



Treace Announces First Patient Treated in Mini3D™ Lapiplasty® Clinical Study

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PONTE VEDRA, Fla., Oct. 01, 2021 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. ("Treace") (Nasdaq: TMCI), a commercial-stage orthopaedic medical device company driving a paradigm shift in the surgical treatment of hallux valgus (commonly known as bunions) through its Lapiplasty® 3D Bunion Correction™ procedure, today announced treatment of the first patient in the Mini3D™ Lapiplasty® clinical study. The study will evaluate outcomes using the Lapiplasty® Mini-Incision™ System.

"The Lapiplasty® Mini-Incision™ System and approach have been adapted to enable the same 3-dimensional correction that address the root cause of the bunion problem typically through a smaller 3.5cm incisions vs. the standard Lapiplasty® system. When compared with traditional minimally invasive surgical osteotomies, the Lapiplasty® Mini-Incision™ enables the proper realignment of the first metatarsal bone, restoring natural anatomy, without the need to cut and shift bone to improve appearance," said Dr. Jody McAleer, DPM, FACFAS Jefferson City Medical Group Department of Podiatry, MO and lead principal investigator.¹ "With the first patient now treated, we look forward to advancing the study and reporting on long term outcomes following the procedure."

John T. Treace, CEO of Treace commented, "We are committed to driving clinical data evaluating our Lapiplasty® 3D Bunion Correction™ procedure. The Mini3D™ study builds on our ongoing ALIGN3D™ study, but through a Mini-Incision™ approach, providing both patients and physicians with another option to surgically manage bunion deformities."

For additional information on the Lapiplasty® Mini-Incision™ system, including benefits and risks, please visit the Treace Medical [website](#).

About the Mini3D™ Lapiplasty® Clinical Study

The Prospective Clinical Study of Tri-planar Tarsometatarsal (TMT) ArthroDesis with Early Weight-Bearing after Lapiplasty® Procedure through a Mini-Incision™ Approach, oMini3D™, is a prospective, multicenter, unblinded post-market study designed to evaluate outcomes of the Lapiplasty® Procedure using the Lapiplasty® Mini-Incision™ System for patients in need of hallux valgus surgery. The study will evaluate for consistent and reliable correction of all three dimensions of the bunion deformity, as well as maintenance of such correction following accelerated return to weight-bearing, initially in a walking boot. The primary effectiveness endpoint is radiographic recurrence of the hallux valgus deformity at 24 months follow up. Key secondary endpoints include change in three-dimensional radiographic alignment; clinical radiographic healing; time to start of weight-bearing in a walking boot and in shoes; pain; quality of life; and range of motion of the big toe joint. The study will treat up to 200 patients in up to 20 centers.

About the ALIGN3D™ Clinical Study

The ALIGN3D™ clinical study is a prospective, multicenter, post-market study designed to evaluate outcomes of Lapiplasty® 3D Bunion Correction™ in the surgical management of symptomatic hallux valgus. The study will evaluate for consistent and reliable correction of all three dimensions of the bunion deformity with the Lapiplasty® Procedure, as well as maintenance of such correction following accelerated return to weight-bearing, initially in a walking boot. The primary effectiveness endpoint is radiographic recurrence of the hallux valgus deformity at 24 months follow up. Key secondary endpoints include change in three-dimensional radiographic alignment; clinical radiographic healing; time to start of weight-bearing in a walking boot and in shoes; pain; quality of life; and range of motion of the big toe joint. The study enrolled 173 patients, aged 14 to 58 years, at 7 clinical sites in the United States with 13 participating surgeons. Final patient follow-up for the primary endpoint is anticipated in the first half of 2023.

About Treace Medical Concepts

Treace Medical Concepts, Inc. is a commercial-stage orthopaedic medical device company with the goal of advancing the standard of care for the surgical management of bunion deformities and related midfoot correction. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction™ system - a combination of instruments, implants, and surgical methods designed to correct all 3 planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and helping patients get back to their active lifestyles. Treace recently expanded its offering with the Adductoplasty™ Midfoot Correction System, designed for reproducible correction of the midfoot which could provide further support to hallux valgus patients. For more information, please visit www.treace.com.

1. Jody McAleer, DPM is a member of Treace's surgeon advisory board.

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