

Health Devices Alerts®

FILE DESCRIPTION

Health Devices Alerts® (HDA), produced by ECRI, is a comprehensive database of reported medical device problems, hazards, recalls, evaluations, and updates. The selections derive from an extensive review of the medical, legal, and technical literature, various national reporting networks and government sources, and ECRI'S own international problem reporting network. Each entry is indexed using ECRI's internationally endorsed Universal Medical Device Nomenclature System (UMDNS). An online thesaurus is available to assist in locating broader, narrower, and related product names. A complete directory of medical devices and manufacturers is available in a companion database, File 188, ECRI's Health Devices Sourcebook®.

HDA covers reports of problems, evaluations, and technology assessments of diagnostic and therapeutic medical equipment and related materials, ranging from sutures to magnetic resonance imaging units, including implanted devices and related accessories, disposable medical products, clinical laboratory reagents, and selected hospital furniture, casework, and systems.

SUBJECT COVERAGE

HDA covers reports of problems with diagnostic and therapeutic medical equipment and related materials, including:

- Radiological Devices
- Implanted Devices and Related Accessories
- Disposable Medical Products
- Clinical Laboratory Reagents
- Product Misuse
- Hospital Furniture
- Ophthalmologic Devices
- Obstetric/Gynecologic Devices
- Dental Equipment
- Surgical Equipment
- Materials Management Products
- Orthopedic Devices
- Physical Medicine Equipment

SOURCES

HDA contains four major types of information relating to medical devices: 1) abstracts (ABS) of articles from the published literature, 2) action items (AI) that ECRI has investigated or verified, 3) Problem Reporting Program (PRP) records from the voluntary, spontaneous reporting system operated by the U.S. Food and Drug Administration (FDA), and 4) Medical Device Reporting (MDR) records from the

mandatory reporting system operated by the FDA.

TIPS

USE FILE 198

to track medical device problems, hazards, recalls, evaluations, and updates.

USE /CO OR CO=

to find companies of interest.

USE /PN OR PN=

to find product names of interest.

DIALOG FILE DATA

Inclusive Dates: 1977 to 2000 (Abstracts)
 1982 to 2000 (AI)
 1984 to 1996 (MDR)
 1977 to 1992 (PRP)

Update Frequency: Closed

File Size: More than 683,000 records

CONTACT

Health Devices Alerts is produced by ECRI, an independent, non-profit agency that evaluates health care technologies. Questions concerning file content should be directed to:

ECRI

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ECRI ABSTRACT RECORD

File 198:Health Devices Alerts(R)
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AN=, SF=
PC=, /PN, PN=
/DE
/ID

00027683 ABS-15894; AI-A1333 SUBFILE: ABS
PRODUCT(s):13-209 PUMPS, ENTERAL FEEDING
COMMON DEVICE NAME: Kangaroo 220 and 330 Enteral Feeding Pumps
IDENTIFIER: Pumps manufactured prior to June 1985

/CO, CO=

MANUFACTURER: Sherwood Medical Co. Sub American Home Products
(101927), 1831 Olive St, St Louis Mo 63103

/TX

ECRI recently received a report involving overinfusion associated with a Kangaroo 330 Enteral Feeding Pump. Over infusion resulted when the pump set was incorrectly installed behind the rotor. To help prevent incorrect installation, Sherwood Medical modified the rotors on the Kangaroo 220 and 330 pumps. In June 1985, Sherwood Medical informed ECRI that it will exchange rotors on pumps manufactured prior to June 1985 for the modified ones, free of charge. (Rotors manufactured prior to June 1985 are metal; the new rotors are plastic.) It emphasizes that most situations involving overinfusion result from user error and can be avoided by following the instructions for correct placement of the set on the rotor. These directions appear in the pump's operating manual, on the pump itself and on the pump set. Hospitals should ensure that all users are familiar with proper assembly and follow user instructions for the Kangaroo 220 and 330 Enteral Feeding Pumps. To help prevent incorrect installation of the pump set, replace all old metal rotors in your Kangaroo 220 and 330 pumps with the modified ones. To order replacement rotors or for more information, contact Sherwood Medical Customer Service, Watertown, NY, at (800) 448-0190: in New York, (315) 788-0300.

SO=
PD=

SOURCE: ECRI, Manufacturer
PUBLICATION DATE: 8905

MEDICAL DEVICE REPORTS RECORD

File 198:Health Devices Alerts(R)
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AN=, SF=
PC=, /PN, PN=
/DE
/ID

00027825 MDR-157579 SUBFILE: MDR
PRODUCT(s): 10-727 CATHETERS, INTRAVENOUS, PERIPHERAL
COMMON DEVICE NAME: SUBCLAVIAN JUGULAR CATHETER SET
IDENTIFIER: MODEL NA CATALOG 38-755-1

/CO, CO=

MANUFACTURER: Deseret Medical, Inc.

/TX

DURING ATTEMPTED PLACEMENT OF 16 GAUGE 12 IN CV CATHETER IN LEFT SUBCLAVIAN FOR ADMINISTRATION OF TPN, THE TIP PORTION OF CATHETER FRACTURED OFF PT TAKENTO OR THE EMBOLIZED CATHETER FRAGMENT WAS REMOVED. APPARENTLY THE CATHETER PORTION WAS DISCARDED AFTER THE CATHETER PORTION WAS DISCARDED AFTER EVENT. CO'S DIRECTIONS FOR CAUTION AGAINST WITHDRAWING CATHETER AGAINST NEEDLE BEVEL AS, CATHETER MAY BE CUT, SEE DIRECTIONS FOR USE AS PACKAGED WITH INDIVIDUAL SUBCLAVIAN CATHETER AND ALSO PRESENT ON A 8 x 10 SHEET IN EACH BOX OF PRODUCT.

SO=
/TX
FP=

SOURCE: M.D.R. REPORT DATED 9/02/88
ECRI COMMENT: This user error is reported virtually every month.
FDA PRODUCT CODE: DQO
MANUFACTURER DISCLAIMER: THIS INFORMATION IS SUBMITTED PURSUANT TO 21 CFR 803. DESERET MEDICAL DOES NOT CONSIDER THIS REPORT OR ITS CONTENTS TO BE AN ADMISSION THAT A DESERET PRODUCT IS DEFECTIVE OR THAT A DESERET PRODUCT HAS CAUSED A DEATH OR SERIOUS INJURY.

SEARCH OPTIONS

BASIC INDEX

SEARCH SUFFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
—	—	All Basic Index Fields	Word	S CATHETERS(W)CENTRAL(W)VENOUS
/CO	CO	Company Name ¹	Word	S SHERWOOD(W)MEDICAL/CO
/DE	DE	Common Device Name	Word	S KANGAROO(W)220/DE
/ID	ID	Identifier	Word	S PUMPS(F)1985/ID
/PN	PN	Product Name ¹	Word & Phrase	S CATHETERS(W)CENTRAL(W)VENOUS/PN
/TX	TX	Abstract, Problem, Action Needed, Comments	Word	S PUMPS, ENTERAL FEEDING/PN S (OVERINFUSION AND KANGAROO)/TX

¹ Searchable in the Basic Index and in the Additional Indexes.

ADDITIONAL INDEXES

SEARCH PREFIX	DISPLAY CODE	FIELD NAME	INDEXING	SELECT EXAMPLES
—	AN	DIALOG Accession Number		
AN=	AN	ECRI Accession Number	Phrase	S AN=ABS-15894 S AN=AI-A1333
CO=	CO	Company Name ¹	Word	S CO=(BECTON(W)DICKINSON)
—	DS	Manufacturer Disclaimer		
ET=	ET	Effect Type ³	Phrase	S ET=SERIOUS INJURY
FP=	FP	FDA Product Code	Phrase	S FP=DQO
PC=	PC	Product Code ²	Phrase	S PC=13-209
PD=	PD	Publication Date of Record Entry	Phrase	S PD=198905
PN=	PN	Product Name ¹	Word & Phrase	S PN=(CATHETERS(W)CENTRAL(W)VENOUS) S PN=PUMPS, ENTERAL FEEDING
—	RF	ECRI Reference Accession Number		
SF=	SF	Subfile ^{5,6}	Phrase	S SF=MDR
SO=	SO	Source Information ⁴	Word	S SO=(ECRI(W)MANUFACTURER)
UD=	—	Update ⁷	Phrase	S UD=9999

² Product codes are assigned to specific medical devices. When no product codes exist for very broad classifications of medical devices, PC=00-000 is assigned.

³ Available only in MDR subfile.

⁴ Display includes Journal Name, Volume, Pagination, and Publication Date.

⁵ MDR is available only in 1984-1996.

⁶ PRP is available only in 1977-1992.

⁷ UD index is present only from UD=199909 forward.

SPECIAL FEATURES

For command descriptions, enter HELP LIMIT, HELP SORT, HELP RANK online.

LIMIT	/ABS -- Abstract Present /AI -- Action Items Records /MDR -- Medical Device Reports Records ⁵ /PRP -- Product Review Problems Records ⁶	SELECT S2/ABS SELECT S3/AI SELECT S2/MDR SELECT S3/PRP
SORT	CO, PD, PN, SF	SORT S6/ALL/CO PRINT S3/5/1-24/SF
RANK	All phrase- and numeric-indexed fields in the Additional Indexes can be ranked.	RANK ET RANK PN S4

PREDEFINED FORMAT OPTIONS

NO.	DIALOGWEB FORMAT	RECORD CONTENT
1	--	DIALOG Accession Number
2	--	Accession Numbers, Subfile, Product Name and Product Code, Common Device Name, Identifier, Company Information, Source, Publication Date, Effect Type, ECRI Comment, FDA Product Code, Manufacturer Disclaimer
3	Medium	Accession Numbers, Subfile, Product Name and Product Code, Source
4	--	Full Record with Tagged Fields
5	--	Full Record
6	Free	Accession Numbers, Subfile, Product Name and Product Code, and Common Device Name
7	Long	Accession Numbers, Subfile, Product Name and Product Code, and Abstract
8	Short	Accession Numbers, Subfile, Product Name and Product Code, Publication Date, and Effect Type
9	Full	Full Record
K	--	KWIC (Key Word In Context) displays a window of text; may be used alone or with other formats

OTHER OUTPUT OPTIONS

For an explanation, enter HELP TYPE, HELP UDF, HELP TAG online.

USER DEFINED FORMATS	Display codes listed in the Search Options tables can be used to customize output.	TYPE S3/PC,PN,CO,DE/1-5
TAG	Output can be displayed with tags identifying each display field.	TYPE S3/CO,PN/1-5
DIRECT RECORD ACCESS	If the accession number of a specific record is known, it can be used to display the record directly.	TYPE 00027683/5 DISPLAY 00027825/CO,DE PRINT 00027933/2

FOR ONLINE HELP:

See HELP FIELDS 198 for searchable fields; HELP FORMAT 198 for output formats; HELP LIMIT 198 for limits; HELP RATES 198 for cost information; HELP SORT 198 for sorts.