Urgent Field Safety Notice

Return of a Medical device to the supplier

Observation of particles in the eye after injection of MBD-05-SD.

Article number	Description	Lot number
MBD-05-SD	MembraneBlue® Dual (Germany)	14813 *Note: for internal reference 2000361035*
MBD-05-SD	MembraneBlue® Dual (Germany)	21014 *Note: for internal reference 2000363660*

October 22nd, 2014

Dear Customer,

According to our information, you have obtained one of the products noted above. This Field Safety Notice is intended to inform you that the product MBD-05-SD as exclusively distributed in Germany, of lots 14813 and 21014 are not to be used and should be returned to D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. following the instructions stated in this document.

On a few occasions, particles have been observed in the vitreous body of the eye following the injection of MBD-05-SD. Currently we do not know the origin of these particles, however it appears that this phenomenon only emerges under certain circumstances. Although the particles were only observed in a few cases, we are not able to guarantee the safe use of the product since the particles could impact the performance of the device and may have an adverse effect on the patient. For this reason D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. decided to recall MBD-05-SD of lots 14813 and 21014 from the German market.

This document contains important information on MBD-05-SD MembraneBlue® Dual, exclusively distributed in Germany.

Please inform all relevant members of your staff.

If you have any questions regarding this issue, please do not hesitate to contact our Customer Service Center on +31 181 45 80 80 on working days from 8:30 AM until 17:30 PM and/or per e-mail qa@dorc.eu for further information or support.

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This notice will be reported to the appropriate Regulatory Authorities.

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

Kind regards,

[redacted]

Manager QA/RA

Date: October 22nd, 2014