

09th July 2018

URGENT - FIELD SAFETY ADVISORY NOTICE

Commercial Name of Affected Product:	RUSCH GREENLITE MAC
Type of action:	Advisory Notice
Teleflex Reference:	EIF-000271
Product code	Lot/Batch
004551003 (correct)	1704331 (correct)
004551004 (incorrect)	1704341 (incorrect)

Dear Customer,

Details of affected devices

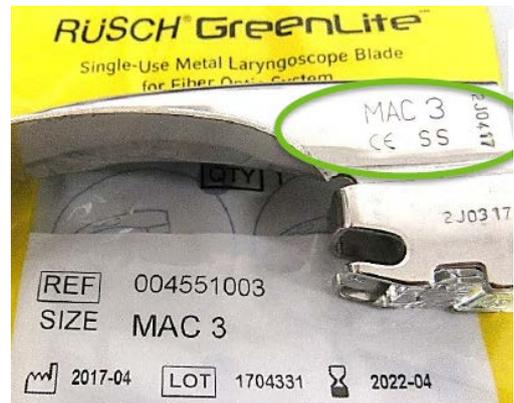
Teleflex is issuing an advisory notification for the above listed product.

Description of the problem

Teleflex is issuing an advisory notice for the product referenced above due to a labelling error on the outer blue box containing 20 individually packaged and labelled units per box. Some boxes are labelled as containing RUSCH GREENLITE MAC 4 devices, when they in fact contain RUSCH GREENLITE MAC 3 devices. The boxes that are incorrectly labelled as containing RUSCH GREENLITE MAC 4 devices are marked with labels that incorrectly list the product code as 004551004 instead of 004551003, and incorrectly list the lot number as 1704341 instead of 1704331.

- Individual units are correctly etched with their size (*refer to image*).
- Units are packaged in individual colour coded pouches in accordance with their size, in this case a yellow pouch.
- Pouches are labelled with the correct product code, lot number and product size.

It is unlikely that the use of these products will result in any adverse health consequences. No patient injuries have been reported related to this issue.



FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

Our records indicate your facility has received product in scope of this advisory notice. Please provide this Advisory Notice to all those who need to be aware of it within your organisation and place a copy with affected product. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice. There is no further action required.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

If you are a distributor, provide this field safety notice to all your customers who have received product in scope of this Field Action. There is no further action required.

If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service

Contact: Nicole Morawiec

Telephone: +41 (0) 31 818 40 90

FAX: +41 (0) 31 818 40 93

E-Mail: info.ch@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Teleflex

Karen Boylan

Karen Boylan
VP, Global RA/QA