



ANALYZING DEVICE RISK USING TEXTUAL DATABASES

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Date Posted

Manufacturer

FDA Review Panel



Product Name Product Code In Vitr	o Devices 📃
Recall Class All ▼ Recall Number PMA/510(K) Number	
Date Posted	
Reason for Recall	
Recalling Firm	
Root Cause	



FDA Device Problem Code Hierarchy (multi-level hierarchy)

- 1. Device Operational Issue
- 2. Physical Property Issue
- 3. Facilities Issue
- 4. Human Factors Issue

Subset: Device Issue

- Device Operational Issue LEVEL 1 Issue associated with any deviations from specifications relating to device operations (e.g. deployment, connection, electrical, computer software, infusion/flow, output, protective measure, and incompatibility issues).
 - **Device Operates Differently than Expected C62955; FDA 2913** *Issue associated with any deviations from expected performance while operating and using the device.*
 - Device displays error message C63205; FDA 2591 Issue associated with a device prompting user with an error message in order to indicate a device problem



FDA Component Code Hierarchy

Alphabetized list of components and sub-components

Subset: Device Component or Accessory

- Absorber C50372; FDA 3028
 - Absorber (CO2) C49804; FDA 401
 - Sound Absorber C49805; FDA 968
- Accumulator C49806; FDA 548
- Actuator C49807; FDA 402
- Adapter (Adaptor) C49808; FDA 431
 - Socket Adaptor C49809; FDA 966



Textual Coding

2012 Recall

<u>Reason for</u> <u>Recall</u>

"The securement cuff on the hemodialysis catheter has the potential to detach from the shaft." **DuraMax**[®] Engineered for Excellence[™]



Angled venous tip and unique, proprietary guidewire lumen positions guidewire in the center of the leading edge of distal tip and provides superior over the wire performance and improved ease of insertion.

> 15.5 F DuraMax catheter facilitates high flow rates at modest arterial pressures. Proprietary lumen design provides improved kink resistance and flexibility in challenging tunnel locations.

Durathane⁶ catheter material affords strength, softness, and resistance to a wide range of commonly used site care agents.



SafeSheath D-Pro[®] double seal peelaway sheath provides safety and security of hemostatic access and greatly reduces the risk of air embolism,

Rotating suture wings

ensure patient comfort and flexibility to position catheter.



Thermoplastic Polyurethane Luers combine toughness, dimensional stability, and chemical resistance.

Curved tip catheter technology reduces vein wall apposition and risk of arterial insufficiency. 3 cm tip stagger reduces

roulation rates.

Robust polyester cuff material allows optimal tissue ingrowth and catheter securement.



Textual Coding

Reason for Recall

"The securement cuff on the hemodialysis catheter has the potential to detach from the shaft."

Problem Code Hierarchy

- Level 1: Operational Issue
 - Level 2: Connection Issue
 - Level 3: Decoupling
 - Level 3: Disconnection

Component Code Hierarchy

□Cuff, catheter, shaft





Quantifying the Qualitative Data



Quantifies the input text and proves a list of parsed terms with corresponding metrics Filter out unwanted terms from the database Statistical clustering of textual data to identify groupings



FDA Device Recall Textual Mining Study

Notable aggregate 11 year results (2002-2012)

- Major Manufacturers
 - Boston Scientific, Guidant, Medtronic and St. Jude Medical
- Major Device Problem Codes
 - Physical Property Issue (56%)
 - Device Operational Issue (37%)
- Major Review Panel
 - Cardiovascular (42%)



FDA Device Recall Textual Mining Study

Major Cardiovascular Devices

- Defibrillators (26%) and Stents (14%)
- All PMA defibrillators were recalled with the exception of four Implantable Cardio Defibrillators (LWS)
- Major Reliability-Related
 Defibrillator Problem Codes
 - Electrical (19%)
 - Software (11%)







Current Research Directions

Probabilistic modeling of textual data

Events

Short Reason Txt

ConMed received complaints of some units exhibiting inaccurate or inconsistent flow rates. It was determined that certain units were assembled with an incorrect component which could result in the devices exhibiting a different flow rate and might reduce the ability of the user to regulate the device at low flow rates.

- Low measurements of Troponin I in the MAS
- 2 Cardiolmmune XL Control which were outside the published control ranges.
 - Currently there is a possibility, at the start of the perimetry
- 3 examination, for the background illumination of the cupola not to turn on. If no illumination of cupola occurs, data obtained from the examination could provide the doctor with results that would appear to be better than actual.
- Retaining pins in handle assembly may disengage and fall into surgical field or compromise handle unlatching.
 Eyezone have distributed soft color lens while on FDA hold and were later found to be misbranded.



Quantified thematic variables for each event

Significant Textual Themes



Recommendations

- There is room for improvement in providing industry with structured expectations for reliability tests
 - Standardized requirements for non-clinical tests
- More structured textual reporting framework
 - to facilitate textual mining risk analysis
 - Field entry and pre-coding
 - High resolution digitization of submission packages



