



January 23, 2018

Attention:1. Head of Surgery
2. Director of Nursing

URGENT MEDICAL DEVICE SAFETY NOTICE

Product Name: Fraizer suction handle

Product code: UM1912 (12 Fr), Lot# - CGCA05-01

MHRA Reference Number: 2018/006/005/291/007

GC Medica, following consultation with ConvaTec and MHRA (Medicines and Healthcare Products Regulatory Agency) is issuing this Safety Alert for the above mentioned product.

Frazier suction handles are used in surgical procedures where fine, delicate suctioning is necessary to evacuate fluid and debris from the operating field. The product has an obturator to keep the tip open whilst bent in shape. The product is intended for single use only.

ConvaTec has received a few complaints, in New Zealand and Norway, from users confirming that the suction tip is swiveling on the handle. These complaints have not resulted in any patient harm. Depending on the type of procedure, there is a potential for serious harm such as delayed recovery/delay in treatment, and tissue damage however, based on our investigation, the probability of any such harm to the patient remains remote to low. It is very likely that the user may still be able to continue suctioning even after the suction tip starts to swivel within the handle. The chances of detecting the swivel by the user remain high.

GC Medica is currently validating a revised manufacturing process after shifting the bending fulcrum of the bending fixture from the handle to the metal tube thus reducing the impact of the bending force on the handle. After successful validation and product testing, we shall introduce the revised product to the market.

Actions to be taken by the user

- Be aware of the potential issue with the Frazier handle as mentioned in this safety alert.
- Complete and return the enclosed acknowledgment form as soon as possible.
- Inform all concerned staff members.
- Inspect the Frazier suction handle for a loose tip prior to use.
- Keep additional/alternative Frazier units on standby just in case you experience swiveling of the suction tip.
- Take clinically appropriate and timely action to continue suctioning with the existing instrument or replace with a new one.

Actions to be taken by the Reseller

- Be aware of the potential issue with the Frazier handle as mentioned in this safety alert.
- Complete and return the enclosed acknowledgment form as soon as possible.
- Inform all concerned staff members and your customers by providing a copy of this safety alert.

In the event, the affected Frazier instrument has been supplied to any other organisations, please provide KINGSMEAD SERVICE LIMITED with this information within 24 hours at +044 - 207 183 2596.

This Safety Alert should be prominently displayed in an appropriate location until stock of the affected product is exhausted. You will be notified via email when a revised new product lot is introduced by GC Medica.



Any queries or concerns related to this alert should be directed to +044 - 207 183 2596.

ConvaTec and GC Medica sincerely regret any inconvenience caused to your institution.

Yours sincerely,

Name of Regulatory Contact Person

Title

Reply Form

Please complete the below form and return to the address provided.

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To: KINGSMEAD SERVICE LIMITED
Attention: Peng Yan
Email Address: office@kingsmead-service.com
Subject: Urgent Medical Device Safety Alert –
Frazier Suction Instrument
.....

From: _____
(Name of institution)

Contact Person: _____
(Please print name)

Telephone Number: _____

Facsimile Number: _____
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- We do not have any stock of the affected Frazier suction instrument

- We do have stock of the affected Frazier suction instrument at our site and agree to follow the instructions provided in this safety alert.



Any other relevant details:

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Signature: _____

Date: _____