



Treace Receives FDA 510(k) Clearance for SpeedPlate™ Rapid Compression Implant Technology

November 28, 2022

PONTE VEDRA, Fla., Nov. 28, 2022 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. ("Treace" or the "Company") (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 that its SpeedPlate™ Rapid Compression Implant System ("SpeedPlate™") has received 510(k) clearance from the FDA to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

The SpeedPlate™ System was designed for rapid delivery of titanium compression implants, serving as enabling fixation technology with Treace's new Micro-Lapiplasty® instrumentation which allows the patented Lapiplasty® procedure to be performed through small, 2cm incisions. The SpeedPlate™ implant platform also serves as a versatile addition to the Company's fixation portfolio, with broad compatibility with conventional Lapiplasty®, Lapiplasty® Mini-Incision™, and Adductoplasty® procedures/systems.

"We are pleased to announce 510(k) clearance of our SpeedPlate™ technology. SpeedPlate™ represents an exciting new fixation platform for Treace as we continue to invest in targeted R&D efforts aimed at making our Lapiplasty® therapy less invasive, faster, and easier for surgeons to perform, reinforcing our mission to improve surgical outcomes for bunion patients and advance Lapiplasty® as the standard of care," said John T. Treace, CEO, Founder, and Board Member. "As with any procedure involving smaller incisions and less tissue dissection, we believe our Micro-Lapiplasty®/SpeedPlate™ offering may translate to even faster patient recovery with less pain and swelling."

The Company anticipates limited release of SpeedPlate™ implants with Micro-Lapiplasty® instrumentation in the first half of 2023 with expanded access in the second 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements, including, but not limited to the anticipated timing of the limited release and expanded access to SpeedPlate™ implants with Micro-Lapiplasty® instrumentation in 2023. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release can be found in the Risk Factors section of Treace's public filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 4, 2022. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

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