



SETTING A NEW STANDARD FOR TREATING HALLUX RIGIDUS

The CARTIVA® Synthetic Cartilage Implant (SCI) is the first and only FDA approved device for the treatment of painful hallux rigidus. Scientific and clinical evidence of safety and effectiveness, proven via a randomized study against fusion, was required to achieve FDA pre-market approval (PMA) in 2016. All other devices marketed for treating hallux rigidus have been cleared by the FDA through the 510(k) process. The 510(k) process requires that manufacturers show their device is similar to older devices marketed in the U.S. since 1976.

CARTIVA SCI for hallux rigidus is made entirely of a biomedical polymer that mimics natural cartilage. It is the 1st new orthopedic articular surface material approved by the FDA since 2001. CARTIVA SCI is backed by Level 1 clinical evidence of safety and effectiveness, established in the largest prospective, randomized, multi-center study ever conducted for this painful condition.

PMA: WHY IS IT MEANINGFUL?

Premarket approval is the most stringent process and is granted based on clinical evidence proving safety and effectiveness. The CARTIVA SCI PMA is the result of a 7-year research process that continues today.

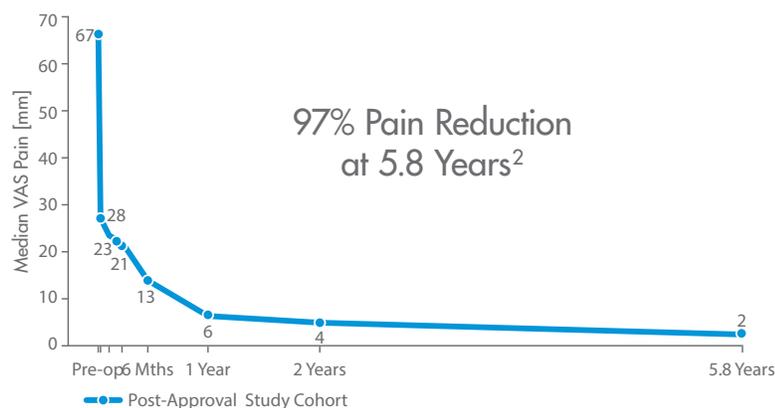
SUMMARY TABLE	CARTIVA® PMA
Scientific and regulatory review process by the US Food and Drug Administration	YES
Confirmed safety and efficacy through valid scientific evidence gathered through a randomized controlled study	YES
Manufacturing data review and facility inspection	YES
Subject to independent review by outside advisory panel	YES
Post-market requirements, including conduct of a post-market clinical study	YES

Conclusions

CARTIVA SCI has the distinction of having the ONLY prospective, randomized, multi-center clinical study resulting in Level 1 clinical data for the treatment of hallux rigidus¹ and now has durable results out to almost 6 years demonstrating 97% pain reduction, 176% functional improvement, with 93% of patients indicating they would undergo the procedure again.²

THE DIFFERENCE IS DATA.™

Wright is setting a new standard in the surgical treatment of hallux rigidus.



OTHER RESEARCH HIGHLIGHTS

- CARTIVA SCI is the **first new orthopedic articular surface material approved by the FDA since 2001** ([P150017](#)).
- CARTIVA SCI study was awarded the **Roger A. Mann Award** twice (2015 and 2017), the top research award given annually by the AOFAS for the best clinical research in foot and ankle.^{1,7}
- CARTIVA SCI received the **Phoenix 2017 Most Promising New Product Award** for outstanding achievement in the medical device and diagnostic industry.
- CARTIVA SCI's **extensive preclinical testing** demonstrates resistance to wear and that it does not fragment.³
- CARTIVA SCI surgeries are **23 minutes faster (40%) than fusion surgeries**.⁴
- CARTIVA SCI patients **return to preoperative activities faster than fusion patients**.⁴
- CARTIVA SCI is backed by a publication on the **first evaluation conducted on the association between patient factors and outcomes for any surgical treatment for hallux rigidus**.⁵
- CARTIVA SCI study shows successful conversions to fusion when needed, demonstrating it as a **"burns no bridges" procedure**.⁶
- CARTIVA SCI is an innovative technology that is being used in **clinical trials** for other joints.

1. Baumhauer JF, Singh D, Glazebrook M, et al. *Foot Ankle Int.* 2016;37(5):457-469. N=130 in Cartiva pivotal trial cohort.

2. Glazebrook M, Blundell C, O'Dowd D, et al. *Foot Ankle Int.* Dec. 2018, <https://doi.org/10.1177/1071100718815469>. N=106 in post-approval study cohort.

3. Baumhauer JF, Marcolongo M. *Foot Ankle Clin.* 2016 Dec; 21(4):891-902.

4. Glazebrook MA, Younger ASE, Daniels TR, et al. *Foot Ankle Surg.* 2017-May;29.

5. Goldberg A, Singh D, Glazebrook M, et al. *Foot Ankle Int.* 2017 Nov; 38(11):1199-1206.

6. Glazebrook M, Baumhauer J, Davies MB. *Foot & Ankle Orthopaedics.* 2017 Sep 11;2(3):2473011417S000044.

7. Baumhauer JF, Singh D, Glazebrook M, et al. *Foot Ankle Int.* 2017 Nov; 38(11):1175-1182.