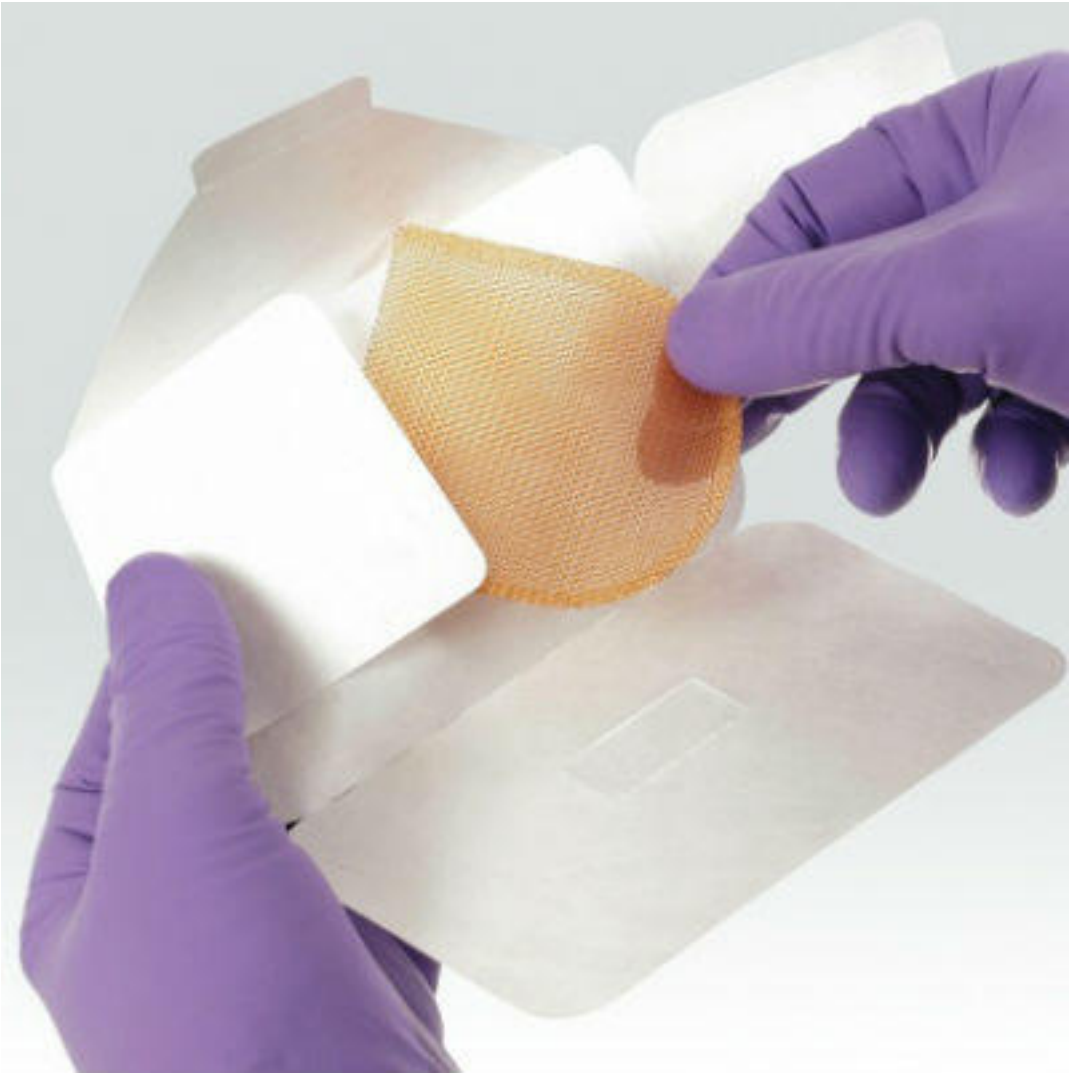
Tyrx Receives FDA Clearance for Aigisrx N Antibacterial Envelope

Business Wire

Expands Access to Proven Antibacterial Technology to Neurosurgery



TYRX, Inc. has announced that it has received U.S. Food and Drug Administration (FDA) clearance to market the AIGISRx N Antibacterial Envelope for use with vagus nerve stimulators, which are currently used to treat seizure disorders and depression. This approval extends TYRX's leadership in the commercialization of implantable medical devices designed to help reduce surgical-site infections (SSIs) associated with implantable devices into the field of neurosurgery.

The AIGISRx N Antibacterial Envelope is intended to hold vagus nerve stimulators securely in place in order to provide a stable environment when implanted in the body. Additionally, the AIGISRx N mesh envelope contains the antimicrobial agents rifampin and minocycline, which are released locally into the tissue in order to help reduce SSIs associated with vagus nerve stimulators implanted in the infraclavicular

fossa.

“The AIGISRx N Antibacterial Envelope provides neurosurgery patients and physicians with a new and proven infection prevention technology which can help improve patient outcomes,” stated Christopher Rumana, MD, FACS, Clinical Assistant Professor at Florida State University, and Chairman of Tallahassee Memorial Hospital Division of Neurosurgery.

“Securing the FDA-clearance to offer our AIGISRx technology to patients and physicians in the neurosurgery arena is an important milestone for TYRX and expands our leadership in the effort to reduce surgical site infections in multiple therapeutic areas of medical device implantation,” commented Robert White, TYRX President and Chief Executive Officer.

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