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News We're Watching: Impella Recall Linked To Deaths, FDA OKs New Sterilization Rules, Boston Sci Plans Expansion

by Hannah Daniel

This week, Abiomed announced a class I recall of Impella heart pumps; the FDA released new device sterilization standards; and Boston Scientific planned a $140m new campus in Minnesota.

Four Deaths Linked To Recall Of Abiomed Impella Heart Pumps

The FDA has designated a recall of various *Impella Left-Sided Blood Pumps* from *Abiomed, Inc.* as class I, its most serious.

The agency said Abiomed recalled the pumps because the instructions for use (IFU) do not adequately address the precautions clinicians need to take when treating patients who have undergone transcatheter aortic valve replacement (TAVR).

The FDA says that the pumps' motor housing may make contact with the distal stent of a TAVR, which could damage or destroy the motor's impeller blades.

A damaged Impella system may have reduced blood flow or pump stoppage, which could be life-threatening in patients requiring high levels of support. There is further risk that pieces of the broken blades could enter the patient's bloodstream.

Abiomed, which initiated the recall in June, reports 30 complaints, 26 injuries, and four deaths related to this issue.

In total, the company recalled 7,895 devices in the US distributed in the US from 1 May 2021.

FDA Recognizes New Standards For Sterilization

The US Food and Drug Administration has recognized three new standards to support the use of low-temperature vaporized hydrogen peroxide in sterilization of medical devices.

International Organization for Standardization's guidance *ISO 22441:2022*, Sterilization of Health Care Products, provides requirements for the use and monitoring of vaporized hydrogen peroxide.

Also recognized were Association for the Advancement of Medical Instrumentation standards *AAMI TIR104:2022*, a guidance on transferring medical devices between radiation sterilization sources, and *AAMI TIR17:2017, (R)2020,* a comprehensive guide on compatibility of materials and sterilization methods.

The FDA is encouraging manufacturers to move away from ethylene oxide sterilization, which is currently used to sterilize almost 50% of medical devices in the US but can also cause health complications from emissions. (Also see "*US FDA Looks To Balance Device Sterilization With Environmental Concerns*" - Medtech Insight, 4 Aug, 2022.)

The FDA is allowed to determine that international standards such as these as meet the requirements of the Food, Drug and Cosmetics Act under the guidance *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.*

While the Federal Register will be updated with these changes in late 2023, the FDA says manufacturers can start using the new and updated standards in premarket submissions.

Boston Scientific Plans Major Expansion In Minnesota

Boston Scientific Corporation is planning to spend about $170m for a new 400,000-square-foot campus in Maple Grove, MN, about 17 miles northwest of Minneapolis, according to the *Star-Tribune*.

The new facility will include research and development labs, training facilities and office space.

The company also considered building a new facility in Georgia or near its headquarters in Marlborough, MA, before selecting the 40-acre site in Maple Grove.

The Boston Scientific campus is part of a larger project to redevelop the former gravel-mine site as the *Minnesota Science and Technology Center*. The project is led by Minnesota-based Ryan Companies and C.S. McCrossan.

According to the *Star-Tribune*, the new campus ensures that about 1,000 Boston Scientific jobs stay in Minnesota; those jobs would have left if the company had chosen one of the other sites.

The new campus is near – but not adjacent to – Boston Scientific's existing facility in Maple Grove. Boston Scientific recently built a new 78,000-square-foot facility there to accommodate growth of its Watchman left-atrial appendage closure device. (Also see "*Cardio Catch-Up: Boston Scientific's Next-Gen Watchman FLX Pro Reduces Thrombi Risk In Trials*" - Medtech Insight, 8 Jun, 2023.)

Boston Scientific has had a large presence in the Twin Cities area since it acquired Maple Grove-based SciMed Life Systems for $865m in 1995. Boston Scientific employs about 8,700 people in Minnesota; the company has also has a facility in Arden Hills, near St. Paul.

Biotricity Expands AI Partnership With Amazon AWS And Google

Remote cardiac monitoring company *Biotricity Inc.* is expanding its relationships with Amazon Web Services and Google, the Redwood City, CA-based company announced on 25 July.

Biotricity has developed a complex neural network to track specific characteristics of electrocardiogram signals within an ambulatory setting. The system depends on Amazon's *AWS Lake* system to manage the enormous volume of ECG data it collects while also supporting continuous and distributed AI-model training.

Biotricity has expanded its machine-learning capabilities with Amazon's *SageMaker* to bring real-time feedback from health care professionals into its AI models.

The company also announced the construction of a cardiac AI model combining Google's TensorFlow machine-learning framework with AWS infrastructure to rapidly improve its cardiac monitoring technology.

"In the near future, we believe the capabilities of our cardiac AI model will allow us to support healthcare professionals in handling exponentially more patients while identifying the most critical data," Biotricity CEO Waqaas Al-Siddiq said. "This will enable healthcare workers to elevate the quality of care while serving a larger number of patients."

The Bioflux advanced remote cardiac monitoring system is intended to "bridge the gap" between remote diagnostics, remote patient monitoring, and chronic care management by giving physicians anytime access to patient data and diagnostics. The company also markets Biotres, a Holter monitor system that detects atrial fibrillation and stroke risks.

The company is ramping-up its subscription-based service, putting it on “a clear path to profitability,” Al-Siddiq said.

Eko Partners With Astellas And WellDoc On Digital Therapeutic

Astellas Pharma, Inc., *WellDoc* and *Eko* have agreed to work together to integrate Eko’s Core 500 digital stethoscope and artificial intelligence technology with Welldoc's cardiometabolic digital therapeutic capabilities to create a proprietary digital therapeutic program for patients with heart failure.

Astellas plans to seek US Food and Drug Administration clearance for the digital therapeutic, currently called Z1608.

Astellas hopes to prove that remote monitoring of heart-failure biomarkers associated combined with automated coaching can reduce the frequency of acute decompensation events in patients living with heart failure.

"We're closer to a future where heart failure is proactively managed rather than reactively treated,” said Eko CEO Connor Landgraf. “We're making significant steps towards transforming heart health by working with partners to bridge the home-clinic care gap." (Also see "*Cardio Catch-Up: Updates From B-Secur, egnite, Vektor, And Other Under-The-Radar Companies*" - Medtech Insight, 20 Jun, 2022.)

MetaSight Plans Metabolomics Development For Multidisease Diagnostics

MetaSight Diagnostics is partnering with Kahn-Sagol-Maccabi (KSM) – the Research and Innovation Center of Maccabi Health Services in Israel – to develop liquid biopsy tests that could potentially simultaneously detect markers of cancer, liver, cardiovascular, kidney and neurological diseases.

The Israeli company announced on 25 July that it is “coming out of stealth” to launch the Israeli Multi-Omics Serum Screening study, a comprehensive metabolomics analysis of hundreds of thousands of de-identified blood-serum samples.

MetaSight has developed a cost-effective high-throughput mass spectrometry technology and now possesses the world’s largest serum molecular dataset, according to MetaSight CEO Tomer Shlomi.

“Integrating this molecular dataset with decades of de-identified electronic health records as

well as prospective research catalyzes the development of accurate non-invasive diagnostic tests for the early detection of a wide range of chronic and acute diseases," he said. "Our collaboration with KSM moves us another step closer to creating a cost-effective multi-disease liquid biopsy, a potential game changer for population health globally."

FDA Issues Labeling Guidance For Hydrogen Peroxide-Based Contact Lens Care Products

The US Food and Drug Administration is providing labeling recommendations for hydrogen peroxide-based contact lens care products (HPCPs) regulated under 510(k)s.

According to the agency, while the safety and effectiveness of HPCPs has been well established, they are not without risks. The FDA says the new recommendations are important because misuse associated with HPCPs has resulted in serious eye injuries. The recommendations listed in the final guidance, the agency says, may help manufacturers develop labeling with information about specific risks and directions for use.

The agency says it has become aware of an increase in the number of adverse event reports related to the misuse of these products, ranging from irritation to severe burning and stinging of the eyes and even blindness.

Based on reports to the FDA, labeling on HPCP packaging "is not easily distinguishable from other lens care products, which FDA believes has likely resulted in improper use."

To address this concern, the FDA convened a meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee and the Risk Communication Advisory Committee in 2017 to discuss additional measures to mitigate the potential risk for misuse of these devices, including appropriate labeling.

According to the FDA, the panel emphasized the need for simple and clear labels to convey warnings and instructions for use and recommended the ability to identify the bottles by utilizing a red tip and red cap as already used on most HPCP solutions. The panel also recommended a redesign and standardization of the labeling so that it is different from other contact lens care products.

The guidance containing the full list of recommendations can be found *here*.

Laboratory Testing Kickback Allegations Settled

Three health care providers have agreed to pay over $525,000 to *settle kickback allegations* for laboratory testing referrals.

Imran Chishti and his Chesterfield, MO practice C Care LLC will pay $125,504 for two separate allegations. From July 2016 to August 2018, C Care was allegedly paid to order lab tests from HealthTrackRx and RealLab (InHealth)by management service organization Infinity Nine Health Group LLC. And from August 2018 to July 2020, C Care was allegedly paid to order lab tests from Genesis Reference Laboratories LLC and RDx Bioscience Inc by Alari Group LLC.

Frisco, TX doctor Shamim Justin Badiyan will pay $182,676 to resolve allegations that from November 2018 to June 2022, he received thousands of dollars from Avior Group LLC in exchange for ordering lab tests from Genesis and RDx. According to the US Department of Justice, RDx and Genesis paid commissions to a third-party contractor Corum Group LLC, which used Avior to pay kickbacks to Badiyan and others.

Finally, St. Louis-based Psych Care Consultants LLC will pay $217,430 to settle allegations that it received money from Alari to order tests from Genesis and InHealth. The DOJ has accused Genesis and InHealth of also paying Corum to use Alari to pay kickbacks to Psych Care Consultants in exchange for referrals.

Medline Announces Environmental, Social and Governance Report

Medical equipment company *Medline Industries, Inc.* has released its *2022 Environmental, Social, and Governance (ESG) Report* highlighting the company's policies and progress on sustainability, inclusion and its impact across more than 125 countries.

The firm says that ESG has become more important in healthcare due to challenges of providing quality care, reducing environmental impact, and addressing health disparities.

Highlights of the report include Medline reprocessing more than 2.3 million medical devices in 2002; diverting 1.1 million pounds of waste from landfills; conducting 592 social audits to ensure *ethical sourcing* throughout its supply chain; installing more than 60,000 solar panels at facilities, and donating 643 metric tons of product to support worldwide medical relief to low-resource regions and those impacted by *natural disasters*.

Medline also says it has invested $34.4m in solar energy since 2016.