

One Avoidable Bad Outcome Is Too Many.

Serious Injuries Associated With Last 5 Years' Use Of Two Intrauterine Pressure Catheters

Results taken from the FDA's MAUDE online database events July 2003 -July 2008.

Intran® Plus (Transducer-Tipped)

No Patient Injuries Reported.

Koala® (Balloon-Tipped)

July 12, 2003--**Serious Injury**
(**placental injury**)
Apgar 0 at 5 minutes
Emergent C-Section

September 1, 2003--**Serious Injury**
(**cord/placental disruption**)
Apgar 0 at 5 minutes
Emergent C-Section

June 2006--**Fetal Death**
(**placental abruption**)
Emergent C-Section
Maternal Blood Transfusion

August 12, 2007--**Serious Injury**
(**placental abruption**)
Apgar 0 at 10 minutes
Vaginal Bleeding, Emergent C-Section

January/February 2008--**Fetal Death**
(**placental/umbilical perforation**)
FHR 190 over 4 minutes then 60 over 5 minutes
Emergent C-Section, Vaginal Bleeding/Clotting

MAUDE Database and Search engine:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>
Select "Catheter, Intrauterine And Introducer" from the Product Class scroll tab
Select desired **dates** and click the **Search** tab