



## Treace Announces Updated ALIGN3D™ Data at the 2022 AOFAS Annual Meeting

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PONTE VEDRA, Fla., Sept. 13, 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 an audio poster presentation of the latest interim analysis from the ALIGN3D™ clinical study at the ongoing 2022 American Orthopaedic Foot & Ankle Society (AOFAS) Annual Meeting in Quebec City, Canada.

The audio poster, "*Radiographic and Patient Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing: Interim Analysis of a Prospective Multicenter Study (ALIGN3D)*", included the interim analysis of 159 patients (of 173 total patients treated) with at least 12 months of follow-up following the Lapiplasty® Procedure. The data showed:

- Early return to weight bearing in a walking boot at an average 8.3 days;
- Low recurrence rate, defined as loss of radiographic correction, was observed in 1.4% of patients (2 out of 144 patients); and
- An 81% reduction in pain (Visual Analog Scale) was reported at 24 months post-procedure (n=107).

The interim analysis also continued to report statistically significant improvement in Patient-Reported Outcomes (PRO) across two validated scoring systems, including the Manchester-Oxford Foot Questionnaire (MOxFAQ) and the Patient Reported Outcomes Measurement Information Systems (PROMIS-29). At 24 months post-surgery (n=107), an 82% and 84% improvement was observed in walking/standing as well as social interaction, respectively, using the MOxFAQ scoring system. Further, statistically significant improvement in physical, mental, and social health scores were reported using the PROMIS-29 scoring system (n=104).

John T. Treace, CEO, Founder and Board Member of Treace said, "Interim data readouts from our ongoing ALIGN3D™ clinical study continue to demonstrate sustained, successful procedural and patient outcomes on additional patients followed through 12-, 24- and 36-months post-surgery. This type of multicenter, prospective study is unique in the field of bunion surgery, and reflects our commitment to investing in clinical programs, building upon our differentiated body of clinical evidence, as we advance the Lapiplasty® Procedure as the standard of care for bunion surgery."

The audio poster, which includes additional details, can be accessed by meeting attendees on a kiosk at the Annual Meeting or on the mobile app. The updated data is also available on the Treace Medical website.

### 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 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 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](http://www.treace.com).

### About AOFAS Annual Meeting

The American Orthopaedic Foot & Ankle Society® (AOFAS) mobilizes its global community of foot and ankle orthopaedic specialists to improve patient care through education, research, and advocacy. The AOFAS Annual Meeting is the premier event for foot and ankle education, offering presentations from renowned speakers, special interest forums and the latest products and technology.

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