

Urgent Field Safety Notice

RECALL

regarding

**VISCOJECT™-BIO 1.8 SINGLE-USE CARTRIDGE SETS, STERILE
VISCOJECT™ 2.2 INJECTOR SET SINGLE-USE, STERILE
MULTIPLE-USE PHACO TIPS AND SLEEVES; STERILE**

Sender:

7. August 2013

Medicel AG
Luchten 1262
CH-9427 Wolfhalden
Switzerland

Addressee:

Firmenname
Adresse
PLZ, Stadt
Land

Identification of Medical Devices concerned:

Description: **VISCOJECT™-BIO 1.8 SINGLE-USE CARTRIDGE SETS, STERILE**
Reference number: **LP604250C**
Lot: **1329D04**
Quantity: **XX Boxes à 10 pieces**
Expiry date: **06-2016**

Description: **VISCOJECT™ 2.2 INJECTOR SET SINGLE-USE, STERILE**
Reference number: **LP604340**
Lot: **132711**
Quantity: **XX Boxes à 10 pieces**
Expiry date: **06-2016**

Description: **MULTIPLE-USE PHACO TIPS AND SLEEVES; STERILE**
Reference number: **PA603500RU**
Lot: **13/176**
Quantity: **XX Boxes à 10 pieces**
Expiry date: **06-2018**

Description: **MULTIPLE-USE PHACO TIPS AND SLEEVES; STERILE**
Reference number: **PA603100CRU**
Lot: **13/174**
Quantity: **XX Boxes à 10 pieces**
Expiry date: **06-2018**

Description of the problem:

During a routine quality inspection we found that the setting of one of our tyvek lid printers was changed wrongly by a service technician of the printer company. Our investigation shows that while doing the service he increased the force used by the printer to hit against the ink ribbon. Our investigation has also shown that this increased force can lead to microscopically small damages of the tyvek lid (micro-perforations) which are visible only by 40 times magnification. Since only one of our printers is affected, this non-conformity does not relate to all products of this lot.

Patients treated with concerned products could be subjected to a potential risk of an inflammation. There are no special measures required if patients have been treated already with one of these products.

Advise on action to be taken by the user:

Please do not use these products for treatment of patients and send back all products to the above mentioned address. After receipt of the returned products we will replace these within a maximum period of three weeks' time.

Please confirm by Fax or Email in advance to the below mentioned contact that you are sending back the products and tell us about the quantities if any of them were used on the patient.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:


Mr Volker Dockhorn

Tel.: +41 71 727 1050, Fax.: +41 71 727 1055, Email: v.dockhorn@medicelag.com

We hope for your understanding in this issue and apologise for any inconveniences caused.

Medicel AG

Volker Dockhorn
General Manager


Chief Operating Officer