

## Important Field Information

### Advice given by the manufacturer of a Medical device to medical staff regarding the use of the device

**Breaking of the glass syringe during the preparation of DORC 'Silicone Oil, 1.000cSts syringe 10ml' in the adapter of the DORC 'VFI Pack for Silicone Oil syringe'.**

Article number	Description	Batch number
SIL1000.S	Silicone Oil, 1.000cSts, syringe 10ml	44914 (2000367565)
1363.DD	VFI Pack for Silicone Oil syringes	All, to date

May 22, 2015

Dear Customer,

According to our information, you have obtained the product SIL1000.S from lot 44914 as noted above. This 'Important Field Information' is intended to inform you that the glass syringe containing the DORC silicone oil (SIL1000.S of lot 44914) could break when mounted in the adapter of the DORC VFI Pack for Silicone Oil syringe (1363.DD). Please note this alert does not apply to either a) manual infusion of silicone oil or b) use of a VFI system provided by an alternative supplier

**This document contains important information for the continued safe and proper use of our medical devices**

Please review the following information with relevant members of your staff

If you need any further information or support concerning this issue, please contact our Customer Service Center on +31 181 45 80 80.

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. apologizes for any inconvenience caused by this problem.

Kind regards,

Peter Ramakers

Manager QA

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<b>AFFECTED PRODUCTS</b>	Silicone Oil, 1.000cSts, syringe 10ml. See table above for product/lotnumber references.
<b>PROBLEM DESCRIPTION</b>	<p>DORC became aware of potential performance issue of the glass syringe of SIL1000.S of lot 44914. When mounting the syringe in the VFI adapter of the VFI Pack for Silicone Oil syringes (1363.DD) the glass of the syringe could break. Root cause analysis revealed that the fit of the syringe into the VFI adapter is too tight because the finger flange of the syringe is thicker than required.</p> <p>This could result in breaking of the glass syringe during the preparation of the 'Silicone Oil, 1.000cSts syringe 10ml'.</p> <p>To date, there have been no reported incidents resulting from this issue.</p>
<b>HAZARD INVOLVED</b>	Breaking of the glass syringe means that the product 'Silicone Oil, 1.000cSts syringe 10ml' becomes unsuitable for use.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	The above-listed products are potentially affected. The batch number of the product is stated on the product labeling.

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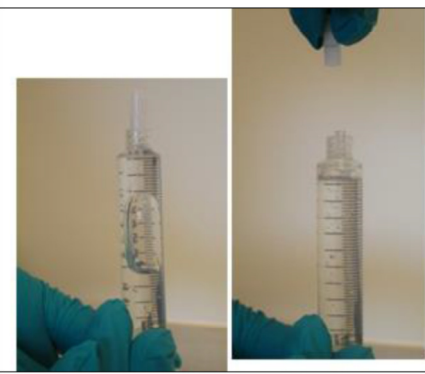


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<b>ACTION TO BE TAKEN BY CUSTOMER/USER</b>	<p><b>Do not use the glass syringe of the SIL1000.S in combination with the adapter of 1363.DD.</b></p> <p>In order to use the silicone oil of SIL1000.S safely, we advise to use it manually with supplied plunger or to transfer the silicone oil from the glass syringe of product SIL1000.S into the plastic syringe as supplied with VFI Pack (1363.DD), using the following procedure (see also the pictures in appendix A):</p> <ul style="list-style-type: none"><li>• Make sure that the syringe tip cap is properly placed on the empty 10cc syringe</li><li>• Hold the tip of the empty syringe downwards and transfer the silicon oil from the prefilled syringe into the empty 10 cc syringe</li><li>• Place the rubber piston into the silicon oil filled 10 cc syringe</li><li>• Hold the silicon oil syringe upwards and remove the syringe tip cap to allow the air to escape</li><li>• Securely attach the silicon oil injection cannula</li><li>• With the plunger press the rubber piston until the silicon oil reaches the cannula</li><li>• Connect syringe adapter of the VFI pack to the silicon oil filled syringe by pushing down and rotating the syringe 90 degrees.</li><li>• Connect the air connector of the tubing to the Silicon oil injection port of the surgical system</li><li>• <b>NOTE: Ensure that the black piston is placed into syringe before connecting the syringe adapter to the silicon oil filled syringe. Failure to do so</b></li></ul>
<b>ACTIONS TO BE TAKEN BY DORC</b>	DORC International is notifying affected users of this issue via direct contact and this 'Important Field Information'.
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact our Customer Service Center on +31 181 45 80 80.

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**Appendix A** – Transfer of the silicone oil from the glass syringe of product SIL1000.S into the plastic syringe as supplied with VFI Pack (1363.DD)

	
1 - Contents of VFI Pack (1363.DD)	2 - Preparation for silicone oil transfer
	
3 - Transfer of Silicone Oil in plastic syringe	4 - Placing of the (black) piston in the syringe
	
5 - Removing the air from the filled syringe	6 - Mounting the adapter to the syringe
	
7 - Locking the adapter to the syringe	