



Total Healthcare Innovation GmbH

THI Total Healthcare Innovation GmbH
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2014 June 16, Feistritz im Rosental
01062014

Field Safety Notice (OXYGEN Sterile Protection)

Dear Customer,

In the interests of safety and product quality for our customers we would like to bring your attention that there has been detected a potential problem in a limited number of the product OXYGEN Sterile Protection (60200).

This field safety notice is intended to inform you about:

- What the problem is and where it can occur
- The actions that should be taken by the customer
- The actions planned by THI to correct the problem

This document contains important information for the continued safe and proper use of the equipment!

Please review the following information with all members of your organization who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

In a limited number of the product OXYGEN Sterile Protection (PN: 60200), a protective cover foil that protects the transparent part of the lens hood system is not removed at some pieces. After sterility test, performed by an independent laboratory, we can assure that the **sterility of the product**, despite the protective cover foil, **is still given**.

Please see the matrix on the following page, which provides instruction on how to identify affected products and actions to be taken.

If you need any further information or support concerning this issue, please do not hesitate to contact THI GmbH (stefan.tripolt@thigmbh.at).

THI GmbH apologizes for any inconveniences caused by this problem.

Sincerely,




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AFFECTED PRODUCTS	A limited number of OXYGEN Sterile Protection PN 60200 is affected by this action. THI has identified the LOT number of all affected products.
PROBLEM DESCRIPTION	In a limited number of the product OXYGEN Sterile Protection (PN: 60200), a protective green cover foil that protects the transparent part of the lens hood system is not removed after the assembling process.
HAZARD INVOLVED	After sterility testing of the affected product THI can ensure that there is no risk when using the product. Sterility of the product is still given.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>A limited number of LOT 201401 OXYGEN Sterile Protection (Product Number: 60200) are affected by this notice. Affected units can be identified by locating the LOT number on the package label. The additional foil is not visible as long as the product is not unpacked.</p>  <p>Picture 1: Additional green protective foil</p>
ACTION TO BE TAKEN	Please inform your customers who received the affected LOT that there might be some products with an additional layer. If you have an affected product (product with and additional foil), contact THI GmbH for replacement.
ACTIONS TAKEN BY THI	Customers who have an affected product will be supplied with a replacement from THI, free of charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact us at: THI GmbH, Gewerbestrasse 4, 9181 Feistritz im Rosental, Tel: 0043 4228 30100, office@thigmbh.at