Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

File Reference: 2013/010657

Axiomed Pty Ltd
17 Caroline Street
REDFERN NSW 2016

Attention:

DEVICE INCIDENT REPORT DIR 31005 - ARTG # 216537 - Tubing, radiographic procedure

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact me on (02) 6232 8536.

Yours sincerely

Peter Farrington

Incident Report and Investigation Scheme
Device Vigilance and Monitoring
Office of Product Review
Therapeutic Goods Administration

16/05/2014

DIR 31005 - ARTG # 216537 - Tubing, radiographic procedure

Reporter Reference #: INC1917

Date of Adverse Event:

Date of Initial Report:
27/05/2013

ARTG #:
216537

Brand Name:
Transflux contrast delivery

Device Class:
Class IIa

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
MHMedical Tec GmbH [59251]

Sponsor:
Axiomed Pty Ltd [59221]
17 Caroline Street

REDFERN NSW 2016

Contact Name:

Phone:

Fax:

Email:

Reporter:

Confidential: Yes

Clinical Event Information:
Transset contrast delivery system is designed to connect contrast injectors to bulk contrast and saline containers. A single-use Transflux CT tube, connected to the Transflux set, is used once for each patient. This procedure encourages multiple use of single use disposables.

Customers in Australia are using the product.

Patient Outcome/Consequences:

Device Analysis Results:
1. The contrast injector syringe is designed and labelled to be single use. The Transflux/Transset system encourages multiple use of the syringe, for which it was not designed. There are two issues with this:
a) Patient cross-contamination; while the non-return value on the Transset minimises backflow, the sterility of the valve itself cannot be guaranteed after the first use
b) Mechanical reliability issues. Lubrication and mechanical strength of the syringe cannot be guaranteed after one use, potentially resulting in contrast leakage and interruption of procedure.

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Type of Problem (Level 1) Type of Problem (Level 2)

Other Other

ARTG registration issues were corrected

Labelling/Instructions for Use Instruction for Use Issue

Cause of Problem (Level 1) Cause of Problem (Level 2)

Unable to confirm complaint

Outcome of Investigation

Referral to other TGA Office

Summary of Investigation:
The complaint stated "Transset contrast delivery system is designed to connect contrast injectors to bulk contrast and saline containers. A single-use Transflux CT tube, connected to the Transflux set, is used once for each patient. This procedure encourages multiple use of single use disposables." The sponsor provided evidence that the Transflux and Transet components are labelled for single use. The IFU indicates processes to be carried out one-per-day and once-per-patient.

The complaint highlighted the the risk of "Patient cross-contamination; while the non-return value on the Transset minimises backflow, the sterility of the valve itself cannot be guaranteed after the first use". This sponsor indicated a study on the microbial safety of an infusion set was published in the journal of Investigative radiology - vol 47, No 4, April 2012. It repeatedly tests the Transflux system and conclusively proves, using a diffusible radiotracer to femto-molar sensitivity that no contaminant can pass the dual one way valves. If used in line with the manufacturer's guidelines and with universal precautions the sterility of the Transflux valves can be guaranteed after the first and all subsequent injections.

The compaint highlighted "Mechanical reliability issues. Lubrication and mechanical strength of the syringe cannot be guaranteed after one use, potentially resulting in contrast leakage and interruption of procedure". The sponsor indicated the Transset system operates at a lower inherent pressure and transmits this lower pressure through the syringes. Since its inception in 2007 no report of a mechanical failure of the Transset and syringe combination system has ever been reported to the sponsor or the manufacturer. If such a failure were to occur there is no issue of risk to the patient as the system is protected by and separated from the patient by the dual valve Transflux device. Hypothetically there may be a slight time delay as new syringes are installed but absolutely no risk to the patient in this event.

Issues with the registration of the device were resolved by the RCU. No further investigation will occur at this time but the TGA will monitor for similar complaints.

Date Completed:
16/05/2014

***** End of DIR 31005 *****