UTAH MEDICAL PRODUCTS, INC.

CORPORATE HEADQUARTERS
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RECALL NOTICE

Voluntary Recall of Potentially Defective Intran Plus IUPC Trays

June 16, 2008

Subject: **RECALL NOTICE**

To: Utah Medical Customer Materials Management Representative

Re: Voluntary Recall of potentially defective Intran Plus IUPC trays

Background.
The sensitive electronic transducer located in the distal tip of the Intran Plus intrauterine pressure catheter (IUPC) is encapsulated in a soft, blunt boot, which design has demonstrated optimal patient safety in over 17 years' use.

UTMD has recently identified an unanticipated interaction between the high impact polystyrene (HIPS) tray holding the catheter and the plasticizer in the IUPC tip, in cases where the tip has been pressed directly against the tray for an extended period of time. This defect does not affect the functioning or the biocompatibility of the IUPC device in any way.

UTMD's investigation, which included devices from sterilization retains since 2003, a duration representing the full 5-year shelf life of IUPCs currently in distribution, has not yet found evidence that the sterility of the tray contents have been compromised by the interaction of the plasticizer in the IUPC tip with the HIPS tray material.

However, the non-DEHP PVC plasticizer implemented in January 2007 seems to weaken the wall enough over time that we cannot rule out the possibility that looking forward, damage to the tray wall in direct contact with an IUPC tip will eventually compromise sterility during a 5-year shelf-life.

Since this defect was identified, UTMD implemented a protective barrier between the HIPS tray wall and the IUPC tip that effectively eliminates the problem.

Recall.
UTMD wishes to recall unused Intran Plus IUPCs for immediate replacement at UTMD's expense with units that have a protective barrier within the tray packaging. We have attached the specific lot numbers of the products we wish you to return, along with specific instructions (below).

This recall is being conducted according to the guidance and under the supervision of the FDA as a Class II Recall.

UTMD believes this packaging defect represents a low patient health risk. As always, we caution that the packaging of all sterile products be visually inspected before use for any open or damaged areas that might compromise sterility. Also, as a general precaution, UTMD requests that its customers always adhere to a FIFO (first-in, first-out) inventory policy, particularly where sterile product is involved.

We appreciate your trust in, and use of, UTMD's products, and we regret your inconvenience.

Sincerely,

Kevin L. Cornwell
CEO

cc: QA File
U.S. FDA

Affected Lots and Instructions
The affected lots shipped to your facility are listed below.

UTMD is asking that you locate and return these lots for exchange from your stock in accordance with the instructions below. We recognize the inconvenience this causes you and your staff. However, this action reflects UTMD's commitment to high quality standards and ensures that its products meet all requirements, as well as your expectations. Please call Customer Service at 800-533-4984 with any questions.

Intran Plus Affected Lots:

For Part Numbers:
IUP-400
IUP-400S
IUP-450
IUP-450S
IUP-500
IUP-550
IUP-600
IUP-600S
IUP-650
IUP-650S
IUP-700
IUP-750

1. Lot Numbers less than 1072755 (all lots received prior to 2008).

2. If your facility has not yet received notification, please contact Marci Clawson at 801-569-4101 to obtain affected 2008 lot numbers shipped to your facility.

Return Instructions:

1) Review the above list of affected lots in stock at your facility.

2) Prepare affected lots for return to: Utah Medical Products, Inc. 7043 South 300 West Midvale, UT 84047

3) After the affected lots are ready for return and replacement, contact UTMD Customer Service at 800-533-4984 for a Return Goods Authorization identification number (RGA).

4) UTMD Customer Service will provide you with its UPS Account Number for the return shipment, or will schedule a UPS pick-up.

5) Customer Service will arrange for shipment of replacement product at UTMD expense, and notify you of its estimated arrival date.

Thank you again for your attention to this matter. If you have any additional questions or concerns regarding the product return, you may also contact Marci Clawson, VP, at 801-569-4101.