MedSun
Medical Product Safety Network

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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.

IMPORTANT
Reminder of System Security

The ONLY persons eligible to report online to MedSun are those who have been provided with their own IDs and passwords by MedSun staff after completing the MedSun orientation program. Please DO NOT let others report online with your ID and password or otherwise allow untrained individuals to access the MedSun secure reporting Web site. If you would like additional staff to report online, please call 800-859-9821 to arrange orientation for them. Thank you for your assistance in this matter.

About the MedSun Program

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Newly Approved Devices

Recently Approved Devices (searchable listing): https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices

Premarket Approval Final Decisions: https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals#monthly

510(k) Final Decisions: https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

In Brief

As of June 29, 2020

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

Chengdu Ai Qin E-Commerce Co., Ltd Issues Nationwide Recall of TTDEYE Brand Colored Contact Lenses

June 24, 2020

Chengdu Ai Qin E-commerce Co., Ltd initiated a nationwide recall of 1362 pairs of colored contact lenses. The relevant series of contact lenses have been found to be distributed without FDA clearance and may pose a threat to health. The recalled products were manufactured August 2018 and may be identified by name of the product and the date of manufacture, "2018-08", found on the package label. The company has received no complaints to date.

Allergan Aesthetics Launches Dedicated Multi-Channel Campaign to Contact Patients Who May Not Be Aware of The Biocell® Recall

June 1, 2020

Allergan Aesthetics, an AbbVie company (NYSE: ABBV), is initiating a new digital campaign to improve device tracking and further identify and reach breast implant patients who have, or have had, BIOCELL® breast implants and/or tissue expanders to inform them of the risk of BIA-ALCL. Since July 2019 when the BIOCELL® recall was announced, robust efforts were made to reach patients, however, the Company is still seeking to directly contact all U.S. BIOCELL® patients that have not yet been notified. This is due to incomplete device tracking data for approximately 52,000 BIOCELL® breast implant units. It is important to note that FDA has made the following recommendation, "If you have no symptoms, we are not recommending the removal of these or other types of breast implants due to the low risk of developing BIA-ALCL. However, if you have any questions, talk to your health care provider."

Medtronic Recalls StealthStation Auto-Registration Feature Due to Inaccuracies During Deep Brain Stimulation (DBS) Procedures

June 1, 2020

Medtronic has recalled the auto-registration feature of the StealthStation DBS Software due to inaccuracies caused by minor patient movements during the auto-registration process when used with NexFrame during a DBS procedure, which may not be detected by the surgeon or the device system. This may provide inaccurate registration data which could lead surgeons to inaccurately navigate lead placement during image guided DBS procedures. This could result in serious or life-threatening patient harm. As of June 2020, a total of 33 medical device reports were identified: 22 related to device malfunction and 11 related to injuries.

Certain COVID-19 Serology/Antibody Tests Should Not Be Used - Letter to Clinical Laboratory Staff and Health Care Providers
June 19, 2020

The U.S. Food and Drug Administration (FDA) recommends that clinical laboratories and health care providers stop using COVID-19 antibody tests that are listed on FDA's "removed" test list, found on the FDA's FAQs on Testing for SARS-CoV-2 webpage. The "removed" test list includes tests where significant clinical performance problems were identified that cannot be or have not been addressed by the commercial manufacturer in a timely manner, tests for which an Emergency Use Authorization request has not been submitted by a commercial manufacturer of a serology test within a reasonable period of time as outlined in FDA's guidance, and tests voluntarily withdrawn by the respective commercial manufacturers.

Although tests on the "removed" test list should no longer be distributed, laboratories and health care providers may still have these tests within their stock, or may have used these tests in the past. The FDA is therefore providing additional information and recommendations to laboratories and health care providers regarding these tests.

Recommendations:

The FDA recommends laboratories and health care providers:

- Stop using the antibody tests listed on FDA's "removed" test list.
- Evaluate, given the patient's clinical presentation and medical history, whether prior test results generated using these tests may have been incorrect, and whether the patient should be retested using an FDA-authorized test.
- Remove from your stock any remaining tests that are listed on FDA's "removed" test list.
- Report any issues with using COVID-19 tests to the FDA.

The complete Letter to Clinical Laboratory Staff and Health Care Providers can be found on FDA's website.

Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection - Letter to Health Care Providers
June 1, 2020

The U.S. Food and Drug Administration (FDA) is concerned that certain filtering facepiece respirators (respirators) from China may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19 based on additional filtration performance testing conducted by the National Institute for Occupational Safety and Health (NIOSH) - National Personal Protective Technology Laboratory (NPPTL) of the Centers for Disease Control and Prevention (CDC) (referred to below as the NIOSH testing). Based on the FDA's increased understanding of the performance and design of these respirators, the FDA has decided that these respirators should not be decontaminated for reuse by health care personnel. As such, the FDA has revised and reissued the May 7, 2020, EUA.

On May 7, 2020, the FDA reissued the April 3, 2020 EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China to revise the third eligibility criterion – the criterion for authorization of respirators based on review of test reports from recognized independent test laboratories submitted to the FDA by the manufacturer or importer – and accordingly removed from Appendix A the respirators that had been authorized under that criterion but were no longer authorized based on this revision. The FDA took this public health action primarily because a number of these respirators failed to demonstrate a minimum particulate filtration efficiency of 95 percent in testing conducted at NIOSH.

On June 6, 2020, the FDA further revised this criterion such that respirators that are authorized under this criterion and that do not meet performance expectations are no longer authorized. Respirators that have a failing grade as indicated by NIOSH testing may be re-labeled as face masks and authorized as face masks for use as source control if certain criteria are met under the Face Mask umbrella EUA. For other information, please see the FDA's enforcement policy on face masks, as described in the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) Guidance.

Non-NIOSH-approved disposable filtering facepiece respirators that meet the other eligibility criteria in the reissued Emergency Use Authorization remain authorized by the FDA for use during the COVID-19 pandemic and continue to be listed in Appendix A.

Considerations:

Health care facilities with these respirators in inventory should review the considerations listed below. The information is specific to respirators that are designed to achieve a

very close facial fit and to filter airborne particles. These considerations are not applicable to surgical masks or face masks that are loose-fitting and create a physical barrier between the health care personnel's mouth and nose and potential contaminants in the immediate environment.

- Respirators that no longer appear in Appendix A of the EUA may not reliably provide a minimum percent particulate filtration efficiency of 95 percent. Refer to the NIOSH assessment webpage to determine whether non-NIOSH-approved disposable filtering facepiece respirators manufactured in China have been tested and to review the testing results.

- A complete list of Respirator Models No Longer Authorized is available on our website.

- NIOSH regularly updates its list of testing results.
    - Respirators that have been tested by NIOSH and failed to demonstrate a Minimum Particulate Filtration Efficiency of 95 percent may be considered for use as face masks for source control if they do not have exhalation valves, to help slow the spread of infection when a person speaks, coughs, or sneezes. Health care facilities should be aware that this use of face masks is different from personal protective equipment for health care personnel.

    - Health care facilities with these respirators that failed the NIOSH testing may wish to consider a number of factors in deciding to use these products as face masks, including current need, inventory, facility practices, and acceptable uses.

- At this time and based on the available information, the FDA believes that any respirators listed in Appendix A may not be reliably decontaminated in any decontamination system authorized for use during the COVID-19 pandemic.

The complete Letter to Health Care Providers can be found on FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during May 2020. 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

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
Applicator, Absorbent Tipped, Sterile Brand: Iclean Nasopharyngeal Swab Model#: 20200505 Lot #: 20200505	HUACHENYANG(SHENZHEN)TECHNOLOGY CO., LTD	RN was obtaining COVID test swab from patient's nare and when she pulled the swab out, half of the swab was still in the patient's nare. MD notified and attempted to remove swab, which was not ultimately retrieved. X-Ray did not show the swab. Plan to observe patient on the assumption that the swab went into the stomach.
Automated External Defibrillators (Non-wearable) Brand: Onestep Model#: 8900-0224-01 Lot #: 4819A Cat #: 8900-0224-01	BIO-DETEK INCORPORATED	Approximately 6 months ago, the Zoll CPR pad failed to complete a defib check and an equipment malfunction message was displayed. Clinical engineering came up and also attempted on more than one Zoll machine and got the same results. Since that time, I have collected 2 additional CPR pads that gave the same malfunction message. Please note that there are 3 pads with different lot numbers that failed the testing process. Clinical Engineering tested all 3 and each of them displayed the green light and display read "defib pad short" as it is supposed to. When they tried to discharge each, it did not discharge- screen said "check Pads".

Device	Manufacturer	Problem
Blade, Saw, General &Plastic Surgery, Surgical Brand: Arthrex Dissector, Sj 3. 0mm X7cm Model#: AR-7300DS Lot #: 10491341 Cat #: AR-7300DS	Arthrex, Inc.	The inner cannula tip of the arthroscopic shaver broke off in the patients soft tissue. A second shaver was then opened and used, it also broke off at the tip in the patients wrist joint. The surgeon then used a mosquito clamp to retrieve both metal tips. Xray was utilized to verify the metal pieces were retrieved. No harm to patient.
Catheter, Retention Type, Balloon Brand: Bardex Lubri-sil I. C. All-silicone Foley Catheter Model#: 1758SI16 Lot #: NGDU3876 Cat #: 1758SI16 Other #: 303416A	C. R. Bard, Inc.	When placing catheter there are no issues with placement or function, however when it is time to remove the catheter there is resistance when trying to deflate the balloon. When and if any fluid does return it is not the sterile water it is supposed to be, it is urine. In order for the catheter to be removed it has to be cut and removed that way. Equipment is foley catheter, size 16fr silicone lot #NGDU3876 on this particular event.
Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Powerpicc Solo2 Catheter Model#: 1194108D Lot #: REDX1468 Cat #: 1194108D	Bard Access Systems, Inc.	Patient noticed PICC line leaking at home, reported to ED. Site care done, leaking persisted. PICC removed. Hole in catheter noted at 4cm.

Device	Manufacturer	Problem
Pump, Infusion Brand: Curlin Administration Set Model#: 340-4126 Lot #: CF1933416	Moog, Inc.	Blincyto 7-day infusion administered through an Adm Set-Curlin Epidural w/0.2 micron filter, tubing leaked from the filter part while patient was on day 3 once, and day 7 three times. We are investigating the leak with the manufacturer.
Restraint, Protective Brand: Posey Economy Limb Holder Other #: 2510	Posey Products, LLC	Patient with traumatic brain injury had bilateral soft wrist restraints applied to prevent pulling at life sustaining tubes/lines. Nurse reported that the patient was agitated and ripped through the "economy limb holder." The ring that holds the strap ripped off of the restraint allowing the patient to pull out an IV. The nurse was near to the patient at the time and was able to reach the patient before the patient could self-extubate. The IV was reinserted with no harm to the patient. The wrist restraint was bagged up and sent to the Quality Department.
Restraint, Protective Brand: Posey Economy Limb Holder Other #: 2510	Posey Products, LLC	Patient displaying increased agitation. Multiple security officers were in the room, along with police officer and multiple nursing staff. The patient was verbally abusive towards the staff. Patient started to pull and rock on the bedside rails and he was able to break through the soft wrist restraints (bilateral soft wrist restraints started for prevention of pulling out life sustaining IVs and tubing. Patient was placed in metal handcuffs. Broken restraint was sent to the Quality Department.
Set, Administration, Intravascular Brand: Split Septum Micro T-connector Model#: NMT8046 Lot #: 19039	HUMMINGBIRD MED DEVICES INC	Blood was backing out of the red lumen on PICC line, noticed blood dripping outside of the hummi tubing. Patient has a Double Lumen right upper leg PICC, the red lumen has a hummi attached for lab draws. The line was flushed and fluid leaked out of the hummi tubing. The hummi was changed out using sterile procedure and flushed to clear out the line. Hummi was saved in a biohazard bag and marked with the location of the leak.

Device	Manufacturer	Problem
Set, Administration, Intravascular Brand: Split Septum Micro T-connector Model#: NMT8046 Lot #: 19039	HUMMINGBIRD MED DEVICES INC	While assessing the patient and performing cares, RN noticed a small leak/crack of the hummi tubing attached to the Red Port of the PICC line. The fluid was leaking where the tubing connects to the hard plastic on the hummi side of the tubing. Red port of the PICC line was clamped, new fluids were ordered from pharmacy, new tubing and fluid were hung with a new hummi attached. NNP was notified of the leaking hummi. The hummi tubing was saved and passed onto the educators.
Table, Operating-room, Electrical Brand: 3602 Ultraslide Model#: 3602 UltraSlide	Skytron LLC	After case was completed, bed was turned back to original position to get ready for extubation, with head at anesthesia, bed locked. Suddenly bed began to rise on its own. Attempted to lower bed with control but when the lower bed button pushed bed stopped rising, once button let go, bed continued to rise again. All this time patient on the OR bed. Bed unplugged and manual switches utilized but bed continued to rise. Dr. had to manually hold down the bed lower button on the manual buttons on the base of the bed so that we could safely transfer patient onto patient bed. Patient safely transferred to patient bed. OR table unlocked via emergency button and moved out of the way. Biomed notified. We have had numerous incidents in the last year involving the buttons getting stuck on the pendant hand control.
Tube, Tracheal (W/wo Connector) Brand: Halyard Model#: 35216	Avanos Medical, Inc.	RN informed Respiratory Tech that Pt had an audible cuff leak on Pt ET Tube. Respiratory Tech inspected Pt ET Tube and confirmed that a cuff leak was present. Respiratory Tech fixed Pt cuff leak. Respiratory Tech left room. RN returned to Respiratory Tech within 5-10 mins stating that the cuff was leaking again. Respiratory Tech used manometer to measure cuff pressure and the manometer read below the green zone. Respiratory Tech then re-inflated cuff with manometer and disconnected the manometer. Respiratory Tech then retested cuff pressure with manometer and the ET Tube cuff pressure had fallen significantly and was no longer holding a proper cuff pressure. Respiratory Tech informed MD who called anesthesia and assisted in ET Tube exchange on the Pt.

Device	Manufacturer	Problem
Tubes, Gastrointestinal (And Accessories) Brand: Bard Dignishield Stool Management System	C. R. Bard, Inc.	Patient was an elderly male with cirrhosis in the ICU for management of encephalopathy. A fecal management system (FMS) was placed for incontinence and lactulose enemas. Four days later, the patient reported significant pressure and urge to have a bowel movement. Previous shift reported that the FMS had no output, even after irrigation, but noted some bleeding around the anus. On removal of the FMS, roughly 130mL was extracted from the inflation tube (45mL standard practice) and the patient expelled 200mL of dark blood-clot like stool. Patient developed hematochezia and hemorrhagic shock requiring transfer to the medical intensive care unit (MICU). On the MICU, patient received massive transfusion protocol. Endoscopic evaluation revealed the source of bleeding as a rectal ulcer (likely pressure induced) and a hemostatic clip was placed. Patient subsequently required a repeat procedure, and vasopressors to stabilize. We have the following design concerns: •Although the lines are color coded – they are adjacent/level with each other that can result in the wrong line being identified for inflation •Inflation lines accept standard syringes that creates the potential for administrations to occur with the inflation line •There is no color indicator when the FMS has been overinflated •When deflating the device, some residual fluid is left in the device that may lead to over inflation when re-inflated
Medical Gloves With Chemotherapy Brand: Starmed Ultra Nitrile Exam Glove Model#: SMTN253 Lot #: 2019-09 L046666 1909 Cat #: SMTN253	Sepmermed USA, Inc	StarMed Ultra Nitrile glove was noted to be ripped from wrist to middle finger. Defective glove and associated box of gloves available for return to manufacturer.

Device	Manufacturer	Problem
Respirator, Surgical Brand: Particulate Respirator Model#: 8210	3M Company	1. DT ICU– allergic reaction requiring ED visit 2. RT last week – caused on asthma exasperation 3. MST RN – swelling of the face 4. ICU RN - caused on asthma exasperation (ED visit)
Respirator, Surgical Brand: Kimberly-clark® Fluidshield™ Pfr95™ Respirator And Surgical Mask Model#: 46767 Cat #: 46767 Other #: NIOSH TC-84A-0005 small	KIMBERLY-CLARK GLOBAL SALES, LLC	I was given a Duckbill mask that a staff member had tried to use the previous day. The straps to the mask disintegrated in her hand while trying to don the mask. On the next day, a different nurse tried to use 2 different duckbill masks and both masks straps disintegrated in her hand while donning the mask. These masks were new. There have not been other reported events. Staff did not use these masks. They were provided other N-95's to wear and no harm was noted.
Dialyzer, High Permeability With Or Without Sealed Dialysate System Brand: Phoenix Model#: Phoenix Other #: PH27233	Gambro Dasco SPA	With 25 minutes left in the patient's treatment he started getting Flow Meter Failure alarms 144,104,300 that were not able to be cleared. It was noted that the dialysis machine was dripping into the pan from underneath the front cover in the center aspect. Patient's run was discontinued. A work order was called in as well as biomed tech personally notified.

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 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.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
This database contains the most recent manufacturer warning letters.

To access additional 2020 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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