Urgent Field Safety Notice

RECALL
regarding
SINGLE-USE SWISS BI-MANUAL I/A SYSTEMS, STERILE
SINGLE-USE SWISS MONO-MANUAL I/A SYSTEMS, 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:	**SINGLE-USE SWISS BI-MANUAL I/A SYSTEMS, STERILE**
Reference number:	**SBS110A**
Lot:	**13/166**
Quantity:	**XX Boxes à 10 pieces**
Expiry date:	**05-2018**

Description:	**SINGLE-USE SWISS MONO-MANUAL I/A SYSTEMS, STERILE**
Reference number:	**SMS135**
Lot:	**13/162**
Quantity:	**XX Boxes à 10 pieces**
Expiry date:	**05-2018**

Description:	**SINGLE-USE SWISS MONO-MANUAL I/A SYSTEMS, STERILE**
Reference number:	**SMS165P**
Lot:	**13/160**
Quantity:	**XX Boxes à 10 pieces**
Expiry date:	**05-2018**

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.

Usually, the print of item code, lot number and expiry date are positioned in the area of the blue sealing area and therefore, the tyvek print is surrounded by the fully sealed tyvek material. However, in a few cases we have also seen that this printing area is slightly moved towards the center of the blister and might exceed the area of the blue sealing border.

Our concerns only relate to those products which were printed with the faulty printer and in which the print is not fully surrounded by the blue sealing area. If those two issues come together, we are concerned that the sterilization barrier function of the tyvek lid might be compromised and therefore, sterility of the products might be compromised.

The functional properties of the product are not related, our concern is only about the integrity of the sterile barrier. However, products which are used in Custom Packs and which are sterilized within the Custom Packs are not considered to be critical in any way since sterility of the whole Custom Pack can be guaranteed by the additional sterilization and its outer packaging and functionality of the IA products are not affected at all by this.

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, unless they were sterilised upfront in Custom Packs, and send back all products to the above mentioned address. If you also would like us to replace products packed in Custom Packs please send these back as well. 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 where 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

[redacted]
Chief Operating Officer