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16 Aug 2024 | **News**

News We're Watching: Globus Warning Letter, FDA Clears Traumagel, Reimbursement For Symplicity Spyral

by Brian Bossetta

This week, surgical robot maker Globus Medical got a warning letter from the US Food and Drug Administration; the FDA cleared a hemostatic gel to stop blood loss; Medicare issued a payment code for Medtronic's renal denervation device; and more.

FDA Sends Warning To Globus Concerning Surgical Robot

After an inspection earlier this year of its Pennsylvania plant, the US Food and Drug Administration sent a letter warning *Globus Medical* of quality systems violations concerning its surgical robot used during spine procedures.

Specifically, the agency said the firm delayed reporting issues with misplaced screws during surgeries with its Class II Excelsius GPS (EGPS) surgical robot and associated interbody spine and cranial modules, which is intended to aid surgeons in locating anatomical structures and spatial positioning and orientation of an instrument holder or guide tube.

"In your responses, you provided data showing counts of misplaced screws per 10,000 screws implanted from 2017 to 2024," the letter states. "However, there was no additional level of data analyses, using appropriate statistical methodology, to determine whether there are any trends associated with part numbers."

Further, the letter says Globus failed to start a corrective and preventative action procedure (CAPA) to investigate claims regarding the misplaced screws.

Gel To Stop Blood Loss Gets FDA Thumbs Up

Brooklyn, NY-based device firm Cresilon Inc. has received FDA clearance for its product Traumagel, which can be applied topically to control moderate to serious bleeding.

The plant-based hydrogel can stop or control bleeding “in a matter of seconds” when applied to a wound, Cresilon says. Unlike existing wound care products that may require a lengthy preparation and application process, Traumagel is sold in prefilled syringes and will work across all types of bleeds.

The company plans to market the gel for use by the military, in emergency medicine, and across other settings where medical professionals routinely encounter traumatic bleeding. Its launch is expected later in 2024.

"The ability to rapidly stop bleeding at the point of care and halt a life-threatening hemorrhage can be the difference between life and death for people with traumatic wounds," said Joe Landolina, CEO and co-founder of Cresilon and inventor of the technology. "The FDA clearance for Traumagel is a monumental milestone for Cresilon and brings us another step forward in our mission to save lives and transform the standard of care in wound treatment.”

This is Cresilon’s second FDA clearance, following a June 2023 510(k) for Cresilon Hemostatic Gel (CHG). CHG is indicated to control bleeding from minor cuts, lacerations, and abrasions.

Medtronic Gets NTAP For Renal Denervation System

In its *Inpatient Prospective Payment System (IPPS) Final Rule* for fiscal year 2025, the Centers for Medicare and Medicaid Servies has approved New Technology Add-on Payment (NTAP) for Medtronic’s Symplicity Spyral renal denervation (RDN) system, also known as the Symplicity blood pressure procedure.

The NTAP will go into effect on 1 October and will be in place for three years.

The Symplicity blood pressure procedure, according to Medtronic, is an innovative, minimally invasive procedure that delivers radiofrequency energy to calm the nerves near the kidneys that can become overactive causing blood pressure to spike.

After sedation, the doctor inserts a single thin tube, or catheter, into the artery leading to the kidney. Once the tube is in place, the doctor administers energy to the system to calm the excessive activity of the nerves connected to the kidney. The tube is removed, leaving no implant behind.

“Medtronic is pleased to see the final rule for the Medtronic Symplicity Spyral application for

NTAP," said Jason Weidman, president of the Coronary and Renal Denervation business in the Medtronic Cardiovascular portfolio. "Although we expect a small number of inpatient renal denervation procedures, this is a notable milestone in developing reimbursement for Symplicity Spyral.

Consumers Prefer Generative AI Support in Healthcare Over Direct Interaction, Survey Reveals

Consumers are more comfortable with the idea of generative AI supporting their doctor than using technology themselves, reported Bain & Company.

Bain's *US Frontline of Healthcare Consumer Survey* investigated consumer comfort level with generative AI applications across five functions, including taking notes during appointments; analyzing radiology scans and making a report to the doctor; analyzing radiology scans and making diagnoses; and providing medical advice or treatment plans to patients calling health care providers or insurers.

Around 37% of consumers were comfortable with generative AI taking notes during appointments and sending follow-ups. Around 21% were comfortable with generative AI analyzing radiology scans and making diagnoses instead of doctors. However, only 19% of consumers were comfortable with generative AI answering the phone of health providers or insurers.

"Done well, generative AI has the ability to alleviate clinicians' administrative burdens, allowing them to focus more of their time and energy on vital face-to-face interactions with patients. As more applications come to market, it will be important to balance their use with the need to treat patients with compassion, tune into their concerns and emotions, and deliver high quality, individualized care," said Erin Ney, partner in Bain & Company's health care and life sciences practice.

Despite this, physicians and administrators are concerned that generative AI could undermine the patient-consultant relationship, 19% of physicians and 17% reported so, said Bain & Company. However, a similar sentiment was seen with telehealth, but now 76% of physicians and 78% of consumers view it as a complement to in-person care, said Bain & Company.

FDA To Establish Rare Disease Innovation Hub

The FDA will hold a public meeting on 16 October, "*Advancing Rare Disease Therapies Through an*

FDA Rare Disease Innovation Hub," to discuss the establishment a rare disease hub to enhance collaboration and cooperation across the FDA's Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research and other centers to advance rare disease therapies.

The meeting, which will be facilitated by the Reagan-Udall Foundation, will provide those in the rare disease community the opportunity to provide input on the priorities of the hub. The FDA plans for the hub to work across rare diseases but especially focus on products intended for smaller populations or for less-understood diseases.

The Center for Devices and Radiological Health will collaborate on the hub, though it will be lead by the directors of CDER and CBER.

Information on the meeting, including topics for discussion and how to register, may be found here.

Formaldehyde Exposure Risk Prompts Device Correction For Breas Medical Ventilators

Earlier this month, Breas Medical issued a nationwide correction of more than 8,000 Vivo 45 LS ventilator devices after tests identified the potential for short-term elevated levels of formaldehyde exposure to users under specific conditions.

Formaldehyde exposure, the FDA said, can lead to adverse pulmonary or neurological effects, such as the potential for transient, reversible airway irritation, or inflammation that could lead to airway hyperresponsiveness in small pediatric patients resulting in additional medical intervention.

The devices in question were manufactured from 4 February 2021 to 1 July 2024.

To date, Breas Medical has not received any reports of patient injury or adverse effects related to this issue.

The company said it is in the process of notifying its distributors and commercial customers of the correction and that users will receive an update to the instructions for use (IFU).

Withings Joins AMA Center For Health Technology & Innovation

Withings Health Solutions has joined the American Heart Association Center for Health

Technology & Innovation Innovators' Network, a health care technology consortium that connects entrepreneurs, providers, researchers, and payers.

Innovators' Network members also have access to recommendations from the AMA as they develop digital healthcare technologies and can collaborate with the AMA Center on building models for clinical outcome studies, lowering the significant cost of developing those studies independently, helping connect the science to technology, and providing evidence that a digital platform improves healthcare outcomes.

“Becoming a member of the Association's Center for Digital Health and Innovation enables all of us to improve patient outcomes and better support healthcare providers,” said Eric Carreel, Withings founder and CEO.

Withings specializes in connected health, with products including smart scales, hybrid watches, blood pressure monitors, and sleep analyzers.