

20 Feb 2014

URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:	Recall		
TELEFLEX REFERENCE:	001/13		
COMMERCIAL NAME OF AFFECTED PRODUCTS:	Catalog Number	Lot Number	
Rusch Bronchopart®	116200	Ref Appendix 2	
Rusch Bronchopart®	116262		
Rusch Bronchopart® White	116201		
Rusch One-lumen bronchial tube, right	115901		
Rusch Tracheopart®	116401		

Dear Customer,

1. Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed products.

2. Description of the problem

Teleflex is recalling the products referenced above as we have received complaints that the Rusch Bronchopart® (116200) may fail to achieve seal of the right lung due to the cuff inflating to one side. If a seal does not occur there is the potential for oxygen de-saturation and loss of volatile anaesthetics, requiring re-intubation of the patient.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of affected product and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned there.
3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned in section 6 who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.

2. As a Distributor you are 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.
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
4. 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.

4. Teleflex

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

5. Transmission of this Field Safety Notice

This notice should be passed on 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

6. Contact reference person

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

Customer Service:

Contact: Shane Kenny

FAX: +353 (0)1 4370773

Telephone: +353 (0)90 6460869

E-mail: orders.intl@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.

For and on behalf of Teleflex,

████████████████████

████████████████

Senior Director of Quality International.

Customer No.

Appendix 1

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX
IMMEDIATE ATTENTION REQUIRED

RETURN COMPLETED FORM IMMEDIATELY TO:
FAX: +353 (0)1 4370773 E-mail: orders.intl@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and 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 _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Rusch Bronchopart® / Rusch Bronchopart® White/ Rusch Tracheopart® / Rusch One-lumen bronchial tube, right	
PRODUCT NUMBER	LOT NUMBER	QUANTITY
<ul style="list-style-type: none"> 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 Action Returns” 		

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

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	Phone / Fax
FORM COMPLETED BY:	TITLE/ROLE
PRINT NAME: _____ SIGNATURE: _____	
DATE:	

Part Numer/Lot Number									
116200260	116200350	12DE18	116200390	116200410	116201410	115901-000080	116200-000280	116200-000280	116200-000350
09LE51	11JE42	116200370	11IE38	13BT44	12AE01	13BT44	09JE41	13DT32	10FE24
10GE31	11JE43	12GE31	11IE39	13DT32	12DE16	13GT16	09KE45	13FT06	10FE25
11JE42	12AE02	12IE39	11JE42	13ET12	12DE17	116200-000260	09KE46	13FT12	10GE28
12DE17	12BE07	12JE44	12EE19	13ET12R	12IE37	09HE34	09LE51	13HT12	10LE49
12EE19	12DE17	13AT44	12JE44	13ET13R	12KE47	09JE41	10BE07	13HT17	10LE51
12IE37	12EE19	13BT44	13AT36	116201350	13AT36	09LE51	10BE09	116200-000350	11AE03
13CT26	12GE27	13CT26	13BT25	09JE40	13FT06	10AE04	10DE16	0908M	11DE15
13DT32	12HE33	13ET13	13BT29	11JE40	115901-000080	10GE30	10JE41	0914M	11GE27
13ET13R	13AE01	13ET13R	13BT37	13FT12R	09GE31	10JE41	10LE52	0915M	11GE30
116200280	13CT26	116200390	13BT44	13GT05	09JE44	11AE04	11AE04	0916M	11HE33
09HE34	13DT33	09HE35	13CT26	116201390	10AE02	11GE29	11HE33	0917M	11IE39
09JE41	13ET12	09JE42	13DT33	09JE44	10BE06	11JE44	11IE38	0918M	11JE43
10BE07	13FT12R	09JE43	13ET12	10CE10	10GE30	11LE51	11JE41	0919M	11JE44
11HE33	13GT11	09JE44	13HT12	10DE18	10KE48	12AE03	11JE44	0922M	11LE49
11JE41	13HT07	09KE46	116200410	116201410	11AE04	12EE20	11LE51	09FE23	12AE01
12BE07	116200370	09LE51	09IE36	10KE47	11GE27	12GE27	12AE03	09FE25	12AE02
12DE17	09JE41	10AE01	09JE43	115901-000065	11GE28	12KE47	12CE12	09GE31	12AE03
13CT26	09JE43	10AE02	10AE05	09HE32	11IE38	12LE49	12EE22	09HE34	12BE07
13DT26	11DE15	10CE11	10BE06	09JE44	11JE41	13AE01	12GE27	09JE43	12CE10
13ET12	11EE20	10DE18	10DE16	09LE51	12AE01	13BT25	12GE30	09JE44	12DE17
13ET12R	11GE27	10EE19	10GE28	10BE06	12BE08	13DT30R	12IE38	09KE45	12EE19
116200350	11HE32	10EE20	10JE41	10DE16	12EE21	13DT32	12KE45	09KE47	12EE22
09HE34	11IE39	10GE29	11DE15	10LE52	12EE22	13FT12	12KE48	09LE51	12FE25
09JE42	11JE42	10JE41	11GE27	11GE27	12GE28	13GT29	13AT36	10AE03	12FE26
09JE43	11JE43	11DE15	11HE34	11GE28	12HE32	13HT12	13BT37	10BE06	12GE27
11AE03	12AE01	11GE30	11JE43	11IE37	12JE43	13HT17	13CT26	10DE15	12GE29
11DE15	12AE03	11HE33	12AE03	11JE41	12KE46	116200-000280	13DT30	10DE17	12HE32
11GE27	12BE06	11IE37	12BE07	11KE47	13AT44	09HE34	13DT30R	10EE22	12HE35

Part Number/Lot Number									
116200-000350	116200-000370	116200-000370	116200-000370	116200-000390	116200-000390	116200-000390	116200-000410	116200-000410	116201-000350
12KE45	0916M	11DE16	12JE44	09FE23	11GE30	13BT37	10EE19	12FE26	09FE23
12KE46	0917M	11GE27	12KE45	09FE24	11GE31	13DT25	10EE20	12GE28	09FE24
12LE51	0919M	11GE28	12KE47	09HE32	11HE33	13DT30R	10EE22	12IE37	09HE32
13AE01	0921M	11GE29	12KE48	09HE33	11IE37	13DT33	10FE23	12IE39	09HE33
13AE02	0922M	11GE30	12LE49	09HE35	11IE38	13ET12	10FE24	12JE43	09JE43
13BT19	09FE24	11GE31	13AE01	09JE43	11JE42	13ET13	10GE28	12KE45	09KE47
13BT25	09GE31	11HE32	13BT25	09JE44	11JE44	13FT12	10JE41	12KE46	09LE51
13DT25	09HE32	11HE33	13BT29	09KE46	11KE48	13FT18	10KE46	12LE49	10AE04
13DT30	09HE33	11IE37	13BT44	09LE52	11LE49	13GT16	10KE47	12LE51	10BE06
13DT32	09HE34	11IE38	13DT26	10AE01	12AE03	13GT29	10LE51	13AE02	10DE15
13DT33	09HE35	11IE39	13DT30	10AE02	12BE08	13HT12	10LE52	13AT28	10DE18
13DT34	09IE38	11JE43	13DT30R	10BE09	12BE09	116200-000410	11AE04	13BT19	10FE24
13ET12	09JE43	11KE48	13DT33	10CE10	12CE11	0903M	11DE15	13BT25	10GE29
13ET13	09KE47	12AE01	13ET12	10CE11	12CE12	0909M	11DE16	13DT26	10GE30
13ET18	09LE51	12AE03	13ET13	10DE15	12CE13	0914M	11GE27	13DT30R	10KE48
13GT05	10AE03	12BE06	13ET23	10DE16	12DE15	0915M	11GE28	13DT31	10LE52
13GT11	10BE06	12CE10	13FT17	10DE18	12DE16	0918M	11GE30	13ET12	11GE31
13GT23	10DE15	12DE14	13GT05	10EE19	12EE19	0922M	11HE34	13ET18	11JE40
13GT29	10DE16	12DE15	13GT16	10FE26	12GE28	09FE23	11JE43	13FT12	11JE42
13HT07	10DE17	12DE16	13HT12	10GE29	12HE32	09GE31	11KE48	13GT11	11JE44
13HT12	10EE20	12EE19	116200-000390	10JE41	12IE38	09HE32	12AE02	13GT24	12BE08
13HT17	10EE22	12EE20	0904M	10KE46	12JE43	09IE36	12AE03	13GT29	12DE15
116200-000370	10FE24	12EE22	0909M	10LE52	12KE45	09JE44	12BE07	13HT12	12EE22
0901M	10GE28	12FE24	0914M	11DE14	12KE46	09KE45	12CE11	13HT17	12GE30
0902M	10KE48	12GE28	0915M	11DE15	12LE49	09LE52	12DE18	116201-000350	12HE32
0906M	10LE49	12GE29	0916M	11EE19	13AE01	10AE05	12EE20	0904M	12IE36
0907M	10LE52	12GE30	0917M	11FE26	13AE02	10BE06	12EE22	0919M	12IE37
0914M	11AE03	12HE33	0918M	11GE27	13AT36	10DE15	12FE24	0921M	12JE43
0915M	11BE09	12JE40	0922M	11GE28	13BT25	10DE17	12FE25	0922M	12KE47

Part Number/Lot Number											
116201-000350	116201-000370	116201-000370	116201-000390	116201-000390	116201-000410	116201-000410	116262-000370	116262-000390	116262-000410	116401-000850	116401-000950
12LE49	10BE06	12HE32	09KE45	12GE28	10BE06	12IE38	0914M	10KE48	12JE40	10LE52	12GE29
13AE01	10EE20	12IE37	09LE52	12GE30	10CE11	12JE40	09GE31	11AE04	13BT25	11FE25	12LE49
13AT44	10FE24	12IE38	10AE04	12GE31	10DE14	12KE45	09HE34	11DE17	13DT33	11GE29	13BT29
13DT25	10GE28	12IE39	10CE10	12HE32	10DE15	12KE47	10AE04	11IE38	116401-000750	11GE30	
13DT26	10JE42	12JE43	10GE29	12JE41	10DE16	12LE51	10CE11	11IE39	09HE34	11HE34	
13DT30	10KE48	12KE45	10JE43	12JE43	10DE18	13AE02	10CE12	11KE48	09IE38	11IE38	
13ET12	10LE50	12LE49	10LE51	12LE49	10EE19	13AT36	10KE47	11LE52	09JE44	11LE51	
13ET23	10LE52	13AE01	11BE09	12LE50	10EE20	13AT44	10LE49	12BE09	10BE09	12AE02	
13FT17	11AE04	13AE02	11FE25	13AE01	10GE28	13BT19	11DE15	12EE19	10GE30	12CE11	
13GT05	11EE19	13AT36	11GE28	13AE02	10KE48	13BT25	11IE37	12KE48	10JE41	12DE14	
13GT24	11GE31	13AT44	11IE37	13AT36	11BE08	116262-000260	11JE41	116262-000410	10LE52	12EE21	
13HT07	11HE32	13BT37	11IE38	13AT44	11BE09	10AE04	11JE44	0914M	11FE25	12IE38	
13HT12	11IE37	13DT30	11IE39	13BT25	11FE25	116262-000280	12BE09	09HE34	11GE28	12LE49	
13HT17	11IE38	13DT32	11JE40	13DT25	11GE30	09JE42	12DE15	09JE43	11HE34	13AE02	
116201-000370	11JE40	13ET18	11JE42	13DT30R	11IE38	10AE04	12GE29	10AE05	11JE41	13DT33	
0904M	11JE41	13ET23	11KE45	13ET13	11IE39	10BE09	12JE41	10BE06	12AE02	13ET12	
0915M	11KE45	13FT06	11KE48	13ET23	11JE41	11GE29	12LE49	10CE11	12DE14	116401-000950	
0917M	12AE01	13GT11	11LE50	13FT06	11KE48	11GE30	116262-000390	10DE15	12GE29	10BE09	
0919M	12AE03	13GT29	12BE06	13GT11	12AE03	13HT07	0914M	10KE48	12JE43	10CE10	
0922M	12BE08	13HT12	12BE08	13HT07	12BE07	116262-000350	0918M	11AE04	12KE48	10JE42	
09FE24	12CE11	13HT17	12CE11	13HT12	12CE11	09HE32	0922M	11DE17	13AE02	10LE52	
09GE28	12CE13	116201-000390	12CE12	116201-000410	12CE12	10AE04	09GE29	11GE29	13BT37	11FE25	
09HE33	12DE14	0904M	12DE14	0904M	12DE15	10CE11	09LE51	11HE34	13DT31	11FE26	
09IE36	12EE22	0914M	12DE16	0915M	12EE20	10CE12	10AE05	11IE39	13FT06	11GE29	
09JE43	12FE25	0917M	12EE19	0922M	12FE23	10KE47	10CE11	12CE11	13GT24	11HE34	
09KE45	12GE28	0922M	12EE20	09FE23	12GE30	10LE52	10DE15	12EE20	116401-000850	11JE43	
09KE47	12GE29	09HE33	12EE21	09HE32	12HE33	11JE42	10DE16	12GE29	09HE32	11LE49	
09LE51	12GE30	09IE36	12EE22	09LE52	12IE36	11JE44	10EE20	12HE32	10BE09	11LE51	
10AE04	12GE31	09JE44	12GE27	10AE05	12IE37	12DE17	10FE26	12IE39	10JE41	12DE14	