Ethicon, Inc. Expands Hemostasis Product Portfolio with Approval of the Company's First Synthetic Internal Use Sealant

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SOMERVILLE, N.J., July 7 /PRNewswire/ -- Ethicon, Inc., a worldwide leader in surgical care, announced today the introduction of ETHICON™ OMNEX™ Surgical Sealant, ETHICON™ Biosurgery's first synthetic sealant designed to achieve adjunctive hemostasis (stoppage of bleeding) in vascular reconstructions by mechanically sealing areas of leakage. The US Food and Drug Administration (FDA) recently granted approval of the Premarket Approval Application (PMA) for ETHICON™ OMNEX™ Surgical Sealant.

ETHICON™ OMNEX™ creates a strong, flexible physical seal independent of the body's clotting mechanisms. It is proven in an ex-vivo model to be two-to-four times as strong as other surgical sealants, is ready for use in less than 30 seconds, and proven to seal to ePTFE grafts and bond securely to friable vessels.(1)

"A basic rule of patient safety and excellent outcomes is to prevent unnecessary bleeding during and immediately after surgery," said Alan B. Lumsden MD, Medical Director of the Methodist DeBakey Heart & Vascular Center and the Chairman of the Department of Cardiovascular Surgery at The Methodist Hospital in Houston.* "The availability of an effective surgical sealant such as ETHICON™ OMNEX™ provides surgeons with a valuable new tool that is clinically proven to decrease the time it takes to seal the surgical site, including ePTFE grafts, and prevent leakage from occurring."

ETHICON™ OMNEX™ is clinically proven to significantly decrease time to hemostasis based on clinical trials conducted to support its safety and effectiveness. Specifically, results from a pivotal, randomized, controlled, open-label, multi-center trial of 151 patients at 13 centers in '/>"/>

SOURCE [1]

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