

GENTHERM

Gentherm Medical Receives FDA Clearance for ThermAffyx™ Patient Safety System

Jul 20, 2026

The company's new patented integrated warming and securement device seamlessly addresses unique challenges in robotic surgery

NOVI, Mich., July 20, 2026 (GLOBE NEWSWIRE) -- Gentherm, a global market leader of innovative thermal management and pneumatic comfort technologies, announced today it received FDA 510(k) clearance for its patented [ThermAffyx™ Patient Safety System](#). This Class II medical device combines active patient warming, securement and pressure reduction in a single platform designed for the more than 3 million robotic-assisted surgical procedures performed annually worldwide. Product trials at healthcare facilities are scheduled to begin in August, with revenue generation expected to commence in Q3 2026.

Historically, surgical teams have pieced together separate solutions to address warming and securement issues. ThermAffyx simplifies that process by combining two critical patient safety functions into a single system that fits naturally into existing surgical workflows.

Traditional underbody securement pads help prevent patient movement but do not provide active warming. This is especially problematic in robotic procedures and surgeries that require the patient to be tilted in Trendelenburg position. Studies have found that only 17% to 21% of a patient's body surface area may be available for forced-air warming during these procedures, and more than one-quarter of robotic surgery patients are hypothermic in recovery, despite warming interventions.

The ThermAffyx Patient Safety System was developed to address this gap by integrating active underbody warming directly into an anti-slip securement pad. The radiolucent heating element is powered by Gentherm's proprietary Carbotex® carbon-fiber heating technology. This is more than a new warming device. It's a purpose-built patient safety platform designed around the realities of modern robotic surgery.

The FDA clearance follows Gentherm's 510(k) submission announced earlier this year and represents a significant expansion of the company's patient temperature management portfolio.

About Gentherm

Gentherm (NASDAQ: THRM) is a global market leader of innovative thermal management and pneumatic comfort technologies. Automotive products include Climate Control Seats (CCS®), Climate Control Interiors (CCI™), Lumbar and Massage Comfort Solutions, and Valve Systems. Medical products include patient temperature management systems. The Company is also developing a number of new technologies and products that will help enable improvements to existing products and to create new product applications for existing and new markets. Gentherm has more than 14,000 employees in facilities across 13 countries. In 2025, the company recorded annual sales of approximately \$1.5 billion and secured \$2.2 billion in automotive new business awards. For more information, go to www.gentherm.com.

Investor Contact
Gregory Blanchette
investors@gentherm.com
248.308.1702

Media Contacts
Haley Baur
media@gentherm.com
248.289.9711

GENTHERM