Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Ireland

17 July 2019

URGENT – FIELD SAFETY NOTICE

Type of Action			Recall		
Teleflex Reference			EIF-000366		
Commercial Name			RUSCH IMEX GOLD 2 WAY 5 cc -RUBBER VALVE RUSCH GOLD 2WAY 5 cc PLASTIC VALVE		
Product code	**Lot number**	**Product code**	**Lot number**	**Product code**	**Lot number**
009822-000120	P18G04	009822-000160	P18G04	180605-000140	P18K03
	P18H10		P18G05		P19D09
	P18I03		P18H05		P19E03
009822-000140	P18G04		P18H10		P19F02
	P18G05		P18I03	180605-000160	P18G04
	P18H05		P18J03		P18G05
	P18I09		P18J08		P18G11
	P18J03		P18K03		P18I03
	P18J08		P19A03		P18K03
	P18J09		P19A07		P18L04
	P18K03		P19A08		P19A08
	P18L04		P19B07		P19C03
	P18L10		P19C03		P19D09
	P19A03		P19F03		P19E03
	P19A08	180605-000140	P18G04		P19E07
	P19A09		P18G05		P19F02
	P19B07		P18G11		
	P19C03		P18I03		

Dear Customer,
Teleflex Medical has voluntarily issued a recall for the product codes and lot numbers listed above.

Description of the problem & immediate actions required
There is a potential that the product may malfunction resulting in non-deflation of the catheter during use. If difficulty is encountered during deflation of balloon with syringe, and alternative methods (catheter cutting/balloon rupturing) are necessary, there may be mucous membrane trauma due to possible surgical intervention to retrieve ruptured balloon and/or fragments. Therefore, there is a remote potential for injury with the risk of surgical intervention required to treat non-deflated urethral catheter balloons.

Product code and lot combinations not referenced above are not in scope of this recall.

Our records indicate you have received products that are subject to this recall.
Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities	**1**
Distributors	**2**

Action list number 1 – Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.
3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Action list number 2 – Distributors

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope to Teleflex.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
4. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
5. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, 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 of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation 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 and cc: Chairman Medical Board and relevant Head of Departments.

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:

Contact: Victor Tan **Telephone:** +65 6439 3123
Designation: Senior QA Engineer **Email**: [redacted]

Teleflex is committed to providing high quality, safe and effective products. We sincerely apologise 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,

[redacted]

Padraig Hegarty VP, QA (Manufacturing)

Teleflex MEDICAL

Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000366

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX:	**Email**:
☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory **DOES** include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. **Return Authorisation No:** _____

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number is clearly visible** on the returns package
- Please label returns as **"Field Safety Returns"**

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSITIUTION ADDRESS	**Phone/FAX**
FORM COMPLETED BY:	**Stamp**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	