

各国不良事件查询方式

- 1、美国 FDA
- 2、澳大利亚 TGA
- 3、加拿大
- 4、英国 MHRA
- 5、日本 PMDA
- 6、中国
- 7、德国 BfArM

一、FDA

- 网站: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

打开网页即是
以下界面

① 不良事件

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

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 reporters¹ (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](#)

Product Problem

Product Class

Event Type Manufacturer

Model Number Report Number

Brand Name Product Code

Date Report Received by FDA (mm/dd/yyyy) to

[Go to Simple Search](#) Records per Report Page [Clear Form](#)

Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters¹ (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. Because of this,

Other Databases

- 510(k)s
- De Novo
- CDRH Export (CEC)
- CDRH FOIA E Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

根据现有信息查询。
如制造商



MAUDE - Manufacturer and User Facility Device Experience

[FDA Home](#) [Medical Devices](#) [Databases](#)[510\(k\)](#) | [DeNovo](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [HDE](#) | [Classification](#) | [Standards](#)
[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#) | [TPLC](#)**①、召回**31 records meeting your search criteria returned- **Manufacturer: Well Lead****导出清单**

New Search		Export to Excel ? Help
Manufacturer		Date Report Received
WELL LEAD	SUNMED	05/07/2020
WELL LEAD	SUNMED	04/30/2020
WELL LEAD	SUNMED	04/30/2020
WELL LEAD MEDICAL CO. LTD	CURAPLEX 36619 NPA KIT	01/04/2019
WELL LEAD MEDICAL CO. LTD	CURAPLEX NASOPHARYNGEAL AIRWAY	01/04/2019
WELL LEAD	SUNMED	10/02/2018
WELL LEAD	SUNMED	10/02/2018
WELL LEAD	SUNMED	06/12/2018
WELL LEAD MEDICAL	ET TUBE W/ STYLET, CUFFED SIZE 7	09/22/2016
GUANGZHOU WELL LEAD	TUBING SUCTION 9/32"	10/26/2015
WELL LEAD MEDICAL	TUBE 6MM X 12 FT C&B	07/24/2015
WELL LEAD MEDICAL CO. LTD	COURCOUR MARK INTUBATION STYLET	03/22/2015

查看单个事件详细信息

FDA U.S. FOOD & DRUG
ADMINISTRATION

SEARCH

Home	Food	Drugs	Medical Devices	Radiation-Emitting Products	Vaccines, Blood & Biologics	Animal & Veterinary	Cosmetics	Tobacco Products
------	------	-------	-----------------	-----------------------------	-----------------------------	---------------------	-----------	------------------

召回信息

[FDA Home](#) [Medical Devices](#) [Databases](#)

This database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") indicates the date FDA classified the recall, it does not necessarily mean that the recall is new. [CBER recall information is available here.](#) [More about Medical Device Recalls](#)

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device
- FDA Guidance
- Humanitarian Exemptions
- Medsur
- Premarket
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

输入现有信息进行查询。
如产品名称、产品code
等

~~Search Database~~

Help

Product Name

Product Code

FFL

In Vitro Devices


Recall Class

All ▼

PMA/510(K) Number

Recall Date

Page 10

 Recall Number

Recall Number

Reason for Recall

--

Recalling Firm

Root Cause

_____ ▼

Sort by

Date Record Classified (Descending) ▼

Quick Search

[Clear Form](#)

Search

② 召回信息

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Medical Device Recalls

FDA Home Medical Devices Databases

1 to 7 of 7 Results
Product Code: FFL

Results per Page

导出清单

New Search Export To Excel ? Help

Product Description	Recall Class	FDA Recall Posting Date	Recalling Firm
Bard Dimension Stone Basket Product Usage: The Bard Dimension Stone Basket Is A Teardrop-Shaped...	2	10/31/2014	C.R. Bard, Inc.
Stone Retrieval Basket Model #: BOS390-105 Used To Entrap And Remove Renal Stones And Calculi Via ...	2	01/13/2009	Sterilmed Inc
Boston Scientific Brand Zero Tip Nitinol Stone Retrieval Basket, 12 Mm, 90 Cm, 1.9 Fr., Sterile, Lat...	2	02/08/2006	Boston Scientific Corp
Boston Scientific Brand Zero Tip Nitinol Stone Retrieval Basket, 12 Mm, 120 Cm, 1.9 Fr., Sterile, La...	2	02/08/2006	Boston Scientific Corp
V. Mueller Pfister-Schwartz Stone Retriever 4-Wire Basket, Without Filiform Tip; A Sterile, Single U...	2	11/05/2004	Cardinal Health
Bard® Dimension® Stone Basket, Rx Only, Sterile, C.R.Bard, Inc., Covington, GA 30014	2	01/09/2004	C.R. Bard, Inc., Urological Division
Bard® Platinum Class® II Flat Wire Stone Basket, Ureteral Stone Dislodger, Rx Only, Sterile, C.R.Bar...	2	01/09/2004	C.R. Bard, Inc., Urological Division

Page Last Updated: 01/22/2021

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

二、澳大利亚

- 网站: <https://apps.tga.gov.au/Prod/sara/arn-entry.aspx>

Australian Government
Department of Health
Therapeutic Goods Administration

Search

Home Safety information Consumers Health professionals Industry About the TGA News room

① 召回信息

Safety information

- Product recalls
 - Recall actions
 - About recall actions
 - Overseas recalls
 - Alerts
 - Early warning system
 - Reporting problems
 - Safety information & education**

② 不良事件

Home > Safety information > Product recalls

A- A+ Share

System for Australian Recall Actions

Please refer to [related information](#) for instructions on how to search SARA.

Important information!

This Database holds information on recall actions that have been undertaken in Australia since 1 July 2012. Recall actions are included into the SARA two days (excluding weekends) after the decision between the responsible entity and the TGA to commence the recall action. This allows time for the responsible entity to distribute the recall communication. In certain circumstances (e.g. consumer level recall actions and recall actions involving implantable medical devices), notices are published on the [alerts page](#).

Note: If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional.

Related information

- [SARA: questions and answers](#)
- [About recall actions](#)
- [Instructions for searching the SARA](#)
- [SARA: about the search results](#)
- [Overseas recalls](#)

Search the System for Australian Recall Actions

1. Select product type [\[Further information about selecting a product type\]](#)

All

① 召回信息

Safety information

- Product recalls
 - Recall actions**
 - About recall actions
 - Overseas recalls
- Alerts
- Early warning system
- Reporting problems
- Safety information & education

[Home](#) > [Safety information](#) > [Product recalls](#)

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Related information

- [SARA: questions and answers](#)
- [About recall actions](#)
- [Instructions for searching the SARA](#)
- [SARA: about the search results](#)
- [Overseas recalls](#)

Search the System for Australian Recall Actions

1. Select product type [\[Further information about selecting a product type\]](#)

All ▼

2. Select products [\[Further information about selecting a product\]](#)

Leave blank to search all recall actions or type at least 3 letters or 5 numbers for

Enter a product name, active ingredient, or ARTG number.


3. Select date range [\[Further information about the date range\]](#)

From	2012	July ▼	1 ▼
To	2021	January ▼	22 ▼

Recall actions from the past two days will not be shown in the system. Why?

输入商品名或其他信息

② 不良事件数据库



Australian Government
Department of Health
Therapeutic Goods Administration

Search TGA

HomeSafety informationConsumersHealth professionalsIndustryAbout the TGANews room

Safety information

- Report a problem or side effect
- Alerts
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- Prescription opioids
- Medicine shortages
- Early warning system
- Black Triangle Scheme
- Safety information & education**
 - Medicines safety
 - Medical devices safety
 - Database of Adverse Event Notifications (DAEN)**
 - COVID-19 vaccines

Home » Safety information » Safety information & education

A- A+ Share

Database of Adverse Event Notifications (DAEN)


30 October 2018

The Therapeutic Goods Administration (TGA) receives adverse event reports associated with medicines and medical devices. These reports come from a wide range of sources, including members of the public, general practitioners, nurses, other health professionals and the therapeutic goods industry.

There are two search facilities below:

- DAEN - medicines** provides information about adverse events related to **medicines and vaccines** used in Australia.
- DAEN - medical devices** provides information about adverse events related to **medical devices** used in Australia.

DAEN - medicines




The Database of Adverse Event Notifications - medicines contains information from reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia.

[Search DAEN - medicines](#)

More information about DAEN - medicines

- [Consumer questions and answers: DAEN - medicines](#)
- Consumer questions and answers about the DAEN -

DAEN - medical devices



The Database of Adverse Event Notifications - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia.

[Search DAEN - medical devices](#)

More information about DAEN - medical devices

- Consumer questions and answers: DAEN - medical

1、安全信息

2、不良事件

3、医疗器械

Search the DAEN - medical devices

You must select one or more medical devices and a date range.

1. Select medical devices [\[Further information about selecting a medical device\]](#)

Well Lead

Searching, please wait...

Devices found for 'Well...'

None selected

- ☐ Medline Assembly Australia Pty Ltd - Medline Haemostat Medline Haemostat Spencer **Wells** 20cm Straight - Surgical procedure kit, obstetrical/gynaecological, single-use, medicated (*Surgical procedure kit, obstetrical/gynaecological, single-use, medicated*)
- ☐ Medline International Two Australia Pty Ltd - **Wellness** Plus Foldable Transport Wheelchair (*Transport wheelchair, collapsible*)
- ☐ **Well** Lead Medical Co Ltd - DISP SIL REINFORCD/FLEX LMA SIZE 4 - Airway, laryngeal, single-use (*Airway, laryngeal, single-use*)
- ☐ **Well** Lead Medical Co Ltd - Pro-breathe LMA size 2 (*Airway, laryngeal, single-use*)
- ☐ **Well** Lead Medical Co Ltd - Introducer/Bougie Adult (*Tube, tracheal*)

2. Select date range [\[Further information about the date range\]](#)

From 2012 July 1
To 2020 October 7

Reports from the last three months have not been included in the database.
[Why?](#)

[Show advanced search options](#) [\[Further information about advanced search options\]](#)

Search

2、更多信息

[Home](#) [Safety information](#) [Consumers](#) [Health professionals](#) [Industry](#) [About the TGA](#) [News room](#)

Safety information

- Report a problem or side effect
- Alerts
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- Prescription opioids
- Medicine shortages
- Early warning system
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- Safety information & education**
 - Medicines safety
 - Medical devices safety
 - Database of Adverse Event Notifications (DAEN)**
- COVID-19 vaccines

Home » Safety information » Safety information & education » Database of Adverse Event Notif (DAEN) » About the DAEN - medical devices

Instructions for searching the DAEN - medical devices

Database of Adverse Event Notifications

19 December 2013

When searching the database please select:

- [1. medical devices](#)
- [2. date range](#)

There is also an [advanced search](#) option where you can restrict your search to particular International Organization for Standardization (ISO) event types.

On this page: [Medical devices](#) | [Date range](#) | [Search results](#) | [Advanced search](#)

Medical devices

Once you have typed the first three characters from a trade name, sponsor, manufacturer, [Global Medical Device Nomenclature \(GMDN\)](#) term (device descriptor e.g. 'hip', 'pump' etc.), or an ARTG number, a list of options will be displayed showing, in order, manufacturer, trade name and the GMDN term shown in brackets.

Select the medical device/s you want to search for by ticking or unticking the boxes.

More information on medical device searches

Searches on trade names, sponsor, manufacturer, GMDN terms, and ARTG numbers will produce different results in most cases.

3、单个/批量查询

3、单个/批量查询

1 [medical device selected](#) between 01/01/2018 - 07/10/2020.

Search results

The results are shown in two tabs.

Number of reports: 1

More information on the search results

Medical device summary

List of reports

Medical device summary

[Further information about the medical device summary](#)

[Information on printing search results](#)

Sort by: Report date - earliest first ▼

Report number	Report date	Trade name	Sponsor	Manufacturer
52346	20/07/2018	DISP SIL REINFORCD/FLEX LMA SIZE 4 - Airway, laryngeal, single-use	Device Technologies Australia Pty Ltd	Wel

Page 1 of 1 Records to display: 25 ▼

[Print version of this report](#)

导出报告

« New search

« Modify search

三、加拿大

- 网站: <https://healthykanadians.gc.ca/recall-alert-rappel-avis/index-eng.php>

Recalls and safety alerts

Canada

Recalls & alerts Kids Food Health Environment Cosmetics

Home » Recalls & alerts

Share Contrast Print

Search recalls and safety alerts

Search tips

Search alerts

Advanced search

高级搜索

Featured alert

Additional ranitidine products recalled as a precautionary measure

Unapproved enhancement products and workout supplements seized: Products may pose serious health risks

Access information when and where you need it

Add the Recall & Safety Alerts to your Web site

Subscribe to health and safety updates

Report side effects, injuries, and other safety concerns

Recent recalls and alerts

	Clover Leaf brand Sardines Boneless Fillets - Garlic&Chive in Oil and Sardines Boneless Fillets - Smoked Jalapeño in Oil recalled due to potential presence of dangerous bacteria	Recall
	2021-01-22 Food	

Advanced search

Category:

- All categories
- All categories
- Consumer products
- Food
- Health products
- Vehicles

Advanced options

Search for:

Search

Clear

Category:

All categories

Advanced options

Search for: All of these words Ureteral Dilation Balloon Cathete

AND

All of these words

AND

All of these words

Exclude

All of these words

Start date (YYYY-MM-DD)

年 / 月 / 日

End date (YYYY-MM-DD)

年 / 月 / 日

Type:

All types

输入关键字

Type:

- All types
- All types
- Advisory
- Recall

Search

Clear



Search results

[Search Alerts](#)[Advanced search](#)**Search terms:**

Use AND, OR, NOT or " " for phrases or specific product names to improve your results.

For example, "peanuts" OR "peanut butter"

Narrow results
by:

1 items found for "Ureteral Dilation Balloon Cathete"

Results per page: 10 ▼

Category:

Health
products (1)

产品类型

查询事件详细信息

[Various Catheter and Stent Sets from Cook's Inc \(2019-01-07\)](#)

Various Catheter and Stent Sets from Cook's Inc (2019-01-07) Affected products Urethral Dilator Set Angled Tip Ureteral Catheter Set Bentson Wire Guide C-Flex Double Pigtail Ureteral Stent Set Sof-Flex Double Pigtail Ureteral Stent Set Sof-Flex Multi-Length Ureteral Stent Set Urethral Dilation...

Posted: 2019-01-07

Type of Recall

communication:

事件类型

Results per page: 1-1 of 1

四、英国

- 网站:

https://www.gov.uk/drug-device-alerts?keywords=&alert_type[:
evices&issued_date[from]=&iss
d_date[to]

[Home](#) > [Medical devices regulation and safety](#)

Alerts and recalls for drugs and medical devices

[Drug Safety Update](#)

From:

[Medicines and Healthcare products Regulatory Agency](#)

Search

175 alerts

输入关键字

☒ Get emails ☒ Subscribe to feed

Nasal Oxygen Cannula



▼ Alert type

▼ Medical specialty

▼ Issued

查询单个事件详细信息

Potentially breached sterile packaging of: rectal tubes, Unoversal drainage systems, SimpaVac, sterile suction connecting tubes, sterile connecting pieces, suction handles/sets (FilterFlow™/Deltaflo), oxygen catheters, sterile nasal oxygen cannulas, sterile oxygen connecting tubes, and sterile forceps (MDA/2019/012)

Manufactured by ConvaTec Limited - use of affected devices may increase risk of patients acquiring infections – extension to MDA/2018/034 as additional devices are affected

Alert type: Device safety information

Medical specialism: Anaesthetics and 15 others Issued: 4 July 2019

Bactroban 2% nasal ointment 3g/ Bactroban 2% cream 15g - Beecham Group plc trading as GlaxoSmithKline UK (CLDA (15)A/06) - 24 August 2015

Beecham Group plc trading as GlaxoSmithKline UK is recalling specific batches of Bactroban 2% Nasal Ointment 3g and Bactroban 2% Cream 15g....

Alert type: Drug alert: company-led Issued: 24 August 2015

Miacalcic 200 IU Nasal Spray Solution - withdrawn throughout the European Union

(Novartis Pharmaceuticals UK) Increased risk of malignancies with long -term use of calcitonin – class 2 action within 48 hours. (EL 13(A)11)

Published 28 February 2019

From: [Medicines and Healthcare products Regulatory Agency](#)

Alert type: **Device safety information**

Medical specialty: **Anaesthetics, Cardiology, Care home staff, Cosmetic surgery, Critical care, Dentistry, General practice, General surgery, Haematology and oncology, Infection prevention, Obstetrics and gynaecology, Orthopaedics, Paediatrics, Theatre practitioners, Urology, Vascular and cardiac surgery**

Issued: **4 July 2019**

Contents

- Medical Device Alert
- Summary
- Action
- Device details
- Manufacturer contacts
- Distribution

事件包含内容

Brexit

[Check how the new Brexit rules affect you](#)

Related content

[Suction catheters, gastro-enteral tubes, intermittent urology catheters and sterile urine drainage bags – potential breach in sterile barrier packaging \(MDA/2018/034\)](#)

[Drug Alert Class 4: Paracetamol Infusion, Accord. \(MDR 07-02/19\)](#)

[All T34 ambulatory syringe pumps need a sponge pad fitted to the battery compartment to prevent battery connection issues \(MDA/2019/013\)](#)

五、日本

- 网站：
www.pmda.go.jp/english/safety/info-services/devices/0002.html

①：医疗器械

②：预防措施

③：警告信息

Post-marketing Safety Measures

- Outline
- Scientific Research and Analyses
- Information Services
 - Drugs
 - Medical Devices
 - PMDA Risk Communications
 - Revisions of PRECAUTIONS
 - Notification on self-check
 - PMDA Alert for Proper Use of Medical Devices
 - PMDA Alert for Proper Use of Medical Devices (for patients)
 - Notifications Related to Safety Measures
 - In-vitro Diagnostics
 - Medical Safety Information
 - Regulatory Information
 - Public comments

Revisions of PRECAUTIONS

PRECAUTIONS in package inserts include information such as Warning, Contraindications, Important Precautions, and Clinically Significant Adverse Reactions. When a new risk is identified, the Pharmaceuticals and Medical Devices Agency (PMDA) thoroughly investigates the risk and discusses a necessity of revision of PRECAUTIONS with expert advisors so that the PMDA can recommend an additional safety measure to the Ministry of Health, Labour and Welfare (MHLW). Following the investigation results from the PMDA, the MHLW issues a notice to revise PRECAUTIONS. Marketing authorization holders consequently revise PRECAUTIONS according to the notice.

Posted date	Device name	Detailed information on revisions of PRECAUTIONS (from MHLW)	Summary of investigation results (from PMDA)
November 22, 2019	Artificial ventilator, etc. expected to be used at home	Revision of Precautions for Artificial Ventilator, etc. Expected to be Used at Home 📄	not applicable
October 10, 2019	Drug-eluting coronary stent Drug-coated balloon dilatation catheter for coronary angioplasty	Revision of Precautions to the Package Inserts of Drug-eluting Coronary Stent or Drug-coated Balloon Dilatation Catheter for Coronary Angioplasty 📄	not applicable
June 7, 2019	Gel-filled Breast Implant	Revision of Precautions to the Package Insert of Gel-filled Breast Implant 📄	not applicable
November 13, 2018	Ultrasonic Surgical	Revision of Precautions to the Package Inserts of	Revision of Precautions to the Package

六、中国

- **警戒快讯网站：**
http://www.cdradr.org.cn/ylqx_1/Medical_aqjs/Medical_aqjs_xxtb/
- **不良事件信息通报网址：**
http://www.cdradr.org.cn/ylqx_1/Medical_aqjs/Medical_aqjs_xxtb/



国家药品监督管理局药品评价中心

Center for Drug Reevaluation, NMPA

国家药品不良反应监测中心

National Center for ADR Monitoring, China

中国药物警戒

请输入要查询的内容

首页

中心简介

药品

医疗器械

化妆品

《中国药物警戒》期刊

首页 > 医疗器械 > 安全警示 > 警戒快讯

安全警示

公告通告

警戒快讯

信息通报

数据发布

警戒快讯

医疗器械警戒快讯 2021年第1期 (总第167期)

2021-01-22

医疗器械警戒快讯 2020年第12期 (总第166期)

2020-12-21

医疗器械警戒快讯 2020年第11期 (总第165期)

2020-11-25

医疗器械警戒快讯 2020年第10期 (总第164期)

2020-11-10

医疗器械警戒快讯 2020年第9期 (总第163期)

2020-09-26

医疗器械警戒快讯 2020年第8期 (总第162期)

2020-09-04

医疗器械警戒快讯 2020年第7期 (总第161期)

2020-07-22


《医疗器械警戒快讯》数据库中所列不良事件主要收集的是美国FDA、英国MHRA、澳大利亚TGA以及加拿大Health Canada的警示或召回数据，**并非境内上报数据**；美国MAUDE数据库属于全数据库，只要按照FDA法规进行报告的MDR，都会录入该数据库；英国MHRA、加拿大Health Canada、澳大利亚TGA等关于医疗器械不良事件/召回/警戒信息的数据库会定时更新，可根据关键词进行进一步筛选，还可通过限制时间或限制关键词的位置等进行精确检索。

七、德国

- 网站：
www.bfarm.de/Site
Globals/Forms/Suc
he/EN/kundeninfo
_Filtersuche_Form
ular_en.html?nn=4
527724

[About us,](#) [Medicinal Products,](#) [Medical Devices,](#) [Federal Opium Agency,](#) [Research,](#) [Service,](#)

Field Corrective Actions

[HOME PAGE](#) → [MEDICAL DEVICES](#) → [INFORMATION ON RISKS](#) → [FIELD CORRECTIVE ACTIONS](#) 

Field Corrective Actions include removals of medical devices from the market or any other corrective action on devices in use. In general, the manufacturer implements field corrective actions by sending an advisory notice to inform operators and users about risks of medical devices, and to advise on what action should be taken to protect the health or the safety of patients, users or other persons. For example, advisory notices may contain the information from the manufacturer that he voluntarily recalls a medical device.

 RSS-Feed of Field Corrective Actions

Please note that advisory notices are issued by the manufacturer, the authorized representative or the importer of medical devices. The respective company takes the responsibility for all information given in the advisory notice.

This form requires encryption.

Form contains one or more errors
This form requires encryption.

输入关键字/产品名

advisory notice.

Ureteral Dilation Balloon C

all items

All dates

filter

1 search results

Date

Title

1

2019.01.16

Urgent Field Safety Notice for Reverse Loaded Wire Guides by Cook Incorporated

Injections / Infusions / Transfusions / Dialysis - catheters

✓ PDF

91KB

筛选报告日期

导出报告



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