

Treace Announces First Patient Treated in MTA3D™ Adductoplasty® Clinical Study

November 21, 2022

PONTE VEDRA, Fla., Nov. 21, 2022 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. ("Treace") (NasdaqGS: TMCI), a medical technology company driving a fundamental 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 MTA3D™ Adductoplasty® Clinical Study. The study will evaluate outcomes of the Adductoplasty® Procedure combined with the Lapiplasty® Procedure for patients in need of hallux valgus (bunion) and metatarsus adductus (midfoot) correction surgery. Midfoot deformities may occur in up to 30% of hallux valgus patients.^{1,2}

The study, "Radiographic and Patient Reported Outcomes Following Combined Adductoplasty® and Lapiplasty® Procedures for Correction of Metatarsus Adductus and Hallux Valgus (MTA 3 D™) is a prospective, multicenter, unblinded clinical study, with up to 80 patients treated in up to 10 U.S. sites. Patients in the study will be followed for 5 years.

"Recurrence rates following traditional hallux valgus correction are found to be significantly higher when certain deformities of the midfoot are present.^{3,4} With Adductoplasty® and Lapiplasty® instrumentation, we now have technologies to enable reproducible correction of both the bunion and coexisting midfoot deformities," said Paul D. Dayton, DPM, MS, FACFAS of Foot & Ankle Center of Iowa and co-lead principal investigator. "With the first patient now treated, we look forward to advancing the MTA3DTM Clinical Study and reporting on outcomes following the procedures." Mark Easley, MD, Chief, Duke University Foot and Ankle Division, is also co-lead principal investigator of the study.

John T. Treace, CEO, Founder and Board Member stated, "We see a significant opportunity to assist surgeons, through our innovative Lapiplasty® and Adductoplasty® systems, in advancing the standard of care in the surgical management of bunions and related midfoot deformities. Our MTA3D™ Clinical Study reinforces our focused leadership in the surgical correction of bunions, as well as our commitment to building upon our differentiated clinical body of evidence."

Drs. Dayton and Easley are paid consultants for Treace. For additional information on the Adductoplasty® and Lapiplasty® Procedures, including benefits and risks, please visit www.treace.com.

About the MTA3D™ Adductoplasty® Clinical Study

The MTA3D™ Clinical Study is a prospective, multicenter, post-market study designed to evaluate outcomes of the combined Adductoplasty® and Lapiplasty® Procedures for patients in need of metatarsus adductus and hallux valgus corrective surgery. The study will evaluate for consistent, maintained radiographic correction and patient reported outcome scores following combined Adductoplasty® and Lapiplasty® procedures. The primary effectiveness endpoint is radiographic recurrence of hallux valgus and metatarsus adductus deformities at 24 months follow up. Key secondary endpoints include clinical radiographic healing; clinical complications; time to start of weight-bearing in a boot and in shoes; time to return to full unrestricted activity; pain; quality of life; range of motion of the 1st big toe joint; and change in osseous foot width. The study will treat up to 80 patients, aged 14 to 60 years, at up to 10 clinical sites in the United States. Patients will be followed for 5 years following the procedures.

About Treace Medical Concepts

Treace Medical Concepts, Inc. is a medical technology company with the goal of advancing the standard of care for the surgical management of bunion and related midfoot deformities. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot and affect approximately 65 million Americans, of which Treace estimates 1.1 million are annual surgical candidates. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction™ System − a combination of instruments, implants, and surgical methods designed to surgically 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 surgical correction of the midfoot to provide further support to hallux valgus patients. For more information, please visit www.treace.com.

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¹ Aiyer AA, et al. Foot Ankle Int. 2014; 35:1292-1297.

² Gribbin CK, et al. Foot Ankle Int. 2017; 38:14-19.

³ Aiyer A, et al. Foot Ankle Int. 2016; 37:165-171.

⁴ Park CH, Lee W. J Bone Joint Surg Am. 2017; 1190-1197.