



THERACLION SECURES KEY U.S. REIMBURSEMENT MILESTONE FOR SONOVEIN® WITH AMA CPT EDITORIAL PANEL APPROVAL OF A NEW CATEGORY III CPT CODE

Malakoff, France, June 8, 2026, 6:00pm (CEST) - Theraclion (ISIN: FR0010120402; Ticker: ALTHE), an innovative company developing a platform for non-invasive therapy using high intensity focused ultrasound (HIFU) for the treatment of varicose veins (the “Company”), today announced that the American Medical Association (AMA) CPT Editorial Panel has approved the creation of a new Category III CPT code for non-invasive (HIFU) treatment of varicose veins, performed using Sonovein®. The new code will become effective on January 1, 2027.

“This is a major step forward in our U.S. strategy,” said Martin Deterre, CEO of Theraclion, “Sonovein® has the potential to transform the varicose vein treatment market by offering physicians and patients a fully non-invasive alternative to current invasive procedures. But for such innovation to reach broad adoption in the United States, reimbursement must be addressed early and seriously. The creation of this new CPT code gives us a concrete foundation to advance our market access strategy, engage with payers and prepare for U.S. commercialization. Together with our clinical results and ongoing FDA review, this confirms that we are moving fast on the right path toward broad market access in the United States.”

Category III CPT codes are designed for emerging medical technologies, services and procedures. They provide a standardized mechanism to report procedures, track utilization, collect clinical data and support evidence development. This new code will support future engagement with healthcare providers, payers and clinical investigators as Theraclion prepares for the potential U.S. commercialization of Sonovein®.

In parallel to the reimbursement pathway effort, the Sonovein® market approval application was submitted to the FDA in December 2025 via the De Novo pathway, following a pivotal study demonstrating 96.8% efficacy. Discussions with the FDA are progressing constructively as part of the review process with exchanges underway, and a decision is now expected toward the end of Q3 or the beginning of Q4 2026. Theraclion continues to execute its U.S. market entry plan, with commercial launch preparations advancing toward a targeted launch by year-end 2026.

The AMA CPT Editorial Panel’s actions do not constitute endorsement of any specific technology or guarantee reimbursement coverage or payment. Payment, coverage, and coding policies remain subject to individual payer determination.

About Theraclion

Theraclion is a French MedTech company developing a non-invasive alternative to surgery through the innovative use of focused ultrasound.

High Intensity Focused Ultrasound (HIFU) does not require incisions or an operating room, leaves no scars, and allows patients to resume normal activities immediately. HIFU concentrates therapeutic ultrasound on an internal focal point from outside the body.



Theraclion is developing Sonovein®, a robotic HIFU platform for varicose vein treatment, CE marked under the MDR (EU 2017/745), with the potential to replace millions of surgical procedures each year. To date, Sonovein® has been adopted by more than a dozen centers worldwide and used in over 4,000 procedures. In the U.S., Sonovein® is not yet available for sale.

Based in Malakoff (Paris), Theraclion's team comprises around 35 people.

For more information, please visit www.theraclion.com and follow the [LinkedIn account](#).

Theraclion is listed on Euronext Growth Paris and is eligible for the PEA-PME scheme

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