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 November, 2018

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

Maquet Datascope Corp./Getinge Group Recalls the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps (IABPs) Due to Possible Malfunction and Failure at High Altitudes
November 1, 2018
Maquet Datascope Corp. is recalling the Cardiosave Hybrid and Cardiosave Rescue IABPs due to the potential of the autofill process to malfunction or fail during use at altitudes above 3200 feet. This failure may result in either interruption or cessation of therapy upon the first maintenance autofill or the inability to start therapy.

Alcon Research, LTD. Recalls CyPass® Micro-Stent Systems Due to Risk of Endothelial Cell Loss
October 24, 2018
The firm announced that the voluntary market withdrawal was based on five-year post-surgery data from the COMPASS-XT long-term safety study. The study demonstrated a clinically and statistically significant increase in corneal endothelial cell loss reported in the CyPass® Micro-Stent group compared to the cataract surgery-only control group. Based on preliminary review of the data from the COMPASS-XT study, the FDA issued a Safety Communication, notifying physicians and patients of the risk of eye damage in people who the device implanted and recommendations for physicians to stop implanting the device.

Endologix, Inc. Recalls AFX Endovascular AAA Systems Due to Risk of Type III Endoleaks
October 15, 2018
Recall due to continued reports of Type IIIa and IIIb endoleaks. When a Type III endoleak occurs, blood continues to flow into the aneurysm, increasing the likelihood of a rupture. Left undetected and without treatment, a Type III endoleak may result in serious patient injury, such as an AAA rupture or death. It is important to note that although this recall applies to all AFX Endovascular AAA Systems, most reports of endoleaks have concerned the AFX with Strata graft material. Endologix has not manufactured the AFX with Strata graft material since July 2014 and health care providers were advised to remove any remaining inventory from shelves in December 2016. However, the AFX with Duraply graft material and AFX2 devices have been distributed for a shorter time and it is unclear if these devices have fewer endoleaks or if they have not been implanted long enough for endoleaks to occur.

CDRH Medical Device Servicing and Remanufacturing Activities Public Workshop – Registration Now Open

The FDA's Center for Devices and Radiological Health (CDRH) will host a public workshop on December 10-11, 2018, as part of the agency's continued commitment to promoting high-quality, safe, and effective medical device servicing and remanufacturing.

The goals of this workshop are to:

- Increase collaboration between the FDA and manufacturers, health care establishments, and independent service organizations;
- Inform the FDA's regulatory approach to medical device servicing and remanufacturing activities;
- Clarify the difference between servicing and remanufacturing activities.

In addition, due to expressed interest from members of the medical device servicing and remanufacturing industry, the public workshop is also intended to discuss opportunities for collaboration among medical device servicing and remanufacturing stakeholders.

Learn More about the Medical Device Servicing and Remanufacturing Activities Workshop and Register Today

Feedback is critical in shaping the agency's thinking on this topic. The agency intends to use information gathered at this workshop and through the public docket, FDA-2018-N-3741, to issue a draft guidance that helps determine whether activities are servicing or remanufacturing.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during October 2018 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
Automated External Defibrillators (Non-wearable) Brand: Heartstart Pad Connector Cable Model#: 453564675561 Lot #: 06-16 Cat #: M3508A	Phillips Medical Systems	The patient was a cardiac arrest. The code team arrived and initiated Advanced Cardiac Life Support (ACLS) protocol. The patient's rhythm changed from pulseless electrical activity (PEA) to Vfib at 2332. RN attempted to charge the defibrillator to 150J and shock, only 120J were delivered per rhythm strip that was printed. After shock delivered the defibrillator did not show a rhythm so the leads had to be placed on the patient. Then it was determined the patient was in sinus rhythm.

Device	Manufacturer	Problem
Angiography/ angioplasty Kit Brand: Angiography Drape SPPack Lot #: 18FBU288 Cat #: DYNJ44464C	Medline Industries, Inc.	Excessive linting was coming from the sterile towels from inside the sterile tray. Lint was discovered floating in the sterile saline in the bowl on the tray. Lint was found wrapped around a wire. A product defect form was filed. A product return form was completed. The wire with the lint wrapped around it was sent to Medline for evaluation. Photos of lint in the sterile bowl were sent to the rep via email.
Bed, Ac-powered Adjustable Hospital Brand: Intouch	Stryker Medical	We purchased 120 Stryker Intouch critical care beds. Since that time there have been 117 occurrences where the beds have malfunctioned. The issues that arose with the beds is that once moved to a certain position they would become stuck and unable to move out of that position. Per Stryker, the bed sensors were failing due to the areas of static electricity in the halls of the hospital. The static was "frying" the sensors on the bed making them unable to be repositioned. The warranty on the beds has been extended. Meeting with Stryker's Account Manager within the next month to discuss the plan.
Catheter, Intravascular, Therapeutic Brand: Cook Spectrum Turbo-jet Model#: G34548 Lot #: 8684031 Cat #: UPICDS-4.0-CT-NT-	Cook Incorporated	Recently the pt's PICC line broke. The break occurred before the wing that inserts into the clave (on the opposite end of the insertion site). Since mid-September 2018, Intervention Radiology (IR) has reported six of these lines breaking, all in the same spot. All products have had a lot number starting with 8, but have been from different lots. Three out of the six lines have been saved and returned to Cook for an investigation. The rep swapped out all stock, so we only have product with lot numbers starting with 9 now. To this point, there have been no events with the new stock. These events all required patients to have the line removed and a new line placed. This puts them at an increased risk of infection. Furthermore, three out of the six lines were on the same patient. Per hospital, the rep has been very responsive. The previous two lines were picked up by the rep and he will pick up the third line next week. The rep switched out our entire stock in less than 24 hours.
Catheter, Retention Type, Balloon Brand: Surestep Foley Tray System Bard Lubrisil Foley Catheter Tray Model#: A942214 Lot #: 1320723222110720104532A Cat #: A942214	C. R. Bard, Inc.	Foley catheter was placed prior to operating room for planned cesarean section (c/s). After c/s complete, the doctors performed fundal massage and Foley cathether fell out. The Foley balloon was only inflated on one side. The fluid was removed, and it proved there was 10cc in balloon. It was re-inflated multiple times (outside of patient) and only inflated on one side. Required a replacement of new Foley catheter in patient. REF # on package A942214.

Device	Manufacturer	Problem
Device, Monitoring, Intracranial Brand: Codman Microsensor Model#: 626631US Lot #: 171041 Cat #: 626631US	Codman and Shurtleff, Inc.	Pt to OR for left frontoparietal temporal craniotomy and evacuation of subdural hematoma. Per RN report: "Surgeon planned to also place a Codman Directlink ICP microsensor and ensured RN had products/equipment/knowledge needed for safe implantation and accurate monitoring. RN completed zeroing process for DirectLink box to transport monitor(with both 0 mmHg and 100 mmHg test settings) while surgeon proceeded with case. Prior to implantation, surgeon passed off end of microsensor to RN for zeroing of sensor. RN read steps aloud and followed steps; microsensor would not zero. RN had contacted rep for company and put rep on speaker phone. Rep instructed to re-zero everything. Everything re-zeroed while reading steps out loud. Sensor would still not zero. Rep instructed to open new microsensor and repeat process. New microsensor opened and process completed (while reading steps out loud with rep on speaker phone.) Second sensor still would not zero. Rep contacted his company counter-part while RN repeated all steps with new Directlink box and cables. Sensor would still not zero. Rep stated his counter-part agreed we were doing all steps correctly and was not sure why the microsensors would not zero. Surgeon had to abandon plan of implanting this microsensor and had to make additional incision and hole in skull for implantation of an external ventricular drain connected to Integra ICP bag. This was more invasive and bulkier than the intended option." Per the surgeon: Attempts were then made to use the Codman fiberoptic intracranial pressure monitoring kit and M8, but it could not be zeroed and it was never placed into his brain. Accordingly, I elected to place a ventriculostomy after we closed. Note: Two codman devices, same device and same lot number, had the same issue.
Device, Vascular, For Promoting Embolization Brand: Concertotm Model#: NV-2-8-HELIX Lot #: A611699 Cat #: NV-2-8-HELIX	Micro Therapeutics, Inc.	The Concerto coil would not feed through micro catheter. Another package was opened and used and this one worked without any difficulty.
Electrosurgical, Cutting Coagulation Accessories Brand: Strykeflow Model#: 0250070530 Lot #: 18102FG2 Cat #: 250-070-530	Stryker Corporation	While doing a laparoscopic sleeve gastrectomy, the surgeon was using the Stryker StrykeFlow suction irrigation tubing. During the case, saline began to leak from the hand piece causing fluid to flow onto the patient and the surgeon. The device was switched out and the procedure was completed as planned. No harm came to the patient. Several similar occurrences have been reported from the OR surgical staff, however, no samples have been saved post-operatively. If a future sample is saved, it will be returned to the manufacturer.

Device	Manufacturer	Problem
Device 1: Gauze/sponge, Internal, X-ray Detectable Brand: G0x0x-0xp0xc(N)-1 Gauze –Rf And X-ray Detectable Model#: G0404-16P01C-1 Lot #: 141208A Cat #: G0404-16P01C-1 Other #: GAUZE, XRAY, RFD, 4"X4", 32PLY, STRL, LF, 10/TR	Covidien, LLC	Pieces of shredded Raytec noted in surgical field during procedure. Three separate packages with different lot numbers on surgical field at that time Lot numbers were 141208A, 170601KF, 170702KF.
Device 2: Gauze/ sponge, Internal, X-ray Detectable Brand: G0x0x-0xp0xc(N)-1 Gauze –Rf And X-ray Detectable Model#: G0404-16P01C-1 Lot #: 170601KF Cat #: G0404-16P01C-1 Other #: GAUZE, XRAY, RFD, 4"X4", 32PLY, STRL, LF, 10/TR	Covidien, LLC	
Device 3: Gauze/ sponge, Internal, X-ray Detectable Brand: G0x0x-0xp0xc(N)-1 Gauze –Rf And X-ray Detectable Model#: G0404-16P01C-1 Lot #: 170702KF Cat #: G0404-16P01C-1 Other #: GAUZE, XRAY, RFD, 4"X4", 32PLY, STRL, LF, 10/TR	Covidien, LLC	

Device	Manufacturer	Problem
Light Source, Fiberoptic, Routine Brand: Luxtec Ultralite Pro Headlight Model#: AX2100BIF	Integra Micro-france	During the closure of the pt's left tibial bone graft site, small amounts of " black specks" were seen in the wound. Thought it may have been dried blood, so copius irrigation of Normal Saline were used (1500pm) Approximately 1/2hr later (1530pm), Surgeon had removed his Luxtec Headlight and noticed 1" x 4" residue of "disintegrating black foam" on his forehead. Therefore, the "black specks" may have indeed dropped into the wound. The faulty head-light crown was then bagged & labelled with a note. The headlight was sequestered and taken to Clinical Technology for evaluation. Around the head band, there are cushion pads held on by velcro. Each pad has a layer of fabric on both sides and foam rubber in the middle. On the headlight in question, the fabric layer was torn off on one side and the foam rubber was crumbling and deteriorated. All headlights in inventory were checked and it was determined all pads should all be replaced. Replacements were or-dered and a preventative maintenance cycle developed so that the pads will be proactively replaced before they reach the point of de-terioration.
Mask, Surgical Brand: Level ISurgical Mask Anti-fog Foam Ties Model#: AT71235, AT752005 Lot #: 1071235, 1752005 Cat #: AT71235, AT752005	Cardinal Health 200, LLC	Surgical mask has a metal piece on both internal sides of the mask that caused facial lacerations of some staff during normal wear for invasive procedures. We are pulling the product from our inventory. A design change to mitigate the risk of injury to clinical staff has been requested. Per hospital, informed product was being removed from clinical departments and inventory.
Monitor, Physi-ological, Pa-tient(With Ar-rhythmia De-tection Or Alarms) Brand: Intellivue Multi Measure-ment Server (Mms) Model#: M3001A Cat #: M3001A	Philips Medical Systems	Philips non invasive blood pressure (NIBP) monitor technology fre-quently results in no readings for shivering patients. We recently moved to Philips in the Labor and Delivery (L&D) ORs and PACUs. This problem has been going on since the Philips monitors were installed. L&D patients often shiver and the technology in the Philips equipment frequently results in "??" which does not provide a read-ing to the clinician. We are noticing dramatically more events of in-correct or no NIBP readings.

Device	Manufacturer	Problem
Restraint, Protective Brand: 8070 Enclosure Net Bed Model#: 8070	Posey Products LLC (a TIDI products Company)	Patient in enclosure bed. Able to work fingers on the inside zipper and get the bed open.
Set, Administration, Intravascular Brand: Bd 20 Gauge Iv Catheter Lot #: 8169681 Cat #: 382633	Becton Dickinson & Co.	A few months ago we switched to new IV catheters. Two reports have since been submitted with concerns about the new product. In early September, the report stated that the shift coordinator has been receiving complaints about the new IV catheters from patients. Patients are reporting that they are hurting them. Recently, the shift coordinator spoke with a patient whose IV has been in for 2-3 minutes and they reported that the site hurt for days after it was removed. The shift coordinator reported that the new catheters do not thread very easily, so they are quick to cause the vein to blow. More recently, a report was received from a nurse that she had a patient whose veins were easily visualized but when trying to insert the IV, it seemed to stick. The patient required three sticks to successfully obtain an IV site.
System, Detection, Bacterial, For Platelet Transfusion Products Brand: Verax Platelet Pgd Test Lot #: Reagent1 -L10026, L10028, L1003	Verax Biomedical Incorporated	VERAX Platelet Pan Genara Detection (PGD) testing is performed on non-pathogen reduced platelets for the detection of bacteria. The test is manufactured by VERAX Biomedical and is FDA approved for the rapid -detection of bacterial contamination of platelet products. Platelet products that have not been pathogen reduced and are still in inventory on days 4 and 5 after collection are tested for bacterial contamination using the VERAX PGD test kit. Last week, two Stem Cell transplant patients received bacterially contaminated platelet. The platelet products were tested for bacterial contamination (VERAX PGD) on day 4 and the results were negative. Patient was transfused at the same location. The testing was performed and Cultures reports positive for Acinetobacter baumannii.
Transducer, Pressure, Catheter Tip Brand: Truwave Disposable Pressure Transducers Model#: RX 6001 Lot #: 60975581 Cat #: INS 1100 Other #: RX 6001	Edwards Lifesciences, LLC	EVD system had broke while patient was at Interventional Radiology. The transducer was broken. It is thought that the transducer is breaking at the connection to the catheter that connects to the patient. Break may be caused by a combination of the user twisting the connection too tight and/or the weight of the cords hanging from one side of the transducer may be causing a weakness at the connection site.

Device	Manufacturer	Problem
Ventilator, Continuous, Facility Use Model#: Evita XL	Draeger, Inc.	Patient was intubated under general anesthesia in OR and Draeger Evita ventilator was used. The ventilator stopped breathing for patient. The device failure code displayed was 13.03.001. The ventilator was replaced and the failed ventilator was brought to clinical engineering for troubleshooting. The patient seemed to suffer no ill effects from the ventilator failure.
Warmer, Infant Radiant Brand: Giraffe Warmer Other #: 116782 	Ohmeda Medical	RN responded to monitor alarming in pt room. RN found patient lying on floor out of giraffe bed, crying, with bottom side rail down. Bed was found in the reverse trendelenburg position which is appropriate for pt. RN hit emergency button and yelled for help. Second RN to bedside- picked pt up from first RN arms and placed pt back in bed. Pt was moving all four extremities appropriately and crying spontaneously. PICU team called APN and MD to bedside to assess pt. Pt placed back on cardiac monitor and Sipap machine after assessment. Neuro check done per MD to assess pt status. Pt with appropriate neuro assessment. Q2 hour neuro checks ordered per PICU team. Giraffe bed removed from room and new junior crib placed in room.
Absorbable Lung Biopsy Plug Brand: Biosentry™ Tract Sealant System Model#: 768022019S Lot #: AABX484 Cat #: 768022019S	Surgical Specialties México, S. de R.L. de C.V.	After a CT guided lung biopsy, a Biosentry Tract Sealant System was being used prevent/reduce risk of pneumothorax. While operating the device, it malfunctioned and subsequently failed to deploy the hydrogel plug. The trocar was removed and hemostasis achieved with manual compression. Post procedure images reflect the absence of a pneumothorax. There was no harm to the patient. Item has been retained by radiology and is pending notification/ handoff to Surgical Specialties field rep.
Device 1: Catheter, Intravascular, Diagnostic Brand: Cook- Model#: G02089 Lot #: 8904123 Cat #: C-PMS-401J-FA **Device 2: Catheter, Intravascular, Diagnostic** Brand: CookModel#: G02054 Lot #: 8229354 Cat #: C-PMS-301-RA	Cook Incorporated Cook Incorporated	Look alike packaging. While restocking the RN noticed that the packaging for the two catheter sets were identical with the exception of the name. The concern is that since the packaging looks the same the wrong catheter could be pulled and possibly used in an emergent situation.

Device	Manufacturer	Problem
Snare, Flexible Brand: Roth Net Model#: 00711057 Lot #: 1606764 Cat #: 00711057	US Endoscopy	During esophagogastroduodenoscopy (EGD) for foreign body removal, the physician was attempting to remove the foreign body specimen when the netting broke away from the looping. Event was rectified, however on second attempt the same occurred again.
Container, Sharps Brand: Newgen Surgical Needle Counter Cat #: NGSMN40FMA Other #: NewGen Surgical Needle Counter - Foam Block / Magnet / Adhesive Tabs	NewGen Surgical	Scalpel went through sharps container and into left index finger. Sharps container by newgen is not a hard type container and allowed scalpel to penetrate container.
Device 1: Gauze/sponge, Internal, X-ray Detectable Brand: G0x0x-0xp0xc(N)-1 Gauze –Rf And X-ray Detectable Model#: G0404-16P01C-1 Lot #: 171121A Cat #: G0404-16P01C-1 Other #: Medtroinc RFID gauze; GAUZE, XRAY, RFD, 4"X4", 32PLY, STRL, LF, 10/TR	Covidien	The gauze is very loosely put together and threads are subject to detach. Affected Lot #'s. Company Location Item Description Status Tracked MANUF-NBR 10 0OR 241763 GAUZE 4X4 16 PLY RFD Active Yes G0404-16P01C-1.

Device	Manufacturer	Problem
Device 2: Gauze/sponge, Internal, X-ray Detectable Brand: G0x0x-0xp0xc(N)-1 Gauze –Rf And X-ray Detecta-ble Model#: G0404-16P01C-1 Lot #: 171109AP Cat #: G0404-16P01C-1 Other #: Med-troinc RFID gauze; GAUZE, XRAY, RFD, 4"X4", 32PLY, STRL, LF, 10/ TR **Device 3: Gauze/sponge, Internal, X-ray Detectable** Brand: G0x0x-0xp0xc(N)-1 Gauze –Rf And X-ray Detecta-ble Model#: G0404-16P01C-1 Lot #: 170702KF Cat #: G0404-16P01C-1 Other #: Med-troinc RFID gauze; GAUZE, XRAY, RFD, 4"X4", 32PLY, STRL, LF, 10/	Covidien Covidien	

Links to FDA/CDRH Databases and Other Information Sources

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

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

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

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

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

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

MedSun Website: http://www.fda.gov/medsun/
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
This database of releasable 510(k)s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

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

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

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

To access additional November 2018 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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