U.S. FOOD & DRUG ADMINISTRATION

MedSun Medical Product Safety Network

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The MedSun Program, which was launched in 2002 by the FDA Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes, and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line reporting system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

If you are interested in having your healthcare facility join MedSun, contact medsun@fda.hhs.gov for additional information or see https://www.fda.gov/medsun for details.

Recalls

As of 9/30/22

Class I Recall **Medtronic Recalls NIM CONTACT Reinforced EMG Endotracheal Tube and the NIM Standard Reinforced EMG Endotracheal Tube for Risk of Airway Obstruction**
09/12/22
Medtronic is recalling the NIM CONTACT Reinforced EMG Endotracheal Tube and the NIM Standard Reinforced EMG Endotracheal Tubes after receiving customer complaints about obstruction of the ET tube while in use in patients. If the tube obstructs, ventilation failure can occur.
If the tube does not ventilate properly or obstructs the airway, patients may suffer oxygen deprivation, brain damage, or death. Medtronic reported that they have received 15 complaints, three injuries, and two deaths associated with this issue between 03/31/20 and 03/31/22.

Class I Recall **Baxter Healthcare Corporation Recalls Clearlink Basic Solution Set with Duovent for Risk of Leaks That May Expose Providers and Patients to Hazardous / Toxic Substances**
09/15/22
Baxter Healthcare Corporation is recalling Clearlink Basic Solution Set with Duovent after increased customer reports of leaks. As the majority of the Clearlink Basic Solution Sets with Duovent are used for the delivery of hazardous drugs (chemotherapy), leakage could expose healthcare personnel, patients, and others to potentially hazardous drugs that may be toxic and/or are irritants. These leaks may also allow air into the set or breach the sterile fluid pathway, thereby increasing the risk of air embolism and contaminated infusions, respectively. Patients may suffer delayed or interrupted therapy or may not receive the necessary amount of their medication. These issues could lead to serious injury or death.

Company Announcement **Voluntary Recall of Certain Over-the-Counter Products Sold at Family Dollar Stores Because They Were Stored Outside of Temperature Requirements**
09/16/22
Family Dollar is initiating a voluntary retail level product recall of certain products regulated by FDA that were stored and inadvertently shipped to certain stores on or around 05/01/22 through 06/10/22 due to product being stored outside of labeled temperature requirements. This notice covers the recall of Over-the-Counter Medical Devices *including pregnancy tests and condoms*.

Medtronic MiniMed 600 Series Insulin Pump System Potential Cybersecurity Risk
09/20/22
FDA is alerting medical device users about a cybersecurity risk for the Medtronic MiniMed 600 Series Insulin Pump System (i.e., MiniMed 630G and MiniMed 670G). There is a potential issue associated with the communication protocol for the pump system that could allow unauthorized access to the pump system. A nearby person may be able to gain access to the pump while the pump is being paired with other system components. If unauthorized access occurs, the pump's communication protocol could be compromised, which may cause the pump to deliver too much or too little insulin. Medtronic issued an Urgent Medical Device Correction regarding the cybersecurity risk as well as actions and recommendations for users to take. For additional questions about this cybersecurity risk, reach out to Medtronic at 1-800-646-4633, option 1.

Class I Recall **Philips Respironics Recalls Certain BiPAP Machines for Plastic Issue that May Expose Patients to Certain Chemicals of Concern**
09/23/22
Philips Respironics (Philips) is recalling certain BiPAP machines that may contain a plastic contaminated with a non-compatible material. If that plastic is in the device motor, it may release certain chemicals of concern called volatile organic compounds (VOCs). The plastic may also cause the machine to fail and stop working suddenly during use. If the plastic causes the machine to fail and stop working suddenly, it may also lead to serious injury or death.

Class I Recall **LivaNova (TandemLife) Recalls LifeSPARC System for Risk of Unintentional Extended Pump Stop During Controller Critical Failure**
09/30/22
LivaNova (TandemLife) is recalling the LifeSPARC Controller, part of the LifeSPARC System, due to a software malfunction that may trigger the device to enter Critical Failure mode—clearing the controller screen and

issuing an alarm that cannot be muted or turned off. While the LifeSPARC Pump should continue to run at the set speed with the allowance of manual speed adjustment in Critical Failure mode, the user has to replace the controller, using instructions from the Operations Manual, before disconnecting the pump from the frozen controller. If the user does not follow these specific instructions and powers off the frozen controller prior to acquiring and setting up the backup controller, the pump may stop for an extended period of time during the replacement process.

Guidance Documents

DRAFT **Computer Software Assurance for Production and Quality System Software**
FDA is issuing this draft guidance to provide recommendations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system. This draft guidance provides recommendations on risk-based computer software assurance activities for computers and automated data processing systems that are used as part of medical device production or the quality system. The draft guidance is intended to describe "computer software assurance" as a risk-based approach to establish confidence in the automation used for production or quality systems, and identify where additional rigor may be appropriate, and describe various methods and testing activities that may be applied to establish computer software assurance and provide objective evidence to fulfill regulatory requirements.

FINAL **Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products**
This final guidance encourages sponsors and applicants using RWD and RWE as part of a submission to identify such use in the cover letter to facilitate FDA's internal tracking of these submissions. The cover letter should describe the purpose(s) of using RWD/RWE, types of study designs that include RWD/RWE, and RWD sources used to generate RWE.

DRAFT **Ethical Considerations for Clinical Investigations of Medical Products Involving Children**
FDA is issuing this draft guidance to assist industry, sponsors and institutional review boards (IRBs) when considering the enrollment of children in clinical investigations of drugs, biological products and medical devices. The public can provide comments on the draft guidance. Any comments should be submitted within 90 days to ensure that the agency considers them when finalizing the draft guidance.

DRAFT **FDA Issues Final Guidance on Clinical Decision Support Software**
This final guidance clarifies the scope of the FDA's oversight of clinical decision support (CDS) software intended for health care professionals as devices. This guidance further clarifies that the FDA's existing digital health policies continue to apply to software functions that meet the definition of a medical device, including those that are intended for use by patients or caregivers.
FDA has developed a graphic to provide a visual overview of certain policies described in the guidance and examples of non-device CDS functions and device software functions for illustrative purposes.

Upcoming webinar on this guidance
On October 18, 2022, FDA will host a webinar for healthcare providers and others interested in learning more about the final guidance.

Safety Communications

Certain Philips Respironics Masks for BiPAP, CPAP Machines Recalled Due to Safety Issue with Magnets That May Affect Certain Medical Devices: FDA Safety Communication

09/06/22
FDA is alerting patients, caregivers, and health care providers that Philips Respironics (Philips) recalled certain masks used with bilevel positive airway pressure (also known as Bilevel PAP, BiPAP, or BPAP) machines and continuous positive airway pressure (CPAP) machines due to a serious safety concern. The recalled masks have magnets (placements shown by black circles in the picture below) and can cause potential injuries or death when use of a recalled mask with magnets interferes with certain implanted metallic medical devices and metallic objects in the body. The recalled Philips masks may be used with other manufacturers' BiPAP and CPAP machines. Click here for the **Letter to Health Care Providers**.

Breast Implants: Reports of Squamous Cell Carcinoma and Various Lymphomas in Capsule Around Implants: FDA Safety Communication

09/08/22
FDA is aware of less than 20 cases of squamous cell carcinoma (SCC) and less than 30 cases of various lymphomas in the capsule around the breast implant. As of 09/01/22, FDA has received 10 medical device reports (MDRs) about SCC related to breast implants and 12 MDRs about various lymphomas related to breast implants. FDA will continue to gather and review all available data from these sources to evaluate the occurrence of cancers in the capsule around breast implants.
This is an emerging issue and our understanding is evolving. For this reason, the FDA is asking health care providers and people with breast implants to report cases of SCC, lymphomas, or any other cancers around the breast implant to the FDA.

UPDATED: Pulse Oximeter Accuracy and Limitations: FDA Safety Communication

09/15/22
September 15, 2022: Advisory Committee Meeting Notice
FDA announced a virtual meeting of the CDRH Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee on 11/01/22, from 9 a.m. to 6 p.m. ET. For additional meeting details, see the meeting announcement in the Federal Register.
Docket Number: FDA-2022-N-2110 (closes December 1, 2022)
The committee will discuss ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentations. The committee will also discuss factors that may affect pulse oximeter accuracy and performance, the available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, and the amount, and type of data that should be provided by manufacturers to assess pulse oximeter accuracy and to guide other regulatory actions as needed. FDA continues to evaluate all available information pertaining to factors that may affect pulse oximeter accuracy and performance. FDA recommendations in this link have not changed. FDA will continue to keep the public informed as significant new information or recommendations become available.

MedSun Webcast Orientations

We're providing you a schedule of upcoming MedSun Webcast orientations. These may be of interest to Lead MedSun Representatives who would like to add or change a reporter. If you would like to orient a new reporter in your hospital, please send your request to your FDA MedSun Representative or contact us at MedSun@fda.hhs.gov or 800-859-9821.

MedSun Webcast Orientation Schedule 1:00 PM to 2:30PM EST (12:00pm CST/11:am MST/10:am PST)	
Tuesday	**4-Oct-22**
Thursday	**3-Nov-22**
Tuesday	**6-Dec-22**

FDA and NIH Launch Public-Private Partnership for Rare Neurodegenerative Diseases

FDA and the National Institutes of Health (NIH) announced the launch of the Critical Path for Rare Neurodegenerative Diseases (CP-RND) – a public-private partnership aimed at advancing the understanding of neurodegenerative diseases and fostering the development of treatments for amyotrophic lateral sclerosis (ALS) and other rare neurodegenerative diseases. The FDA and NIH have selected the Critical Path Institute (C-Path) as the convener of this partnership.

"There is a crucial need to develop new treatments that can improve and extend the lives of people diagnosed with rare neurodegenerative diseases, including ALS. Collaboration across public and private sectors can accelerate the progress to address this urgent need," said FDA Chief Medical Officer, Hilary Marston, M.D., M.P.H. "The partnership we are announcing today will leverage the shared expertise of all participants to create a path towards new breakthroughs in treating these diseases. We look forward to working with NIH, C-Path, and other public and private partners to carry out this important effort."

"This public-private partnership will convene the entire ALS community to develop novel strategies and approaches to therapy development and clinical testing with the goal to finally produce a treatment that stops the tragic progression of ALS," said Walter Koroshetz, M.D., director of the National Institute of Neurological Disorders and Stroke (NINDS), part of the NIH.

To learn more about the Critical Path for Rare Neurodegenerative Diseases, visit https://c-path.org/programs/cp-rnd/ or contact the C-Path team at cp-rnd@c-path.org.

Safe Medical Device Act Requires Reporting of Certain Events

Because the hospital's insights are so important to making sure that medical devices are safe and effective, some problems with medical devices are actually required by law to be reported by hospitals, including deaths and serious injuries related to the use of medical devices.

Reporting to FDA is mandatory for events where a medical device may have caused or may have contributed to a patient death or serious injury.

A "serious injury" means an injury or illness that:

- is life-threatening;
- results in permanent impairment of a body function or permanent damage to a body structure; or
- necessitates medical or surgical intervention to preclude permanent impairment.

A good tip to remember when it comes to mandatory reporting is, "you only need to suspect that a device was part of an event to report it and you don't have to know for sure." The suspicion that a device was involved is enough to trigger the requirement for a report

Unsure if you should report an event as mandatory or voluntary? Your FDA MedSun Analyst can help. Just call or email us!

Letters to Health Care Providers

Abbott MitraClip Device: Potential for Clip Lock Malfunctions - Letter to Health Care Providers
09/08/22
FDA is alerting health care providers about potential clip lock malfunctions with MitraClip Clip Delivery Systems manufactured by Abbott. An increased rate of reports of clip lock malfunctions has been observed before and after clip deployment. These events appear to occur in approximately 1.3% of MitraClip procedures and have been observed with all device models.

UPDATE: Recommendations for Certain Medtronic Electromyogram Endotracheal Tubes and Risk of Airway Obstruction – Letter to Health Care Providers
09/16/22
FDA is updating the Letter to Health Care Providers issued on 04/27/22, to ensure health care providers in the operating room setting are aware of the voluntary recall initiated by Medtronic for the risk of airway obstruction with the NIM CONTACT Reinforced EMG Endotracheal Tube and NIM Standard Reinforced EMG Endotracheal Tube. If the tube obstructs and does not ventilate properly, patients may suffer oxygen deprivation, brain damage, or death. Medtronic issued a customer letter and is working to update and provide new device instructions for use to customers. Additionally, FDA issued a notification of this Class I recall, the most serious type of recall.

Become a part of FDA's Patient Engagement Collaborative (PEC)

FDA announced a call for applications for new members of the Patient Engagement Collaborative (PEC). The PEC is a group of patient organizations and individual representatives who discuss ways to enhance patient engagement in medical product development and other regulatory discussions at the FDA.

The following individuals are encouraged to apply:

- Patients who have personal disease experience.
- Caregivers who have personal experience supporting someone with a health condition (e.g., a parent, child, partner, family member or friend).
- Representatives from patient groups who have direct or indirect disease experience.

The application period is open through October 19, 2022. Interested candidates are encouraged to apply early.

Understanding patients' experiences is critical to support medical product regulation and help ensure safe, effective and innovative medical products are available. The FDA listens closely to feedback from PEC members and uses their insights to inform patient engagement and regulatory decision making. We encourage interested individuals to participate in this unique opportunity to help advance public health.

Contact PatientEngagementCollaborative@fda.hhs.gov with questions.

FDA Meetings, Conferences and Workshops

FDA Grand Rounds! **Quality Considerations for the Multi-Attribute Method (MAM) for Therapeutic Proteins**
October 13, 2022 12:00 PM - 1:00 PM ET
The multi-attribute method (MAM) is a liquid chromatography-mass spectrometry (LC-MS) based peptide mapping approach used for the identification and quantitation of product quality attributes (PQAs) in therapeutic proteins. The Emerging Technology Program (ETP) has assessed the use of MAM in quality control environments and laboratory resources have been developed to improve the FDA's understanding of the approach. Please **pre-register** at least two days before the event to ensure you receive the access link and outlook invitation for the session. Materials for this session are here. For technical assistance please contact: Madison.Hanson@fda.hhs.gov.

Webinar - Clinical Decision Support Software Final Guidance
October 18, 2022 1:00 PM - 2:15 PM ET
FDA is hosting this webinar for health care providers and others to discuss and answer questions about the Clinical Decision Support Software final guidance. Registration is not necessary. For questions about this guidance document, contact the CDRH Digital Health Center of Excellence at digitalhealth@fda.hhs.gov. For questions about this webinar, contact CDRH's Division of Industry and Consumer Education (DICE) at dice@fda.hhs.gov, 1-800-638-2041, or 301-796-7100.

COVID-19 Evidence Accelerator: What We've Learned, Where We're Headed Webinar
October 20, 2022 1:00 p.m. ET
A public meeting hosted by the Reagan-Udall Foundation for the FDA and Friends of Cancer Research, to highlight accomplishments and share learnings, including how best to leverage real-world data and improve data interoperability, to address current and future health challenges.

Co-sponsored Public Workshop - Expediting Innovation of Bioelectronic Implants for Vision Restoration Virtual Workshop
October 24, 2022 8:30am – 4:30pm ET
October 25, 2022 8:30am – 4:30pm ET
CDRH is co-sponsoring this public workshop with the University of Pittsburgh .The purpose is to provide a forum for all stakeholders to share their perspectives on the safety and effectiveness of bioelectronic implants for vision restoration. Registration required.
Contact information: Michelle Gabriele Sandrian, CDRH, 301-796-6620, CDRH-VisionWorkshop@fda.hhs.gov

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee Meeting Announcement Advisory Committee Meeting
November 1, 2022 9:00am – 6:00pm ET
Docket Number: FDA-2022-N-2110 (closes December 1, 2022)
The committee will discuss ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentations. The committee will also discuss factors that may affect pulse oximeter accuracy and performance, the available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, and the amount, and type of data that should be provided by manufacturers to assess pulse oximeter accuracy and to guide other regulatory actions as needed.

Bridging Efficacy and Safety to the Obese: Considerations and Scientific Approaches Virtual Workshop
November 9, 2022 8:30 AM - 4:15 PM ET
FDA in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) will hold a virtual public workshop entitled "Bridging Efficacy and Safety to the Obese: Considerations and Scientific Approaches. The purpose of this workshop is to review the implications of obesity in adult and pediatric patients on safety, efficacy, drug dosing and disposition.

The workshop is free and registration is required.
For more information and to view the draft agenda, click here.
Contact information: Althea Cuff, Office of Clinical Pharmacology, CDER, FDA, OCPWorkshops@fda.hhs.gov

Bench to Bedside: Integrating Sex and Gender to Improve Human Health was developed in partnership between the FDA Office of Women's Health and the National Institutes of Health (NIH) to explore sex and gender related differences in key disease areas over 6 modules: Immunology, Cardiovascular Disease, Pulmonary Disease, Neurology, Endocrinology, and Mental Health. Through the joint providership of Johns Hopkins University School of Medicine and NIH. CME is available. Click here to review the modules, course authors, reviewers, leadership, and more information on claiming credit. Course expires 11/30/2023.

Click here to find more upcoming FDA Meetings, Conferences and Workshops!

Funding Opportunity Announcement

Academic development of a training program for Good Laboratory Practices in high-containment environments

FDA seeks to continue a robust, collaborative, and educational program using problem-based learning techniques designed to bring researchers and regulators together to educate each other on the challenges related to these issues and to identify solutions that are acceptable from both scientific and regulatory perspectives.

This program consists of the continued development and implementation of a certified, academic training course for instruction in Good Laboratory Practices (GLP) in a biosafety level (BSL) 4 high-containment environment.

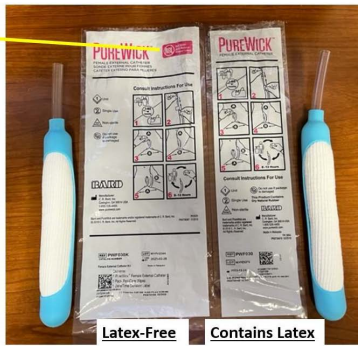
Applications are due by October 3, 2022.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device related events sent by MedSun Reporters during the prior month. The reports are presented as submitted by MedSun Representatives and in some instances, have been summarized and/or edited for clarity. The MedSun report database is here.

The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

Device	Manufacturer	Problem
Type: Immunoassay Method, Troponin Subunit **Brand:** Architect Stat Troponin-I **Model #:** 2K41-27 **Device Identifier (DI):** 00380740048525 **Lot #:** 63718UN22 **Cat #:** 2K41-27	Abbott Laboratories	Abbott Chemistry Manufacturer initiated a recall of a specific Troponin reagent lot number (63718UN22). Lot was in use for 3 days before we knew of the recall. Patient testing of troponin was stopped for 6 hours while we sourced a different lot and got the test ready for patient use. Testing resumed. Medical Director notified and patient lookback is in process for the potentially affected results. Preliminary information suggests there was no clinically significant difference in the values from the new lot to the recalled lot; the Medical Director will review and sign off once the lookback is complete.
Type: Holder, Head, Neurosurgical (Skull Clamp) **Brand:** Mayfield **Model #:** A1114A **Other #:** Part Number A1114A	Integra Lifesciences Corporation	Plans were made for elective resection. Surgery started and approx. 2hrs in, the pt's head moved. Pt checked. Pt's head was found to have partially slipped out of the Mayfield head holder with left side of face pressed against metal Mayfield head holder. Head holder was subsequently removed and replaced with a horseshoe pillow Mayfield attachment. Metal Mayfield head holder was tested for malfunction by neurosurgery specialist tech and found to be intact without issue. Surgeons continued surgery as patient seemed unharmed by the event at the time. End of case the pins, which were left in, were removed. Upon removal, it was found that the pin on the left lateral side of the skull had caused a 12 cm injury that required further surgical intervention.
Type: Needle, Hypodermic, Single Lumen **Brand:** BD Safetyglide	Becton, Dickinson and Company	The needle was being used to draw up a vaccine when the clinical staff noted it was not working. Additional needle(s) taken from the box and also did not draw up the vaccine.

Model #: 305916 **Lot #:** 2007149 **Cat #:** 305916		
Type: Set, Administration, Intravascular **Brand:** Duo-vent **Model #:** 1C8507 **Lot #:** DR22C09055 **Cat #:** 1C8507	Baxter Healthcare Corporation	IV tubing infusing epoprostenol had a small hole form in the IV tubing. Blood backed up into the tubing. Patient became hypotensive and short of breath. Required intervention with phenylephrine to support blood pressure (before source of the issue was identified), and ECMO settings were increased to support the patient. No apparent force was applied to the tubing; this appeared to happen spontaneously. IV tubing was Baxter "Solution set with DUO-VENT spike". IV tubing was saved for inspection.
Type: Collector, urine, powered, non-indwelling catheter **Brand:** PureWick Female External Catheter **Model #:** PWF030K **Device Identifier (DI) #:** 00801741183614 **Cat #:** PWF030K	C. R. Bard, Inc.	The latex-free PureWick and latex-containing PureWick are almost identical. The only identifier is on the outer package and once it is opened, the user cannot tell the difference. This is a safety concern for caring for patients with latex allergies.  ➢ Similar packaging-size, color and information (latex-free is slightly wider) ➢ The actual PureWicks are the same size and color ➢ No identifiable markers to differentiate on actual device ➢ Small box on the top of the packaging is the only identifier for latex-free ➢ Once the packaging is discarded, there is no visible differences  No discernable markings on the back 
Type: Catheter, Embolectomy **Brand:** Fogarty Arterial Embolectomy Catheter **Model #:** 120804FP	Edwards Lifesciences LLC	Tip of the catheter (where the balloon is) came out of the sterile package in a defective manner. The balloon on multiple catheters had holes and others were starting to disintegrate and had separated from the tip of catheter making the product unusable.

Cat #: 120804FP **Other #:** 4F		
Device #1: **Type:** Restraint, Protective **Brand:** Mitts -No Finger Separators **Model #:** 2810 **Cat #:** 2810 **Device #2:** **Type:** Restraint, Protective **Brand:** Mitts -No Finger Separators **Model #:** 2810 **Cat #:** 2810	Posey Products, LLC Posey Products, LLC	Patient bit through Posey mittens, sending beads everywhere in a patient that was at risk for aspiration. Packaging was not saved. **This is a reported 3rd incidence (3 different instances) of tearing or breakage causing beads to be exposed to patient. Patient was fitted with newly implemented Posey Mitts #2810. Patient clawed way through the mittens from the inside out, sending the tiny beads inside of them all over the patient and onto the floor.
Type: Restraint, Protective **Brand:** Mitts -No Finger Separators **Model #:** 2810 **Cat #:** 2810	Posey Products, LLC	At around 1630, found patient with contents (Styrofoam balls/beads) of mitten all over the bed. Cleaned patient and notified manager of defective mitten. Mitten removed and new mitten placed on patient.
Type: Catheter, Embolectomy **Brand:** Fogarty **Model #:** 120804FP **Lot #:** 64025084 **Cat #:** 120804FP	Edwards Lifesciences LLC	The patient had a clotted graft and was planned for a surgical embolectomy. They were using the size 4 arterial embolectomy catheter. The catheter was added to the surgical field and during the pre-procedure test of the device, it malfunctioned when the balloon was tested; the balloon did not expand or burst, but it did not blow up and fluid leaked out from tiny holes. A 2nd catheter from the same lot was tested and it also malfunctioned. Then, a 3rd catheter from the same lot was also tested and had the same malfunction. A 4th catheter from a different lot was tested and worked as expected.
Type: Transducer, Gas Flow **Brand:** Neonatal Flow Sensor Insert **Model #:** 8410179 **Cat #:** 8410179	Draegerwerk AG & Co. KGaA	When the neonatal flow sensor was removed from the sterile processing package and placed in line with vent for testing, the neonatal flow sensor would not work. The knobs on the insert were bent in slightly and the flow sensor repeatedly failed calibration. It was unseated and placed in the housing several times, failing calibration every time. It is felt that the processing is causing the plastic to harden and

		the knobs to bend or break more easily when being removed or placed in the flow sensor. This directly affects the chip inside the flow sensor. This has happened 9 times in 15 processings so a failure rate greater than 50%.
Type: Tubing, Pump, Cardiopulmonary Bypass **Brand:** Perfusion Tubing Systems **Lot #:** 2205400015 **Cat #:** 44063700	LivaNova Deutschland GmbH	We had just finished the procedure, the cross clamp was off, and rewarming was almost complete. Our bladder temp was 35.8 with a goal of 36.5. The arterial line pressure was 215mmhg. Our max. arterial line pressure is maintained <300mmhg. It was flowing at 3.98 liters per minute (LPM) RPM 2555, Arterial Line Pressure was 215 mmHg, bladder temp was 35.8, DO2 286. These parameters were maintained throughout the case. At this point, the tubing coming from the venous reservoir into the biohead connecting to the inlet hub of the oxygenator, disconnected. The team clamped both the arterial line and the venous line. Anesthesia positioned the patient in deep Trendelenburg. Because of the amount of blood being pumped onto the floor, initially it was difficult to determine where the disconnection occurred. When I located the tube I clamped my arterial line proximal to my arterial line filter and reconnected the tubing to the oxygenator inlet hub. The drive line (venous reservoir into the biohead connecting to the inlet hub to the oxygenator) and the oxygenator did not de-prime, so I started to recirculate the blood from the oxygenator into the venous reservoir to make sure no air was in the oxygenator. The blood loss that ended up on the floor was approximately 2L. This was the volume in my venous reservoir. No additional patient volume was lost during this incident. The next step was to clamp the arterial line distal to the arterial line filter, remove the clamp that was proximal to the arterial line filter and recirculate blood through the filter, the manifold, and into the venous reservoir to make sure no air was anywhere in my arterial line. The team at the field noticed some air was located in the arterial cannula. This air was sucked in by the root vent through the purse strings and into the cannula. The vent was turned off, the arterial line was briefly disconnected, and the cannula was refilled by the surgeon. The arterial line was reconnected to the arterial cannula, the line and cannula were inspected for air, and once we were satisfied with the integrity of the arterial line. Bypass was restarted. The whole process described above took approximately 2 minutes. The HCT was low due

		to blood loss and 4 units of Pack Red Cells (PRCs) and 2 units of Fresh Frozen Plasma (FFP) were given on bypass. We came off pump with good hemodynamic function and the patient was transferred to the Cardiovascular Intensive Care Unit (CVICU). Patient was extubated evening of surgery and neuro status was stable at discharge.
Type: Pump, Infusion, Elastomeric **Brand:** Home Pump CSeries **Model #:** C Series **Cat #:** C100020	Avanos Medical, Inc.	Patient went home with fluorouracil infusion pump. When he returned 46 hours later, the pump was still full. The nurse verified that all clamps were open and everything was taped as it should be. All clamps were open but the filter was no longer taped to the skin. Dressing was reinforced and patient was sent home. Patient returned 24 hours later and the pump had not infused on this occasion because the clamp to the pump was not open. Patient returned on and the pump had still not infused and all clamps were open and the filter had been taped to the skin. Pump was then disconnected and returned to pharmacy.

About the MedSun Program

The MedSun Program, which was launched in 2002 by the FDA Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes, and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line reporting system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

If you are interested in having your healthcare facility join MedSun, contact medsun@fda.hhs.gov for additional information or see https://www.fda.gov/medsun for details.

Links to FDA CDRH Databases and Other Information Sources

Establishment Registration & Device Listing:
This database includes medical device manufacturers registered with FDA and medical devices listed with FDA. It is updated monthly and contains multiple links to other FDA databases.

Global Unique Device Identification Database (GUDID):
A searchable database administered by the FDA which serves as a reference catalog for every device with a unique device identifier (UDI) and contains additional GUDID specific resources.

Human Factors Website:
A site providing information about human factors design, testing and use considerations. Other links include information about the CDRH Human Factors Team activities, including their contact information.

Medical Device Connectors Website:
A site providing information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other. Examples of misconnections, additional resources, and other links reside on this site.

MAUDE (Manufacturer and User Facility Device Experience):
The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. This site also contains links to other FDA databases.

Medical Device Safety Website:
One-stop for safety information with links to FDA medical device safety communications, recent letters to healthcare providers, recent medical device recalls, and more device safety related links.

MedSun Website:
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]:
This database of releasable 510(k)s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via web interface for more recent records. It is updated monthly and contains multiple links to other FDA databases.

Premarket Approvals (PMA):
The Premarket Approval (PMA) database of premarket approvals of Class Ill devices may be searched by a variety of fields and is updated monthly. This site contains multiple links to other FDA databases.

Product Classification:
This database can be used to determine the classification of a device and the regulations it is subject to. It has a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information. Multiple links to other FDA databases are included on this site.

Warning Letters:
This database contains the most recent manufacturer warning letters. Site is searchable.

To access more 2022 newsletter articles, including a selection of recent MedSun reports, product and patient-safety related information, go to www.fda.gov/medsun.

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This monthly newsletter provided by MedSun at the FDA is intended to inform you of FDA-related information on a variety of topics, including new product approvals, significant labeling changes, safety warnings, notices of upcoming public meetings, proposed regulatory guidances and opportunity to comment, and other information of interest to patients and patient advocates. Subscribe or update your subscriber preferences.