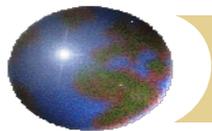


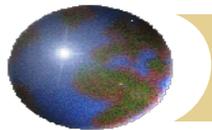
US FDA Postmarket Surveillance

*Presenter: Timothy A. Ulatowski
VP, NSF Health Sciences*



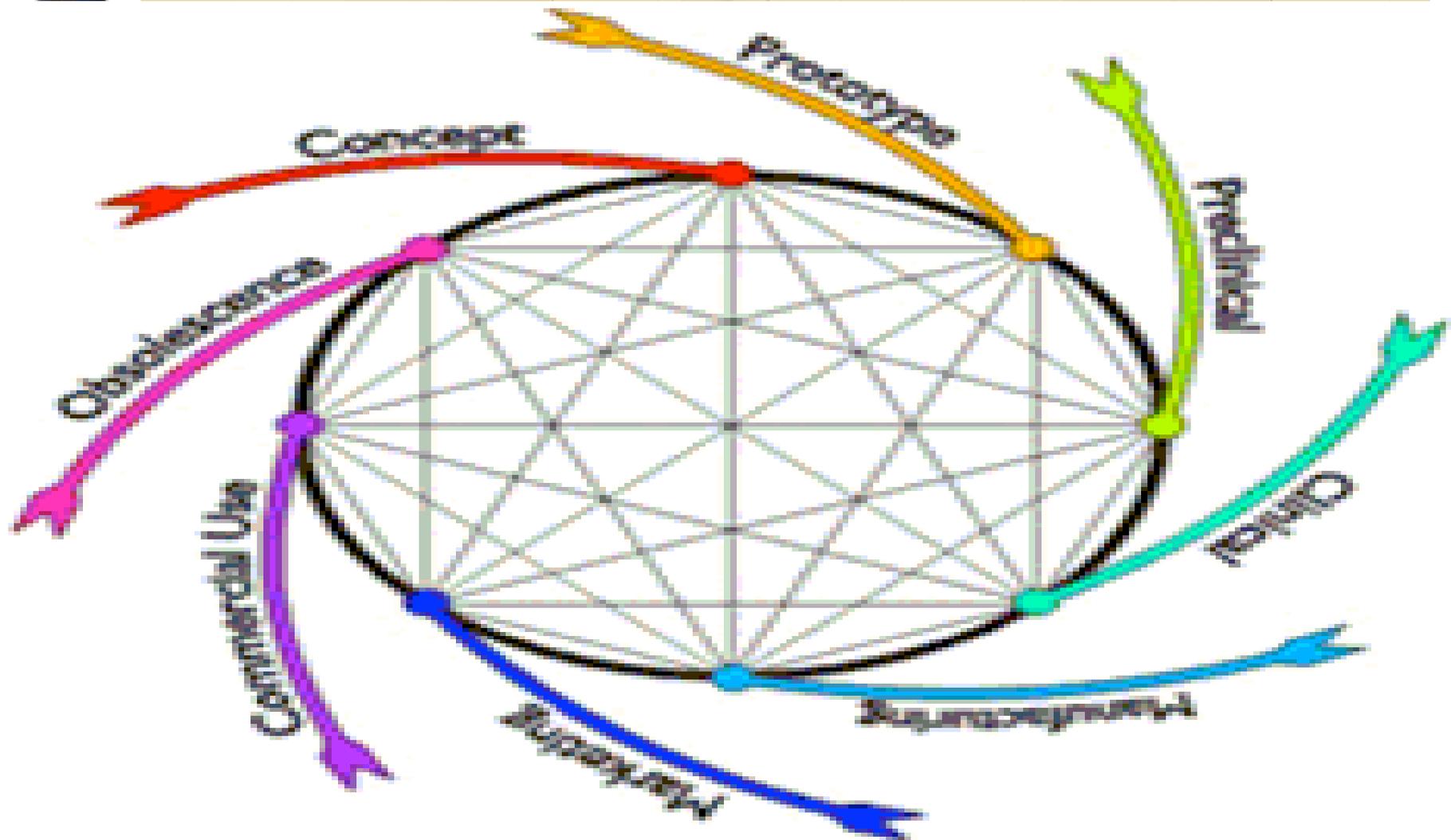
Postmarket Surveillance Overview

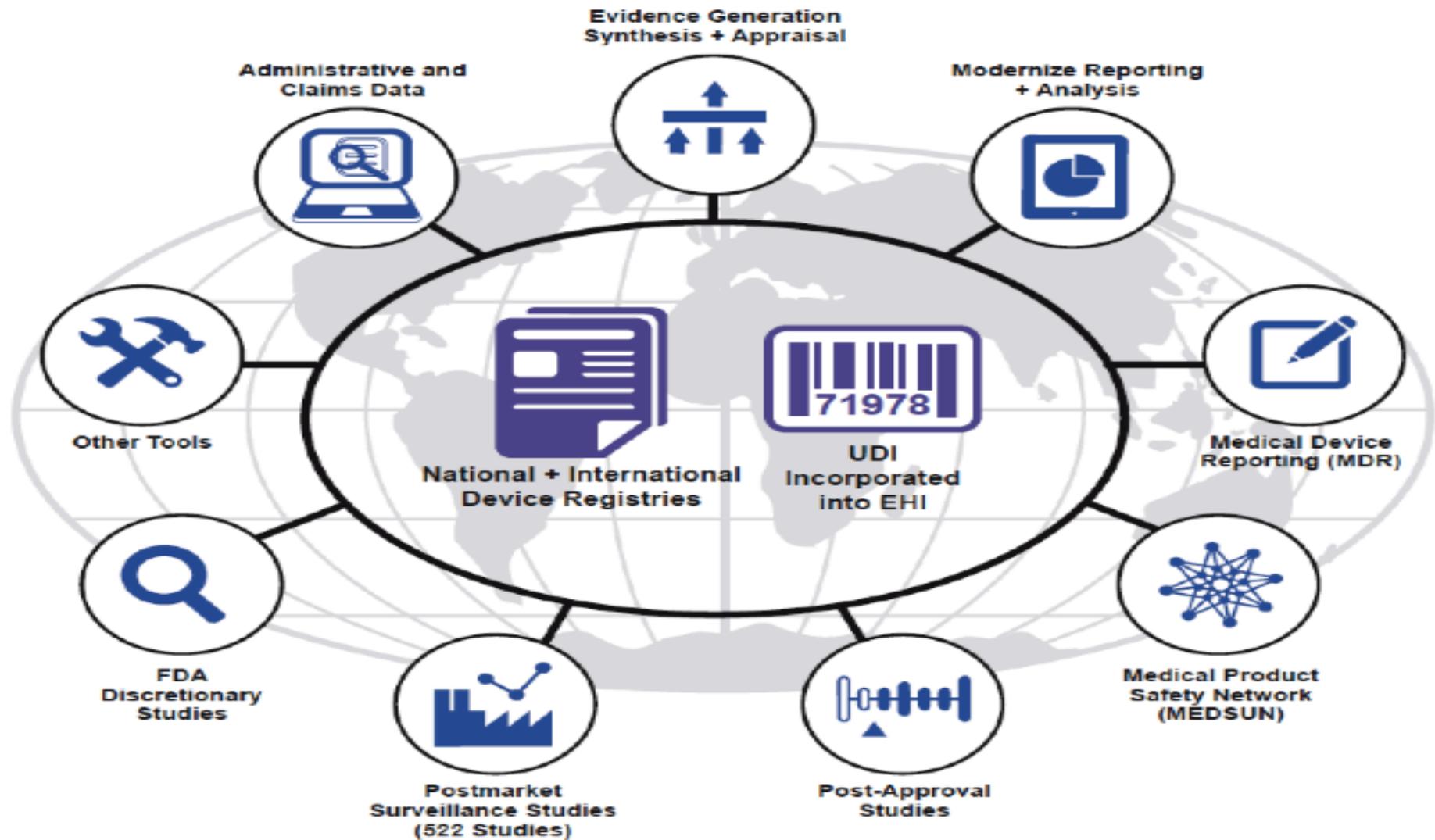
- ✚ FDA regulates the device total product lifecycle
- ✚ Quality system and risk management controls
- ✚ Medical device reports
- ✚ Postmarket PMA approval requirements
- ✚ Postmarket surveillance “522” studies

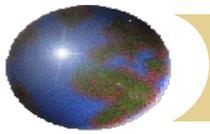


Overview

- ✚ Corrections and removals controls
- ✚ MedSun
- ✚ Unique Device Identifier
- ✚ Registries
- ✚ Medical Device Epidemiological Network
- ✚ Safety Alerts

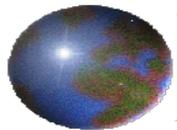






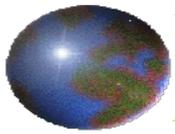
Quality System

- ✚ Manufacturer responsibility for QS postmarket activities which are monitored by FDA
- ✚ FDA also has proactive means to assess QS postmarket performance



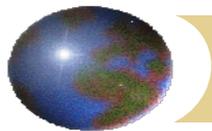
Quality System - manufacturer

- ✚ QS regulation: Corrective and Preventive Action Subsystem
 - ✚ Collecting signals
 - ✚ Investigating complaints/root cause
 - ✚ Trending
 - ✚ Escalation as needed (HHE, CAPA, field action)
 - ✚ Internal quality audits



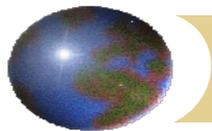
Quality System

- ✚ FDA QS monitoring and action:
 - ▣ Requirements for periodic inspection of facilities/bioresearch monitoring
 - ▣ Compliance and enforcement



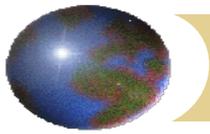
Risk Management- manufacturer

- ❖ Establish, document, and maintain a system to collect and review information in post-production phase
- ❖ Are previously unrecognized hazards/hazardous situations present
- ❖ Is estimated risk still acceptable
- ❖ Feedback to risk analysis



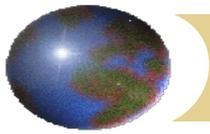
Medical Device Reports (MDRs)

- ✚ Mandatory reports of death, serious injury, or malfunctions that could result in death or serious injury
- ✚ Manufacturer, user facility, importer
- ✚ 5 work/10 work/30 calendar days from becoming aware of reportable event where device may have caused or contributed



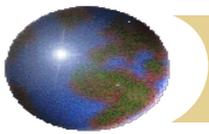
MDRs

- ✚ Voluntary reports from health professionals or consumers using Form 3500
- ✚ Mandatory reports using Form 3500A
- ✚ Initial reports and supplemental reports after obtaining more information
- ✚ Foreign manufacturer needs US agent



MDRs

- ✚ If product is exported and also sold in US then MDR reports must be submitted for a foreign reportable event
- ✚ There are definitions of terms
- ✚ Procedures and implementation must comply with regulations



MAUDE - Manufacturer and User Facility Device Experience

◀ FDA Home ▶ Medical Devices ▶ Databases

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters ¹ (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

[Learn More](#)

[Disclaimer](#)

Search Database



Help



Download Files

Date Report Received by FDA
(press CTRL key for multiple years)

ALL YEARS

2014

2013

2012

2011

[Go to Advanced Search](#)

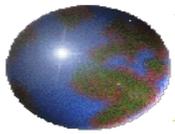
10



Records per Report Page

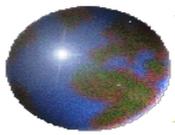
[Clear Form](#)

Enter a single word (e.g., electromechanical), an exact phrase (e.g., electromechanical pump) or multiple words. To Search by Brand Name, Manufacturer, Event Type, 510K Number, PMA Number, Product Code, or date, select *Go To Advanced Search* button.



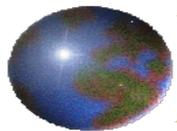
MDRs

- ❖ What does FDA do with MDR reports
 - ❖ Enters into MAUDE system
 - ❖ Assesses death reports immediately
 - ❖ Trends reports
 - ❖ Communicates with manufacturers, as needed
 - ❖ Initiates compliance and enforcement action, as needed



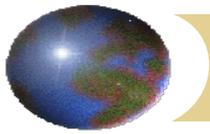
Postmarket PMA Approval Rqmts

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.



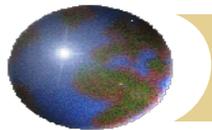
PMA Postapproval Rqmts

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.



PMA Postapproval Rqmts

- ✚ Required postapproval clinical study
 - ▣ Assessment of subpopulation
 - ▣ Additional follow up data
- ✚ Other surveillance controls in PMA approval orders I will discuss

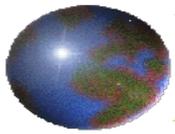


Postmarket Surveillance Study

- ✦ Called “522” studies

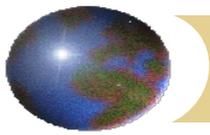
- ✦ FDA may require a 522 study:

- ✦ Confirm nature, severity, frequency of suspected problems or connection to devices
- ✦ More data needed on change to in home use or different population
- ✦ Resolve long term or infrequent use issues



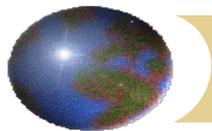
522 Study

- ✦ Only for Class II or III devices:
 - ❑ Failure reasonably likely to have serious consequences
 - ❑ Significant pediatric use
 - ❑ Implanted more than 1 year
 - ❑ Life sustaining/supporting and used outside of health care facility



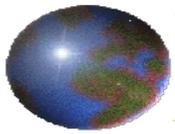
522 Study

- ✚ FDA issues order
- ✚ Manufacturer submits study plan
- ✚ FDA and manufacturer agree on plan
- ✚ Interim and final reports
- ✚ Guidance
- ✚ Active studies posted



Corrections and Removals

- ✦ Device violates law or is a risk to health (recall)
- ✦ “Correction” in the field; otherwise physical “Removal” from point of use
- ✦ Report to FDA within 10 working days from initiation

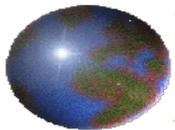


Corrections and Removals

✦ No reports for:

- ✦ Improving performance or quality and not to reduce risk to health or remedy a violation
- ✦ Market withdrawal
- ✦ Routine servicing
- ✦ Stock recovery

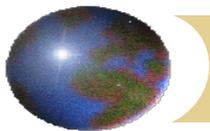
✦ FDA assesses plan, communication, classifies



Corrections and Removals

Recall actions:

-  Voluntary
-  FDA requested
-  Mandatory



Recalls

Recalls, Market Withdrawals, & Safety Alerts

The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See [Additional information about recalls](#) for a more complete listing.

For recall notices older than 60 days, see the [Recall and Safety Alerts Archive](#).

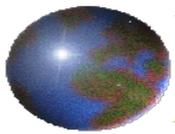
 Sign up to receive Recalls, Market Withdrawals and Safety Alerts.

Filter by Keyword(s):

Filter by Recall Type:

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FDA Pacific Recall Coordinators

Los Angeles District

Southern CA, AZ

Dyana Stone & Thanh Tran

Recall Coordinators

19701 Fairchild

Irvine, CA 92612

Fax: 949-608-4401

dyana.stone@fda.hhs.gov

Phone: 949-608-4440

thanh.tran@fda.hhs.gov

Phone: 949-608-3504

San Francisco District

Northern CA, HI, NV

Marjorie Schultz/Sam Ali (M-W),

Recall Coordinators

1431 Harbor Bay Parkway

Alameda, CA 94502

Fax: 510-337-6705

Phone: 510-337-6898 (M. Schultz)

Phone: 510-337-6869 (S. Ali)

orasanrecalls@fda.hhs.gov

Seattle District

AK, ID, MT, OR, WA

Anh Trinh Nguyen

Recall Coordinator

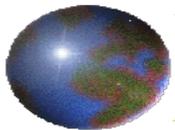
22215 26th Ave. SE, Suite 210

Bothell, WA 98021

Phone: 425-302-0467

Fax: 425-302-0403

orasearecalls@fda.hhs.gov



MedSun

▶ **MedSun: Medical Product Safety Network**

[MedSun Newsletters](#)

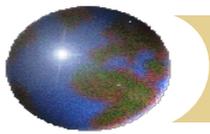
[Educational Webinar Materials](#)

[Recognize and Report Device Problems](#)

[Search MedSun Reports](#)

MedSun: Medical Product Safety Network





How MedSun Works

Participants use an Internet-based system that is designed to be an easy and secure way to report adverse medical device events. Each facility has online access to the reports they submit to MedSun so that they can be tracked and reviewed at any time.

The MedSun Subnetworks

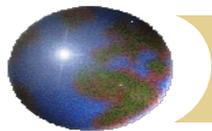
These Subnetworks are designed to collect and share information about actual and potential adverse events from specific clinical areas of MedSun facilities using high-risk products.



HeartNet: Focuses on identifying, understanding, and solving problems with medical devices used in electrophysiology laboratories.

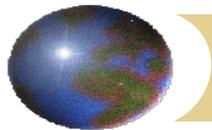


KidNet: Focuses on identifying, understanding, and solving problems with medical devices used in neonatal and pediatric intensive care units.



Unique Device Identifier

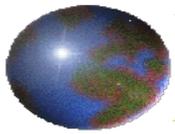
- ✦ Devices to carry UDI
- ✦ More accurate reporting, reduce medical errors, enhance analysis
- ✦ UDI = Mandatory Device Identifier + Conditional, variable Production Identifier
- ✦ Global Unique Device Identification Database



Registries

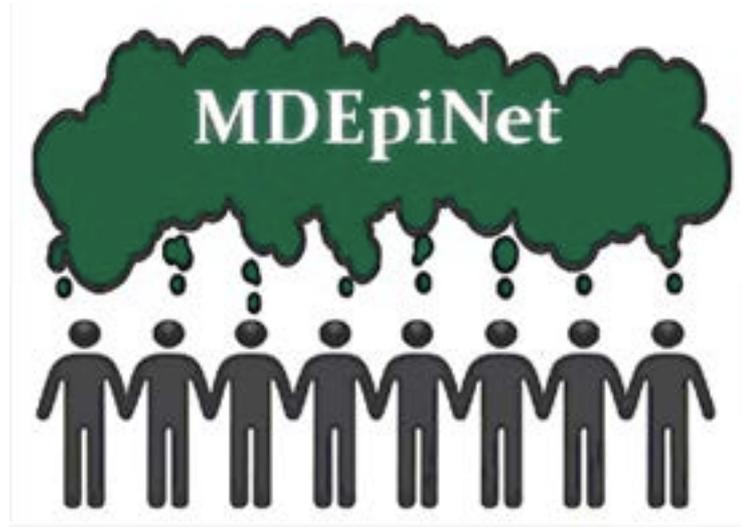
- ✚ International Consortium of Orthopedic Registries – 30 registry collaboration

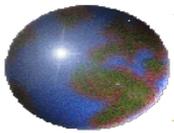
- ✚ Transcatheter Aortic Valve Registry



MDEpiNet

✚ New methodologies, new data systems,





Safety Alerts

Medical Device Safety

▶ Safety Communications

Information About Heparin

Medical Device Safety Archive

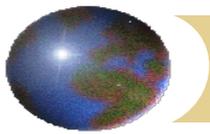
Tubing and Luer Misconnections:
Preventing Dangerous Medical
Errors

Safety Communications

Search the Safety Communication Section

Medical Device Safety and Recalls: Get e-mail updates





Example Safety Communication

Philips HeartStart FRx, HeartStart HS1 Home, and HeartStart HS1 OnSite Automated External Defibrillators (AED)

Date Issued: Dec. 03, 2013

Audience:

- First responders who use Philips HeartStart FRx AED
- Consumers who have purchased Philips HeartStart HS1 Home or HeartStart HS1 OnSite AEDs

Medical Specialty: Cardiology, Electrophysiology, Internal Medicine, Family Medicine

Device:

An automated external defibrillator (AED) is a device that analyzes the heart rhythm in victims of sudden cardiac arrest, and delivers an electrical shock to restore normal rhythm.

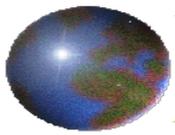
The Philips HeartStart FRx AED may be used by first responders including Emergency Medical Services (EMS) and fire departments.

The Philips HeartStart HS1 Home AED may be used in the home.

The Philips HeartStart HS1 OnSite AED may be used in public locations including airports, community centers, schools and government buildings.

Purpose:

The FDA is alerting all users of the Philips HeartStart FRx, HS1 Home and HS1 OnSite AEDs manufactured between 2005 and 2012 that these devices may fail to deliver a shock in the event of an emergency.



Alerts

Public Health Advisory: Risk of Burns during MRI Scans from Transdermal Drug Patches with Metallic Backings

Tubing and Luer Misconnections: Preventing Dangerous Medical Errors

Rare Serious Erosion Events Associated with St. Jude Amplatzer Atrial Septal Occluder (ASO)