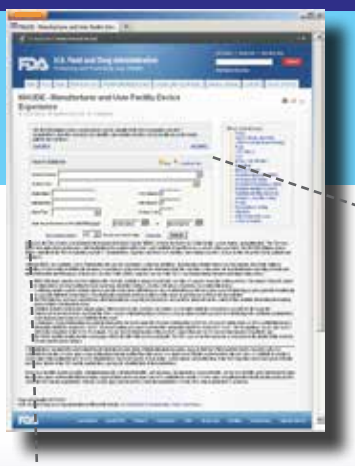
IUPC's & Patient Risk

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			
Event Type		Manufacturer	
Model Number		Report Number	
Brand Name	"Intran" or "Koala"	Product Code	
Date Report Received by FDA *(mm/dd/yyyy)*	"01/01/2008"	to	Current Date

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

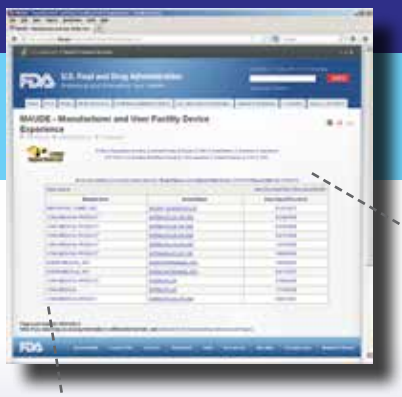
What is the MAUDE database?

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:

5 records meeting your search criteria returned- **Manufacturer:** *Utah* **Brand Name:** *Intran* **Report Date From:** *01/01/2008* **Report Date To:** *09/30/2018*

New Search | Export to Excel | Help

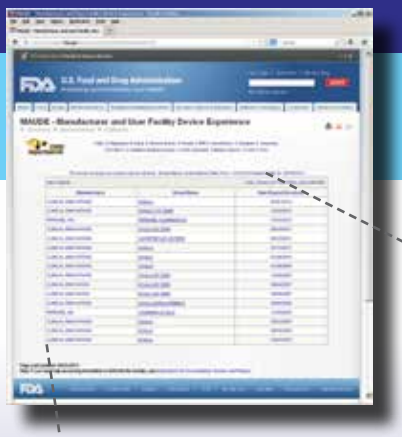
Manufacturer	Brand Name		Date Report Received
UTAH MEDICAL PRODUCTS, INC.	INTRAN PLUS IUP-400	No Patient Injury	03/20/2009
UTAH MEDICAL PRODUCTS INC.	INTRAN PLUS IUP-400	No Patient Injury	02/25/2009
UTAH MEDICAL PRODUCTS, INC.	INTRAN PLUS IUP-400	No Patient Injury	02/11/2009
UTAH MEDICAL PRODUCTS, INC.	INTRAN PLUS IUP-400	No Patient Injury	12/18/2008
UTAH MEDICAL PRODUCTS	INTRANPLUS IUP-C50	No Patient Injury	10/09/2008

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]

Injury is Too Many.



Search results for Koala®:

11 records meeting your search criteria returned- **Brand Name:** *Koala* **Report Date From:** *01/01/2008* **Report Date To:** *09/30/2018*

New Search | Export to Excel | Help

Manufacturer	Brand Name		Date Report Received
PERMOBIL AB (PAB)	PERMOBIL CHAIRMAN KOALA	Not an IUPC	09/05/2018
CLINICAL INNOVATIONS	KOALA INTRAUTERINE PRESSURE MONITORING K	No Patient Injury	01/29/2015
CLINICAL INNOVATIONS	KOALA EXTERNAL CABLE/CATH	No Patient Injury	01/29/2015
CLINICAL INNOVATIONS, INC.	KOALA	Death	01/31/2013
CLINICAL INNOVATIONS	KOALA 1 PC 5000	Death	10/23/2012
PERMOBIL, INC.	PERMOBIL CHAIRMAN KOALA MINI-FLEX	Not an IUPC	10/16/2012
CLINICAL INNOVATIONS	KOALA IPC 5000	Serious Injury	08/18/2011
CLINICAL INNOVATIONS LLC	CATHETER IUPC EXTERNAL KOALA	Death	05/27/2011
CLINICAL INNOVATIONS	KOALA	Serious Injury	01/13/2011
CLINICAL INNOVATIONS LLC	KOALA	Death	01/29/2010
CLINICAL INNOVATIONS, INC.	KOALA	Death	01/28/2008

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

The Koala, a balloon-tipped catheter, is 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 mechanically transfers the intrauterine pressure signal to an external transducer. Koala is not truly "sensor-tipped".

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

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