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 post-market surveillance efforts.

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

Guidance Documents

DRAFT Extended Comment Period for Draft Guidance on Patient Labeling Recommendations for Laser-Assisted In Situ Keratomileusis (LASIK) Lasers

FDA announced the comment period for the draft guidance: Laser-Assisted in Situ Keratomileusis (LASIK) Lasers - Patient Labeling Recommendations published on July 28, 2022, has been extended by 30 days, and will close on November 25, 2022.

This draft guidance, when finalized, is intended to:

- provide recommendations on content and formatting for patient labeling information for LASIK devices to ensure complete communication of risk information in an understandable format.
- help ensure that physicians can share and patients can understand information on the benefits and risks of LASIK devices.

Submit comments on this draft guidance

- Submit comments under docket number FDA-2022-D-1253 at www.regulations.gov by Nov 25, 2022

FDA Meetings, Conferences and Workshops

Joint Public Workshops - Medical Devices for Opioid Use Virtual Workshop

November 7, 2022 10:00 AM – 4:30 PM ET
November 8, 2022 10:00 AM – 4:00 PM ET

FDA is announcing two free connected public workshops with the National Institutes of Health (NIH) "Diagnostic and Monitoring Medical Devices for Opioid Use" and "Risk Prediction Devices of Opioid Use and Opioid Use Disorder – Opportunities and Challenges." These workshops promote medical device innovation through discussions with stakeholders about important factors to inform the conduct of clinical studies for medical devices to diagnose, monitor, and manage individuals across the spectrum of opioid use, with a goal to foster the safe use of opioids. Questions: Contact CDRH opioid_device_workshop@fda.hhs.gov.

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 free 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.
Contact information: Althea Cuff, Office of Clinical Pharmacology, CDER, FDA, OCPWorkshops@fda.hhs.gov

Ophthalmic Devices Panel of the Medical Devices Advisory Committee Meeting Public Meeting
November 10, 2022 9:00 AM – 5:00 PM ET
The advisory committee meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee is open to the public. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Webcast link is found here.

FDA Grand Rounds: Medical Extended Reality: Applications and Challenges Webcast
November 17, 2022 12:00 PM – 1:00 PM ET
This lecture will provide an overview of augmented and virtual reality technology and of the landscape of potential medical applications. The second part of the lecture will focus on regulatory science efforts to address evaluation challenges for using augmented and virtual reality in medicine. Registration is free. Activity Outline is located here. Questions: Visit www.FDA.gov/GrandRounds or contact Madison Hanson, Madison.Hanson@fda.hhs.gov

FDA-CDER-CDRH, SNMMI, and MITA Workshop | Quantitative Brain Amyloid PET Imaging in Patients with Alzheimer's Disease Workshop
November 17, 2022 8:30am – 5:05pm
Goals of the workshop include seeking feedback from stakeholders on Brain Amyloid PET Imaging in clinical use and clinical trials, discussing the role of Brain Amyloid PET Imaging to address an unmet public health need, ensuring the leading experts using Brain Amyloid PET Imaging have an opportunity to share recent developments, and more. This workshop is intended for a diverse group of scientists, responsible for the evaluation of quantitative positron emission tomography (PET) measures of amyloid deposition in the brain in clinical trials and clinical use in patients with suspected or confirmed Alzheimer's disease. Register here.
Questions: Contact Libero Marzella MD, Ph.D., libero.marzella@fda.hhs.gov

2022 FDA Digital Transformation Symposium Webcast
December 5, 2022 8:00 AM – 5:00 PM ET Theme: Technology Transformation
December 6, 2022 8:00 AM – 5:00 PM ET Theme: Data Modernization & Cybersecurity
December 7, 2022 8:00 AM – 5:30 PM ET Theme: Enterprise Modernization
Hear from FDA leaders on how the agency is leveraging advances in data, cloud, user experience, cybersecurity, IT governance, and operational/organizational excellence to protect public health.
Participate and engage in information sharing with industry, tech, and vendor communities on how FDA can continue to collaborate with stakeholder constituents to drive innovation, key initiatives, and achieve successful technology solutions. The symposium is free. Register here. Questions: Contact ODT-Communications@fda.hhs.gov

Bench to Bedside: Integrating Sex and Gender to Improve Human Health
Explore 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!

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 which 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: Polymer Patient Examination Glove **Brand:** Cleanguard **Lot #:** 660000	Ace Glove SDN. BHD.	When donning on gloves, the gloves would not open without tearing. No harm to staff or patient.
Type: Filler, Bone Void, Calcium Compound **Brand:** STIMULAN	Biocomposites LTD	Patient was admitted for revision of periprosthetic hip fracture. The patient was implanted with 20cc STIMULAN Calcium beads with Vancomycin 4g and Tobramycin 2.4g mixed. Five days post operative, the patient developed confusion and fatigue and was brought to the emergency department and found to be hypercalcemic with Calcium 14.2. The BUN (blood urea nitrogen) was 56 and Creatinine 3.4. The patient required aggressive hydration and placement of a tunneled dialysis catheter and had to receive hemodialysis for 3 consecutive days. The patient does not have a history of renal disease. The patient required an 18-day admission. Upon review of imaging, on post operative day the beads are clearly visible on x-ray. 12 days later, the joint was re-imaged, and the beads appear to have dissolved. The manufacture website indicates "STIMULAN is absorbed in approximately 30-60 days". The patients AKI (acute kidney injury) resolved, and patient was transferred back to SNF (skilled nursing facility).
Type: Pump, Infusion	Iradimed Corp.	One of our Iradimed Mridium 3860+ pumps broke due to liquid that got into the pump drug library

Brand: Iradimed **Model #:** 3860+ **Cat #:** 3860+		card slot. This card slot sticks out slightly from the back of the device and is exposed to the clinical environment. A metal bar covers the card preventing it from being removed easily but does not isolate the card from any environmental factors. There was a spill and liquid easily entered the sim card slot rendering the pump useless. This is an issue since pumps are mounted on IV poles under liquid IV bags. A spill can easily happen and quickly damage the device.
Type: Laryngoscope, Rigid **Brand:** Rusch Greenspec Handle: Medium **Lot #:** 200901 and 200801 **Cat #:** 004411100	Teleflex Incorporated	Following the manufacturer's Instructions For Use, some of the blades and handles are coming out of sterile processing with some rust. Also, on the panel on the blade where the light is transmitted, there is evidence of warping on some of them, the lip and the end of the fiberoptic channel on some of the blades have become sharper, and noticeable wear and tear of connecting parts between blade and handle on processed blades. Providers are having to wrap gauze around the handles to avoid injury when using the device.
Type: Bed, AC-powered Adjustable Hospital **Brand:** Intouch **Model #:** 2141 **Cat #:** 2141-PX2-000	Stryker Corporation	Device maintenance of Stryker InTouch critical care bed requires the replacement of two batteries on the bed every two years. Current batteries are starting to fail after 18 months. Hospital has had previous issues with this same problem in the past, as such we are using two different brands on the beds at this time: the Stryker approved model and another brand equivalent. Both are failing earlier that intended making the bed difficult to push in the drive mode as motor the turns off. The manufacturer recommends using Stryker batteries, problem still present with manufacturer and off-brand batteries.
Device 1: **Type**: Laryngoscope, Rigid  **Brand:** Gliderite Single-Use Stylet -Small **Model #:** 0803-0118 **Lot #:** GS77314 **Cat #:** 0803-0118 **Device 2**: **Type:** Laryngoscope, Rigid	**Device 1**: Verathon Medical ULC **Device 2**: Verathon Medical ULC	Peds patient received in Emergency Room from outlying rural clinic with past-medical history of recurring urinary tract infection (UTI) due to anatomical abnormality: transferred here due to respiratory arrest, sepsis after being sick several days with fever and sick symptoms - Sats 70% at room air. Placement of intraosseous access device (IO) for labs. Patient coded - approximately 25-minutes of Cardiopulmonary Resuscitation (CPR). At first attempt of intubation - the stylet for glidescope malfunctioned (snapped) prompting a repeat attempt with different tube & stylet. Patient was bagged between attempts with no difficulty and patient never desaturated. Patient was successfully intubated, Return of spontaneous circulation (ROSC) and transferred to pediatric intensive care unit (PICU). The respiratory therapist (RT) team notes this breakage has been happening recently - so there were 5 GlideRites of this same Ref & Lot numbers

Brand: Gliderite Single-use Stylet-small **Model #:** 0803-0118  **Lot #:** GS77314 **Cat #:** 0803-0118 **Device 3**: **Type:** Laryngoscope, Rigid  **Brand:** Gliderite Single-use Stylet-small **Model #:** 0803-0118 **Lot #:** GS77314 **Cat #:** 0803-0118 **Device 4**: **Type:** Laryngoscope, Rigid  **Brand:** Gliderite Single-use Stylet-small **Model #:** 0803-0118 **Lot #:** GS77314 **Cat #:** 0803-0118 **Device 5**: **Type:** Laryngoscope, Rigid  **Brand:** Gliderite Single-use Stylet-small **Model #:** 0803-0118 **Lot #:** GS77314 **Cat #:** 0803-0118 **Device 6**: **Type:** Laryngoscope, Rigid	**Device 3**: Verathon Medical ULC **Device 4**: Verathon Medical ULC **Device 5**: Verathon Medical ULC **Device 6**: Verathon Medical ULC	pulled from ED after making sure there were other replacement items for use. In addition, there were 3 other GlideRites pulled (with different Ref & Lot numbers) out of precaution. Unfortunately, we have no data on the other patients with whom this similar event took place. Additionally to note: the initial device was not retained but it is noted that it is of the Ref 0803-0118, Lot GS 77314.

Brand: Gliderite Single-use Stylet-small  **Model #:** 0803-0118 **Lot #:** GS77314 **Cat #:** 0803-0118 **Device 7**: **Type:** Laryngoscope, Rigid  **Brand:** Gliderite Single-use Stylet-small **Model #:** 0803-0118 **Lot #:** GS79353 **Cat #:** 0803-0118 **Device 8**: **Type:** Laryngoscope, Rigid  **Brand:** Gliderite Single-use Stylet-small **Model #:** 0803-0118 **Lot #:** GS79353 **Cat #:** 0803-0118 **Device 9**: **Type:** Laryngoscope, Rigid  **Brand:** Gliderite Single-use Stylet-small **Model #:** 0803-0118 **Lot #:** GS79353 **Cat #:** 0803-0118	**Device 7**: Verathon Medical ULC **Device 8**: Verathon Medical ULC **Device 9**: Verathon Medical ULC	
Type: Closed Antineoplastic And Hazardous Drug Reconstitution And	Equashield Medical LTD	Patient was receiving Doxorubicin chemotherapy, 30 min infusion. RN (registered nurse) checked infusion around the time it should have finished and noticed pump had been pulling from primary

Transfer System **Brand:** Equashield **Lot #:** 2213283A		line of NS (normal saline) as well as secondary line of chemotherapeutic drug. RN clamped the primary line to ensure remainder of chemotherapeutic drug infused.
Type: Tube, Tracheal (W/wo Connector) **Brand:** Shiley Lo-pro Oral/nasal Endotrach Tube Cuff, Murphy Eye **Model #:** 86051 **Lot #:** 22GO343JZX **Cat #:** 86051 **Other**: 7. 0 mm	Covidien LP	Patient being intubated for surgical procedure with a Shiley 7.0mm Endotracheal tube. Immediately the anesthesiologist found the cuff leaking/not holding air to secure it during the procedure. A new ET tube was obtained with a different lot number. The second ET tube experienced no problems. In review of our inventory and discussion with other OR leaders, our two other ORs had similar experiences with leaking air from this lot of ET tubes. All three ORs removed this lot # ET tube from their inventory. This information was also shared with upper-level leadership as our hospital system all use the same device. Unknown at this time response from manufacturer.
Type: Staple, Implantable **Brand:** Signia **Model #:** SIGPHANDLE	Covidien LP	Surgery brought up a concern with chargeable staplers. Chargers aren't working properly and not lasting very long. Potential for patient issues.
Device 1: **Type:** Staple, Implantable **Brand:** GIA Stapler with DST Series Technology **Model #:** TA9035S **Cat #:** TA9035S **Device 2**: **Type:** Staple, Implantable **Brand:** GIA Stapler with DST Series Technology **Model #:** GIA8038S **Cat #:** GIA8038S	**Device 1**: Covidien LP **Device 2**: Covidien LP	Patient underwent a laparoscopic assisted right colectomy for an unresectable cecal polyp. The patient did not have any significant pre-operative concerns. This was an elective surgery with no nutritional concerns. The surgery was uneventful. One linear GIA 80 stapler and a TA 90 were used. Staple lines reinforced per surgeon's usual practice with 3-0 vicryl. At the end of the case, everything checked out and patient was rechecked by surgeon peri-op and post-op that the patient was not significantly hypotensive and was well hydrated. On post-op day 1-1/2, patient was returned to surgery after began experiencing abdominal pain, distension, and was tachycardic. CT (oral/IV contrast) showed anastomotic leak. Findings in OR was a complete disruption of the GIA staple line. There was no evidence of torsion, no obstruction and no signs of ischemia. The GIA staple line fell apart because of a technical issue with the stapler itself. At the time of reporting, patient is still hospitalized.
Type: Set, Blood Transfusion **Brand:** Clearlink Y-type Blood/Solution Set with	Baxter	Nurse was preparing to administer blood and observed that the newly opened package of blood tubing had caps/spikes that looked cloudy/dirty and the drip chamber appeared to be "scuffed." The nurse opened six additional tubing packs from

Standard Blood Filter **Model #:** 2C8750 **Lot #:** DR22G13116; DR22F24093 **Cat #:** 2C8750		two different lots, and they all appeared similar (cloudy/dirty caps/spikes and some chambers looked almost cracked. This issue was noticed before patient connection and so there was no harm to a patient. The nurse examined a total of 7 sets of tubing from two lot numbers that appeared cloudy. The nurse used single spike tubing to administer the blood. Nurse sent email directly to Baxter to report her findings. Follow up: Manager contacted a representative at Baxter and explained what the nurse had encountered with the cloudy spikes/chambers. The manager asked for any insight they could share about using sets that have this issue. The representative shared information that this product is not made with natural rubber latex. Set discoloration does not affect safety or functionality. The nurse manager is unable to find this statement printed in a visible area on the packaging. Baxter may consider including this statement where the nurse will notice it, directly on the product packaging.
Type: Dialyzer, High Permeability With Or Without Sealed Dialysate System **Brand:** Prismax Accessory, Auto Effluent **Model #:** 115370 **Lot #:** 22F1001	Baxter Healthcare Corporation	The patient was receiving CRRT with the Baxter PrisMax machine. The RN set up the machine with a PrismaFlex Extra Corporeal Circuit with Filter, TherMax Blood Warmer, and Auto Effluent Drain Accessory. When set -up was complete, the RN started therapy per the machine's instructions. Soon after starting the therapy, the RN received the following low priority alarm "Fluid in Drip Tray". The alarm is triggered by drip tray sensors detecting fluid. The RN was directed to check for any disconnections, punctures, or leaks. The RN noticed a leak in the small effluent bag (1 liter) on the lower portion of bag where tubing enters the bag. The RN was going to remove the Auto Effluent drain and set-up another type of effluent bag. The machine wanted the RN to change the entire circuit. The Baxter individual told the RN to patch up the hole in the bag as best as possible or just change the entire circuit again. When the RN was explaining the situation to 1-800 person and the RN felt the Baxter person conveyed this issue had been ongoing. The entire PrisMax circuit was changed.
Type: Laparoscope, General & Plastic Surgery **Brand:** StrykeFlow **Model #:** 0250070500 **Lot #:** 21343FG2 **Catalog #:** 250-070-500	Stryker Corporation	Device exchanged out during the case when brown fluid noticed in tubing.

Type: Pack, Hot Or Cold, Disposable **Brand:** MedPride **Lot #:** 205851 **Catalog #:** MPR-41289	Shield Line LLC	MedPride Instant Hot Pack is extremely hot after activating. It is difficult to manage with your bare hands. Even when wrapped in a pillowcase as instructed by their guidelines it is still too hot. Health care provider tested it by placing it over sweater sleeve and it left their arm red after only a few minutes. The pack states that it heats up to 176 degrees Fahrenheit. This was a substitution product for us. Our normal product, from a different manufacturer, reaches 100-110 degrees Fahrenheit with a max of 111.8 degrees Fahrenheit. We are concerned the MedPride product could burn a staff member or patient — especially a patient with sensory impairment due to medical status, medications, etc.
Type: Tubes, Gastrointestinal (And Accessories) **Brand:** AMT Bridle	Applied Medical Technology, INC	While removing the Bridle and nasogastric tube (NGT) from the patient, the bedside registered nurse and charge RN noticed that the patient was experiencing a lot of pain. When assessing, the septum of the patient had been cut and the Bridle was stuck in-between the septum. The Bridle was cut and slowly guided out of the septum/nose. Wound care was provided after removal. MD was notified and a wound care consult was placed. Package had been thrown out at the time the NG and Bridle was placed.

Links to FDA CDRH Databases and Other Information Sources

FDA CDRH Databases and other information sources are located here and here.

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Food and Drug Administration

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