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):

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm595393.htm

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm589381.htm

In Brief

As of June 25 2021

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

Stop New Implants of the Medtronic HVAD System

June 3, 2021

Medtronic has stopped the sale and distribution of the Heartware Ventricular Assist Device (HVAD) System because:

- There is an increased risk of neurological adverse events and mortality associated with the internal pump.
- There is a potential for the internal pump to stop. If the internal pump stops, it may delay restarting or fail to restart.

Both problems may lead to death or serious injuries. Therefore, health care providers should no longer implant the Medtronic HVAD System. Providers should continue to manage care of patients with a previously implanted Medtronic HVAD system according to the Urgent Medical Device Communication Notification letter.

Stop Using Innova SARS-CoV-2 Antigen Rapid Qualitative Test: FDA Safety Communication

June 10, 2021

FDA is warning the public to stop using the Innova SARS-CoV-2 Antigen Rapid Qualitative Test for diagnostic use. The FDA has significant concerns that the performance of the test has not been adequately established, presenting a risk to health. In addition, labeling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during the clinical studies of the tests. Finally, the test has not been authorized, cleared, or approved by the FDA for commercial distribution or use in the United States, as required by law. This Safety Communication is related the April 23, 2021 Class I Recall for the Innova SARS-CoV-2 Antigen Rapid Qualitative Test.

DeRoyal Industries Recalls Surgical Procedure Packs for Mislabeled Lidocaine

June 25, 2021

DeRoyal is recalling the surgical procedure packs because the packs contain 1% lidocaine that has been mislabeled as 0.5% bupivacaine. Though both lidocaine and bupivacaine are local anesthetics, their dosing is different. If 1% lidocaine is given to the patient instead of 0.5% bupivacaine, the patient may be underdosed and experience pain during the procedure. If 0.5% bupivacaine is given to the patient instead of 1% lidocaine, it may cause an overdose of bupivacaine with potential life threatening or fatal consequences. This recall is related to a Hospira recall for the same mislabeling issue.

Flexible Bronchoscopes and Updated Recommendations for Reprocessing:
FDA Safety Communication

FDA is providing updated information about medical device adverse event reports and recommendations for health care providers on bronchoscopes. This is a supplement to the 2015 Safety Communication.

FDA reminds health care staff responsible for reprocessing bronchoscopes and accessories of the importance of carefully following the manufacturer's reprocessing instructions. Additionally, the FDA recommends the following:

- Consider using sterilization (i.e., precleaning, leak testing, cleaning, and sterilization) instead of high-level disinfection (HLD) when feasible, because sterilization has a greater safety margin than HLD.
    - If HLD is used, it should include precleaning, leak testing, cleaning, HLD, rinsing with tap/utility water, flushing with alcohol/critical water, and drying.
    - Use only manufacturer-specified cleaning accessories, high-level disinfectants, enzymatic cleaning agents, and detergents.
- You should not use damaged devices or those that have failed a leak test, as they could be a potential source of contamination.
- Follow the manufacturer's instructions regarding storage of bronchoscopes to minimize the likelihood of contamination or collection and retention of moisture.
- Follow the manufacturer's recommendations for preventive maintenance and repair of the device and accessories.
- Develop schedules for routine inspection and periodic maintenance in accordance with the manufacturer's instructions, including written documentation of the reprocessing processes, and training and monitoring of those processes.
- You should not reprocess or reuse single-use bronchoscopes.

The FDA is providing the following **new** recommendations to health care providers:

- Consider using a single-use bronchoscope in situations where there is increased risk of spreading infection or when immediate reprocessing is not feasible.
- When treating patients with COVID-19, refer to recent recommendations from the American Association for Bronchology & Interventional Pulmonology.

To read the full safety communication, all of FDA's recommendations, and information on bronchoscope related medical device reports please visit FDA's website.

Update: FDA Recommends Transition from Use of Non-NIOSH-Approved and Decontaminated Disposable Respirators -
Letter to Health Care Personnel and Facilities

FDA is recommending health care personnel and facilities transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including non-NIOSH-approved imported respirators such as KN95s. This recommendation is in follow-up to the April 9, 2021, letter in which the FDA recommended a transition away from decontamination or bioburden-reduction systems for cleaning and disinfecting disposable respirators, which were being reused by health care personnel.

Based on the increased domestic supply of new respirators approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) and consistent with CDC's updated recommendations, the FDA believes health care personnel and facilities can transition away from using non-NIOSH-approved respirators and from utilizing decontamination and bioburden reduction systems. These crisis capacity conservation strategies have been used to address respirator shortages during the COVID-19 outbreak.

The FDA recommends that health care personnel and facilities:

- Limit decontamination of disposable respirators. Decontaminated respirators and respirators that have undergone bioburden reduction should be used only when there are insufficient supplies of new filtering facepiece respirators (FFRs) or when any new respirators are unavailable.
- Limit use of all non-NIOSH-approved respirators, including imported respirators, to only when there are insufficient supplies of new NIOSH-approved FFRs or when any new respirators are unavailable.
- Transition away from a crisis capacity strategy for respirators, such as use of non-NIOSH approved respirators and decontamination of N95 and other FFRs.
- Increase inventory of available NIOSH-approved respirators, including:
    - N95s and other FFRs
    - Elastomeric respirators, including new elastomeric respirators without an exhalation valve that can be used in the operating room
    - Powered air-purifying respirators (PAPRs).

To read the full letter and all of FDA's recommendations for health care providers please visit FDA's website.

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HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during June 2021. 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

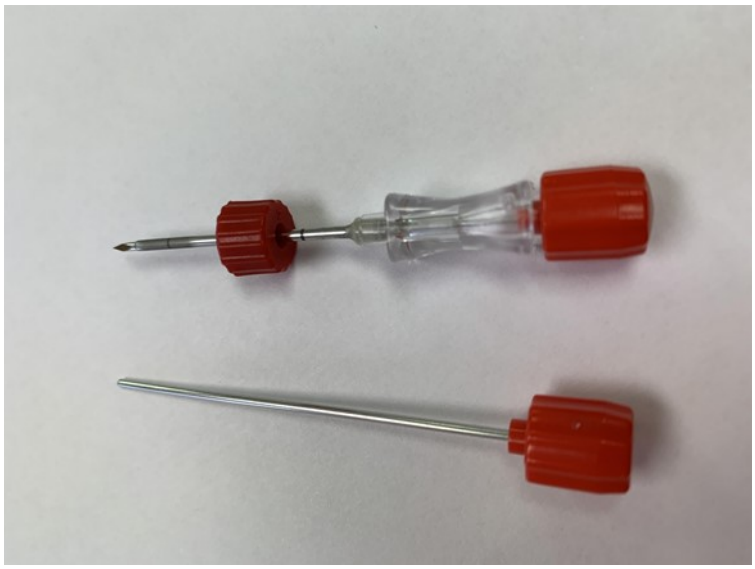
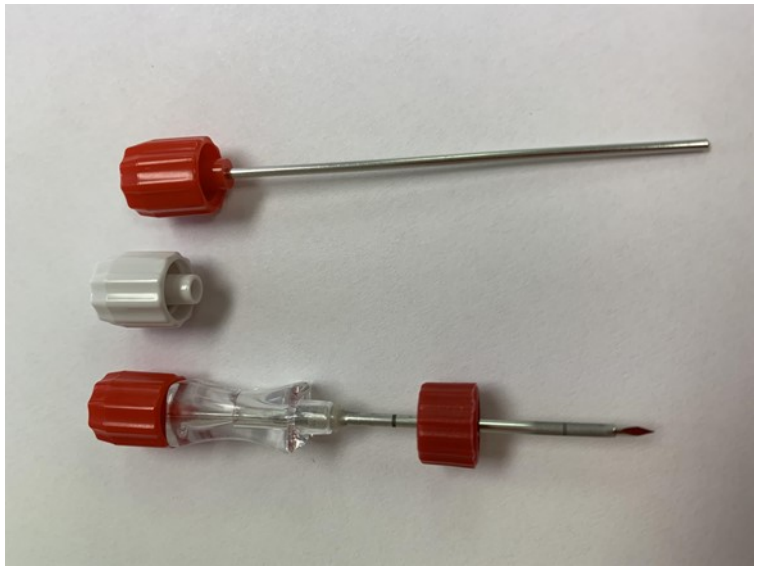
Special Note:

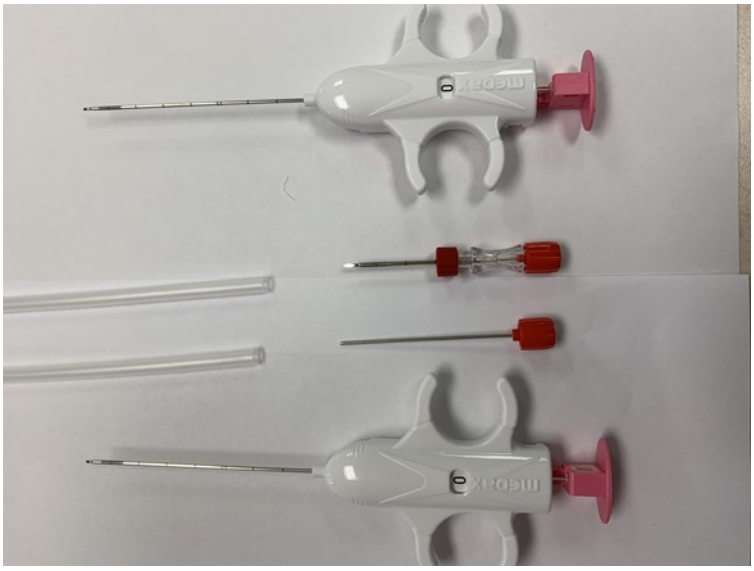
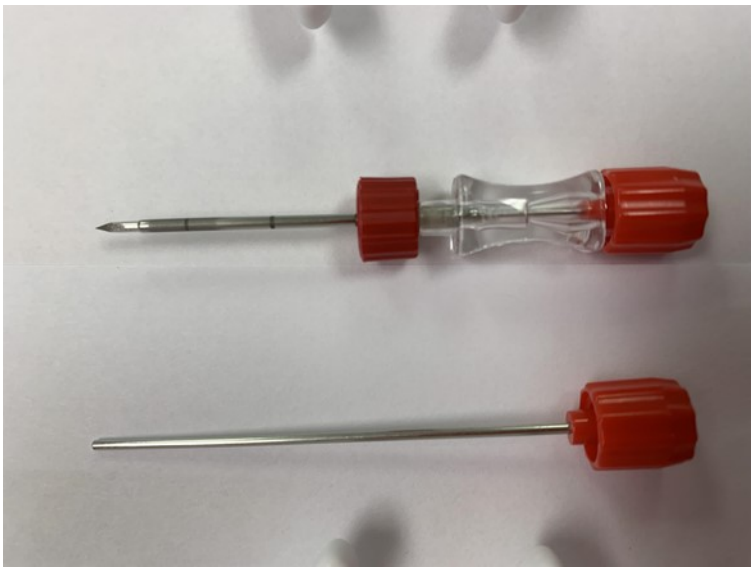
The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years 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.

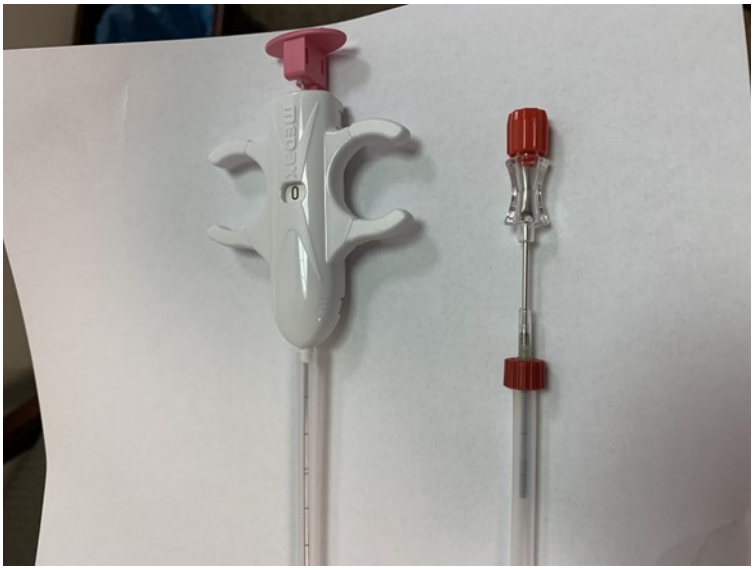
Device	Manufacturer	Problem
Clamp, Vascular Brand: Femostop Gold Femoral Compression System Model#: C11165 Lot #: 7655193 Cat #: C11165	St. Jude Medical, Inc.	Patient was picked up in catheterization lab with fem stop in place on right groin. When arrived to ICU, patient's right leg was cold, mottled, had numbness/tingling, and without pedal/patient pulses. Air was unable to be let out of device related to device malfunction or user error when applied. Cardiovascular monitor tech and consultant at bedside to remove fem stop device. Patient without pedal pulses for 10 minutes. Doppler of posterior tibial artery pulses achieved in 10 minutes, pedal pulses dopplerable within 2 hours, both pulses then palpable 12 hours after incident.
Introducer, Catheter Brand: Cook Flexor Ansel Guiding Sheath Model#: G56221 Lot #: 13763424 Cat #: KCFW-6.0-35-70-RB-HFANL0-HC	Cook, Inc.	During the procedure, the sheath became stuck in the body and was unable to be removed or advanced by physician. Sheath became fractured, requiring the sheath and wire to be cut. Patient transferred to another hospital resulting in surgery to remove a retained wire from the right common femoral artery and retrieval of the retained sheath from the left superficial femoral artery. Patient discharged home from outside hospital.

Device	Manufacturer	Problem
System, X-ray, Tomography, Computed Brand: Canon Aquilion Prime Model#: CGS-72A/2B	Canon Medical System, USA, Inc.	Scanner would not build images after scanning the patient, so images were not visible at all. This resulted in a three hour patient care delay on a trauma protocol while this was worked on. Equipment has had problems like this before which were looked into by biomed last week, but are clearly unresolved. Wait time was greater than three hours for results. Patient discharged home with follow up with Neurosurgery. Sent healthcare technology manager for follow up. Canon was notified by Computed Tomography (CT) manager today. Radiology Radiostereometric Analysis team added to discussion. Update from radiology: Event reviewed, service and CT technologists were unable to duplicate slowness. Multiple tests were run.
Thermometer, Electronic, Clinical Brand: A&D Medical Digital Thermometer Model#: DT-105 Lot #: 202005 Cat #: DT-105	A & D Medical	Remote Patient Monitoring (RPM) requires patients to check vitals (including temp) at home with the thermometer provided by the RPM program. The patient brought the thermometer in to show the nurse it has been reading abnormally low (1-2 degrees lower than what the nurse gets with the clinic thermometer). There is potential for missed fevers with a malfunctioning thermometer since this patient is closely monitored post chimeric antigen receptors-T cell infusion for fevers, cytokine release syndrome, and neurotoxicity. Per patient report, the thermometer has not been working for several days and a new thermometer was ordered but still not functioning properly. Another new thermometer was ordered through the RPM program.
Warmer, Thermal, Infusion Fluid Brand: Rapid Infuser Ri-2 Lot #: 2021-0308 Other #: 903-00006 three spike disposable set	Belmont Instrument Corporation	Initiated massive transfusion using Belmont Rapid Infuser RI-2 to a trauma patient. Noted blood leaking out of side of the rapid infuser machine and when the door of rapid infuser was opened, blood was seen to be leaking at a connection near the circle. It was noted that the tubing was correctly loaded. Obtained second set of tubing which was loaded into a different Belmont Rapid Infuser machine and primed tubing with saline. When starting to infuse blood, team member noted saline to be leaking from side of rapid infuser machine again. Tubing was observed to be leaking at the same place near a connection by the circle as the first set of tubing. Unfortunately team member was unable to get the packaging for the tubing as housekeeping was very efficient and had taken the garbage with the tubing package away already. Lot number of tubing in same cabinet is 2021-0308. Patient remained stable but incident did delay care for approximately 10 minutes as patient did not receive blood during the time of priming tubing and finally needing to use a regular blood tubing with a pressure bag. One of the two disposable tubing sets was saved and a company representative was contacted to pick up the device.

Device	Manufacturer	Problem
Implantable Pulse Generator, Pacemaker (Non-CRT) Brand: Assurity Mri™ Model#: PM2272 Cat #: PM2272	St. Jude Medical, Inc.	Patient was due for routine remote check. Health care providers (HCPs) did not receive a transmission and patient was contacted three days afterwards to send a remote transmission. Patient remote monitor was not able to connect and was transferred to St. Jude Medical tech services to troubleshoot the monitor. Patient was unable to connect his remote monitor, and was brought into the clinic ten days after the original failed routine remote check to troubleshoot his monitor and to possibly provide him with a new monitor. Patient monitor status showed it was connected. The St. Jude Medical tech representative anticipated an issue with the "RF chip" and recommended a software update to patient's pacemaker. HCPs were unable to connect the programmer to PT pacemaker, and unable to elicit a response from the pacemaker when a magnet was placed over the device. An EKG was obtained that showed patient was in a junctional rhythm with heartbeats in the mid 30's to 40's. Doctor was notified of these findings and the patient was taken to the catheterization laboratory for an emergent generator change. Through conversation with the St. Jude representative, HCPs were focusing on the remote monitor and connectivity. HCP did not receive an alert or any indication that the patient's pacemaker had experienced any performance issues. Patient denied any new or worsening symptoms throughout all of our communications with him.
Instrument, Biopsy Brand: Medeasy Model#: ML18080-K0 Lot #: 06186-20 Cat #: ML18080 -K0	Medax Srl Unipersonale	Patient with history of chronic obstructive pulmonary disease and increasing shortness of breath was admitted for a soft-tissue right breast biopsy. Prior to inserting needle into patient, the Medax Srl Unipersonale Medeasy soft tissue semi-automatic biopsy needle 18G x 80 mm (Lot # 06186-20, Cat # ML18080-KO) came unglued. The defective needle was never placed into the patient. Another of the same type and Lot # of that needle was opened and used. This is not the first event for this product, reported same incident with this type of device in the recent past.

Device	Manufacturer	Problem
		  

Device	Manufacturer	Problem
Instrument, Biopsy Brand: Medeasy Model#: ML18080-K0 Lot #: 0618620	Medax Srl Unipersonale	Patient with history of Stage IV follicular lymphoma was admitted for an ultrasound biopsy of lymph node. While physician was doing the procedure, the Medax Srl Unipersonale Medeasy soft tissue semi-automatic biopsy needle came unglued. Another biopsy needle was used and it came unglued as well. Both biopsy needles had the same lot #. A third biopsy needle was used without problems. No known harm done to patient. This is the 6th report of this biopsy needle coming unglued. Purchasing department is aware and has all lot numbers: 21-121, 21-75, 21-67, 21-64.  

Device	Manufacturer	Problem
		
Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days Brand: First Picc S/I Peripherally Inserted Central Catheter Model#: 384232 Lot #: 11354483 Cat #: 384232	Argon Medical Devices, Inc.	Peripherally located neonatal central catheter was planned to be removed. RN unwrapped blanket and found NeoPICC was snapped below the stat lock hub. Line was pulled out in its' entirety without issue.
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers Brand: Trophon EPR Model#: N00010	Nanosonics Ltd.	Clinical Engineering has received four recent events where the Trophon EPR has failed and leaked the chemical disinfectant both inside and outside the unit. Observation indicates that the bottom of the plastic reservoir is breaking where the hose connects. Manufacturer initially told user that equipment needs preventive maintenance at 5000 cycles. When these new issues were reported to the manufacturer, hospital was told that the devices need to be sent in annually. One of the four units was sent in for a different issue, the manufacturer discovered the reservoir was leaking. Device 1 - Chemical leaking inside unit. Device 2 - Unit was sent in for door repair, Nanosonic stated that the chemical reservoir was leaking also.

Device	Manufacturer	Problem
		Device 3 - Unit is failing and giving 3188 error code, found that the chemical reservoir was leaking. Device 4 - Disinfection is leaking chemicals all over counter.
Incubator, Neonatal Transport Brand: Airborne 750i Model#: A750i Cat #: 731-0160 	International Biomedical	During set up and preparation of the in-house transport isolette, the nurse noticed a strong electrical smell from the isolette chamber. She immediately unplugged the unit from AC power and removed the isolette from the care area. Biomedical Engineering (BME) retrieved the unit and opened device for inspection. BME found the high current bridge rectifier burnt along with the bridge lead going to the power terminal block. BME also noted swelling of the 12V 28Ah internal battery. Review of the service history on this isolette and other of the same model noted the same component failure in two previous repairs on two separate devices. Parts ordered and isolette scheduled for repair.
Bone Cement Brand: Simplex Hv Lot #: 013AC844CB Cat #: 6194-1-001	Osartis GmbH	Stryker HV cement is used during total knee arthroplasty procedures. Surgeon reported during case that this cement is chronically inconsistent in handling characteristics and working time. The Stryker HV cement continues to be less sticky, rubbery, and does not adhere as well to the implants like cement that surgeon has utilized in the past.
Applicator, Absorbent Tipped, Sterile Brand: Virus Transport Medium with Swab Lot #: 20200515	Hardy Diagnostics	RN attempted to obtain COVID-19 polymerase chain reaction (PCR) per order. Swab inserted through left nare. After removing from nare, swab not intact. Tip of the swab was not able to be seen in the patient's nare. Certified Case Manager (CCM) contacted. Plans to consult ENT. Specimen able to be obtained from right nare with a new swab. Per Consultation Note: "ENT consulted for COVID swab broken off in nose. Patient intubated in the ICU with positive COVID. Chart reviewed. Patient non-responsive during examination and retrieval of swab. Endoscope used to view the left nasal cavity. Alligator forceps used to remove the swab. NG (nasogastric) tube secured in right nasal cavity. No other lesions noted of nasal cavities."

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:
https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/medical-device-connectors
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: https://medsun.fda.gov/
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 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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