

URGENT – Field Safety Notice

FAO:	Perfusionists ICU Managers Theatre Managers Medical Device Safety Officers
Customer:	
Title:	Application Period for Paragon Oxygenators
FSN Number:	2018-01-16
Date of Issue:	6 th March 2018
Product Codes:	<i>Paragon PMP Oxygenators</i>
Serial Numbers:	<i>All Serial Numbers</i>
Type of Action:	Customer Notification
Definition:	<i>"Application Period"</i> – refers to the recommended length of time that the device can be used on a patient

Description

The purpose of this Field Safety Notice is to make customers aware that the application period of the Paragon PMP oxygenators has been reduced from 15 days to 24 hours.

This is not as a result of any product failure or deficiency and the product is unchanged. The company anticipates re-validating a prolonged duration of use and when this is completed a further FSN will be issued.

Corrective Action

The instructions for use booklet has been amended to show this reduced application time.

Advice or Action to be Taken by the User

Please ensure that all relevant personnel are aware of the information contained within this FSN.

Please read **Section 1.6** of the attached IFU relating to the application times.

Users should continue to assess the risk to patient should the application time be extended.

Please complete and return the acknowledgement form as soon as possible.

Contact Details

Chalice Medical Ltd
Manton Wood Enterprise Park
Worksop
UK
S80 2RS

Please contact your individual Sales Manager for further details.

Referenced Attachment

FSN Acknowledgement
Paragon Oxygenator IFU

Transmission of this Field Safety Notice

All personnel who are involved with the storage and use of the Paragon Oxygenators should be made aware of the contents of this FSN.

All relevant National Competent Authorities have been advised of this Field Safety Notice.

Sincerely



Carol Middleton
Quality Manager

FSN Acknowledgment

FSN Reference Number: 2018-01-16

Please complete this acknowledgment form confirming receipt of the FSN and send back to cmiddleton@chalicemedical.com at Chalice Medical immediately.

Hospital	
Address	
Form Completed By	
Title / Role	
Date	