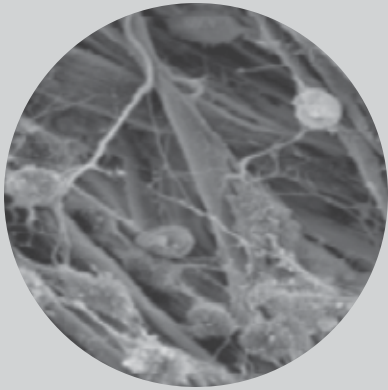
MACI can be used in areas such as the trochlea and patella, where there may be fewer options to treat cartilage damage.

Knee cartilage injuries will often get worse with time if left untreated. If conservative treatment has not worked to relieve pain associated with knee cartilage damage, MACI may be an appropriate treatment option.

**Important Safety Information:** MACI is contraindicated in patients with a known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin. MACI is also contraindicated for patients with severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders. MACI is also not indicated for use in patients who have undergone prior knee surgery in the past 6 months, excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant.

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## Cells from a patient's healthy knee cartilage biopsy are expanded and uniformly seeded onto a collagen membrane

The MACI membrane is seeded with a density of 500,000 to 1,000,000 viable autologous cartilage cells per cm<sup>2</sup>, equal to the approximate density found in native adult articular cartilage<sup>1</sup>

Every MACI implant undergoes rigorous release testing to ensure:

### VIABILITY

Verifies a sufficient amount of viable chondrocytes for implantation is available

### IDENTITY

Uses genetic markers to identify chondrocyte cells

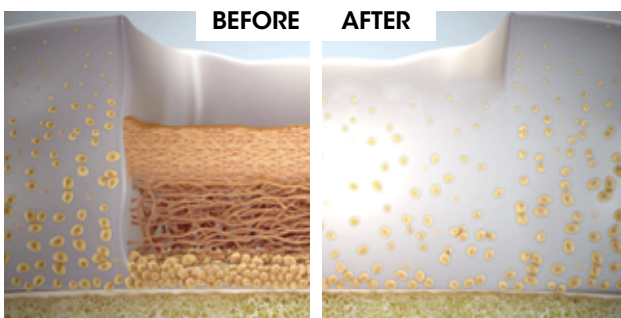
### POTENCY

Validating the ability to form a durable repair tissue

### STERILITY

Used throughout the process to detect most organisms within 48 hours\*

\*sterility results are not available at the time of shipping



Over the course of a year, the matrix continues to expand and fill the defect<sup>3</sup>

Each MACI implant consists of **autologous cultured chondrocytes** on a resorbable porcine Type I/III collagen membrane

After implantation, chondrocytes migrate from the resorbable collagen scaffold and adhere to the subchondral bone **forming new cartilage**<sup>2</sup>

As the matrix matures, it produces a **durable repair tissue** which expands to fill the defect<sup>3</sup>

For more information, please see [Indication and Important Safety Information](#) and [full Prescribing Information](#).

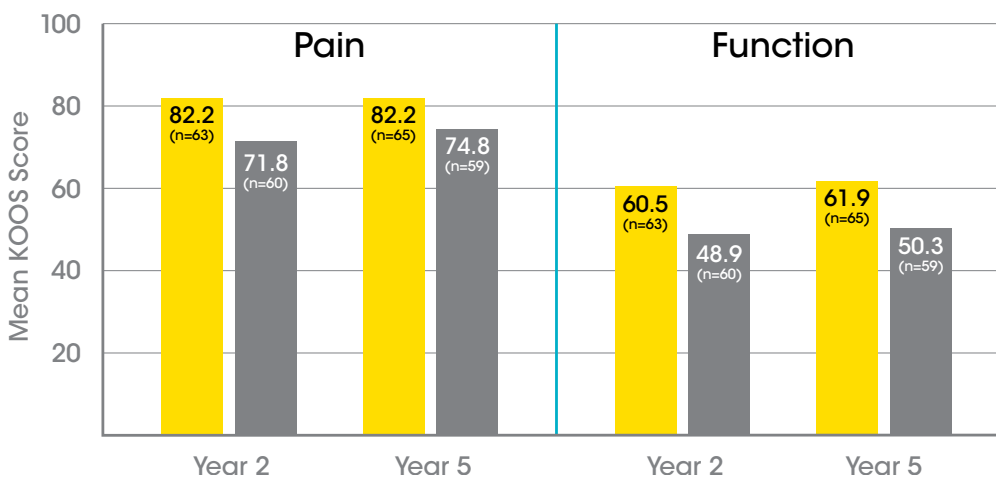


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# MACI VS. MICROFRACTURE: IMPROVEMENTS IN PAIN AND FUNCTION<sup>3</sup>

## MACI IS PROVEN IN CLINICAL STUDIES

Mean Patient-Reported KOOS Scores at Year 2 and Year 5<sup>4</sup>



Baseline KOOS Scores  
for MACI patients:  
37.1 Pain / 15.4 Function

Baseline KOOS Scores  
for Microfracture patients:  
35.2 Pain / 11.9 Function

■ MACI  
■ Microfracture

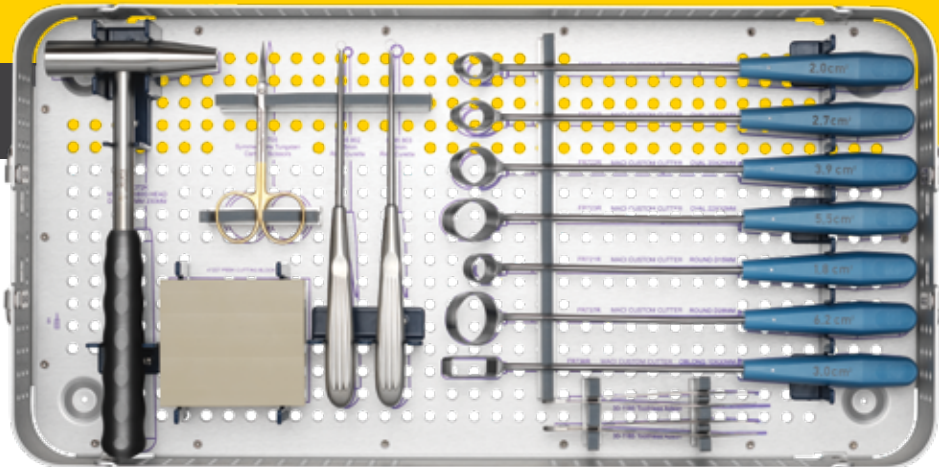
A significantly greater proportion of patients treated with MACI experienced **clinically meaningful improvements in both pain and function** at 2 years when compared to microfracture<sup>3</sup>

In a follow-up extension study, improvements in pain and function at Year 2 were maintained with MACI at Year 5<sup>4</sup>

**Important Safety Information:** MACI is contraindicated in patients who are unable to follow a physician-prescribed post-surgical rehabilitation program. The safety of MACI in patients with malignancy in the area of cartilage biopsy or implant is unknown. Expansion of present malignant or dysplastic cells during the culturing process or implantation is possible.

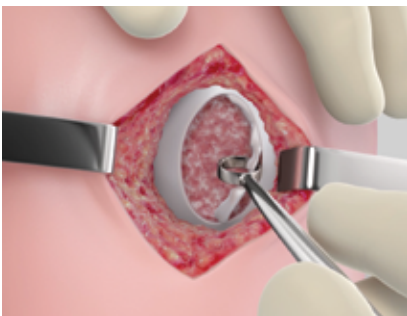
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# MACI IS AUTOLOGOUS CHONDROCYTE IMPLANTATION, SIMPLIFIED

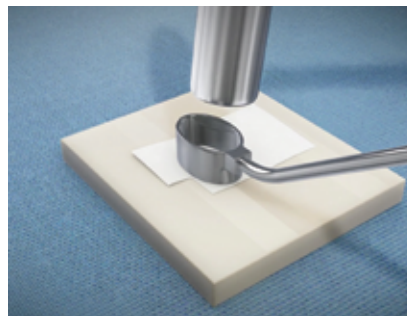


The MACI Implantation Kit offers a complete set of surgical tools designed to simplify the procedure, minimize handling of the MACI implant, and ensure an exact fit to your patient's cartilage defect.

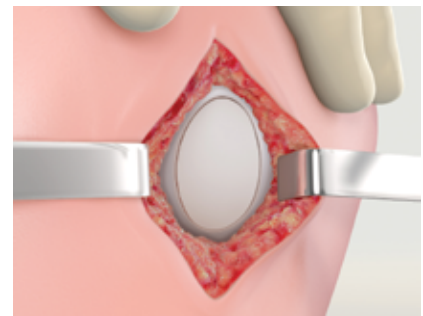
## MACI provides key benefits over traditional ACI



**Less invasive**, may be done through a mini-arthrotomy in fewer steps than traditional ACI



**Cells are delivered** on a shapeable, resorbable matrix that can be easily cut to fit any defect



**Sutureless and easy to affix**, can be secured in place using only fibrin sealant in most cases

For more information, please see [Indication and Important Safety Information](#) and [full Prescribing Information](#).



A patient support program for MACI providing insurance approval coordination and treatment information

MyCartilageCare offers support for your patients including:



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SUPPORT



TREATMENT  
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## INDICATION

MACI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product that is indicated for the repair of single or multiple symptomatic, full-thickness cartilage defects of the adult knee, with or without bone involvement.

MACI is intended for autologous use and must only be administered to the patient for whom it was manufactured. The implantation of MACI is to be performed via an arthrotomy to the knee joint under sterile conditions.

The amount of MACI administered is dependent upon the size (surface in cm<sup>2</sup>) of the cartilage defect. The implantation membrane is trimmed by the treating surgeon to the size and shape of the defect, to ensure the damaged area is completely covered, and implanted cell-side down.

### Limitations of Use

Effectiveness of MACI in joints other than the knee has not been established.

Safety and effectiveness of MACI in patients over the age of 55 years have not been established.

## IMPORTANT SAFETY INFORMATION

MACI is contraindicated in patients with a known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin. MACI is also contraindicated for patients with severe osteoarthritis of the knee, inflammatory arthritis, inflammatory joint disease, or uncorrected congenital blood coagulation disorders. MACI is also not indicated for use in patients who have undergone prior knee surgery in the past 6 months, excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant.

MACI is contraindicated in patients who are unable to follow a physician-prescribed post-surgical rehabilitation program.

The safety of MACI in patients with malignancy in the area of cartilage biopsy or implant is unknown. Expansion of present malignant or dysplastic cells during the culturing process or implantation is possible.

Patients undergoing procedures associated with MACI are not routinely tested for transmissible infectious diseases. A cartilage biopsy and MACI implant may carry the risk of transmitting infectious diseases to healthcare providers handling the tissue. Universal precautions should be employed when handling the biopsy samples and the MACI product.

Final sterility test results are not available at the time of shipping. In the case of positive sterility results, health care provider(s) will be contacted.

To create a favorable environment for healing, concomitant pathologies that include meniscal pathology, cruciate ligament instability and joint misalignment, must be addressed prior to or concurrent with the implantation of MACI.

Local treatment guidelines regarding the use of thromboprophylaxis and antibiotic prophylaxis around orthopaedic surgery should be followed. Use in patients with local inflammations or active infections in the bone, joint, and surrounding soft tissue should be temporarily deferred until documented recovery.

The MACI implant is not recommended during pregnancy. For implantations post-pregnancy, the safety of breast feeding to infant has not been determined.

Use of MACI in pediatric patients (younger than 18 years of age) or patients over 65 years of age has not been established.

The most frequently occurring adverse reactions reported for MACI (≥5%) were arthralgia, tendonitis, back pain, joint swelling, and joint effusion.

Serious adverse reactions reported for MACI were arthralgia, cartilage injury, meniscus injury, treatment failure, and osteoarthritis.

## REFERENCES

1. Foldager C, Gomoll A, et al. Cell Seeding Densities in Autologous Chondrocyte Implantation Techniques for Cartilage Repair. *Cartilage*. 2012;3(2):108–117.
2. Brittberg M. Cell carriers as the next generation of cell therapy for cartilage repair: a review of the matrix-induced autologous chondrocyte implantation procedure. *Am J Sports Med*. 2010 Jun;38(6):1259-71.
3. Saris D, Price A, Widuchowski W, et al. for the SUMMIT study group. Matrix-applied characterized autologous cultured chondrocytes versus microfracture: two-year follow-up of a prospective randomized trial. *Am J Sports Med*. 2014;42:1384-1394.
4. Brittberg M, Recker D, Ilgenfritz J, Saris D. SUMMIT Extension Study Group. Matrix-applied characterized autologous cultured chondrocytes versus microfracture: Five-year follow-up of a prospective randomized trial. *Am J Sports Med*. 2018;46(6):1343-1351.



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Please see [full Prescribing Information](#) or visit [MACI.com](#).



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MACI is autologous chondrocyte  
implantation, simplified.

Repair knee cartilage damage  
using a patient's own cells.



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For additional information about MACI or to contact a Representative,  
please call **800-453-6948** or visit [MACI.com](http://MACI.com).

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