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Wright Medical Announces FDA Pre-Market Approval For Additional Sizes Of CARTIVA® Synthetic Cartilage Implant (SCI) Device

CARTIVA SCI will now be available in 6 mm and 12 mm

Wright Medical, a global leader in the orthopedic extremities market, today announced that it received Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) for commercial distribution of the CARTIVA® Synthetic Cartilage Implant (SCI) in two additional sizes, 6 mm and 12 mm. Additionally, the company received approval of labeling to incorporate the post approval study results now that the FDA has closed out the post approval study and have concurred that Wright Medical has met all the requirements.

The CARTIVA SCI is intended to treat hallux rigidus, or osteoarthritis of the big toe, the most common arthritic condition in the foot.[1] First approved in 2016, the CARTIVA SCI has been available in two sizes, 8 mm and 10 mm, for selection by the physician. The additional dimensions of 6 mm and 12 mm offer physicians and patients more options to customize implantation for a more accurate fit. The approval came as a result of Wright Medical's 180-day supplement, which confirmed that the device's indication remains the same for the newly-approved dimensions.

"We understand that no two patients are the same, and every patient deserves a journey tailored to their needs – from diagnosis to treatment," expressed Patrick Fisher, President of Lower Extremities and Biologics at Wright Medical. "We pursued this expansion of the CARTIVA SCI device to offer a more comprehensive, customizable range of sizes to meet the needs of both physicians and patients."

CARTIVA SCI offers an alternative to the historical standard of care, fusion surgery, by not only reducing pain and improving foot function but also preserving toe movement.[3] The procedure can provide long-term pain reduction and motion preservation, but time and proper recovery are critical to unlocking the benefits of the CARTIVA SCI. On average, patients will start to experience clinically meaningful pain reduction and functional improvement after six to nine months that will continue to improve over time. In a post-approval, multi-center, prospective, randomized study, the long-term benefit of the CARTIVA SCI was demonstrated in patients who experienced 97% reduction in pain at 5.8 years post-procedure, and 93% of patients were satisfied and said they would have the procedure again.[4]

"It's exciting that we can now offer patients suffering from hallux rigidus treatment options like the CARTIVA SCI that can reduce pain without sacrificing range of motion," said Judith Baumhauer, M.D., M.P.H., Professor and Associate Chair of Academic Affairs, University of Rochester Medical Center. "The expansion of the CARTIVA portfolio to add new sizes allows me to not only feel more confident in treating a broader range of patients, but also to ensure optimal patient outcomes."

Big toe arthritis affects 1 in 40 people over the age of 50.[2] Patients suffering from big toe arthritis often experience tenderness, achiness and pain which over time can develop into joint stiffness that makes even walking painful.[3] Many patients will assume that the only surgical option is fusion surgery, a procedure that relieves pain, but eliminates motion of the big toe in the process. The CARTIVA SCI is a safe and effective surgical implant solution that can reduce pain and preserve long-term mobility.[4]

Commercial launch of the CARTIVA SCI in 6 mm and 12 mm is expected to begin in the second half of 2019. For more information about the CARTIVA SCI, visit www.Cartiva.net.

About Wright Medical

Wright Medical Group N.V. is uniquely positioned with leading technologies and specialized sales forces in three of the fastest growing areas of orthopedics – Upper Extremities, Lower Extremities and Biologics. That leadership is further enhanced by one of the most comprehensive extremity and biologic product portfolios in the industry as well as strong platforms for future new product development. From new material technologies to advanced products and instrumentation, Wright is committed to delivering innovative, value-added solutions improving quality of life for patients worldwide.

About Cartiva SCI

Cartiva's Synthetic Cartilage Implant (SCI) is indicated for treating arthritis at the base of the great toe and received U.S. Premarket Approval in July 2016.[1] The SCI is composed of a biocompatible, durable, low-friction organic polymer that functions similarly to natural cartilage and can be implanted in about 35 minutes.[1] Unlike fusion, Cartiva reduces joint pain without sacrificing the foot's natural movement and retains mobility and range of motion.[3,5] Due to a less restrictive rehabilitation protocol, Cartiva patients typically return to function and activities of daily living faster than patients who undergo a fusion procedure.[5]

REFERENCES

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