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Safety Information Luer Connectors relating to TIVA Sets

Field Safety Notice

Internal Reference: - FSN 16-001
Date: - 10th November 2016
Product Code: - TIVA sets as set out in section 2
Applicable Products: - See section 2 of this document.
MHRA Incident Reference: - 2013/008/002/401/008

Incident Details: - between February 2015 and March 2016

1. Description of Issue MHRA Incident

1.1. The current acrylic check valve can crack when over tightened on second use due to the absorbing of lipid based drugs into the polymer causing a loss of integrity. The current acrylic check valve is lipid resistant according to the component manufacturer Borla however there is a failure rate of about 1 in 30,000 according to our usage.

1.2. After evaluation of the polycarbonate check valve the manufacturing specification to the TIVA sets will use the new component. This has been agreed with the Critical Sub-contractor SO.F.A.P.

1.3. The current component is Check Valve AS50693 Order code 4868 and will be replaced with AS51039 Order Code 2305.

2. List of Product Affected

PRODUCT CODE	DESCRIPTION
GCM-1003	10 METRE TIVA MRI SET
GCM-223	3 WAY TIVA SET 2.2 METRE
GCM-223B	3 WAY MULTIPLE INFUSION TIVA SET 2.2 METRE BASIC
GCM-253	3 WAY TIVA SET 2.5 METRE
GCM-253B	3 WAY MULTIPLE INFUSION TIVA SET 2.5 METRE BASIC
GCM-303B	3 WAY MULTIPLE INFUSION TIVA SET 3.0 METRE BASIC
GCM-304	4 WAY TIVA SET 4.0 METRE
GCM-SPCA	SEDATION PCA SET 2.2 METRE

3. Investigation Findings

3.1. The current acrylic check valve used by the GCM TIVA sets can crack when exposed to lipids and after over tightened the is further exasperated on the second use if overtightened or this could be due to the absorption of lipid based drugs into the polymer causing fragility or a combination of both factors. The current acrylic check valve is lipid resistant according to the

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component manufacturer however there is a failure rate of about 1 in 30,000 according to our usage records.

3.2. A suitable replacement using polycarbonate has been field tested and has been used in all production runs since August 2016.

4. Corrective Action

4.1. The replacement component has been tested and approved for all future production runs.

4.2. The IFU will be updated to include procedural recommendations regarding the over tightening of Luer lock connectors.

4.3. A link to the Global Components Medical Limited web site for the downloading of reference material has been added to the IFU and reference papers placed on the web site.

5. Further Information and Support

5.1. The updated IFU including guidelines to prevent unnecessary over-tightening of Luer connector.

5.2. Visit GCM web site for reference material - http://www.global-medical.co.uk/index.html

6. Report by Management - Regulatory Reviewer [Synopsis]

6.1. An extensive literature review and enquiries with the manufacturer has been conducted and these enquiries indicates that there have been some reported incidents or technical issues with the Lipid resistant acrylate.

6.2. Luer lock taper connection stress cracking

The performance of Luer locks (6% conical taper connectors with a screw thread or lug method of assembly) must be maintained throughout the duration of their use in the fluid delivery system. These medical devices are designed to ensure a leak-free condition, whilst being quick and easy to remove and replace as demanded by the patient's treatment program. In addition to tests focusing on the assembly of the connector, industry standards also prescribe tests to meet durability demands while connected at a reference fastening torque. This particular requirement needs a test stand capable of applying both a torque (0.12 N.m) and an axial force (27.5 N) held for 5 seconds, to assemble the Luer lock initially.

To complete the stressing of the components, a constant temperature of 20 ± 5 °C (27 ± 5 °C in tropical climates) is maintained for a period of 48 ± 1 h. The components should be free from cracking at the completion of the test. Additional consideration should be given for specific environmental conditions applicable to the device's use – which may include contact with chemicals in addition to elevated temperatures.

Applicable Standards: ISO 594-2, BS EN 1707, BS EN 20594-2m ISO 80369

6.3. As a consequence, of our investigation GCM has now issued an amended IFU in October 2016.

Yours sincerely,

Murray Humphries

Managing Director