MedSun
Medical Product Safety Network

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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In This Issue:

About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (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 system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1

Premarket Approval Final Decisions: https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM561666.pdf

510(k)s Final Decisions: https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM569547.pdf

In Brief

As of September 5, 2017

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

Forced Air Thermal Regulating Systems: Healthcare Provider Letter

August 30, 2017

The FDA recently became aware that some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery). After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection. FDA continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted.

Implantable Cardiac Pacemakers by Abbott (formerly St. Jude Medical): Safety Communication

August 29, 2017

The FDA has reviewed information concerning potential cybersecurity vulnerabilities associated with St. Jude Medical's RF-enabled implantable cardiac pacemakers and has confirmed that these vulnerabilities, if exploited, could allow an unauthorized user to access a patient's device using commercially available equipment. This access could be used to modify programming commands to the implanted pacemaker, which could result in patient harm from rapid battery depletion or administration of inappropriate pacing.

Zenith Alpha Thoracic Endovascular Graft by Cook Medical: Recall Correction and Removal of Specific Sizes from Market

August 25, 2017

This correction removed the indication for blunt thoracic aortic injury, also known as BTAI or “transection” of the aorta because Cook has received an increase in reports of graft thrombosis and occlusion with these grafts specifically in the treatment of BTAI. Cook also initiated a voluntary recall of Zenith Alpha Thoracic products in sizes of 18-22mm, including the 26-22mm tapered device.

Liquid-filled Intragastric Balloon Systems: Letter to Healthcare Providers

August 10, 2017

FDA is issuing an update to alert health care providers of five reports of unanticipated deaths that occurred from 2016 to present in patients with liquid-filled intragastric balloon systems used to treat obesity. Four reports involve the Orbera Intragastric Balloon System, manufactured by Apollo Endo Surgery, and one report involves the ReShape Integrated Dual Balloon System, manufactured by ReShape Medical Inc.

Real-World Evidence Final Guidance and Webinar

FDA has released a final guidance document on the Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. This guidance clarifies how the agency determines whether real-world data may be sufficient for use in regulatory decisions, without changing the evidentiary standards we use to make those decisions. It clarifies how we plan to evaluate real-world data to determine whether it may be sufficiently relevant and reliable for various regulatory decisions, and it also clarifies when an Investigational Device Exemption (IDE) may be needed to collect and use real-world data for purposes of determining the safety and effectiveness of a device.

Real-world data, which relate to patient health status and/or the delivery of health care routinely collected from a variety of sources, can provide powerful insight into the benefits and risks of medical devices, including how they are used by health care providers and patients**.** This guidance is a cornerstone of our strategic priority to build a national evaluation system for health technology (NEST).

On October 10, 2017 from 1:00-2:30pm EST, the FDA will hold a webinar about this guidance. Registration is not necessary.

To hear the presentation and ask questions:
Dial: 800-779-8625; passcode: 7388850 | International: 1-210-234-0098; passcode: 7388850.

To view the slide presentation during the webinar:
https://www.mymeetings.com/nc/join.php?i=PWXW5328003&p=7388850&t=c

More information about this webinar or our complete webinar series can be found on the Medical Device Webinars and Stakeholder Calls webpage.

AAMI Foundation Webinars

The AAMI Foundation is offering two free webinars this month – Multiple IV Infusion Safety and A Journey to Reducing Alarm Fatigue: Tips on What Not to Do. The infusion safety webinar is a two-part series which addresses the risks with secondary IV infusions and how to mitigate them.

Multiple IV Infusion Safety Part I: Making the Invisible Visible -
September 11, 2017 – 12PM-1PM EST
To register - https://register.gotowebinar.com/register/2163634758441793283

Multiple IV Infusion Safety Part II: Where's My Line?
September 25, 2017 – 12PM-1PM EST
To register - https://register.gotowebinar.com/register/7172730458635836675

The second webinar, A Journey to Reducing Alarm Fatigue: Tips on What Not to Do will feature one hospital's alarm fatigue success stories as well as lessons learned. The webinar will also cover operational and clinician barriers impacting alarm reduction as well as recommendations to reduce non-actionable alarms.

A Journey to Reducing Alarm Fatigue: Tips on What Not to Do
September 18, 2017 – 12PM-1PM EST
To register - https://attendee.gotowebinar.com/register/5702953892159805187

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during August 2017. The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

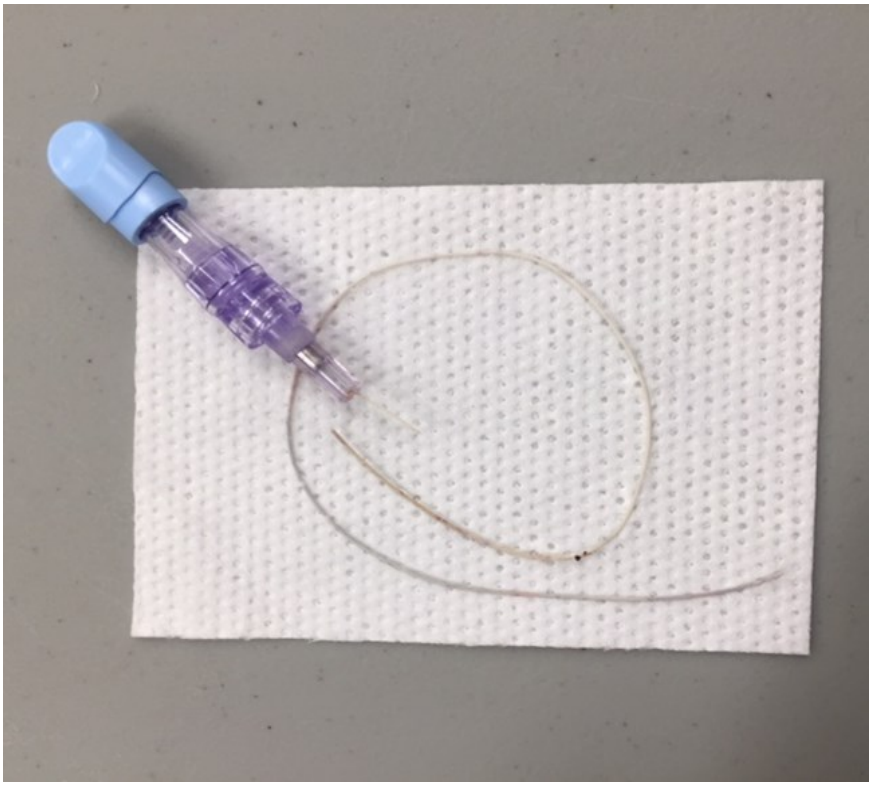
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm


Special Note:

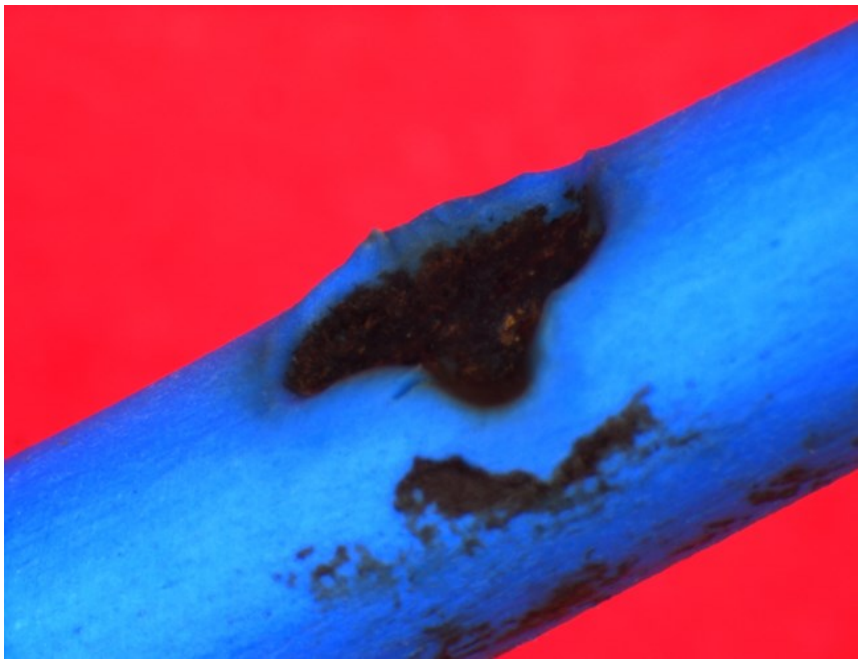
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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
Drill Bit, Reamer Model#: AR-1450 Cat #: AR-1450 Other #: Stryker 4400 drill	Arthrex, Inc.	Outpatient surgery for left flatfoot reconstruction with gastrocnemius recession, lateral column lengthening, cotton osteotomy, and flexor digitorum longus (FDL) tendon transfer. During surgery, prior to use of the drill, the scrub tech noted that the reamer contained what was described as "white stuff" that plugged up the drill. The drill and reamer were removed from service and returned to vendor. There have been no other events of this type associated with this equipment. After investigation it was determined that failure to comply with established process for cleaning of the drill was a contributing factor.

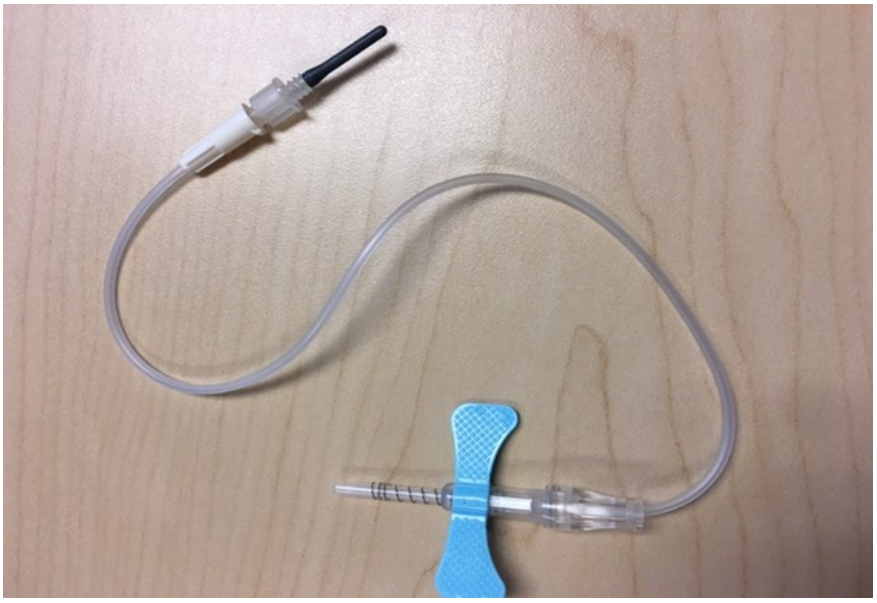
Device	Manufacturer	Problem
Device 1: Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Cook Spectrum Turbo-ject Picc Set - Minocycline/ rifampin Impregnated Lot #: 7421921 Cat #: UPICS-3.0-CT--ABRM-1110	Cook Incorporated	Event #1 – 3 FR Single lumen Spectrum PICC Lot # 7421921 Hub (portion where the needleless connector attaches) of catheter completely separated from the PICC Catheter inserted for single indication – continuous milrinone infusion Event #2 – 3 FR Single lumen Spectrum PICC Lot # 7143607 "Leaked from hub area" Catheter inserted for a single indication – continuous milrinone infusion Event #3 – 3FR Single lumen Spectrum PICC Lot # 6265569 "Leaking –crack in hub" Catheter inserted for a single indication – continuous treprostinil infusion
Device 2: Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Cook Spectrum Turbo-ject Picc Set - Minocycline/ rifampin Impregnated Lot #: 7143607 Cat #: UPICS-3.0-CT--ABRM-1110	Cook Incorporated	Event #4 – 3 FR Single lumen Spectrum PICC Lot # 6813179 Started to leak at hub area and prior to removal, hub completely separated from the PICC Catheter inserted for a single indication – continuous treprostinil infusion
Device 3: Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Cook Spectrum Turbo-ject Picc Set - Minocycline/ rifampin Impregnated Lot #: 6265569 Cat #: UPICS-3.0-CT--ABRM-1110	Cook Incorporated	

Device	Manufacturer	Problem
Device 4: Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Cook Spectrum Turbo-ject Picc Set - Minocycline/ rifampin Impregnated Lot #: 6813179 Cat #: UPICS-3.0-CT--ABRM-1110	Cook Incorporated	Event #1 – 3 FR Single lumen Spectrum PICC Lot # 7421921 Hub (portion where the needleless connector attaches) of catheter completely separated from the PICC Catheter inserted for single indication – continuous milrinone infusion Event #2 – 3 FR Single lumen Spectrum PICC Lot # 7143607 "Leaked from hub area" Catheter inserted for a single indication – continuous milrinone infusion Event #3 – 3FR Single lumen Spectrum PICC Lot # 6265569 "Leaking –crack in hub" Catheter inserted for a single indication – continuous treprostinil infusion Event #4 – 3 FR Single lumen Spectrum PICC Lot # 6813179 Started to leak at hub area and prior to removal, hub completely separated from the PICC Catheter inserted for a single indication – continuous treprostinil infusion
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: L-cath™ S/I Picc S/I Model#: 26GA (1.9F) x 30cm Lot #: 11162385 Cat #: 384539	Argon Medical Devices, Inc.	Nurse was discontinuing a PICC line that was no longer needed. She carefully removed the tape, cotton balls and opposites, one layer at a time. When she pulled back the cotton balls, she saw the PICC line sitting on top, with it open and dripping IV fluid. It was quickly clamped it off, and nurse proceeded to remove the PICC per protocol. The line had somehow become severed or ripped right up from the hub about 1 cm. The rest of line was intact. Temporary harm requiring intervention but no lasting issues with patient. Please see picture below: 

Device	Manufacturer	Problem
Circuit, Breathing (WConnector, Adaptor, YPiece) Brand: Bio-med Breathing Circuit Model#: 20306 Lot #: 08022117 Cat #: 2030-6 	Bio-Med Devices, Inc.	Upon attaching infant transport ventilator circuit to MVP-10 transport ventilator, clinician was unable to pressurize the circuit. Tried multiple times. Switched circuit out with a new unopened package with same result. Clinician then discovered that the diaphragm from the exhalation valve was missing from all the ventilator circuits recently tried. A total of six circuits were missing the diaphragm from the exhalation valve.
Ventricular (Assisst) Bypass Brand: Excor Vad Model#: D03I-111 Lot #: 12-3260 Other #: Hospital asset number 514301 	Berlin Heart GmbH	During an internal transport, the battery alarmed "batteries discharged" within 13 minutes of leaving the patient room. The batteries should last a minimum of 30 minutes. The patient was immediately returned to the patient's room and the system was plugged into wall power. No patient harm. The system had been plugged in and charging over night before the transport attempt. The system has been returned to Berlin Heart and the root cause was determined to have been a defective battery. Both batteries were replaced. This is a recurring problem.
Light, Surgical, Ceiling Mounted Brand: Mira Led Series Minor Surgical Lights Model#: Mira 50 Cat #: L-MED50-CM-SC	Amico Lights Corporation	While adjusting the overhead LED exam light in the emergency department exam room, the LED light head separated from the ceiling mount arm and was caught by the Nurse before hitting the patient's gurney. The exam lamp cantilever arm sprang back towards the ceiling and could not be grabbed. Inspection of the separated light head noted cracking and separation of the plastic LED lamp shroud and deflector assembly right where the assembly attached to the ceiling mount arm. Engineering inspection of the remaining exam lamps in the department noted similar cracking at the light assembly and arm mounting section.

Device	Manufacturer	Problem
Electrosurgical, Cutting &; Coagulation &; Accessories Brand: Edge Model#: E1465 Lot #: 70300264X Cat #: E1465	Covidien LP	During breast augmentation procedure, surgeon noticed outer edge of left nipple where incision was, burned prior to inserting the breast implant. The insulation on the outside of the insulated needle tip cautery was found to have two small areas where the insulation was not there. A new needle tip and a hand held cautery were opened. All items were retrieved and will be returned to the manufacturer. Surgeon repaired the burned area and completed the procedure as planned with no serious injury to the patient. Clinical Engineering viewed the needle tip under a light microscope. Images are available of the torn insulation. Hospital will be returning the product to manufacturer for failure analysis. Please see picture below: 
Shunt, Central Nervous System Brand: Accudrain External Csf Drainage System Model#: SP0214 Cat #: SP0214	Integra Lifesciences Corporation	When the patient was in MRI, the tech from MRI and RN from ICU were getting ready to move the patient back to the bed when they noted that the patients pillow was wet. They then noted that the stopcock most proximal to the patient had fallen out and the spinal fluid was dripping out. There were no signs of trauma to the tubing and no cracks noted. The white stopcock was missing completely.

Device	Manufacturer	Problem
Device 1: Pack, Hot Or Cold, Water Circulating Brand: Breg Model#: POLAR CARE CUBE Lot #: 272130207 Cat #: 10701 Other #: L3 **Device 2: Pack, Hot Or Cold, Water Circulating** Brand: Breg Model#: POLAR CARE CUBE Lot #: 272176039 Cat #: 10701 Other #: L240 **Device 3: Pack, Hot Or Cold, Water Circulating** Brand: Breg Model#: POLAR CARE CUBE Lot #: 272176039 Cat #: 10701 Other #: L137 **Device 4: Pack, Hot Or Cold, Water Circulating** Brand: Breg Model#: PAD KNEE/SHLDR Lot #: 272151403 Cat #: 02320 Other #: L137	Breg, Inc. Breg, Inc. Breg, Inc. Breg, Inc.	Patient cold therapies post-ortho surgery; using cold packs which leaked. Patient A. had knee surgery on 4 months ago. They were discharged and a week later her knee pad was not getting cold. The patient's caregiver felt the device and it was very hot. They unplugged it and called the hospital. Patient B. Patient states that after they were discharged home, the polar care began leaking out of the main unit. They brought the unit back to orthopedics and it was exchanged for a new one. Patient C. Patient brought polar care back to the hospital after discharge as parts had broken and wanted a replacement. Patient was given a new polar care and old one stored for risk management. Patient D. Polar Care PAD for knee was leaking. RN replaced it with another one and that worked fine. Defective pad was taken to Care coordinator to exchange.

Device	Manufacturer	Problem
Device 5: Pack, Hot Or Cold, Water Circulating Brand: Polar Care Cube Lot #: 272180610 Cat #: 10701 Other #: L57	Breg, Inc.	Patient E. Polar Care Cube is leaking at the end of the hose where it attaches to the pad that goes on the patient's knee. It was replaced with a new one and the defective one sent to risk management
Set, Administration, Intravascular Brand: BD Vacutainer Ultratouch Push Button Blood Collection Set Lot #: 7156633 Cat #: 367364	BECTON, DICKINSON AND COMPANY	Unused device was packaged with spring outside of the needle guard. Please see pictures below:  

Device	Manufacturer	Problem
Tubes, Gastro-intestinal (And Accessories) Brand: Oral/ enteral Syringe, Single-use Model#: 302836 Lot #: 7118729 Cat #: 302836 	Becton, Dickinson And Company	Upon checking placement of infant's OG gavage tube, it was noted that the end of the plunger in a 30 cc oral syringe was broken. A very sharp piece of plastic was created from the break. The RN immediately disconnected the syringe and plunger from the infant's tube and noted no pieces appeared to have come loose in the bed. The RN proceeded to care for the infant and started feeding using a new oral syringe which appeared to be fully intact and functional. The damaged syringe was given to Clinical Engineering and photos of the damage were acquired. In addition to the piece of the plunger that broke off, there also appears to be several cracks where more pieces might have broken if this was not caught by the nurse. We will return the device for failure analysis.
Orthosis, Corrective Shoe Brand: Ponseti Mitchell Braces 	MD Orthopedics	Newborn wearing Ponseti Mitchell boots (braces); Staff notes wounds on right foot and today noted Stage III pressure ulcer on her left posterior ankle from the boots. Also noted was erythema also on her right toe, Stage I from pressure. Wound care nurse assessed ulcers; per nurse, physician states boots need to be tight. Nurses questions if vendor should be notified as boots should not cause multiple pressure ulcers.
System, X-ray, Tomography, Computed Brand: Optima Model#: CT580	GE Healthcare	The CT scanner has two different software components that are incompatible. This results in frequent shutdowns of the equipment and multiple repair calls to manufacturer. ========== Manufacturer response for CT Scanner, GE Optima 580 Big Bore (per site reporter) ========== Complaint- CT SCANNER - IMAGE WORK STATION NOT WORKING Service notes- RECURRING KNOWN ISSUE W/SUSE RED HAT LINUX ISSUE AND IMAGEWERKS DB CORRUPTION. GE REF#1-211742668091. When we first experienced this issue GE suggested replacing a computer at a cost of $10K. So we replaced it. When problem resurfaced our in-house engineer called and spoke with an in-house GE engineer who said this is a known problem and there is no way to resolve. The computer replacement actually wasn't the right thing to do.

Device	Manufacturer	Problem
Shunt, Central Nervous System Brand: Accu-drain External Csf Drainage System Model#: SP0214 Cat #: SP0214	Integra Lifesciences Corporation	When the patient was in MRI, the tech from MRI and RN from ICU were getting ready to move the patient back to the bed when they noted that the patients pillow was wet. They then noted that the stopcock most proximal to the patient had fallen out and the spinal fluid was dripping out. There were no signs of trauma to the tubing and no cracks noted. The white stopcock was missing completely.
System, Nuclear Magnetic Brand: Ingenia 1.5t	Philips Medical System	During MRI exam of thigh and leg, patient received a suspected thermal burn to right thigh. Ice packs were placed with improvement. Later felt warm again and exam was terminated. Upon inspection the patient had a few spots to the inner thigh that was red and splotchy.
System, X-ray, Tomography, Computed Brand: Brilliance Ict Model#: 728306	Philips Medical Systems (cleveland), Inc.	During extended/long run-off procedures the system will stop scanning and generates a memory overflow error. This has been ongoing for 6 months to a year; the manufacturer field service representative has installed several parts. After this last occurrence the issue has been escalated to their specialists Please see pictures below:  

Links to FDA/CDRH Databases and Other Information Sources

Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/default.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: http://www.fda.gov/medicaldevices/safety/default.htm
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.

MedSun Website: http://www.fda.gov/medsun/
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)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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 the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
This database contains the most recent manufacturer warning letters.

To access additional September 2017 newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

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