Medical Device Adverse Events: You Don't Know What You Don't Know

DEVICE EVENTS™

Madris Tomes, MBA

Founder and CEO, Device Events (current)

Adverse Events Sub-group Lead, AHA's Learning UDI Community

FDA Public Health Analyst, Unique Device Identification (UDI), and Subject Matter Expert for Adverse Event Reporting

Co-author, UDI Demonstration Abstract (cardiac stents) with Mercy, Mayo, Boston Scientific, Duke, Medtronic, Abbott, and the FDA

FDA Device Liaison to CMS for Sunshine Act

Broadcast Public Relations for Firestone Tire Recall (2000)

Featured in: New York Times (front page business section), CNN, Washington Post Magazine, CNBC Power Lunch, Reuters, NBC NY

www.linkedin.com/in/madris

DEVICE EVENTS™

***95%** of the medical devices on the market have not gone through clinical trials. Most people, doctors included, do not know this.

It takes **2 months to 2 years** for medical device patterns/signals to be identified, investigated, and reported by the FDA.

"Today, we do not track medical device adverse effects reported by physicians before an actual recall is issued."

VP at the second largest Group Purchasing Organization (GPO) In the US

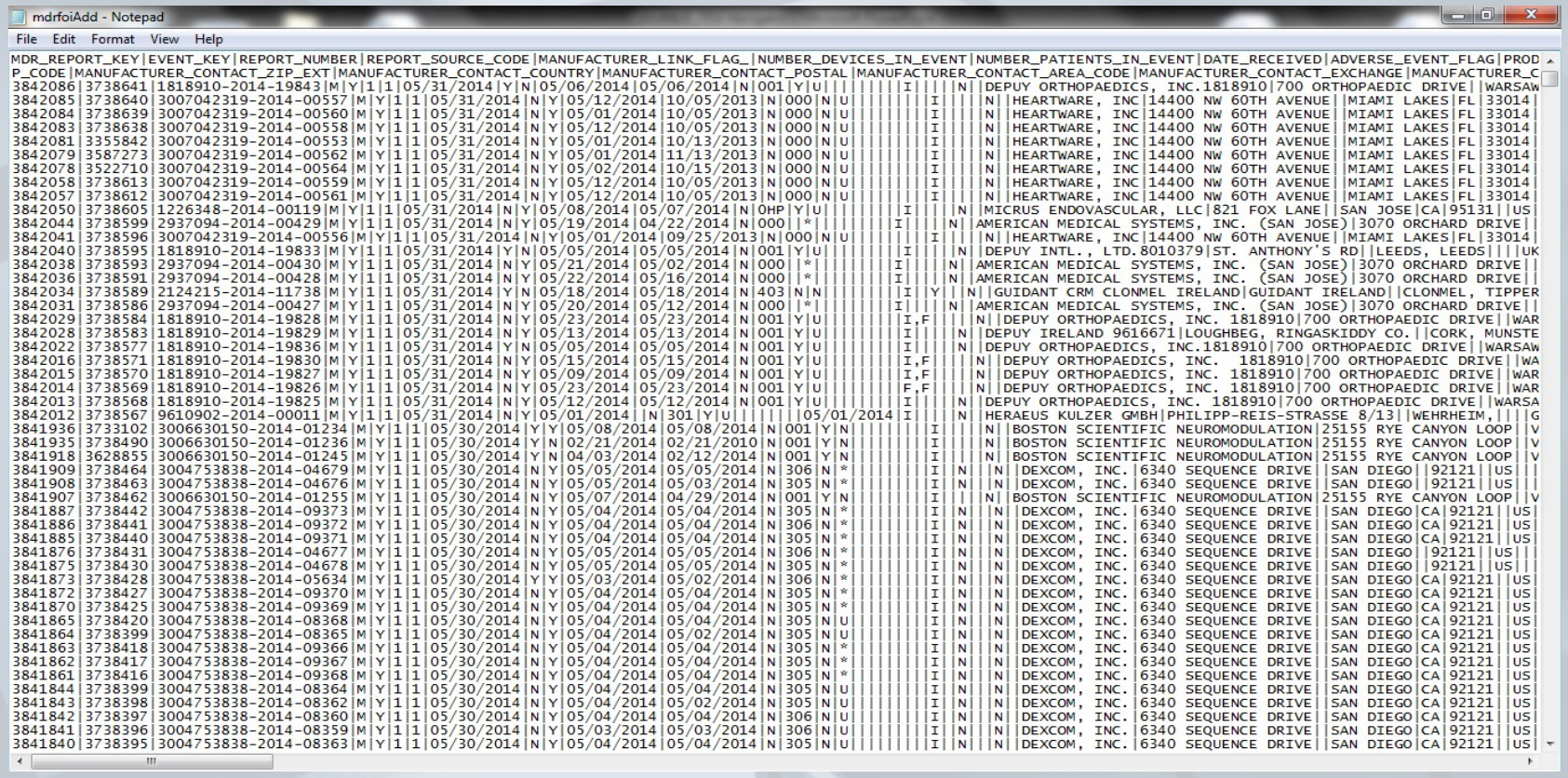
***National Center for Health Research**

DEVICE EVENTS™

Recent Headlines Demonstrate the Cost of Impenetrable Data

DEVICE EVENTS™

With over **6 million reports** in **Public MAUDE**, the data is impenetrable, unusable and not timely.



mdrfoiAdd - Notepad

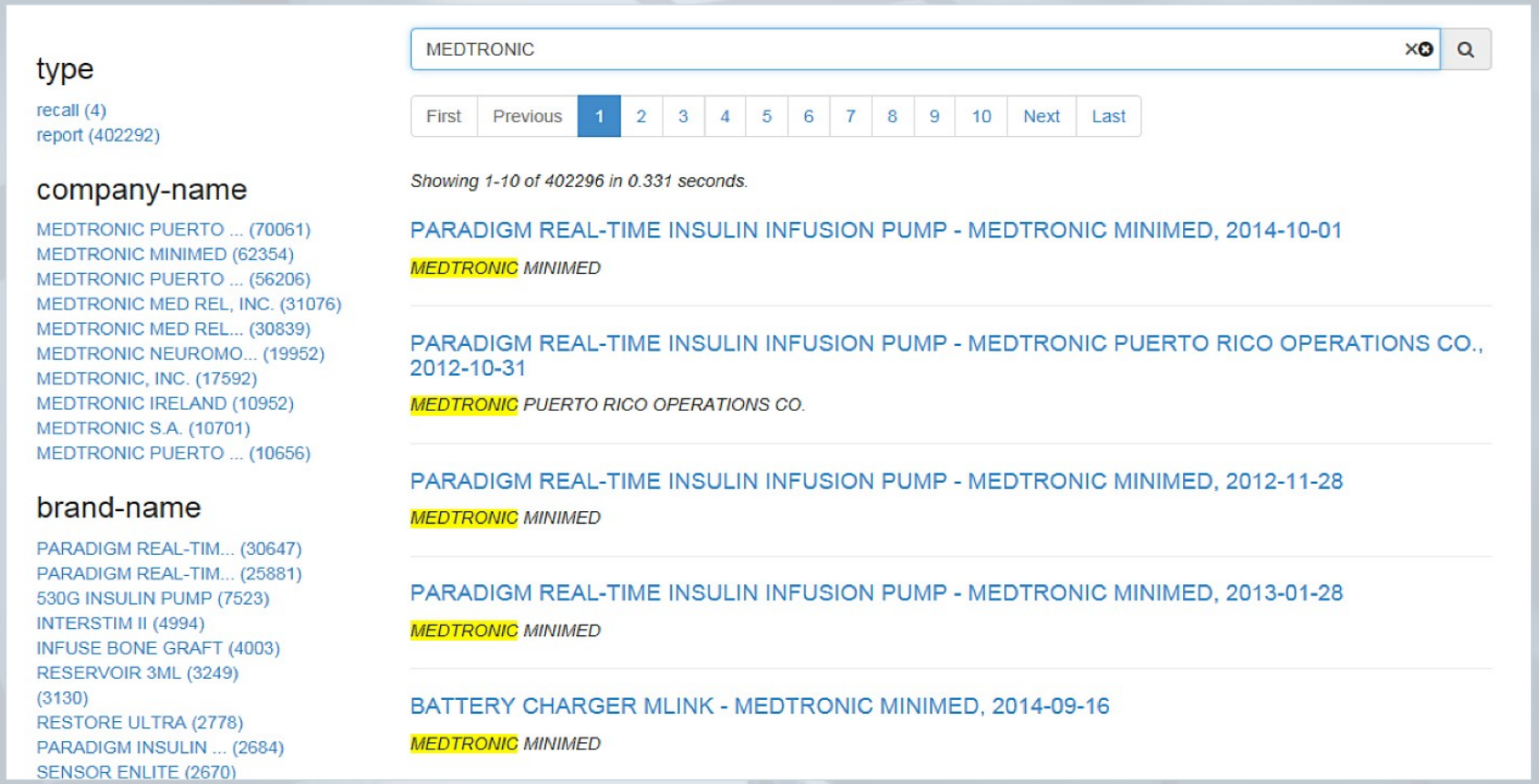
File Edit Format View Help

```
MDR_REPORT_KEY|EVENT_KEY|REPORT_NUMBER|REPORT_SOURCE_CODE|MANUFACTURER_LINK_FLAG_|NUMBER_DEVICES_IN_EVENT|NUMBER_PATIENTS_IN_EVENT|DATE_RECEIVED|ADVERSE_EVENT_FLAG|PROD
P_CODE|MANUFACTURER_CONTACT_ZIP_EXT|MANUFACTURER_CONTACT_COUNTRY|MANUFACTURER_CONTACT_POSTAL|MANUFACTURER_CONTACT_AREA_CODE|MANUFACTURER_CONTACT_EXCHANGE|MANUFACTURER_C
3842086|3738641|1818910-2014-19843|M|Y|1|1|05/31/2014|Y|N|05/06/2014|05/06/2014|N|001|Y|U|||||||I|||N||DEPUY ORTHOPAEDICS, INC.1818910|700 ORTHOPAEDIC DRIVE||WARSAW
3842085|3738640|3007042319-2014-00557|M|Y|1|1|05/31/2014|N|Y|05/12/2014|10/05/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842084|3738639|3007042319-2014-00560|M|Y|1|1|05/31/2014|N|Y|05/01/2014|10/05/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842083|3738638|3007042319-2014-00558|M|Y|1|1|05/31/2014|N|Y|05/12/2014|10/05/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842081|3355842|3007042319-2014-00553|M|Y|1|1|05/31/2014|N|Y|05/01/2014|10/13/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842079|3587273|3007042319-2014-00562|M|Y|1|1|05/31/2014|N|Y|05/01/2014|11/13/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842078|3522710|3007042319-2014-00564|M|Y|1|1|05/31/2014|N|Y|05/02/2014|10/15/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842058|3738613|3007042319-2014-00559|M|Y|1|1|05/31/2014|N|Y|05/12/2014|10/05/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842057|3738612|3007042319-2014-00561|M|Y|1|1|05/31/2014|N|Y|05/12/2014|10/05/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842050|3738605|1226348-2014-00119|M|Y|1|1|05/31/2014|N|Y|05/08/2014|05/07/2014|N|0HP|Y|U|||||||I|||N||MICRUS ENDOVASCULAR, LLC|821 FOX LANE||SAN JOSE|CA|95131||US|
3842044|3738599|2937094-2014-00429|M|Y|1|1|05/31/2014|N|Y|05/19/2014|04/22/2014|N|000||*|||||||I|||N||AMERICAN MEDICAL SYSTEMS, INC. (SAN JOSE)|3070 ORCHARD DRIVE||
3842041|3738596|3007042319-2014-00556|M|Y|1|1|05/31/2014|N|Y|05/01/2014|09/25/2013|N|000|N|U|||||||I|||N||HEARTWARE, INC|14400 NW 60TH AVENUE||MIAMI LAKES|FL|33014|
3842040|3738595|1818910-2014-19833|M|Y|1|1|05/31/2014|Y|N|05/05/2014|05/05/2014|N|001|Y|U|||||||I|||N||DEPUY INTL., LTD.8010379|ST. ANTHONY'S RD||LEEDS, LEEDS|||UK
3842038|3738593|2937094-2014-00430|M|Y|1|1|05/31/2014|N|Y|05/21/2014|05/02/2014|N|000||*|||||||I|||N||AMERICAN MEDICAL SYSTEMS, INC. (SAN JOSE)|3070 ORCHARD DRIVE||
3842036|3738591|2937094-2014-00428|M|Y|1|1|05/31/2014|N|Y|05/22/2014|05/16/2014|N|000||*|||||||I|||N||AMERICAN MEDICAL SYSTEMS, INC. (SAN JOSE)|3070 ORCHARD DRIVE||
3842034|3738589|2124215-2014-11738|M|Y|1|1|05/31/2014|Y|N|05/18/2014|05/18/2014|N|403|N|N|||||||I|Y||N||GUIDANT CRM CLONMEL IRELAND|GUIDANT IRELAND||CLONMEL, TIPPER
3842031|3738586|2937094-2014-00427|M|Y|1|1|05/31/2014|N|Y|05/20/2014|05/12/2014|N|000||*|||||||I|||N||AMERICAN MEDICAL SYSTEMS, INC. (SAN JOSE)|3070 ORCHARD DRIVE||
3842029|3738584|1818910-2014-19828|M|Y|1|1|05/31/2014|N|Y|05/23/2014|05/23/2014|N|001|Y|U|||||||I,F|||N||DEPUY ORTHOPAEDICS, INC. 1818910|700 ORTHOPAEDIC DRIVE||WAR
3842028|3738583|1818910-2014-19829|M|Y|1|1|05/31/2014|N|Y|05/13/2014|05/13/2014|N|001|Y|U|||||||I|||N||DEPUY IRELAND 9616671|LOUGHBEG, RINGASKIDDY CO.||CORK, MUNSTE
3842022|3738577|1818910-2014-19836|M|Y|1|1|05/31/2014|Y|N|05/05/2014|05/05/2014|N|001|Y|U|||||||I|||N||DEPUY ORTHOPAEDICS, INC.1818910|700 ORTHOPAEDIC DRIVE||WARSAW
3842016|3738571|1818910-2014-19830|M|Y|1|1|05/31/2014|N|Y|05/15/2014|05/15/2014|N|001|Y|U|||||||I,F|||N||DEPUY ORTHOPAEDICS, INC.  1818910|700 ORTHOPAEDIC DRIVE||WA
3842015|3738570|1818910-2014-19827|M|Y|1|1|05/31/2014|N|Y|05/09/2014|05/09/2014|N|001|Y|U|||||||I,F|||N||DEPUY ORTHOPAEDICS, INC. 1818910|700 ORTHOPAEDIC DRIVE||WAR
3842014|3738569|1818910-2014-19826|M|Y|1|1|05/31/2014|N|Y|05/23/2014|05/23/2014|N|001|Y|U|||||||F,F|||N||DEPUY ORTHOPAEDICS, INC. 1818910|700 ORTHOPAEDIC DRIVE||WAR
3842013|3738568|1818910-2014-19825|M|Y|1|1|05/31/2014|N|Y|05/12/2014|05/12/2014|N|001|Y|U|||||||I|||N||DEPUY ORTHOPAEDICS, INC. 1818910|700 ORTHOPAEDIC DRIVE||WARSA
3842012|3738567|9610902-2014-00011|M|Y|1|1|05/31/2014|N|Y|05/01/2014||N|301|Y|U|||||||05/01/2014|I|||N||HERAEUS KULZER GMBH|PHILIPP-REIS-STRASSE 8/13||WEHRHEIM,||||G
3841936|3733102|3006630150-2014-01234|M|Y|1|1|05/30/2014|Y|Y|05/08/2014|05/08/2014|N|001|Y|N|||||||I|||N||BOSTON SCIENTIFIC NEUROMODULATION|25155 RYE CANYON LOOP||V
3841935|3738490|3006630150-2014-01236|M|Y|1|1|05/30/2014|Y|N|02/21/2014|02/21/2010|N|001|Y|N|||||||I|||N||BOSTON SCIENTIFIC NEUROMODULATION|25155 RYE CANYON LOOP||V
3841918|3628855|3006630150-2014-01245|M|Y|1|1|05/30/2014|Y|N|04/03/2014|02/12/2014|N|001|Y|N|||||||I|||N||BOSTON SCIENTIFIC NEUROMODULATION|25155 RYE CANYON LOOP||V
3841909|3738464|3004753838-2014-04679|M|Y|1|1|05/30/2014|N|Y|05/05/2014|05/05/2014|N|306|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO||92121||US|||
3841908|3738463|3004753838-2014-04676|M|Y|1|1|05/30/2014|N|Y|05/05/2014|05/03/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO||92121||US|||
3841907|3738462|3006630150-2014-01255|M|Y|1|1|05/30/2014|N|Y|05/07/2014|04/29/2014|N|001|Y|N|||||||I|||N||BOSTON SCIENTIFIC NEUROMODULATION|25155 RYE CANYON LOOP||V
3841887|3738442|3004753838-2014-09373|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841886|3738441|3004753838-2014-09372|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|306|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841885|3738440|3004753838-2014-09371|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841876|3738431|3004753838-2014-04677|M|Y|1|1|05/30/2014|N|Y|05/05/2014|05/05/2014|N|306|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO||92121||US|||
3841875|3738430|3004753838-2014-04678|M|Y|1|1|05/30/2014|N|Y|05/05/2014|05/05/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO||92121||US|||
3841873|3738428|3004753838-2014-05634|M|Y|1|1|05/30/2014|Y|Y|05/03/2014|05/02/2014|N|306|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841872|3738427|3004753838-2014-09370|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841870|3738425|3004753838-2014-09369|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841865|3738420|3004753838-2014-08368|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|U|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841864|3738399|3004753838-2014-08365|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/02/2014|N|305|N|U|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841863|3738418|3004753838-2014-09366|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841862|3738417|3004753838-2014-09367|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841861|3738416|3004753838-2014-09368|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|*|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841844|3738399|3004753838-2014-08364|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|U|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841843|3738398|3004753838-2014-08362|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/02/2014|N|305|N|U|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841842|3738397|3004753838-2014-08360|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|306|N|U|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841841|3738396|3004753838-2014-08359|M|Y|1|1|05/30/2014|N|Y|05/03/2014|05/03/2014|N|306|N|U|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
3841840|3738395|3004753838-2014-08363|M|Y|1|1|05/30/2014|N|Y|05/04/2014|05/04/2014|N|305|N|U|||||||I|N||N||DEXCOM, INC.|6340 SEQUENCE DRIVE||SAN DIEGO|CA|92121||US|
```

What You See in Public MAUDE

DEVICE EVENTS™

Over **1300 Variations** of the Name “Medtronic” Have Been Submitted to the FDA in the last 2 years alone.



Without Matching and Cleansing, True Adverse Event Counts are Inaccurate

DEVICE EVENTS™

DEVICE EVENTS™

About Us | Challenges | Who We Help | Software Features | News & Events | Contact Us | Login

Mission Statement

Our mission is to contribute to better patient outcomes and improve patient safety while reducing the risk associated with medical device decisions by healthcare organization and providers.

We empower users with information to make more informed decisions about the medical devices they use, before device recalls are issued by the FDA.



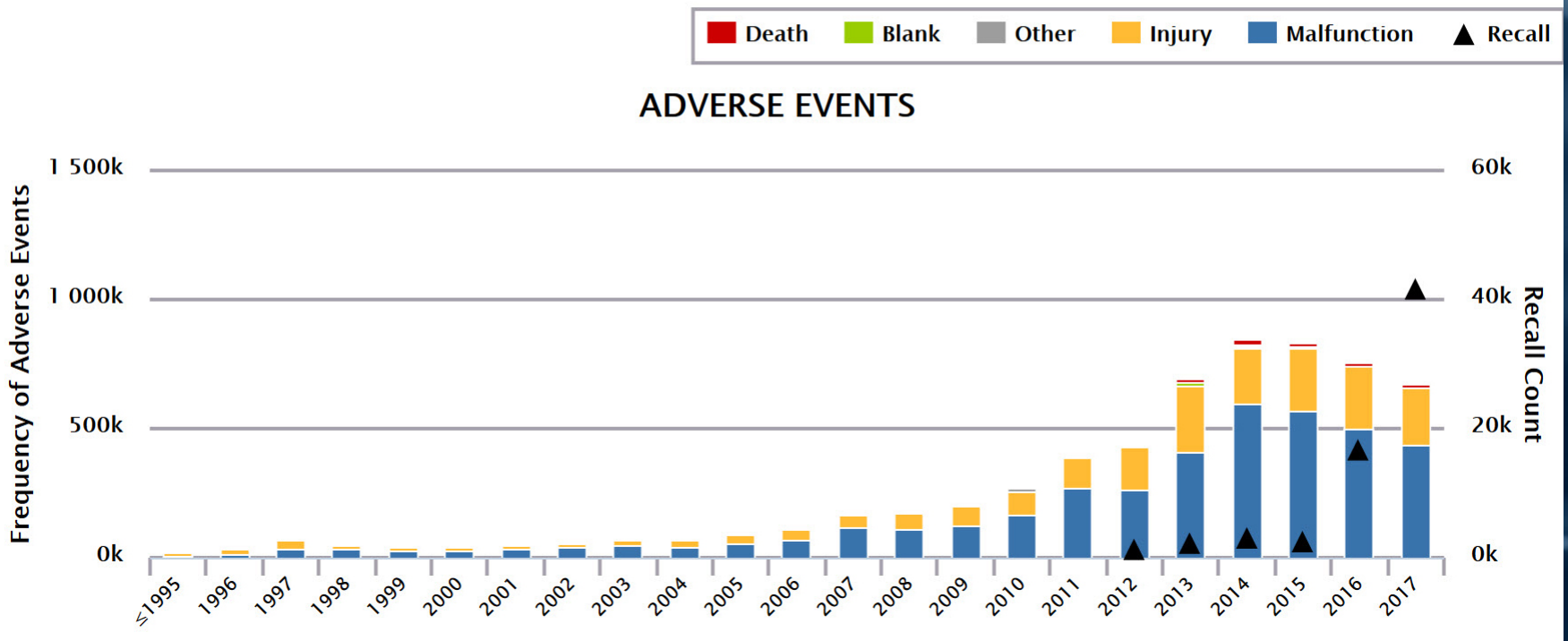


The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

Showing 1-25 of 8,078,755 in 3.500 seconds.

Search Preview | Chart (Beta)



The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

Report Type

Check All | Uncheck All

- ☑ Injury (36,022)
- ☑ Malfunction (2,441)
- ☑ Death (378)
- ☑ Other (280)
- ☑ *blank* (102)

Report Source

Check All | Uncheck All

- ☑ Manufacturer report (38,611)
- ☑ Voluntary report (412)
- ☑ User Facility report (155)
- ☑ Distributor report (45)

Reporter Occupation

Check All | Uncheck All

- ☑ ATTORNEY (18,605)
- ☑ PHYSICIAN (9,999)
- ☑ OTHER (6,535)
- ☑ PATIENT (1,446)
- ☑ HEALTH PROFESSIONAL (863)
- ☑ NOT APPLICABLE (435)
- ☑ *blank* (266)
- ☑ SERVICE PERSONNEL (221)
- ☑ UNKNOWN (197)

BOSTON SCIENTIFIC CORP BECAME AWARE OF A REPORTABLE EVENT THAT WAS REPORTED AS INVOLVING 6-605 COBALT CHROMIUM (COCR) ALLOY STENT; HOWEVER, BOSTON SCIENTIFIC DOES NOT MFR 6-605 COBALT CHROMIUM (COCR) ALLOY STENT. AS REPORTED: IN 2007, MY HUSBAND HAD AN ANGIOPLASTY PERFORMED. THREE DAYS LATER, HE HAD A STENT IMPLANT. IT IS A STENT WITH 6-605 COBALT CHROMIUM (COCR) ALLOY. ACCORDING TO THE PATIENT'S GUIDE TO STENT IMPLANTATION BOOKLET IT STATES "PERSONS ALLERGIC TO L-605 COBALT CHROMIUM (COCR) ALLOW MAY SUFFER AN ALLERGIC REACTION TO THIS... COBALT

UNKNOWN HIP - Zimmer Biomet , 2016-03-23 , 5521014

Problem: Material erosion

THE USER FACILITY IS OUTSIDE OF THE UNITED STATES. CURRENT INFORMATION IS INSUFFICIENT TO PERMIT CONCLUSIONS AS TO THE CAUSES OF THE EVENTS. EVENT DETAILS AND PRODUCT IDENTIFICATION WAS NOT PROVIDED FOR THE PATIENTS MENTIONED IN THE JOURNAL ARTICLE. BRAND NAME - UNKNOWN CERAMIC AND COBALT - CHROMIUM HEADS. INITIAL REPORTER NAME - THIS ARTICLE WAS WRITTEN BY SOK CHUEN TAN, ADRIAN C.K. LAU, CHRISTOPHER DEL BALSO, JAMES L. HOWARD, BRENT A. LANTING, AND MATTHEW G. TEETER. DEVICE LOCATION UNKNOWN.
...: CERAMIC AND OXIDIZED ZIRCONIUM VS COBALT ...

R3 COCR LINER - Smith & Nephew , 2016-04-13 , 5573436

IT WAS REPORTED THAT RIGHT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM LEVELS.
IT WAS REPORTED THAT RIGHT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM LEVELS.

R3 COCR LINER - Smith & Nephew , 2016-04-14 , 5576549

IT WAS REPORTED THAT LEFT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM LEVELS.
IT WAS REPORTED THAT LEFT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM

Report Type

Check All | Uncheck All

- ☑ Injury (35,536)
- ☑ Malfunction (2,628)
- ☑ Death (365)
- ☑ Other (273)
- ☑ *blank* (122)

Report Source

Check All | Uncheck All

- ☑ Manufacturer report (38,369)
- ☑ Voluntary report (377)
- ☑ User Facility report (133)
- ☑ Distributor report (45)

Reporter Occupation

Check All | Uncheck All

- ☑ ATTORNEY (18,419)
- ☑ PHYSICIAN (9,814)
- ☑ OTHER (6,484)
- ☑ PATIENT (1,448)
- ☑ HEALTH PROFESSIONAL (867)
- ☑ NOT APPLICABLE (437)
- ☑ MEDICAL EQUIPMENT COMP... (246)
- ☑ UNKNOWN (225)

WITH THE COBALT CHROME HEAD; IMPLANTED THE PT. THE HIP WAS THEN SUCCESSFULLY REDUCED AND THE SURGERY WAS COMPLETED SUCCESSFULLY.
...TIME OF MFG. (B)(4) LINERS BELONGING TO THIS LOT HAVE BEEN IMPLANTED AND NO INCIDENTS HAVE BEEN REPORTED UP TO NOW. COCR FEMORAL HEAD - REF 01.25.012 / LOT 102159 (B)(4): ALL PARAMETERS WERE FOUND TO BE CONFORMING TO... ... CRCO ...

UNKNOWN HIP - Zimmer Biomet , 2015-11-19 , 5235657

INFORMATION WAS RECEIVED BASED ON REVIEW OF A JOURNAL ARTICLE TITLED, METAL ION LEVELS IN PATIENTS WITH MODULAR ACETABULAR HIP COMPONENTS, MATCHING CRCO LINERS WITH TITANIUM CUPS. THE JOURNAL ARTICLE AIMED TO EXAMINE METAL ION BLOOD LEVELS IN TOTAL HIP REPLACEMENT PATIENTS WHO RECEIVED TITANIUM ACETABULAR CUPS COUPLED WITH COCR ACETABULAR LINERS; AND TO INVESTIGATE THE INFLUENCE OF PARAMETERS INCLUDING AGE AND GENDER. THE STUDY CONSISTED OF THIRTY-NINE (39) PATIENTS WHO WERE IMPLANTED WITH TITANIUM ACETABULAR CUPS, COCR LINERS AND...

COBALT CHROMIUM - Boston Scientific , 2008-07-01 , 1080860

BOSTON SCIENTIFIC CORP BECAME AWARE OF A REPORTABLE EVENT THAT WAS REPORTED AS INVOLVING 6-605 COBALT CHROMIUM (COCR) ALLOY STENT; HOWEVER, BOSTON SCIENTIFIC DOES NOT MFR 6-605 COBALT CHROMIUM (COCR) ALLOY STENT. AS REPORTED: IN 2007, MY HUSBAND HAD AN ANGIOPLASTY PERFORMED. THREE DAYS LATER, HE HAD A STENT IMPLANT. IT IS A STENT WITH 6-605 COBALT CHROMIUM (COCR) ALLOY. ACCORDING TO THE PATIENT'S GUIDE TO STENT IMPLANTATION BOOKLET IT STATES "PERSONS ALLERGIC TO L-605 COBALT CHROMIUM (COCR) ALLOW MAY SUFFER AN ALLERGIC REACTION TO THIS... COBALT

UNKNOWN HIP - Zimmer Biomet , 2016-03-23 , 5521014

Problem: Material erosion

THE USER FACILITY IS OUTSIDE OF THE UNITED STATES. CURRENT INFORMATION IS INSUFFICIENT TO PERMIT CONCLUSIONS AS TO THE CAUSES OF THE EVENTS. EVENT DETAILS AND PRODUCT IDENTIFICATION WAS NOT PROVIDED FOR THE PATIENTS MENTIONED IN THE JOURNAL ARTICLE. BRAND NAME - UNKNOWN CERAMIC AND

Record Type

Check All | Uncheck All

- ☑ GUDID Record (43,659)
- ☑ Adverse Event Report (39,223)
- ☑ Recall (181)

Report Type

Check All | Uncheck All

- ☑ Injury (36,022)
- ☑ Malfunction (2,441)
- ☑ Death (378)
- ☑ Other (280)
- ☑ *blank* (102)

Report Source

Check All | Uncheck All

- ☑ Manufacturer report (38,611)
- ☑ Voluntary report (412)
- ☑ User Facility report (155)
- ☑ Distributor report (45)

per page

Showing 1-25 of 83,073 in 0.357 seconds.

Search Preview | Chart (Beta)

COBALT CHROMIUM - Boston Scientific , 2008-07-01 , 1080860

BOSTON SCIENTIFIC CORP BECAME AWARE OF A REPORTABLE EVENT THAT WAS REPORTED AS INVOLVING 6-605 COBALT CHROMIUM (COCR) ALLOY STENT; HOWEVER, BOSTON SCIENTIFIC DOES NOT MFR 6-605 COBALT CHROMIUM (COCR) ALLOY STENT. AS REPORTED: IN 2007, MY HUSBAND HAD AN ANGIOPLASTY PERFORMED. THREE DAYS LATER, HE HAD A STENT IMPLANT. IT IS A STENT WITH 6-605 COBALT CHROMIUM (COCR) ALLOY. ACCORDING TO THE PATIENT'S GUIDE TO STENT IMPLANTATION BOOKLET IT STATES "PERSONS ALLERGIC TO L-605 COBALT CHROMIUM (COCR) ALLOW MAY SUFFER AN ALLERGIC REACTION TO THIS... COBALT

UNKNOWN HIP - Zimmer Biomet , 2016-03-23 , 5521014

Problem: Material erosion

THE USER FACILITY IS OUTSIDE OF THE UNITED STATES. CURRENT INFORMATION IS INSUFFICIENT TO PERMIT CONCLUSIONS AS TO THE CAUSES OF THE EVENTS. EVENT DETAILS AND PRODUCT IDENTIFICATION WAS NOT PROVIDED FOR THE PATIENTS MENTIONED IN THE JOURNAL ARTICLE. BRAND NAME - UNKNOWN CERAMIC AND COBALT - CHROMIUM HEADS. INITIAL REPORTER NAME - THIS ARTICLE WAS WRITTEN BY SOK CHUEN TAN, ADRIAN C.K. LAU, CHRISTOPHER DEL BALSO, JAMES L. HOWARD, BRENT A. LANTING, AND MATTHEW G. TEETER. DEVICE LOCATION UNKNOWN.
...: CERAMIC AND OXIDIZED ZIRCONIUM VS COBALT ...

Company Name

Check All | Uncheck All

- ☑ Johnson & Johnson (27,255)
- ☑ Biomet Orthopedics, Llc (6,492)
- ☑ Zimmer Biomet (4,413)
- ☑ Zimmer, Inc. (3,663)
- ☑ Boston Scientific (3,359)
- ☑ Globus Medical, Inc. (2,756)
- ☑ Stryker (2,532)
- ☑ Smith & Nephew, Inc. (2,500)
- ☑ Microport Orthopedics ... (2,221)
- ☑ Howmedica Osteonics Corp. (1,716)
- ☑ Exactech, Inc. (1,532)
- ☑ Encore Medical, L.p. (1,413)
- ☑ Nuvasive, Inc. (1,338)
- ☑ Smith & Nephew (1,031)
- ☑ Stelkast Incorporated (868)
- ☑ Aesculap Ag (733)
- ☑ Wright Medical Technol... (730)
- ☑ Ortho Development Corp... (680)
- ☑ Corentec Co., Ltd (671)
- ☑ Consensus Orthopedics,... (647)

less...

PATIENT HAD ADVERSE LOCAL TISSUE REACTION. COBALT SERUM 3.2 CHROMIUM SERUM 0.5, COBALT ASPIRATE 1300 CHROMIUM ASPIRATE 770. PATIENT UNDERWENT POST PRIMARY LEFT HIP REVISION, EXCHANGED 40MM HEAD AND LINER FOR 36MM LINER AND BIOLOX HEAD.
...REGARDING ALTR INVOLVING A V40 COCR LFIT HEAD 40MM/+8 WAS REPORTED. THE EVENT WAS NOT CONFIRMED. DEVICE EVALUATION NOT PERFORMED AS NO DEVICE WAS RETURNED. A REVIEW OF THE PROVIDED MEDICAL RECORDS BY A CLINICAL CONSULTANT INDICATED. NO CERTAIN ROOT CAUSE OF FAILURE CAN BE ESTABLISHED FOR THIS CASE DUE...

UNKNOWN HIP - Zimmer Biomet , 2015-11-19 , 5235657

...WAS RECEIVED BASED ON REVIEW OF A JOURNAL ARTICLE TITLED, ﷺMETAL ION LEVELS IN PATIENTS WITH MODULAR ACETABULAR HIP COMPONENTS, MATCHING CRCO LINERS WITH TITANIUM CUPS.ﷺ THE JOURNAL ARTICLE AIMED TO EXAMINE METAL ION BLOOD LEVELS IN TOTAL HIP REPLACEMENT PATIENTS WHO RECEIVED TITANIUM ACETABULAR CUPS COUPLED WITH COCR ACETABULAR LINERS; AND TO INVESTIGATE THE INFLUENCE OF PARAMETERS INCLUDING AGE AND GENDER. THE STUDY CONSISTED OF THIRTY-NINE (39) PATIENTS WHO WERE IMPLANTED WITH TITANIUM ACETABULAR CUPS, COCR LINERS AND MONOBLOCK STEMS....

R3 - Smith & Nephew , 2014-06-11 , 3867453

PAIN, WEAKNESS OF THE LEGS AND HIPS, ELEVATED COBALT AND CHROMIUM LEVELS, FLUID ACCUMULATIONS AROUND THE HIP, TISSUE DAMAGE, NECROSIS AND EXPOSURE TO METAL DEBRIS REPORTED.
IT WAS REPORTED THAT REVISION SURGERY WAS PERFORMED. THE PATIENT EXPERIENCED COBALT AND CHROMIUM LEVELS WHICH REPORTEDLY RESULTED IN A STROKE, PARALYSIS, AND BLOOD CLOTS.

TAPERLOC HIP FEMORAL STEM - Zimmer Biomet , 2009-09-01 , 1463416

The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

Reporter Occupation

Check All | Uncheck All

- ☑ OTHER (2,183,520)
- ☑ PHYSICIAN (1,140,783)
- ☑ PATIENT (800,191)
- ☑ NOT APPLICABLE (361,295)
- ☑ *blank* (355,333)
- ☑ HEALTH PROFESSIONAL (271,612)
- ☑ NURSE (212,994)
- ☑ OTHER HEALTH CARE PROF... (211,762)
- ☑ MEDICAL EQUIPMENT COMP... (210,626)
- ☑ UNKNOWN (183,060)
- ☑ BIOMEDICAL ENGINEER (161,707)
- ☑ ATTORNEY (149,801)
- ☑ RISK MANAGER (83,061)
- ☑ LAY USER/PATIENT (46,603)
- ☑ SERVICE AND TESTING PE... (35,801)
- ☑ DENTIST (34,730)
- ☑ PATIENT FAMILY MEMBER ... (32,191)
- ☑ NO INFORMATION (27,752)
- ☑ PHARMACIST (26,528)
- ☑ MEDICAL TECHNOLOGIST (16,176)

AUTO SUTURE POWERE MULTIFIRE ENDO GIA 60-3.5 - Medtronic , 1997-04-07 , 83210

DURING A THORACOSCOPIC BULLECTOMY PROCEDURE, THE INSTRUMENT DID NOT FIRE. THE SURGEON APPLIED ANOTHER DEVICE WITHOUT PT INJURY. 6/3/97-SUPPLEMENTAL REPORT #1 SUBMITTED TO FDA. DEVICE EVALUATION INDICATED AND CODES ENTERED IN H3 AND H6. THE STAPLE CARTRIDGE WAS NOT RETURNED FOR EVALUATION PREVENTING THE CO FROM RELIABLY DETERMINING THE EXACT CAUSE FOR THE DIFFICULTY REPORTED.

RADIFOCUS GUIDEWIRE - Terumo Corporation, Ashitaka , 2016-09-14 , 5950066

THE ACTUAL DEVICE WAS NOT RETURNED TO THE MANUFACTURING FACILITY FOR EVALUATION. THE INVESTIGATION HAS YET TO BE COMPLETED. A FOLLOW UP REPORT WILL BE SUBMITTED WHEN THE INVESTIGATION IS COMPLETE BUT NO LATER THAN 30 DAYS FROM THE DATE THAT THIS REPORT WAS SENT. A REVIEW OF THE DEVICE HISTORY RECORD AND PRODUCT RELEASE DECISION CONTROL SHEET OF THE PRODUCT CODE/LOT# COMBINATION WAS CONDUCTED WITH NO RELEVANT FINDINGS. A SEARCH OF THE COMPLAINT FILE FOUND NO REPORT OF THIS NATURE WITH THE INVOLVED PRODUCT/LOT# COMBINATION. (B)(4). ALL...

SPRINT QUATTRO SECURE - Medtronic , 2009-08-10 , 1433797

Problem: Oversensing

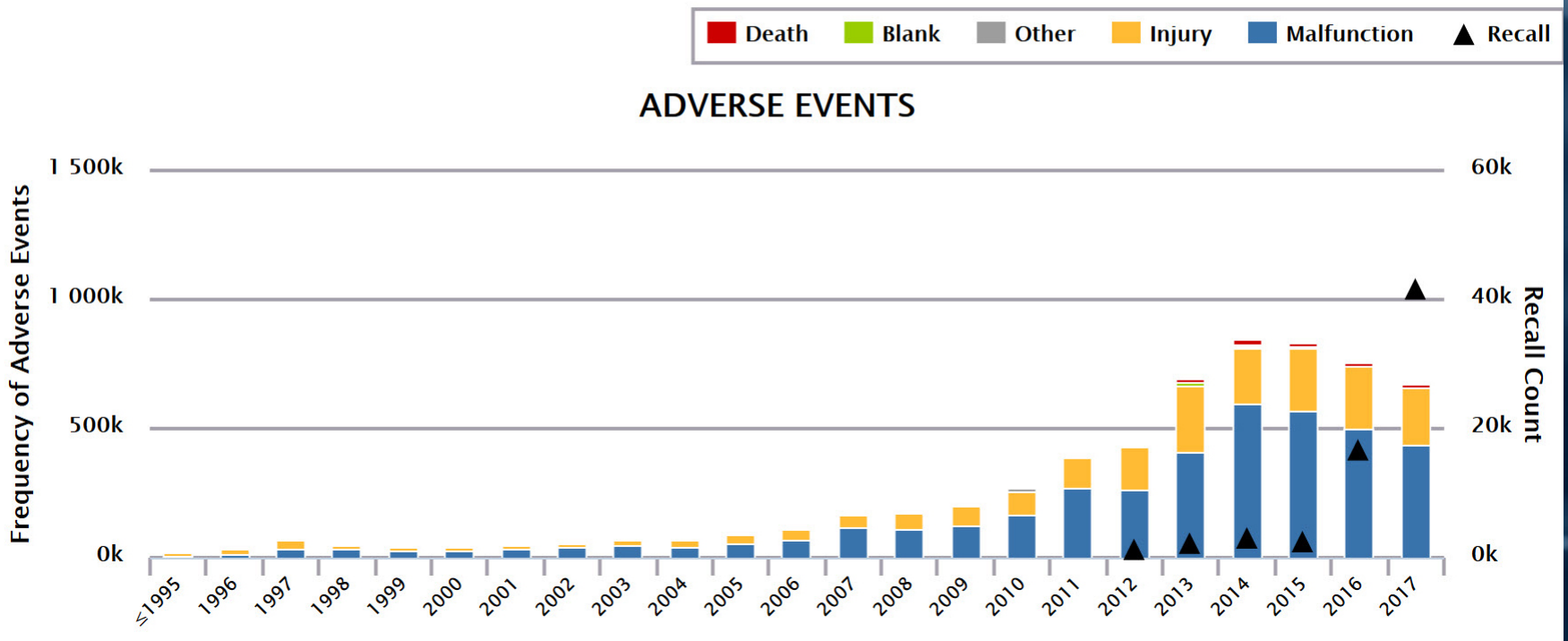
THIS EVENT OCCURRED OUTSIDE THE US WHERE THE SAME MODEL IS DISTRIBUTED. ALL INFORMATION PROVIDED IS INCLUDED IN THIS REPORT. IF ADDITIONAL RELEVANT INFORMATION IS RECEIVED, A SUPPLEMENTAL REPORT WILL BE SUBMITTED. PATIENT INFORMATION IS NOT GENERALLY AVAILABLE DUE TO CONFIDENTIALITY CONCERNS. IT WAS REPORTED THAT THERE WAS OVERSENSING, NOISE, AND INSULATION DAMAGE ASSUMED FOLLOWING AN X-RAY. THE LEAD WAS REPLACED. NO PATIENT COMPLICATIONS HAVE BEEN REPORTED AS A RESULT OF THIS EVENT, AND THE PATIENT'S STATUS WAS REPORTED AS "GOOD".

INGENIO - Boston Scientific , 2016-07-26 , 5823939

ADDITIONAL INFORMATION HAS BEEN REQUESTED. THIS REPORT WILL BE UPDATED SHOULD FURTHER INFORMATION

Showing 1-25 of 8,078,755 in 3.500 seconds.

Search Preview | Chart (Beta)



The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

Search by Date

- ☐ Event Date
- ☐ Manufacturer Rec'd Date
- ☐ Report Date
- ☐ FDA Received Date

Record Type

Check All | Uncheck All

- ☑ Adverse Event Report (215,908)
- ☑ GUDID Record (3,384)
- ☑ Recall (291)

Report Type

Check All | Uncheck All

- ☑ Death (128,030)
- ☑ Malfunction (44,890)
- ☑ Injury (37,245)
- ☑ Other (2,285)
- ☑ *blank* (1,158)

Report Source

Check All | Uncheck All

- ☑ Manufacturer report (205,245)
- ☑ User Facility report (5,876)

criticalEvent

☑ Use Critical Event Thesaurus (219,583)

Keywords Show

First | Previous | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Next | Last

25 *per page*

Showing 1-25 of 219,583 in 2.157 seconds.

Search Preview | *Chart (Beta)*

DC BEAD - Biocompatibles Uk Ltd , 2016-02-25 , 5459677

THE PATIENT DIED BY LIFE [DEATH]. DC BEADS WERE OBSERVED IN TESTES. [PROCEDURAL COMPLICATION] . CASE DESCRIPTION: INITIAL INFORMATION RECEIVED ON (B)(6) 2016: THIS SPONTANEOUS MEDICAL DEVICE CASE WAS RECEIVED FROM A PHYSICIAN VIA THE COMPANY DISTRIBUTOR CONCERNING MALE PATIENT OF AN UNSPECIFIED AGE. THE PATIENT'S MEDICAL HISTORY... ...RECEIVED DC BEAD (DOSE, LOT NUMBER AND EXPIRATION DATE UNKNOWN) AS TRANSCATHETER ARTERIAL CHEMOEMBOLIZATION (TACE) FOR MULTIPLE HEPATOCELLULAR CARCINOMA (HCC) ON AN UNKNOWN DATE. ON AN UNKNOWN DATE, THE PATIENT

HOMECHOICE - Baxter , 2014-01-08 , 3562955

IT WAS REPORTED THAT A PERITONEAL DIALYSIS (PD) PATIENT (PT) PASSED AWAY . THE PT WAS HOSPITALIZED (DATE UNSPECIFIED) PRIOR TO DEATH . DIANEAL THERAPY WAS ONGOING AT THE TIME THE PATIENT EXPIRED . ON AN UNREPORTED DATE, THE PT EXPERIENCED CHEST PAIN AND WAS SUBSEQUENTLY HOSPITALIZED. THE PATIENT DIED WHILE IN THE HOSPITAL. THE CAUSE OF DEATH WAS REPORTED BY THE PATIENT REPRESENTATIVE AS CARDIAC FAILURE BUT THIS WAS NOT CONFIRMED BY THE PERITONEAL DIALYSIS REGISTERED NURSE. AN AUTOPSY WAS NOT PERFORMED. ADDITIONAL INFORMATION WAS REQUESTED BUT...

The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

CIDEX OPA SOLUTION - Johnson & Johnson , 2009-01-20 , 2228319

Problem: Use of Device Issue

THE CUSTOMER ALLEGED THAT AFTER DISINFECTING AN OLYMPUS SCOPE WITH CIDEX OPA, A CULTURE FROM THE SCOPE TESTED POSITIVE FOR (B)(6). THE CUSTOMER STATED THAT ONLY ONE SCOPE HAD TESTED POSITIVE FOR (B)(6) BUT THE FACILITY WILL BE TESTING ALL THE SCOPES. THE CUSTOMER STATED THAT A PRE-CLEANING PROCEDURE WAS PERFORMED. THE CUSTOMER DID NOT KNOW THE COMPLETE SUBMERGE TIME IN THE CIDEX OPA SOLUTION. AN ASP PRODUCT SUPPORT SPECIALIST REVIEWED THE INSTRUCTION FOR USE (IFU) FOR... ...5 MINS. THE CUSTOMER STATED THE SCOPE THAT TESTED POSITIVE FOR (B)(6)...

OLYMPUS EVIS EXERA BRONCOVIDEOSCOPE - Olympus , 2011-10-25 , 2317085

Problem: No Known Device Problem

THIS REPORT IS TO ADDRESS PT 4 OF 4 PTS ASSOCIATED WITH MICROORGANISM CONTAMINATION FOLLOWING BRONCHOSCOPY. OLYMPUS FOLLOWED UP WITH THE USER FACILITY TO OBTAIN ADD'L INFO REGARDING THE REPORT, AND WAS INFORMED THAT 1 OF 7 PTS TESTED POSITIVE FOR (B)(6) IN BAL SAMPLES AND 4 OF 7 PTS TESTED POSITIVE FOR (B)(6) IN SPUTUM CULTURES. THREE PTS DIAGNOSED WITH (B)(6) DID NOT UNDERGO BRONCHOSCOPY. THE PT IN THIS REPORT WAS SAID TO HAVE UNDERGONE DIAGNOSTIC BRONCHOSCOPY. THE PT'S BAL WASHINGS TESTED POSITIVE FOR (B)(6) WAS POSITIVE FOR (B)(6). THE PT...

Device Name

Check All | Uncheck All

- ☑ Set, Administration, F... (909)
- ☑ System, Peritoneal, Au... (489)
- ☑ Pump, Infusion, Insulin (411)
- ☑ Controller, Temperatur... (374)
- ☑ Dialyzer, High Permeab... (374)
- ☑ Bronchoscope (Flexible... (329)
- ☑ Ventricular (Assisst) ... (312)
- ☑ Duodenoscope And Acces... (245)
- ☑ Colonoscope And Access... (232)
- ☑ Coronary Drug-Eluting ... (168)
- ☑ System, Test, Automate... (167)
- ☑ Accessories, Soft Lens... (136)
- ☑ Analyzer, Chemistry (P... (124)
- ☑ Stimulator, Spinal-Cor... (109)
- ☑ Device, Hemostasis, Va... (106)
- ☑ Stimulator, Autonomic ... (91)
- ☑ Mesh, Surgical, Polymeric (76)
- ☑ *blank* (75)
- ☑ Stimulator, Spinal-Cor... (72)
- ☑ Replacement Heart-Valve (60)

less...

SORIN HEATER-COOLER SYSTEM 3T - LivaNova , 2015-12-01 , 5256348

Problem: Bacterial contamination of device

SORIN GROUP (B)(4) RECEIVED A REPORT THAT THE SORIN HEATER-COOLER SYSTEM 3T TESTED POSITIVE FOR MULTIPLE TYPES OF BACTERIA. THIS ISSUE WAS DISCOVERED DURING MAINTENANCE, SO THERE IS NO KNOWN PATIENT INVOLVEMENT.
...THIS MEDWATCH REPORT IS BEING FILED ON BEHALF OF SORIN GROUP (B)(4). SORIN GROUP (B)(4) RECEIVED A REPORT THAT THE SORIN HEATER-COOLER SYSTEM 3T TESTED POSITIVE FOR MULTIPLE TYPES OF BACTERIA. THIS ISSUE WAS DISCOVERED DURING MAINTENANCE, SO THERE IS NO KNOWN PATIENT INVOLVEMENT. A REVIEW OF THE DHR COULD NOT IDENTIFY ANY...

HEARTMATE II LVAS - St. Jude , 2016-07-11 , 5784527

...VENTRICULAR ASSIST DEVICE (LVAD) ON (B)(6) 2011. IT WAS REPORTED THAT ON (B)(6) 2016, THE PATIENT PRESENTED TO THE EMERGENCY DEPARTMENT WITH COMPLAINT OF EPISTAXIS, LIGHTHEADEDNESS, GENERALIZED MALAISE, FATIGUE, CHEST PAIN, HEADACHE, FEVER, CHILLS, AND VOMITING. URINE CULTURES WERE POSITIVE FOR ESCHERICHIA COLI AND BLOOD CULTURES WERE POSITIVE FOR STAPHYLOCOCCUS. THE BACTEREMIA WAS REPORTED TO BE ASSOCIATED WITH AN LVAD RELATED CHRONIC INFECTION. THE PATIENT WAS ALSO EXPERIENCING A GASTROINTESTINAL BLEED. THE PATIENT WAS ADMITTED AND...

EVIS EXERA II ULTRASONIC BRONCHOFIBERVIDEOSCOPE - Olympus , 2016-03-30 , 5536858

Problem: Fungus in device environment

...FACILITY TO OBSERVE THEIR REPROCESSING PRACTICES. ESS VISITED THE FACILITY ON (B)(6) 2016 TO REVIEW THE REPROCESSING STEPS AND FOUND NO DEVIATIONS TO THE REPROCESSING PROCEDURE. DURING THE IN-SERVICE VISIT, IT WAS FOUND THAT ONE OF THE SINKS IN THE ENDOSCOPY ROOM HAD TESTED POSITIVE FOR AN UNSPECIFIED FUNGUS. ESS AND A FIELD SERVICE ENGINEER (FSE) OBSERVED THAT THE PUR WATER PRE-FILTER

Report Type

Check All | Uncheck All

- ☑ Injury (36,022)
- ☑ Malfunction (2,441)
- ☑ Death (378)
- ☑ Other (280)
- ☑ *blank* (102)

Report Source

Check All | Uncheck All

- ☑ Manufacturer report (38,611)
- ☑ Voluntary report (412)
- ☑ User Facility report (155)
- ☑ Distributor report (45)

Reporter Occupation

Check All | Uncheck All

- ☑ ATTORNEY (18,605)
- ☑ PHYSICIAN (9,999)
- ☑ OTHER (6,535)
- ☑ PATIENT (1,446)
- ☑ HEALTH PROFESSIONAL (863)
- ☑ NOT APPLICABLE (435)
- ☑ *blank* (266)
- ☑ SERVICE PERSONNEL (221)
- ☑ UNKNOWN (197)

BOSTON SCIENTIFIC CORP BECAME AWARE OF A REPORTABLE EVENT THAT WAS REPORTED AS INVOLVING 6-605 COBALT CHROMIUM (COCR) ALLOY STENT; HOWEVER, BOSTON SCIENTIFIC DOES NOT MFR 6-605 COBALT CHROMIUM (COCR) ALLOY STENT. AS REPORTED: IN 2007, MY HUSBAND HAD AN ANGIOPLASTY PERFORMED. THREE DAYS LATER, HE HAD A STENT IMPLANT. IT IS A STENT WITH 6-605 COBALT CHROMIUM (COCR) ALLOY. ACCORDING TO THE PATIENT'S GUIDE TO STENT IMPLANTATION BOOKLET IT STATES "PERSONS ALLERGIC TO L-605 COBALT CHROMIUM (COCR) ALLOW MAY SUFFER AN ALLERGIC REACTION TO THIS... COBALT

UNKNOWN HIP - Zimmer Biomet , 2016-03-23 , 5521014

Problem: Material erosion

THE USER FACILITY IS OUTSIDE OF THE UNITED STATES. CURRENT INFORMATION IS INSUFFICIENT TO PERMIT CONCLUSIONS AS TO THE CAUSES OF THE EVENTS. EVENT DETAILS AND PRODUCT IDENTIFICATION WAS NOT PROVIDED FOR THE PATIENTS MENTIONED IN THE JOURNAL ARTICLE. BRAND NAME - UNKNOWN CERAMIC AND COBALT - CHROMIUM HEADS. INITIAL REPORTER NAME - THIS ARTICLE WAS WRITTEN BY SOK CHUEN TAN, ADRIAN C.K. LAU, CHRISTOPHER DEL BALSO, JAMES L. HOWARD, BRENT A. LANTING, AND MATTHEW G. TEETER. DEVICE LOCATION UNKNOWN.
...: CERAMIC AND OXIDIZED ZIRCONIUM VS COBALT ...

R3 COCR LINER - Smith & Nephew , 2016-04-13 , 5573436

IT WAS REPORTED THAT RIGHT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM LEVELS.
IT WAS REPORTED THAT RIGHT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM LEVELS.

R3 COCR LINER - Smith & Nephew , 2016-04-14 , 5576549

IT WAS REPORTED THAT LEFT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM LEVELS.
IT WAS REPORTED THAT LEFT HIP REVISION SURGERY WAS PERFORMED DUE TO ELEVATED COBALT AND CHROMIUM

Search by Date

- ☐ Event Date
- ☐ Manufacturer Rec'd Date
- ☐ Report Date
- ☐ FDA Received Date

Record Type

Check All | Uncheck All

- ☑ Adverse Event Report (215,908)
- ☑ GUDID Record (3,384)
- ☑ Recall (291)

Report Type

Check All | Uncheck All

- ☑ Death (128,030)
- ☑ Malfunction (44,890)
- ☑ Injury (39,545)
- ☑ Other (2,285)
- ☑ *blank* (1,158)

Report Source

Check All | Uncheck All

- ☑ Manufacturer report (205,245)
- ☑ User Facility report (5,876)

criticalEvent

☑ Use Critical Event Thesaurus (219,583)

Keywords Show

First | Previous | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Next | Last

25 *per page*

Showing 1-25 of 219,583 in 2.157 seconds.

Search Preview | *Chart (Beta)*

DC BEAD - Biocompatibles Uk Ltd , 2016-02-25 , 5459677

THE PATIENT DIED BY LIFE [DEATH]. DC BEADS WERE OBSERVED IN TESTES. [PROCEDURAL COMPLICATION] . CASE DESCRIPTION: INITIAL INFORMATION RECEIVED ON (B)(6) 2016: THIS SPONTANEOUS MEDICAL DEVICE CASE WAS RECEIVED FROM A PHYSICIAN VIA THE COMPANY DISTRIBUTOR CONCERNING MALE PATIENT OF AN UNSPECIFIED AGE. THE PATIENT'S MEDICAL HISTORY... ...RECEIVED DC BEAD (DOSE, LOT NUMBER AND EXPIRATION DATE UNKNOWN) AS TRANSCATHETER ARTERIAL CHEMOEMBOLIZATION (TACE) FOR MULTIPLE HEPATOCELLULAR CARCINOMA (HCC) ON AN UNKNOWN DATE. ON AN UNKNOWN DATE, THE PATIENT

HOMECHOICE - Baxter , 2014-01-08 , 3562955

IT WAS REPORTED THAT A PERITONEAL DIALYSIS (PD) PATIENT (PT) PASSED AWAY . THE PT WAS HOSPITALIZED (DATE UNSPECIFIED) PRIOR TO DEATH . DIANEAL THERAPY WAS ONGOING AT THE TIME THE PATIENT EXPIRED . ON AN UNREPORTED DATE, THE PT EXPERIENCED CHEST PAIN AND WAS SUBSEQUENTLY HOSPITALIZED. THE PATIENT DIED WHILE IN THE HOSPITAL. THE CAUSE OF DEATH WAS REPORTED BY THE PATIENT REPRESENTATIVE AS CARDIAC FAILURE BUT THIS WAS NOT CONFIRMED BY THE PERITONEAL DIALYSIS REGISTERED NURSE. AN AUTOPSY WAS NOT PERFORMED. ADDITIONAL INFORMATION WAS REQUESTED BUT...

The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

Record Type

Check All | Uncheck All

- ☑ Adverse Event Report (6,591,307)
- ☑ GUDID Record (1,419,978)
- ☑ Recall (67,470)

Report Type

Check All | Uncheck All

- ☑ Malfunction (4,123,403)
- ☑ Injury (2,183,714)
- ☑ Death (128,422)
- ☑ Other (100,383)
- ☑ *blank* (55,385)

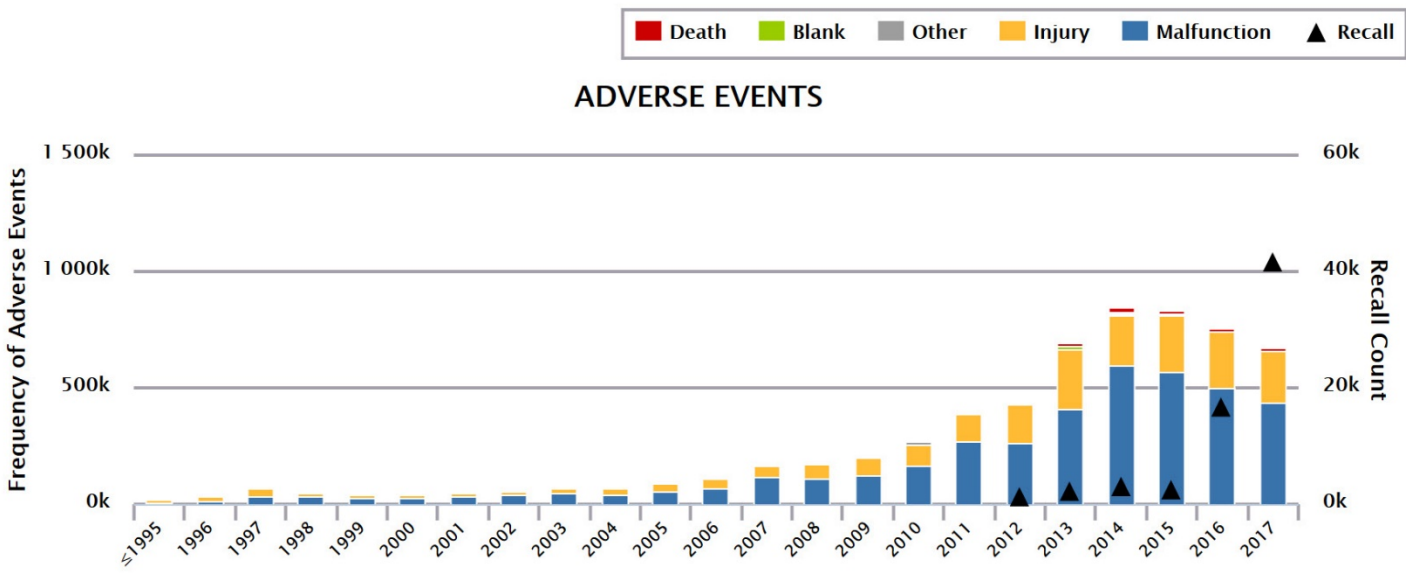
Report Source

Check All | Uncheck All

- ☑ Manufacturer report (6,344,293)
- ☑ Voluntary report (106,405)

Showing 1-25 of 8,078,755 in 3.500 seconds.

Search Preview | Chart (Beta)



The Current State of Adverse Events

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

Device Name

Check All | Uncheck All

- ☑ Set, Administration, F... (909)
- ☑ System, Peritoneal, Au... (489)
- ☑ Pump, Infusion, Insulin (411)
- ☑ Controller, Temperatur... (374)
- ☑ Dialyzer, High Permeab... (374)
- ☑ Bronchoscope (Flexible... (329)
- ☑ Ventricular (Assisst) ... (312)
- ☑ Duodenoscope And Acces... (245)
- ☑ Colonoscope And Access... (232)
- ☑ Coronary Drug-Eluting ... (168)
- ☑ System, Test, Automate... (167)
- ☑ Accessories, Soft Lens... (136)
- ☑ Analyzer, Chemistry (P... (124)
- ☑ Stimulator, Spinal-Cor... (109)
- ☑ Device, Hemostasis, Va... (106)
- ☑ Stimulator, Autonomic ... (91)
- ☑ Mesh, Surgical, Polymeric (76)
- ☑ *blank* (75)
- ☑ Stimulator, Spinal-Cor... (72)
- ☑ Replacement Heart-Valve (60)

less...

SORIN HEATER-COOLER SYSTEM 3T - LivaNova , 2015-12-01 , 5256348

Problem: Bacterial contamination of device

SORIN GROUP (B)(4) RECEIVED A REPORT THAT THE SORIN HEATER-COOLER SYSTEM 3T TESTED POSITIVE FOR MULTIPLE TYPES OF BACTERIA. THIS ISSUE WAS DISCOVERED DURING MAINTENANCE, SO THERE IS NO KNOWN PATIENT INVOLVEMENT.
...THIS MEDWATCH REPORT IS BEING FILED ON BEHALF OF SORIN GROUP (B)(4). SORIN GROUP (B)(4) RECEIVED A REPORT THAT THE SORIN HEATER-COOLER SYSTEM 3T TESTED POSITIVE FOR MULTIPLE TYPES OF BACTERIA. THIS ISSUE WAS DISCOVERED DURING MAINTENANCE, SO THERE IS NO KNOWN PATIENT INVOLVEMENT. A REVIEW OF THE DHR COULD NOT IDENTIFY ANY...

HEARTMATE II LVAS - St. Jude , 2016-07-11 , 5784527

...VENTRICULAR ASSIST DEVICE (LVAD) ON (B)(6) 2011. IT WAS REPORTED THAT ON (B)(6) 2016, THE PATIENT PRESENTED TO THE EMERGENCY DEPARTMENT WITH COMPLAINT OF EPISTAXIS, LIGHTHEADEDNESS, GENERALIZED MALAISE, FATIGUE, CHEST PAIN, HEADACHE, FEVER, CHILLS, AND VOMITING. URINE CULTURES WERE POSITIVE FOR ESCHERICHIA COLI AND BLOOD CULTURES WERE POSITIVE FOR STAPHYLOCOCCUS. THE BACTEREMIA WAS REPORTED TO BE ASSOCIATED WITH AN LVAD RELATED CHRONIC INFECTION. THE PATIENT WAS ALSO EXPERIENCING A GASTROINTESTINAL BLEED. THE PATIENT WAS ADMITTED AND...

EVIS EXERA II ULTRASONIC BRONCHOFIBERVIDEOSCOPE - Olympus , 2016-03-30 , 5536858

Problem: Fungus in device environment

...FACILITY TO OBSERVE THEIR REPROCESSING PRACTICES. ESS VISITED THE FACILITY ON (B)(6) 2016 TO REVIEW THE REPROCESSING STEPS AND FOUND NO DEVIATIONS TO THE REPROCESSING PROCEDURE. DURING THE IN-SERVICE VISIT, IT WAS FOUND THAT ONE OF THE SINKS IN THE ENDOSCOPY ROOM HAD TESTED POSITIVE FOR AN UNSPECIFIED FUNGUS. ESS AND A FIELD SERVICE ENGINEER (FSE) OBSERVED THAT THE PUR WATER PRE-FILTER

Device Name

Check All | Uncheck All

- ☑ Set, Administration, F... (909)
- ☑ System, Peritoneal, Au... (489)
- ☑ Pump, Infusion, Insulin (411)
- ☑ Controller, Temperatur... (374)
- ☑ Dialyzer, High Permeab... (374)
- ☑ Bronchoscope (Flexible... (329)
- ☑ Ventricular (Assisst) ... (312)
- ☑ Duodenoscope And Acces... (245)
- ☑ Colonoscope And Access... (232)
- ☑ Coronary Drug-Eluting ... (168)
- ☑ System, Test, Automate... (167)
- ☑ Accessories, Soft Lens... (136)
- ☑ Analyzer, Chemistry (P... (124)
- ☑ Stimulator, Spinal-Cor... (109)
- ☑ Device, Hemostasis, Va... (106)
- ☑ Stimulator, Autonomic ... (91)
- ☑ Mesh, Surgical, Polymeric (76)
- ☑ *blank* (75)
- ☑ Stimulator, Spinal-Cor... (72)
- ☑ Replacement Heart-Valve (60)

less...

SORIN HEATER-COOLER SYSTEM 3T - LivaNova , 2015-12-01 , 5256348

Problem: Bacterial contamination of device

SORIN GROUP (B)(4) RECEIVED A REPORT THAT THE SORIN HEATER-COOLER SYSTEM 3T TESTED POSITIVE FOR MULTIPLE TYPES OF BACTERIA. THIS ISSUE WAS DISCOVERED DURING MAINTENANCE, SO THERE IS NO KNOWN PATIENT INVOLVEMENT.
...THIS MEDWATCH REPORT IS BEING FILED ON BEHALF OF SORIN GROUP (B)(4). SORIN GROUP (B)(4) RECEIVED A REPORT THAT THE SORIN HEATER-COOLER SYSTEM 3T TESTED POSITIVE FOR MULTIPLE TYPES OF BACTERIA. THIS ISSUE WAS DISCOVERED DURING MAINTENANCE, SO THERE IS NO KNOWN PATIENT INVOLVEMENT. A REVIEW OF THE DHR COULD NOT IDENTIFY ANY...

HEARTMATE II LVAS - St. Jude , 2016-07-11 , 5784527

...VENTRICULAR ASSIST DEVICE (LVAD) ON (B)(6) 2011. IT WAS REPORTED THAT ON (B)(6) 2016, THE PATIENT PRESENTED TO THE EMERGENCY DEPARTMENT WITH COMPLAINT OF EPISTAXIS, LIGHTHEADEDNESS, GENERALIZED MALAISE, FATIGUE, CHEST PAIN, HEADACHE, FEVER, CHILLS, AND VOMITING. URINE CULTURES WERE POSITIVE FOR ESCHERICHIA COLI AND BLOOD CULTURES WERE POSITIVE FOR STAPHYLOCOCCUS. THE BACTEREMIA WAS REPORTED TO BE ASSOCIATED WITH AN LVAD RELATED CHRONIC INFECTION. THE PATIENT WAS ALSO EXPERIENCING A GASTROINTESTINAL BLEED. THE PATIENT WAS ADMITTED AND...

EVIS EXERA II ULTRASONIC BRONCHOFIBERVIDEOSCOPE - Olympus , 2016-03-30 , 5536858

Problem: Fungus in device environment

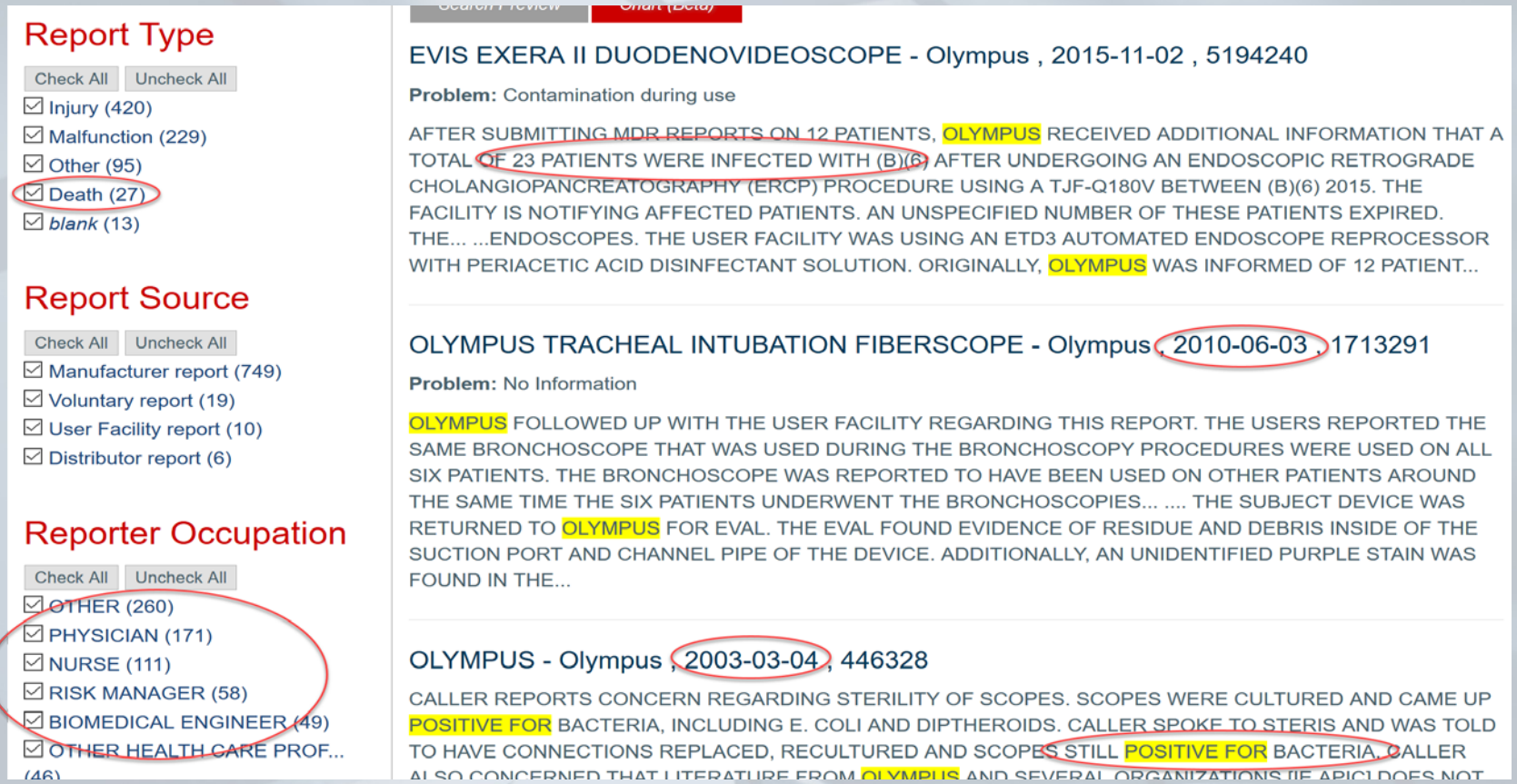
...FACILITY TO OBSERVE THEIR REPROCESSING PRACTICES. ESS VISITED THE FACILITY ON (B)(6) 2016 TO REVIEW THE REPROCESSING STEPS AND FOUND NO DEVIATIONS TO THE REPROCESSING PROCEDURE. DURING THE IN-SERVICE VISIT, IT WAS FOUND THAT ONE OF THE SINKS IN THE ENDOSCOPY ROOM HAD TESTED POSITIVE FOR AN UNSPECIFIED FUNGUS. ESS AND A FIELD SERVICE ENGINEER (FSE) OBSERVED THAT THE PUR WATER PRE-FILTER

Although duodenoscopes and heater-coolers have received the most attention by the media, peritoneal dialysis machines, bronchoscopes, colonoscopes and cystoscopes are also testing positive for drug resistant, dangerous bacteria.

Patterns Across Device Types

DEVICE EVENTS™

Scenario: Your hospital is named in a lawsuit for use of a device. View when the device company knew of the issues.



Search on Contaminations in Olympus scopes

DEVICE EVENTS™

Searching for Contaminations

- Positive for b(6): 1083 reports
- Mycobacteria, NTM: 146 reports then; 1,077 now
- CRE, ESBL: 140 reports then; 302 now
- Pseudomonas, klebsiella: 324 reports then; 380 now
- Candida lipolytica: 31 reports then; 38 now
- MRSA: Critical Events

Reports are redacted more often than they are not

DEVICE EVENTS™

DEVICE EVENTS™

DEVICE EVENTS™