

Urgent Field Safety Notice
OCS™ Lung Console
REF #: 2000

March 2, 2018

TransMedics' reference: FSCA 2018-001

Dear OCS Lung Console Customer,

TransMedics is issuing a voluntary Field Safety Corrective Action (FSCA) affecting two (2) OCS Lung consoles in the European market. As part of our product quality monitoring process, we identified two plastic components used in the manufacture of the OCS Lung Console that did not meet specification. TransMedics has performed a detailed product risk assessment and the results demonstrate that this as a very low risk and the console is safe to use. TransMedics plans to replace these units as soon as the process defined below is complete.

Our records show that you have an impacted OCS Lung Console installed at your facility. In response, TransMedics kindly requests that you complete the attached Customer Response Form and return to the address/ contact listed.

Upon receipt of the completed Customer Response Form, a TransMedics Customer Service Representative will contact you to coordinate the replacement of your OCS Lung Console.

Please share this notification with others in your organization as appropriate. If your OCS Lung Console has been moved to another facility (or another area of your facility), please forward this Field Safety Corrective Notice to this facility immediately and notify TransMedics so that we can ensure proper notification is delivered.

Please contact myself at the number below, your local support representative, or TransMedics' Customer Service by phone at +1 (978) 552-0999 or email (service@transmedics.com) with any questions.

Please complete the attached form and return it using one of the methods specified.

TransMedics has notified the appropriate Regulatory Agency in your country of this action.

On behalf of the company, I thank you for being a TransMedics customer. We appreciate your cooperation and apologize for any inconvenience that this issue may cause. Please be assured that patient safety and product quality remain our primary concern.

Sincerely,

Mko'Hara

Michael O'Hara
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Internal reference: FSCA 2018-001