

## TREATMENT EXPERIENCE

# CARTISTEM® in Clinical Use: More Than a Decade of Treatment Experience in Korea

Approved in Korea since 2012, with real-world use reported by the manufacturer.

Prepared by St. Luke Hospital · Based on the manufacturer's announcement published via PR Newswire, 3 June 2026.

**Focus:** How long CARTISTEM® has been in clinical use, and how that experience is documented.

## Key points

- **Approved in Korea since January 2012:** CARTISTEM® received market approval from Korea's Ministry of Food and Drug Safety for the indication described in the Korean product information.
- **More than 36,000 patients treated in Korea:** The manufacturer reported in June 2026 that over 36,000 patients in South Korea had received CARTISTEM® since its 2012 launch.
- **Long-term real-world evidence:** Real-world data from approximately 550 patients treated at least three years earlier forms part of the confirmatory evidence accepted by the FDA for the U.S. filing strategy.
- **Follow-up at St. Luke Hospital:** In cases treated at our Joint Center, follow-up imaging and clinical review have been documented at intervals of one to five years after treatment. Individual results vary.
- **About benefits and risks:** Like any surgical or cell-based treatment, CARTISTEM® has potential risks as well as potential benefits, and it does not guarantee cartilage restoration, pain relief, or the avoidance of joint replacement. Your orthopedic specialist will explain the expected benefits, limitations, risks, alternatives and rehabilitation before you decide.

## Original source

Manufacturer announcement (PR Newswire, 3 June 2026)

**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. Progress in clinical development does not indicate that regulatory approval will be granted. **Medical information notice.** This summary is provided for general information and does not replace an in-person medical consultation, diagnosis, or treatment recommendation. Treatment at St. Luke Hospital is provided within the Korean approved indication, following an individual orthopedic assessment. Outcomes vary between patients.