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:

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)
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 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”.

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