

Dear distributor,

DORC became aware that the use of the 1363.DD VFI Pack for Silicone oil syringes in combination with certain batches of 10ml prefilled glass syringes containing silicone oil (i.e. SIL-1000-S and SIL-5000-S with expiry dates as of 2017-12) could result in breaking of the finger flange of the glass syringe, leaving the contents of the syringe (silicone oil) untouched.

The following products are potentially affected:

Article number	Description	Batch number		
1363.DD	VFI Pack for Silicone Oil syringes	140585	160291	170775
		1406103	160390	170806
		140630	1604113	170939
		140638	160515	171009
		140919	160612	1712140
		140973	160786	1712150
		141051	160821	1712168
		150301	160931	171218
		150473	160937	171260
		1505133	160949	180135
		150518	161148	180209
		150614	161216	1802100
		150778	170120	180370
		150820	170272	1804121
		150992	170311	1804148
		151079	1704186	1804149
		151108	170473	1804180
		151196	170512	1806149
		151227	170599	180628
		151248	170628	180745
160167	170704	1808166		
160225	1707135			

Root cause analysis revealed that the problem is due to the combined use of the syringe and the adaptor. In extreme tolerance fields of the adaptor and the syringe there is a transgression force build up between the adapter and the syringe, incidentally resulting in breaking of the syringe flange.

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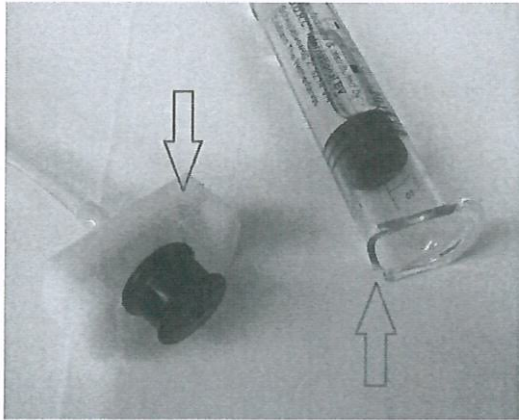
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Breaking of the flange of the glass prefilled silicone oil syringe (i.e. SIL-1000-S and SIL-5000-S) is related to the following potential harms:

- Wound damage: due to the breakage the surgeon might make a sudden movement which can increase the sclerotomy
- Tissue damage: the glass might cut the user.

Please note that all silicone oil batches supplied to your country can be safely used with the current adaptor (i.e. 1363.DD). However, as a preventive measure, in order to prevent potential breaking of the finger flange of the glass prefilled silicone oil syringes (i.e. SIL-1000-S and SIL-5000-S) with an expiry date as of 2017-12 the distribution of these batches to your country will be on hold as long as the current VFI Pack for Silicone Oil syringes (i.e. 1363.DD) is available at your customers to be used in combination with prefilled glass syringes containing silicone oil (i.e. SIL-1000-S and SIL-5000-S with an expiry date as of 2017-12).

D.O.R.C. has initiated a design change of the syringe adaptor included in the VFI pack (i.e. 1363.DD) to solve this potential issue. When available this adaptor can be supplied to customers as an exchange for the current syringe adaptor.

Please inform me with regard to your activities to notify this issue to the national competent authority in compliance with local legislation and the follow-up to end-users to exchange the current VFI Pack for Silicone Oil syringes (i.e. 1363.DD) for the new design when available. Please ensure that D.O.R.C. receives completed Distributor Reply Forms and Customer Reply forms prior to the return of the current VFI Pack for Silicone Oil syringes (i.e. 1363.DD).

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

Manager RA

Date: 07-09-2015

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