

FAN ID: 22-09-2024

Language: English

Type: Advice from manufacturer regarding use by customer

## Field Corrective Action

Silicone Oil – 1000/2000/5000 – Pre-Filled Syringe injection with surgical system  
(product codes SIL-1000-S, SIL-2000-S, SIL-5000-S)

FAN Identifier: 22-09-2024

Att: [name customer]  
[address customer]  
[postal code, city]  
[country]

Dear Customer,

The purpose of this letter is to inform you about a corrective action required for users of the DORC range of Silicone Oil products supplied in pre-filled syringes when performing injection controlled by a surgical system. The corrective action is being implemented to reduce the risk of breakage of syringes during injection.

This letter refers specifically to the DORC range of Silicone Oil supplied in pre-filled syringes. The range includes the 1000cs, 2000cs and 5000cs variants, all supplied in pre-filled 10ml syringes. According to our information, you have ordered DORC Silicone Oil in pre-filled syringe during the last 02 years.

The new precaution addresses a recently identified risk associated with the handling of silicone oil injections where the pre-filled syringe is connected to a surgical system to perform injections during ophthalmic surgery. The risk and resulting precaution identified during the investigation of incidents that occurred during product use. It has been determined that breakage of the syringe can occur during use when the injection pressure is elevated above 4.0 bar. For this reason, DORC is implementing a new instruction to limit the injection pressure to a maximum of 4.0 bar during injection of silicone oil. The benefits of the use of Silicone Oil can continue when using pressure lower than the new ~~recommended~~-level.

Please review this information and share with relevant members of your staff and ensure that is communicated to any other organizations who may have received this product from you).

If you need any further information or support concerning this letter, please contact our Customer Technical Service Center on +31 181 45 80 80 or at [TSC@dorcglobal.com](mailto:TSC@dorcglobal.com).

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. is committed to ensure patient safety and therefore decided to share this important information with you prior to implementation in the Instructions for Use.

Sincerely,

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<b>Affected product, commercial name</b>	Silicone Oil Syringes – 1000/2000/5000
<b>Affected product article number</b>	SIL-1000-S, SIL-2000-S, SIL-5000-S
<b>How to identify affected products</b>	The Field Corrective Action applies to injection of Silicone Oil when connected to a surgical system
<b>Reason for Field Corrective Action</b>	The increased occurrence of this issue has elevated the overall risk, and led DORC to take this corrective action. In these incidents it has been determined that injection pressure used may have contributed to the breakage of the syringe during use.
<b>Risk of continued use</b>	Silicone Oil in pre-filled syringes can continue to be used providing that users follow the instructions regarding pressure settings during injection:  <u>Precaution</u> Pressure used during injection of DORC silicone oil from a pre-filled DORC supplied syringe must not exceed 4.0 bar pressure.
<b>Risks of previous use</b>	None - There have been no adverse events reported related to past use under standard procedures
<b>Customer actions</b>	We request that you take the following actions: <ul style="list-style-type: none"> <li>• Please pass the information provided in this Field Corrective Action on to all those who need to be aware of it (including other organizations who might have received this product from you).</li> <li>• Complete the attached Field Corrective Action Acknowledgement Form, sign it and return a scan or photo of the signed form by email to at <a href="mailto:TSC@dorcglobal.com">TSC@dorcglobal.com</a>.</li> </ul>
<b>Manufacturer actions</b>	<ul style="list-style-type: none"> <li>• Informing you about the newly identified risk and resulting warning and precaution through this Field Safety Notice.</li> <li>• To add the additional warning and precaution to the IFU.</li> </ul>

## Acknowledgement Form

By completing and signing the section below I confirm that I have read and understood the Field Safety Notice identified by FAN ID: 22-09-2024 and that this information was provided to all those who need to be aware of it.

<b>Responder information</b>
<b>Organization name:</b>
<b>Full name of responder:</b>

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<b>Title:</b>
<b>Contact phone:</b>
<b>Contact address:</b>
<b>Date of completion:</b>
<b>Signature of responder:</b>

Please send a scanned copy or photo of this completed form per email as soon as possible to: [TSC@dorcglobal.com](mailto:TSC@dorcglobal.com)