IUPC's & Patient Risk

FDA adverse event reports associated with two IUPC's.

Results taken from FDA's MAUDE online database.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

To search for reports associated with the **INTRAN® Plus** or **Koala®** IUPC, navigate web browser to the MAUDE online database and fill in the fields as highlighted below:

Search Database

Help Download Files

Product Problem

Product Class

Brand Name "Intran" or "Koala"

510K Number K

Manufacturer

PMA Number P

Event Type

Product Code

Date Report Received by FDA *(mm/dd/yyyy)* "01/01/2000" to Current Date

Go to Simple Search 25 Records per Report Page Clear Form Search

What is the MAUDE database?

The Manufacturer And User Device Experience or MAUDE database represents reports of adverse events involving medical devices. The online search allows you to search CDRH (Center for Devices and Radiological Health) database information on medical devices which may have malfunctioned or caused a death or serious injury.

(Source: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)

UTAH MEDICAL PRODUCTS INC.

One Avoidable

Search results for INTRAN® Plus:

11 records meeting your search criteria returned - **Brand Name:** *Intran* **Report Date From:** *01/01/2000* **Report Date To:** *09/19/2013*

New Search — Help | Download Files | More about MAUDE

Manufacturer	Brand Name		Date Report Received
MEDTRONIC XOMED, INC	SPLINT 1524055 DOYLE	Not an IUPC	01/31/2013
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	03/20/2009
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	02/25/2009
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	02/11/2009
UTAH MEDICAL PRODUCT	INTRAN PLUS IUP-400	No Patient Injury	12/18/2008
UTAH MEDICAL PRODUCT	INTRANPLUS IUP-C50	No Patient Injury	10/09/2008
EVERA MEDICAL, INC.	EVERA INTRANASAL SPL	Not an IUPC	10/04/2007
EVERA MEDICAL, INC.	EVERA INTRANASAL SPL	Not an IUPC	08/17/2007
UTAH MEDICAL PRODUCT	INTRAN PLUS	No Patient Injury	07/08/2005
UTAH MEDICAL	INTRAN PLUS	No Patient Injury	11/15/2004
UTAH MEDICAL PROD IN	INTRAN PLUS IUP-400	No Patient Injury	03/01/2001

If the two catheter designs are comparable, and variation in clinician skill evenly distributed among brands, isn't it reasonable to expect similar reported injury rates?

The MAUDE data supports the idea that injuries are related to product design. The Koala IUPC accounts for 100% of the MAUDE reported serious injuries and deaths.

Utah Medical believes the safety difference may be explained by the unique, transducer-tipped design of Intran Plus where the pressure sensing electronics are encapsulated in the soft, blunt tip of the catheter, which is placed inside the uterus. This design is not only responsible for insertion safety, it results in the most accurate possible IUP measurement because it eliminates pressure signal transmission artifact that frequently occurs with mechanical IUP systems.[1] The Koala, a balloon-tipped catheter, is

Injury is Too Many.

Search results for Koala®:

16 records meeting your search criteria returned - **Brand Name:** *Koala* **Report Date From:** *01/01/2000* **Report Date To:** *09/19/2013*

New Search | Help | Download Files | More about MAUDE

Manufacturer	Brand Name		Date Report Received
CLINICAL INNOVATIONS	KOALA	Death	01/31/2013
CLINICAL INNOVATIONS	KOALA 1 PC 5000	Death	10/23/2012
PERMOBIL, INC.	PERMOBIL CHAIRMAN KO	Not an IUPC	10/16/2012
CLINICAL INNOVATIONS	KOALA IPC 5000	Serious Injury	08/18/2011
CLINICAL INNOVATIONS	CATHETER IUPC EXTERN	Death	05/27/2011
CLINICAL INNOVATIONS	KOALA	Serious Injury	01/13/2011
CLINICAL INNOVATIONS	KOALA	Death	01/29/2010
CLINICAL INNOVATIONS	KOALA	Death	01/28/2008
CLINICAL INNOVATIONS	KOALA IPC 5000	Serious Injury	10/30/2007
CLINICAL INNOVATION	KOALA IPC 5000	Serious Injury	09/04/2007
CLINICAL INNOVATION	KOALA IPC 5000	Serious Injury	09/04/2007
CLINICAL INNOVATIONS	KOALA INTRAUTERINE P	Death	06/08/2006
PERMOBIL AB	CHAIRMAN KOALA	Not an IUPC	11/26/2003
CLINICAL INNOVATIONS	KOALA	Serious Injury	09/22/2003
CLINICAL INNOVATIONS	KOALA	Serious Injury	08/16/2003
CLINICAL INNOVATIONS	KOALA	Serious Injury	02/07/2003

Note: A detailed description of each adverse event report may be found by clicking on the underlined link in the "Brand Name" column.

a mechanical transmission system that relies on an extracorporeal transducer that is reused and not regularly calibrated. The design is similar to saline-filled catheters, except in the case of Koala, an air-column rather than a liquid-column transfers the intrauterine pressure signal to an external transducer.

[1] Beeson et al. Variable intrauterine pressure tracings with two catheters. Feb 2005, SMFM Annual Meeting, Reno, NV. Poster.

http://www.utahmed.com/intran.htm

PN: 58335 REV: 093013

UTAH MEDICAL PRODUCTS

FEMCARE-NIKOMED

Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047

Toll Free: 800.533.4984
Fax: 801.566.2062
info@utahmed.com