

CLINICAL TRIAL INFORMATION

About the U.S. Phase 3 Clinical Trial of CARTISTEM®

What the registered U.S. study involves, and what its registration does and does not mean for patients.

Prepared by St. Luke Hospital · Based on the public trial record (ClinicalTrials.gov NCT07339111) and the manufacturer's announcement of 8 July 2026.

Purpose: To describe the U.S. study accurately, without implying approval or endorsement.

What the study is

- **Registration:** The study is registered on ClinicalTrials.gov, the clinical trial registry maintained by the U.S. National Institutes of Health, under identifier **NCT07339111**. The sponsor is MEDIPOST, Inc.
- **Design:** A pivotal Phase 3 study with a planned enrolment of approximately 300 participants in two treatment groups. The comparator is **surgical debridement** — that is, CARTISTEM® is being compared with a surgical procedure, not with injection treatments.
- **Objective:** To assess knee pain and knee function at two years after treatment compared with the comparator procedure, and to explore effects on the progression of osteoarthritis.
- **Eligibility as published:** Adults aged 18–75 with a cartilage defect of modified Outerbridge Grade 3 or 4 and a combined lesion area of 2–9 cm², with Kellgren–Lawrence grade 2 or 3 in the index knee. Full criteria are published on the trial record.
- **Progress:** The manufacturer reported in July 2026 that the first U.S. participant had been treated.

What the study is not

- **Registration is not approval.** Listing a study on ClinicalTrials.gov does not mean that the U.S. Food and Drug Administration, the National Institutes of Health, or any other authority has approved, endorsed, or evaluated the treatment. Regulatory review happens only after a study is complete and an application is filed.
- **An ongoing trial is not an available treatment in the United States.** CARTISTEM® is not approved for commercial use there.
- **Trial participation is separate from treatment in Korea.** Enrolment decisions are made by the participating U.S. trial sites, not by St. Luke Hospital. Treatment at our Joint Center is provided within the Korean approved indication, after individual orthopedic assessment.

- **If you are considering the U.S. study:** eligibility criteria, participating sites and contact details are published on the trial record. We are happy to discuss how the published criteria relate to your own imaging and clinical findings, but we cannot enrol patients into that study.

Sources

ClinicalTrials.gov trial record — NCT07339111

Regulatory notice. CARTISTEM® is approved in the Republic of Korea (MFDS, January 2012). It is **not approved for commercial use in the United States or in Japan**, where it remains under clinical investigation. Registration of a clinical trial does not constitute approval or endorsement of a treatment by any regulatory authority, and progress in clinical development does not indicate that approval will be granted. **Medical information notice.** This document provides general information and does not replace an in-person medical consultation, diagnosis, or treatment recommendation. The suitability of any option described here depends on individual assessment by a treating orthopedic specialist. Outcomes vary between patients.

St. Luke Hospital · Joint Center, Seoul, Korea · slmc.co.kr · Summary compiled September 2026