Medical Product Safety Network

February 2016

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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 250 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: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm482639.htm

510(k)s Final Decisions: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm479836.htm

In Brief

As of January 27, 2016

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=Expand+Index&w=01272016&lang=eng

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

Automated Endoscope Reprocessors (AERs) Validation Testing
(February 2, 2016)
FDA has updated its' Reprocessing of Reusable Medical Devices webpage with information on which manufacturers completed their AER validation testing with adequate results. The FDA continues to work with AER manufacturers as they validate that their AER can effectively clean and disinfect duodenoscopes. The page will be updated as FDA accepts validation test results for other AER manufacturers.

Moves Ventilator System by Thornhill Research: Class I Recall
(January 27, 2016)
Excess glue on the battery connectors may prevent the battery from powering the device after the battery is stored. This issue may prevent the ventilator from providing patient breathing support.

Baxter IV Solutions (Select Lots): Recall
(January 27, 2016)
Baxter is voluntarily recalling four lots of intravenous (IV) solutions to the hospital/user level due to the potential for leaking containers and particulate matter. Leaking containers could result in contamination of the solution.

Optisure Dual Coil Defibrillation Leads by St. Jude Medical: Class I Recall
(January 27, 2016)
A manufacturing error may have caused damage to the insulation layer of one of the shock coils. Depending on device programming and the depth of the cut, this could result in the inability of the defibrillator to deliver electrical therapy to the patient.

Brainlab Cranial Image-Guided Surgery (IGS) System: Class I Recall
(January 15, 2016)
Recall due to potential inaccuracies in the display by the navigation system compared to the patient anatomy.

Duodenoscope Model TJF-Q180V by Olympus: FDA Safety Communication
(January 15, 2016)
Updated status information about the Agency's 510(k) clearance decision on the device.

Pleural and Pneumopericardial Drainage Sets by Stryker Fuhrman - Class I Recall
(January 11, 2016)
The manufacturer received two reports that the catheter included in the Drainage Set broke off in the pleural cavity while inserting the device into the patient. Both cases resulted in the need for medical intervention.

Medical Product Safety Network (MedSun) Final Survey Report
Topic: Hospitals' Adoption of Medical Device Unique Device Identification (UDI)
Survey Year: 2015

Introduction

Over the last several years, Informatics specialists from FDA's Center for Devices and Radiological Health have been working with medical device manufacturers and other stakeholders on plans to have Unique Device Identification (UDI) available for medical devices in machine-readable form. They have also been developing the FDA's searchable Global Unique Device Identification Database (known as GUDID). When fully implemented, UDI will provide many benefits to industry, FDA, consumers, health care providers and health care systems by making it easier to identify and resolve medical device problems, among many other things.

As part of these efforts, FDA UDI specialists wanted to gauge the extent to which hospital staff responsible for operations related to medical device supply chain and materials management operations are aware of UDI implementation and/or published information about its benefits. They also wanted to know whether hospitals are actively planning to make use of UDI in their operations. To help learn more about these issues, the UDI team requested a survey of hospitals that participate in FDA's Medical Product Safety Network.

Methodology

A small sample of hospitals, most of which participate in FDA's Medical Product Safety Network (MedSun), was identified for the survey recruitment based on factors such as location, bedsize, and, in some cases, FDA staff's knowledge of their activities related to UDI (such as UDI-related conference participation during the previous year). After sites were recruited, FDA staff from the MedSun Survey team and FDA leaders in UDI activities had the opportunity to hear from staff from 6 healthcare organizations located in 6 areas of the continental US about their knowledge of and preparations for adopting UDI for ongoing use with various hospital activities.

The sites included two healthcare systems, one university-based hospital, two pediatric hospitals, and one not-for-profit hospital that was part of a large healthcare system. All of the hospitals had at least 200 beds, and most of them also had outpatient services such as clinics or outpatient diagnostic services associated with their organizations.

The respondents included biomedical or clinical engineers, applications/IT managers, directors of supply chain operations, procurement directors, and materials managers with lead roles in their hospitals' operations. Generally there

were two primary respondents per site (e.g., the Director of Biomedical Engineering and either the Director of Supply Chain Operations or the Director of Materials Management).

Overview of Responses

The following sections describe the responses to this survey.

Knowledge About FDA's and Other Organizations' Implementation of UDI:
One hospital system's respondents were very well informed about the implementation of UDI, and they had been actively working on UDI adoption with their system's leadership and staff. They also were collaborating with others outside their organization, such as supply chain specialists in other healthcare systems known for their leadership in UDI adoption.

The respondents from the other sites expressed some knowledge of UDI gained from one or more sources, such as review of the FDA website, attendance at the Pew Charitable Trust conference held in December 2014, information they had received from an organization that has been certified by FDA to assign unique device identifiers, and/or review of information they received from the Association for Healthcare Resource and Materials Managers (AHRMM). The pediatric hospitals mentioned the communications about UDI (specifically GTINs) from supply chain leaders in the Children's Hospital Association. Although all of these respondents had heard of UDI efforts related to medical devices, many indicated that they did not feel confident about their knowledge about all of the specific uses of UDI.

Knowledge About the Benefits of UDI for Hospitals:

One healthcare system's respondents were very knowledgeable about the documented advantages of UDI for hospitals. Two sites' respondents indicated that they were somewhat aware of the documented advantages; however they were not convinced at this time about the cost-savings or other benefits of UDI for supply chain operations.

Most of the hospital staff mentioned that they saw definite advantages of UDI adoption for recalls management purposes. Several respondents indicated that they thought that many of advantages of UDI for hospitals would take "many years" to be realized. Despite doubts two respondents expressed about some of the cost-saving advantages discussed in the advance materials provided before the interviews, all of the respondents indicated that they fully supported the development of UDI for medical devices and thought it would be important to their hospitals in future years.

Generally the respondents indicated that they thought that it would be helpful to hospitals' use of UDI for FDA staff (or others knowledgeable about UDI's advantages for hospitals) to encourage vendors of certain commonly used products to routinely include UDI fields for medical devices and related capabilities in their products. The types of products mentioned included:

- EHR (Electronic Healthcare Record) products (such as those offered by EPIC, Cerner and others),
- CMMS (Computerized Maintenance Management System) products, and
- ERP (Enterprise Resource Planning) products.

In this way, FDA and product vendors would be helping to lay the groundwork for hospitals to routinely include UDI when staff used these types of products. This would allow hospitals to be in a position to obtain the associated benefits without the expenses (in vendor charges and hospital staff time) of customizing these software products to accommodate UDI.

Hospitals Plans to Use UDI:
Currently most of the sites in the survey did not have feasibility studies or pilot programs in place concerning UDI adoption, often due to competing priorities for their time and attention as well as hospital resource constraints. However, one of the sites, a healthcare system, has been working very actively on plans to use UDI in their operations. This site, a healthcare system, has made great strides in this effort, and has developed several documents that they offered to share publicly for use by interested hospitals throughout the country.

Another site, also a healthcare system, indicated that they had made progress in their use of GTIN identifiers (equivalent to the Device Identifier portion of the UDI), and that they insist that the manufacturers that provide them with products include the GTIN at the time of delivery or else the products are returned to the manufacturer. They have integration activities in place to link their ERP, Chargemaster, and Electronic Health Records systems.

A pediatric hospital indicated that they have had some success with the use of GTIN identifiers provided by their suppliers and that they will be involved in educating staff about the use of GTINs for a variety of processes in the coming months.

Current Use of Electronic Health Records and Methods to Record Medical Device Implant Information:

All of the hospitals in the survey had an Electronic Health Record. Generally the respondents indicated that a record was kept about patients' implanted medical devices, generally in a surgical record (which in some cases was linked or otherwise transferred to the patient's electronic health record). Some hospitals kept medical device implant information in paper form for their records as well as in an electronic format. Specific identifiers such as Brand Name, Manufacturer, Catalog Number, were generally kept. Several respondents indicated that the information about patient implants was keyed into the surgical record, while others used a system for scanning the product information into the record.

Other Comments:
The respondents offered specific suggestions for organizations that FDA staff should contact to encourage their assistance with FDA's efforts to encourage UDI adoption.

All of the respondents included in the survey indicated their willingness to be contacted again by FDA staff about their activities related to UDI adoption in the coming months as their plans become more definite; many of these sites may be candidates for partnering with FDA to track the benefits of UDI adoption.

There was some confusion expressed about which versions of certain software products include UDI. It may be useful, if possible, if FDA or relevant professional associations would routinely provide information for hospitals about the specific versions of the products that currently include UDI for their EHR, CMMS, ERP or other relevant software products.

Summary

All of the respondents that we spoke with indicated that they were supportive of UDI and thought that it will be very helpful to healthcare organizations like theirs in the future. They often mentioned the advantages for recalls management.

Some respondents indicated that they thought it would take several years before the benefits of UDI could be realized for their hospitals. Very few of the hospital representatives that we spoke with indicated that they were actively working on feasibility studies or other preparations to take full advantage of UDI. One hospital system's supply chain specialists indicated that they are dedicating substantial resources to adoption of UDI, and they provided a number of documents that have been developed for that purpose.

Most of the respondents indicated that they thought it would be very helpful if the various resources that they use (such as ERP systems, Electronic Health Records, CMMS systems) included UDI. They encouraged FDA to communicate with specific associations and relevant software vendors to encourage them to help move UDI adoption forward for use in the healthcare community.

The respondents to this survey provided very useful information for FDA's research into UDI adoption. The survey demonstrated the wide variations in knowledge about and planning for the UDI advances that are currently in process (e.g., the UDI requirements this year pertaining to implantable, life-supporting and life-sustaining devices and other requirements scheduled over the next few years).

The survey provides information that will lead to additional FDA communication about the advantages of UDI adoption with leaders from a variety of associations such as state biomedical engineering associations, supply chain-related associations and associations of particular types of hospitals, as well as with leaders from additional hospitals and healthcare systems.

Survey Limitations

Although the findings add to FDA's knowledge of hospitals' current and planned adoption of UDI, there are several limitations to the survey methodology. These include the small convenience sample of respondents. In view of these limitations, the respondents' perspectives may not represent the perspectives of all device users.

Therefore, these findings represent only one piece of information. No conclusions can be made based on this report alone. Instead, the report allows FDA to have a better understanding of the readiness and knowledge of UDI among healthcare providers.

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Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary action.

MedSun Hospitals Invited to Consider Joining the Unique Device Identification (UDI) Learning Community

A summary of key UDI adoption activities is shown below, along with information about how to indicate your hospital's interest in the learning community, other steps hospitals may take to move forward with UDI adoption, and how to learn more about UDI.

FDA Requirements for Medical Device Manufacturers for UDI Labeling and for Data for GUDID:

There are several policies and incentives that make 2016 through 2019 a key period for focusing on the adoption and use of UDI as part of an overall movement to improve the capture of structured device data in electronic health information. The 2013 regulation requiring manufacturers to apply a unique device identifier (similar to the barcodes that have been used for many years for medications) to the label of medical devices and to submit UDI data to FDA was the culmination of over 10 years of effort by multiple stakeholders across the device supply chain. Support for the UDI regulation was based upon recognition that the lack of a unique device identifier had significant negative impact on patient and device safety, and had adversely affected the efficiency and effectiveness of device evaluation and decision making.

FDA currently estimates that the majority of manufacturers have met the regulatory compliance dates in 2014 and 2015 for labeling their devices with machine-readable UDI information and for submitting standard device identification data to FDA's Global Unique Device Identification Database (GUDID, pronounced Good- I-D). This includes not only Class III medical devices (i.e., the highest of FDA risk categories for medical devices) but also other implantable, life-sustaining and life-supporting medical devices. The UDI regulation calls for manufacturer compliance in the coming years (in 2016 and 2018) for product labeling and database submissions for lower risk medical devices.

Currently there are more than 500,000 medical devices included in the GUDID, a number which is growing daily. We encourage you to visit this publicly available site for GUDID, known as *AccessGUDID*, which includes key data attributes associated with UDI-marked devices and is now available in a variety of downloadable formats. We believe that you will find the standard device identification worth the visit to the site.

Requirements for Electronic Health Records Vendors:

In addition to FDA's regulatory requirements for UDI pertaining to manufacturers, two other federal organizations, the Office of National Coordinator for Health IT (ONC) and the Center for Medicare and Medicaid Services (CMS) have placed additional requirements on Health IT vendors by including UDI in the ONC's 2015 EHR Certification Criteria and as part of CMS's Meaningful Use Stage 3 Incentive program's Common Clinical Data Set. The ONC and CMS regulations, published on October 6, 2015 and required in 2018, require Health IT developers and hospitals to create and use an implantable device list based upon the UDI which includes key data from the GUDID.

Specifically, the certification criteria instruct developers to be able to record the UDI associated with a patient's implantable device and split the UDI into a device identifier (called the DI, which includes static information such as the labeler's name and the version or model information) and one or more production identifiers. (These production identifiers are the variable part of the UDI, and would include all of the following that are available: lot, serial number, expiration date, manufacturer date, and, for certain blood products – distinct identification code). The DI portion of the UDI is then used to retrieve key information from the *AccessGUDID* database about the product's labeler and version/model, and provides source information for generating a patient's implantable device list (as discussed above).

In 2018, patients leaving hospitals or outpatient surgery centers that have taken full advantage of UDI should be able to receive a list of any implantable devices that they have received during their care (such as intraocular lenses, a hip or knee implant, or an implanted mitral valve) containing the UDI, Company Name, Brand, Model, Description, and indicators concerning Magnetic Resonance Safety and latex content. Because UDI has been designated as part of the set of key electronic patient health information (in the Common Clinical Data Set), major health standards development organizations such as HL7, NCPDP, and X12 are working diligently to include UDI in their key health exchange standards to ensure interoperability. This work supports the ONC-specified implantable device list items being able to be documented on patient care documents (such as discharge records) for patients with an implantable device.

Goals:

The goals for all of these standards and regulatory efforts by various federal agencies may be summarized as:

1 - to ensure that patients and their care providers have access to key information about their implantable devices at any point where they have access to electronic health information, and

2 - to support safer and more effective device use and evaluation.

Recording implantable UDI device information in a patient's electronic health record will open the door to opportunities to improve the capture of structured device data in those systems that send data to EHRs, as well as those that will

eventually be receiving data from those systems. What this means for supply chain is an opportunity to link the DI and standard core device information from the *AccessGUDID* with software used for purposes such as inventory control and billing. The inclusion of UDI in clinical information will also offer an opportunity for systems that record adverse events and patient outcomes (such as device registries) to use implantable UDI information recorded in the Common Clinical Data Set as the source of their information. If these systems include UDI, then supply chain, clinical, research and industry analysts will all benefit from more standardized information to detect safety signals, conduct and manage recalls and evaluate device performance and design improvements.

Expected Benefits:

As UDI capture and exchange become more prevalent across the healthcare ecosystem and as implantable device information is linked to patient outcomes, there are a number of expected benefits, including:

- Increased standardized data capture and interoperability of device data from time of receipt in an item master to patient charge in the financial management systems and even into device registries;
- More rapid and accurate recording of device data and retrieval for improved patient care;
- Improved adverse event reporting, since recording and parsing the UDI into DI and PI will identify the specific model and version, as well as key information such as lot and serial number that will help in analysis of the adverse event;
- Improved product recall management, since the device identifier is a link between hospital IT systems and the FDA recall database that will improve the ability to track and remove devices subject to recall, as well as improve patient safety by identifying patients with implanted recalled devices;
- Ability to use GUDID attributes as basis for clinical decision support on whether a device is magnetic resonance (MR) safe, contains latex or is expected to be packaged as sterile; and
- Improved device data to support device evaluation research with the ultimate benefit of supporting patient and clinical decision making.

Early Adopter Organizations:

The number of early adopter organizations starting UDI pilot and demonstration projects is growing. These organizations are in various stages of UDI adoption, working collaboratively with FDA and each other, providing feedback to improve regulatory policy and standards development as well as sharing best practices on UDI adoption. The early adopters include:

- Mercy Health, St. Louis, MO;

- Mayo Clinic, Rochester, MN;
- Intermountain Healthcare, Salt Lake City, Utah;
- Geisinger Health System, Danville, PA;
- Beth Israel Deaconess, Boston, MA; and
- Franciscan Missionaries of Our Lady Health System, Baton Rouge, LA.

These organizations have generally been advocates for UDI for several years, and this has led to interest by other healthcare systems in achieving the benefits of UDI adoption. FDA is participating in adoption activities to ensure that the regulatory requirements put in motion by the UDI, ONC, and CMS rules will meet the goal of adequately identifying a device through its distribution and use with a patient.

FDA is very interested in promoting a learning environment where feedback from early UDI adopters is incorporated and applied to updates to the GUDID, and used to improve labeling and submission requirements to meet the 2016 and 2018 UDI compliance dates for Class I and Class II products. We know that adoption of high risk and implantable device information will give early adopters and FDA significant insight into the potential of UDI. However, true supply chain savings will occur when the majority of medical devices are labeled with UDI and have their identifying data stored and used as a public resource in *AccessGUDID*.

To Indicate Your Hospital's Interest in the UDI Learning Community:
FDA staff are working with AHRMM and other organizations to coordinate and support sharing of existing and future UDI adoption best practices across healthcare systems, and welcome participation from MedSun sites in that process. To indicate your interest, contact medsun@fda.hhs.gov or terrie.reed@fda.hhs.gov.

What Else Can You Do?
Consider the areas of your hospital or healthcare system that would benefit most from UDI adoption. The surgical suite and the cardiac catheterization lab are often leading contenders for cost savings reasons according to some early adopter hospitals. You may want to follow the lead of some early adopters in developing pilot projects to collect and analyze available UDI information for one or two well-defined areas to learn your current state of UDI availability for various products, gain experience with producing certain benefits (such as less staff time spent keying device details for recordkeeping), and garner support for UDI-related activities from staff in those areas.

For purchases of systems and software, consider the importance of accommodating UDI information when you are involved in value analysis or purchasing decisions for software/systems such as:

- Enterprise Resource Planning systems (ERP), or other supply chain management/inventory management systems,
- Systems for tracking the maintenance of medical devices such as Computerized Maintenance Management Systems,
- Electronic Health Records (also known as Electronic Medical Records), and
- Charge Master/billing/accounting systems.

Ask the vendors you are doing business with now or considering doing business with in the future about their specific plans for including UDI information for medical devices if they do not include it in their software/systems at this time.

Additional Information:
To learn more about UDI and its benefits for healthcare organizations and patients, see the websites listed below.

- FDA UDI Site and AccessGUDID site
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
  - AccessGUDID
- 2015 ONC EHR Certification Criteria
  - https://www.federalregister.gov/articles/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base
- CMS requirements that eligible providers and hospitals must meet to qualify for Electronic Health Record (EHR) incentive payments
  - https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications
- Recommendations for a National Medical Device Evaluation System
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
- The Mercy Unique Device Identifier demonstration project: Implementing point of use product identification in the cardiac catheterization laboratories of a regional health system

  - http://mdepinet.org/the-mercy-unique-device-identifier-demonstration-project-implementing-point-of-use-product-identification-in-the-cardiac-catheterization-laboratories-of-a-regional-health-system/

- Pew Charitable Trusts and Mercy Health System Video on the benefits of UDI—August 2014
  - http://www.pewtrusts.org/en/multimedia/video/2014/udi-and-hospitals-improved-inventory-management-more-time-with-patients
- Final Report of the International Medical Device Regulators Forum (IMDRF) UDI Working Group—December 9, 2013
  - http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf
- Brookings Roadmap for UDI Implementation-- June 2013
  - http://www.brookings.edu/about/centers/health/projects/development-and-use-of-medical-devices/udi
- Unique Device Identifier (UDI) Implementation in the Electronic Information of a Single Health System: An MDEpiNet Demonstration
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/BenefitsofaUDIsystem/UCM416128.pdf
- GUDID Technical Information
  - AccessGUDID
    - Searching - http://accessgudid.nlm.nih.gov
    - APIs – http://accessgudid.nlm.nih.gov/docs
    - Downloads - http://accessgudid.nlm.nih.gov/download
- Implantable Device List - ONC Certification Companion Guide
  - https://www.healthit.gov/sites/default/files/2015Ed_CCG_a14-Implantable-device-list.pdf

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during January 2016. 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 less than 21 years of age

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Device	Manufacturer	Problem
Apparatus, Autotransfusion **Brand: Orthopat**	Haemonetics Corporation	Patient's Orthopat alarmed to check disk reservoir. I opened top lid of machine and noted some dried blood on inner ring, lifted gray metal ring up and found a yellow plastic cap with a small amount of dried and wet blood. This yellow cap is also noted to be used to close off the two tubes on top of the side collection chamber. Called the on call Orthopat rep and they said to clean the blood out of the disk reservoir with bleach wipes and leave machine off.

Anesthesia Conduction Kit **Brand: Pencan Spinal Needle Tray 24 Ga. X4In. (100 Mm), Bupivacaine 0. 75% With Dextrose 8. 25% Tray (Kit)** **Model#: 333868** **Lot #: 61464284** **Cat #: 333868**	B. BRAUN AESCULAP JAPAN CO., LTD.	Upon laying the patient supine, patient continued to have full motor strength in their lower extremities. They denied any numbness, tingling or heaviness in their legs. We could not elicit any level of anesthesia. This occurred on two separate occasions with two separate patients in approximately 8 days.
Bronchoscope (Flexible Or Rigid) **Brand: Aeris** **Lot #: 22457133F** **Cat #: KGO830** 	Bryan Medical, Inc	An 8mm balloon dilator was being used in the airway during a DML/bronch (Direct Microlaryngoscopy) procedure. The balloon was inflated using a pressure regulated balloon dilation syringe and placed in the patient for dilation. Once inflated, the balloon would not deflate with the syringe and had to be cut with a knife to be removed from the patient. The max pressure in the balloon did not exceed 17ATM, as stated by the manufacturer as the max pressure the balloon can withstand. A 7mm balloon was then used with the same syringe with no malfunction. The patient was not harmed. ========== Manufacturer response for Balloon dilator, Bryan (per site reporter) ========== Manufacturer wishes to test it.

Catheter, Intravascular, Diagnostic **Brand: Pressure Monitoring Set** **Model#: G13489**	Cook Inc.	As nurse was pulling out the left femoral arterial line, there was no resistance felt, but about 1/4 of the way out, the line snapped (outside of the patient), but the wire inside the catheter was intact. Nurse continued to pull line out, and the line snapped again, and again the wire inside the catheter was intact. Intensivist notified, and MD pulled the catheter out the rest of the way- the tip was intact. Catheter was saved in a baggie for future inspection. Abdominal x-ray done to verify all parts were out.
Catheter, IV **Brand: Protect IV Plus Safety Or Acuvance** **Cat #: 3066 or 3359** **Other #: 20 1' 1/4 or 20 1' 3/4 inch gauge**	Smith Medical	IV catheter placed and when discontinued four days later it was found that the catheter had broken off the hub. Ultrasound showed the catheter was lodged in the basilic vein anticubital fossa. The patient went to surgery the following day to have the catheter removed.
Chair, Medical **Brand: Sauder Wieland Cove Recliner, With Wood Cap** **Model#: 53981WP**	Wieland Designs Inc.	The first incident happened approximately three months ago and since then there have been a total of 4 incidents. There is a sleep lever that is located on the inside of the recliner that sticks out. On the Adult Medical Unit they have lots of elderly patients with sensitive skin. This is the info from the first patient safety report: The patient reached his arm down to grab onto seat cushion and scraped across the handle that sticks out which adjusts across the backrest. On the last incident which occurred approximately 1 month ago, I spoke to the patient. The elderly patient was sitting in the chair and brought her arm up from under the blanket and she tore the skin on her arm by hitting the control on the inside of the chair. Approximately three months ago, we met with the Engineer from the manufacturer who makes the recliner. This week, we met with a group to discuss issues including staff from the distributor who we get our recliners from. The Engineer is going to put a prototype together by either changing the lever by making it recessed or by

		moving it to the outside of the arm of the recliner so we can trial it. I will keep you posted on how that goes. We have these recliners in other parts of hospital but have not had any issues. It seems to be with the elderly patients with sensitive skin. I created a knowledge sharing document stating if there is a patient with sensitive skin, to place a pillow over the lever until we get things figured out. ========== Manufacturer response for Sleep Recliner, Wieland Cove (per site reporter) ========== We are working with the Engineer to come up with a solution.
Cochlear Implant **Brand: Hires 90k** **Model#: HiRes 90K**	Advanced Bionics LLC	Patient with bilateral cochlear implants was scheduled for a cardiac MRI. The implants were researched through our normal process beginning with MRISafety.com (the gold standard for implant safety). That website led us to the manufacturer's website which stated that the implants identified by the patient were safe to be in a 1.5T scanner. He was in the room less than 2 minutes and about four feet from the scanner when he indicated that he did not feel right. He was immediately removed from the room. It has been confirmed by an outside ENT provider that the patients cochlear implant magnet had shifted requiring a minor procedure. Unknown how long the cochlear implants had been in place prior to the MRI. The patient had not removed the components of the device prior to entering the MRI room--the cochlear implants were fully intact.
Device 1: High Speed Curved Diamond Bur **Brand: High Speed Curved Diamond Bur** **Lot #: 0210093035 Cat #: 1885078HSE Other #: 13mm x 5mm x 70 degrees** **Device 2: High Speed**	Medtronic Xomed Inc. Medtronic Xomed Inc.	During endoscopic sinus surgery, the sinus drill was inserted into the patient´s right sinus and visible on the screen. Upon activating the foot pedal, the tip of drill #1 broke off in the patient´s sinus. The surgeon retrieved the broken piece and reported seeing no missing pieces left in the sinus. Inspection of the drill bit indicated coiled sheath that spirals around the inner piece seemed to have twisted off. An x-ray was performed to ensure there were no parts left in the patient´s sinus. Opened a second drill bit (#2). This piece showed the drill was about to break apart as well and it was removed from the field in one piece. Opened a third drill bit (#3). This drill would not fit into the drill handpiece. In addition, the hydrodebrider handpiece was manufactured wrong; it was missing a piece to be able fit into the machine/equipment. Additional supplies were used when the burr became loose (drill #4 and drill #5).

Tapered Diamond Bur **Brand: High Speed Tapered Diamond Bur** **Lot #: 0209998504 Cat #: 1883672HS Other #: 4mm x 70 degrees** **Device 3: High Speed Tapered Diamond Bur** **Brand: High Speed Tapered Diamond Bur** **Lot #: 0210267381 Cat #: 188367HS Other #: 4mm x 70 degrees** **Device 4: High Speed Tapered Diamond Choanal Atresia Bur** **Brand: Xps High Speed Tapered Diamond Choanal Atresia Bur** **Lot #: 0210169481 Cat #: 1883673HS Other #: 4mm x 15 degrees** **Device 5: Lavage Jet** **Brand:**	Medtronic Xomed Inc. Medtronic Xomed Inc.	

Hydrodebrider **Lot #: 0209989521** **Cat #: 1914001** **Device 6: High Speed Curved Diamond Bur** **Brand: High Speed Curved Diamond Bur** **Lot #: 0208772777** **Cat #: 1885078HSE** **Other #: 13cm x 5mm x 70 degrees**		
Hotpack Instant **Brand: Accu-therm Hot Pack** **Lot #: CN15282** **Cat #: MDS138005**	Medline Industries Inc	Hotpack was covered with a t-shirt and placed on patient. Patient sustained second degree burns with blisters. The instructions for use on the label of this device are unclear. The instructions indicate to cover the device with a cloth. Instructions also indicate not to place the device on an infant, but do not provide an age range or a lower age limit for device use. When activated and shaken, the device does not distribute heat evenly. There are areas of increased heat in the device, especially in the corners. A new pack was activated and a section of it reached 178 degrees. This facility is concerned for the potential this device has to burn a child. All of this product was removed from use and will be returned to the manufacturer. The facility is replacing this device with a different product.

Infant Manual Resuscitation **Brand: Manual Resuscitator Bvm, Curaplex, O2 Bag Reservoir, Oxygen Tubing, Infant** **Cat #: 301-C4000** 	Tri-anim Health Services Inc	RN bagging patient with the infant resuscitation bag. RT called to bedside to assist with bagging due to inability to maintain PEEP. RT was unable to set pressure relief valve to "closed" position on the resuscitation bag. RT changed bag and same occurrence. RT changed bag the third time and was able to close the pressure relief valve and maintain PEEP. Patient had no sequelae.
Device 1: Infusion System Large Volume Pump, Alaris **Brand: Alaris** **Model#: 8100** **Device 2: Infusion System PC, Alaris** **Brand: Alaris** **Model#: 8015** **Device 3: Infusion System Syringe Pump, Alaris** **Brand: Alaris** **Model#: 8110**	Carefusion Carefusion Carefusion	The CareFusion Alaris system large volume pump and syringe pump started alarming Communication Error 1-2 hours after the infusions had started. The error message interrupted the carrier IVF with epi and norepi running at a rate of 0.31 mcg/kg/hr. The syringe pump with a heparin infusion running was also interrupted when this Communication Error occurred. The infusions were restarted as quickly as possible to try to maintain patient stability, but within a few minutes the pumps started alarming again with the same message. The infusions were moved to a different pump at this time and resumed. The infusions were restarted quickly enough both times and avoided any major harm to the patient, but there were changes in the blood pressure while we were having problems with the pumps. This facility has had multiple problems with these devices & has been in communication with the manufacturer. The problems persist.

Device 1: **IV Administration Set** **Brand: Maxguard Extension Set** **Model#: MX9175** **Lot #: 15105719** **Cat #: MX9175** **Device 2:** **IV Administration Set** **Brand: Maxguard Extension Set** **Model#: MX9175** **Lot #: 5096134** **Cat #: MX9175**	Carefusion Carefusion	One of the needleless connectors in this set does not work. The internal blue portion that compresses when accessed with a syringe is turned incorrectly, which prohibits flow into the set. This has happened multiple times. When discovered, the line must be changed. These sets have failed in a number of locations in our organization. All remaining stock of this were returned to CareFusion along with sample sets for testing. No patients were harmed, but there were many failures of this product. ========== Manufacturer response for Extension set with Needleless y-site, MaxGuard Extension Set (per site reporter) ========== Looking at product for analysis
Needle, Hypodermic, Single **Brand: 3ml Bd Luer-lok With Bd Precisionglide** **Cat #: 309588**	BD Medical	When drawing a dose, a radiopharmacy technician noticed that there was a crack in the 3mL syringe they were using. This specific syringe was properly stored to allow for radioactive decay. Upon further inspection five more syringes were identified to have manufacturer defects. These defects range from holes to cracks to rough spots on the plastic. Those five syringes were sequestered and will be returned to the manufacturer. The lot numbers were not identified, however four of the five in our possession have the same number, C233, molded into the plastic on the syringe. The fifth has a number of 129 on the syringe. A sales representative from BD was contacted. He offered to come pick up the syringes I have and ensure they are returned to the manufacturer for failure analysis.

Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene **Brand: Vascu-guard Peripheral Vascular Patch** **Model#: 10504028** **Lot #: SP1SC12-1037620**	Baxter Healthcare Corp.	During a carotid endarterectomy, the new version of the vascu-Guard Peripheral Vascular Patch was placed on the field and soaked in normal saline for approximately forty five minutes. The patch appeared to be "rough" on each side. The less of the rough sides of the patch was placed on the inside of the vessel, toward blood flow. Upon completion duplex, a large thrombus appeared on the patch wall, which resulted in clamping and reopening the carotid artery to remove the thrombus which was adhered to patch. Vascu-Guard rep left the building prior to use of patch. Addendum: This issue was reported to substitute product has been ordered in until resolution of the issue occurs. The Vascu-guard patches had a packaging change. The product was unchanged although we had been noticing that with new packaging that there is stippling on the graft from the foam which appears as though both sides are rough.
Pulmonary Balloon Dilatation Catheter **Brand: Cre Pulmonary** **Model#: M00550340** **Lot #: 17954290**	Boston Scientific	The balloon failed to fully deflate preventing the surgeon from withdrawing the catheter from the bronchoscope. The scope was withdrawn and balloon had to be cut from catheter.
Recorder, Event, Implantable Cardiac, (Without Arrhythmia Detection) **Model#: DM2100**	St. Jude Medical	Per Cardiologist report: "I placed a St. Jude loop recorder in her as a workup two years ago... On the date of this event, I interrogated the loop recorder. The loop recorder has continued to show artifact and does not always work correctly. It will auto record artifact and then it cannot be used for the patient. We have had the technician come out to reprogram it, and I have previously called the software engineers for the company, but it is not fixable... I interrogated the loop recorder today. It is not working." ========== Manufacturer response for Implanted loop recorder, Implantable Cardiac Monitor (per site reporter) ========== Will return for evaluation

Short Term Iv Catheter **Brand: BD Insyte Autoguard** **Lot #: 5254617** **Cat #: 381412** **Other #: 8015547** **H4847-1 B(11-11)**	BECTON DICKINSON & CO.	IV catheter needle did not retract while placing peripheral IV. Catheter placed without difficulty and flushed without difficulty and flushed easily with no evidence of malfunction. Unit pulled all with same lot number from stock. The actual catheter from this event was discarded. Other catheters from the same lot are available for testing.
Staple, Implantable **Brand: Roticulator** **Lot #: P4C0300X** **Cat #: 017617**	Covidien	Roticulator stapler misfired causing surgeon to have to oversew bronchus. Surgeon was using this stapler on the bronchus and according to surgeon, the stapler was closed and compressed the structure, but when the handle was pulled the stapler did not fire and he tried it twice. When he took the stapler out, the staples were at full height and not fired and were loose in the chest cavity. Then the surgeon removed the staples and hand closed the bronchus with simple interrupted 4-0 PDS sutures.
Stapler, Surgical **Brand: Echelon Flex** **Lot #: M93119** **Cat #: PLEE60A**	Ethicon Endo-Surgery, Inc.	While firng stapler reload #9, the PLEEA 60 stapler malfunctioned. The staples were fired but knife did not seem to cut. A new stapler was obtained and used for subsequent firings without incident. Additional tissue had to be excised to rectify the damage cause by initial device. The defective device was removed from the field and sequestered at the OR main desk for evaluation by Risk Management.

Stapler, Surgical **Brand: Echelon Flex Powered Plus** **Lot #: M92X11 Cat #: PLEE60A**	Ethicon Endo-Surgery, LLC	During the procedure, there was three firings of the green colored 60mm staple cartridge with seam guards. On the 4th firing, a clicking noise was heard. When the firing was complete, the stapler was removed and it was noted that out of the four rows of staples, only the left 2 rows had fired and the right 2 rows were still in the cartridge. Thankfully the left side of stomach was stapled and sealed correctly. The specimen side was not. The procedure was able to continue and finish as planned with no negative outcome. If this had been reversed, this would have caused harm to the patient. ========== Manufacturer response for Endoscopic Linear Cutter 60mm Powered Plus stapler, Echelon Flex Powered Plus stapler (per site reporter) ========== The hospital representative for this equipment was notified and I have received email from him. I will be letting him know when this device is ready for him to pick up in my office.
Transducer, Blood-pressure, Extravascular **Brand: Transpac IV Monitoring Kit With Safeset Reservoir** **Lot #: 3093599 Cat #: 42648-06**	ICU Medical Inc	Nurse was priming a new art line tubing. After hooking it up to the patient, she noticed the waveform was dampened so tried to pull back the plunger/reservoir. She could not get any blood return so repositioned the patient's wrist and pulled back the plunger again. Then noticed a lot of air in the reservoir but not in the tubing. The plunger/reservoir was broken so only the plastic part of the plunger pulled back, but the suction device stayed in place and was not pulling back the blood. No blood ever made it to the reservoir. The patient was not harmed.
Tube, Tracheal (W/wo Connector) **Brand: Parker Flex-tip** **Lot #: 1501NC0101L Cat #: H-PFNC-75**	Parker Medical	This patient required tracheal intubation for maxillary surgery. A 7.5 Parker nasal endotracheal tube (ETT) was prepared; the balloon cuff was intact when checked pre-intubation. The ETT was placed via the right nostril in 12 seconds under direct laryngoscopy. Magill forceps were not used. A large gas leak was evident immediately. The ETT was removed and a 2 centimeter tear in the balloon cuff was obvious. A second Parker nasal ETT was placed easily, again under direct laryngoscopy without Magill forceps. The balloon cuff appeared intact. However, thirty minutes later, slow gas leak was detected. The case proceeded and when the ETT was removed, again, there was a 1 centimeter tear in the pilot balloon. Both endotracheal tubes were from Lot 1501NC0101L, reference number H-PFNC-75. Manufacturer response for Parker Endo-tracheal tube, Parker nasal ETT (per site reporter)

		========== The manufacturer rep has been contacted.
Electrosurgical, Cutting, Coagulation **Brand: Thunderbeat** **Lot #: MK946951** **Cat #: TB-0535FC**	Olympus Corporation	The Thunderbeat was being used in a laparoscopic case and it made a noise, which indicated it was not cutting/cauterizing properly. Connections were checked & it started functioning. Afterwards, the scrub noticed one of the jaws was missing on the Thunderbeat while it was still in the patient. It was withdrawn and the staff searched in the abdomen until they found the missing piece.

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/PostmarketRequirements/HumanFactors/ucm119185.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/cdrh/medicaldevicesafety/
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 Ill 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.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm
This database contains the most recent manufacturer warning letters.

Archived FDA Patient Safety News Stories Available Online

From 2002-2011 “FDA Patient Safety News” (PSN), was a monthly video news show for health professionals. PSN presented information on new product approvals, recalls, and safety alerts, and offered tips on protecting patients. To find out more about the show, read the archived stories, and watch or download the videos please visit: http://www.accessdata.fda.gov/psn/

Contact the MedSun Program Staff:

Telephone: 800-859-9821

Fax: 800-859-1292

E-mail: medsun@fda.hhs.gov

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993