

## **Field Safety Notice (FSN)**

### **GCE Combi valve products 0718112, 0718139, 0718140, 0718113 and 0718138**

Dear Customer,

**This document contains important information for continued safe and proper use of the GCE Combi valve products 0718112, 0718139, 0718140, 0718113 and 0718138 (the “Affected Products”) in BOC UK & Ireland and in BOC Australia companies.**

Please review, disseminate the following information and follow the instructions set out in this letter to all relevant persons within your organisation or to any organisation to which the Affected Products have been supplied. Please consider end users and others within the supply chain in the circulation of this notice.

#### **Purpose of this FSN**

To inform you about:

- action(s) you as a customer must take to minimize potential risk(s)
- actions planned or already taken by GCE to reduce potential risk
- potential issues and the circumstances in which they may occur.

#### **Background information**

GCE, s.r.o. has received information that the hose barb on one Affected Product, (used by BOC UK and BOC Australia only), had become detached during use.

The U-clip and hose barb were returned to GCE in a disassembled state from the flow head. The U-clip was unusually deformed and could not be inserted correctly into the flow head.

The problem was investigated with a focus on the assembly process. The assembly process has several check points that ensure the hose barb is correctly assembled. One such test involves the flow testing where a tube is fitted and removed from the hose barb. The production information has been reviewed for the valve identified checked, showing no anomalies. The information indicates that the hose barb was in place throughout our assembly process. We continue to investigate the root cause.

However, despite our determination that the Affected Products were functioning correctly when they were produced and sold to BOC UK and BOC Australia, during our investigations we found an opportunity to improve the assembly process and further reduce the possibility of an error. It was found that the U-clip insertion tool could be improved so that the alignment is at a closer tolerance. We also saw an opportunity to upgrade the design to further improve the engagement of the U-Clip. We see these steps as representing part of the continuous improvement of our products and processes.

There have been a few reported issues of the type described above, demonstrating a low failure rate of all Affected Products with this design of the hose barb fixation in the flow head.

## Recommended measures

### Immediate

- Immediate actions to contain the impacts of the failure and ascertain if there are other potential failures in the field are as follows:
  - BOC operation plants to implement additional checks to determine that the hose barb is securely fitted. This activity will identify the following:
    - if the hose barb is secure, the cylinder can be used
    - if the hose barb is loose or it is possible to detach it, the cylinder should not be used
  - review with GCE on a regular basis the results of the additional checks.

### Permanent

- GCE will, in relation to the Affected Products:
  - retrofit an improved flow setting hand wheel and longer U-clip to ensure that the U-clip is fully engaged, and the hose barb secured
  - replace the flow setting hand wheel and U-clip according to the instructions provided in the replacement parts package, and
  - retain the replaced flow setting hand wheels and U-clips, to enable full reconciliation of components fitted during the retrofit programme

GCE will make provision for all replacement parts.

The notice has been sent to all relevant competent medical authorities of the countries to which the product was delivered. Please follow your local medical device requirements and consider if you need to file a report.

GCE is committed to providing high quality, safe products and their continued success. We are committed to deliver the solutions needed. If there are any further clarifications or required information, please do not hesitate to contact your local sales representative, key account representative or any GCE Sales Unit. For local contact information please go to [www.gcegroup.com](http://www.gcegroup.com).

Further information and support can be sought by contacting your GCE representative directly or using the e-mail address [FSCA@gcegroup.com](mailto:FSCA@gcegroup.com).

We sincerely apologise for any inconvenience these actions and activities may cause.  
With warm regards,

Signature



Name: Ing. Jan Polan

Position: Quality Manager

<b>Device description</b>	GCE Combi valve
<b>General requirements to the customer</b>	Customer will receive new design flow setting hand wheels, U-clips, for GCE trained workers to carry out the replacement of the Affected Products in situ based on the attached procedure at customer locations.
<b>Risk of use</b>	If the hose barb falls out, it is not possible to provide the user with gas from the hose barb outlet.
<b>Affected products</b>	A total of 68 798 pieces comprising product numbers: <ul style="list-style-type: none"> <li>• 0718112</li> <li>• 0718139</li> <li>• 0718140</li> <li>• 0718113</li> <li>• 0718138</li> </ul>
<b>Description of Actions GCE has taken</b>	The notice was sent to all relevant competent medical authorities of the countries to which the Affected Products were delivered and to the supervisory competent authority of the manufacturer (SUKL). The Affected Products held by GCE, s.r.o. are blocked to prevent further use.
<b>Actions to be taken by customers</b>	Flow hand wheels and U-clips shall be captured in separate "scrap component" bags.
<b>Distribution and circulation of this FSN</b>	This Field Safety Notice is communicated to all BOC UK and BOC Australia customers, who are using the Affected Products as well as to the competent authorities in affected markets. Receivers should pass this FSN on to all people with a need to be advised from within your organisation or to any organisation where the Affected Products have been supplied. Please consider end users and others within the supply chain in the circulation of this notice.
<b>Further information and support</b>	If you need further information or support concerning this information and steps set out in this FSN, please contact your local GCE representative in your country or <a href="mailto:FSCA@gcegroup.com">FSCA@gcegroup.com</a> .

# Customer Reply Form

## 1. Field Safety Notice GCE, FSN reference number 2022\_07\_22

FSN Date*		22 July 2022
Product/ Device name* <i>(Please indicate appropriate product)</i>	<input type="checkbox"/>	Affected Products: <ul style="list-style-type: none"> <li>• 0718112</li> <li>• 0718139</li> <li>• 0718140</li> <li>• 0718113</li> <li>• 0718138</li> </ul>
Batch/Serial Number(s)		

## 2. Customer Details – please fill in

Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

## 3. Customer action undertaken on behalf of Healthcare Organisation

<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/>	I performed all actions requested by the FSN.	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	<i>Customer to complete or enter N/A</i>
<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	I do have affected devices. I do have ..... pieces of the Affected Products <i>Customer to indicate the amount of affected medical devices in active service</i>	<input type="checkbox"/> I do not have any affected devices in active service.
<input type="checkbox"/>	I have a query please contact me	<i>Customer to enter contact details if different from above and brief description of query</i>
Print Name		<i>Customer print name here</i>
Signature		<i>Customer to sign here</i>
Date		<i>Customer to insert date</i>

**4. Return acknowledgement to sender**

Email	FSCA@gcegroup.com
<b><i>Please return this form by the end of July 2022</i></b>	

*Mandatory fields are marked with \**

It is important that your organisation takes the actions detailed in the FSN and confirms receipt of the FSN. Your reply is the important evidence, which we need to monitor the progress of the corrective actions and is further shared with local Competent Authorities.

**INSTRUCTIONS:** Please return the completed and signed Reply Form to GCE via email at [FSCA@gcegroup.com](mailto:FSCA@gcegroup.com) or give it back to your local GCE sales representative who will forward the scan of this reply form at [FSCA@gcegroup.com](mailto:FSCA@gcegroup.com)