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Agency for Medical Innovations

ATTENTION – SAFETY ALERT!
Voluntary Product Recall!

TO: All users of
- **A.M.I. EcoPort F6 und F8 und**
- **A.M.I. Clip-a-Port F6 und F8**

Products.

FROM: [redacted] General Manager A.M.I.
Director Q&A and Regulatory Affairs

DATE: 28. September 2009

Dear Customer,

The family of A.M.I. Infusion Ports has been available since the beginning of 2009 to the international markets and we are happy about the acceptance our products gained within such short period of time, in many countries around the world.

Just now we learned about an incidence (fortunately without serious complications for the patient) which occurred in connection to the use of one of our EcoPort F6 products. A leak from the connection between Port and Catheter was reported. As of today, since the launch of the A.M.I. EcoPort and Clip-a-Port Family we have received a total of 2 product complaints, including the most recent one. The examination of the 1st complaint did not allow us to make any final product related conclusion.

The reported leak from the connection between Port and Catheter was confirmed in the laboratory. We had the opportunity to check the total explanted system. The following situation is confirmed,

- Catheter was not in full length pushed onto the connection pin,
- which resulted, due to a technical weakness of the connection pin, in leaking of the infusion solution into the surrounding tissue.

Please teach the following precaution to your customers and sales people:

- For the safety of such Infusion PortSystems, it is mandatory to push the catheter in the full length onto the connection pin – until the catheter stops at the outside wall of the port - although this might be sometimes difficult to accomplish, especially when Polyurethane Catheters are used, which are not yet at body temperature. This is extremely important when the System is later used for so called "high pressure infusion".

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As a result from this incident, the following Correction Measurements were immediately taken:

- Manufacturing of connection pins is revised. As a result, the safety of the connection between Port and Catheter will be safe, even if the catheter is pushed for 2/3 of length onto the connection pin only.
- The 100% inline port tightness inspection is adjusted and will in future also cover the full length of the connection pin and
- for the ports which are on stock at your customers, we ask you to
  - **immediately recall these ports and to inform A.M.I. about the customer name, product code and LOT Number,**
  - **offer to your customers an immediate free of charge exchange of their ports against our VarioPort System - which is shipped to you free of charge and in exchange for the recalled EcoPorts and/or Clip-a-Ports Systems,**
  - **request from our customer service department a Return Authorization Number (RAN) – a.) RAN for products recalled from customers, b.) RAN for products shipped back from your stock - and**
  - **immediately return your stock of Clip-a-Port and EcoPort products back to A.M.I. These ports are going to be replaced in 3 weeks from now with ports carrying the improved connection pin.**

From mid of October onwards, revised A.M.I. EcoPorts and A.M.I. Clip-a-Ports, featuring the improved connection pin are again available to all our customers.

The Safety of Patients is our Concern!
We will always, openly and without any delay, communicate safety relevant issues to our customers.
Thank you for your confidence.

Best regards,

[redacted]
General Manager

[redacted]
Director QA & RA

PS:
If you have any questions about handling this voluntary product recall, please call our Customer Service Department or touch base with [redacted]