

Urgent Field Safety Notice
MHRA REF: 2023/001/009/601/010



FSCA -11th January 2023

Field Safety Corrective Action - Product Recall

Dear Customer

This letter is to inform you of a potential patient safety issue concerning Instrapac® Tubegauze Applicator, Thudicum Nasal Specula and Backhaus Towel Clip (10cm) products

You have been sent this Field Safety Corrective Action notice because our records indicate that you may have received potentially faulty product.

We request your co-operation in identifying and quarantining potentially affected batches of products in the interests of patient safety.

Description of the problem:

Robinson Healthcare, the legal manufacturer of the Instrapac® range of single-use instruments, has been made aware of a potential manufacturing defect concerning the sterile barrier integrity of its tubegauze applicators, thudicum nasal specula and towel clip (10cm).

We have not received any reports of serious consequential patient harm to date, or external reports from the field, but given the sterility of the product may be compromised the company has made the decision to conduct a full recall of all products which may be affected.

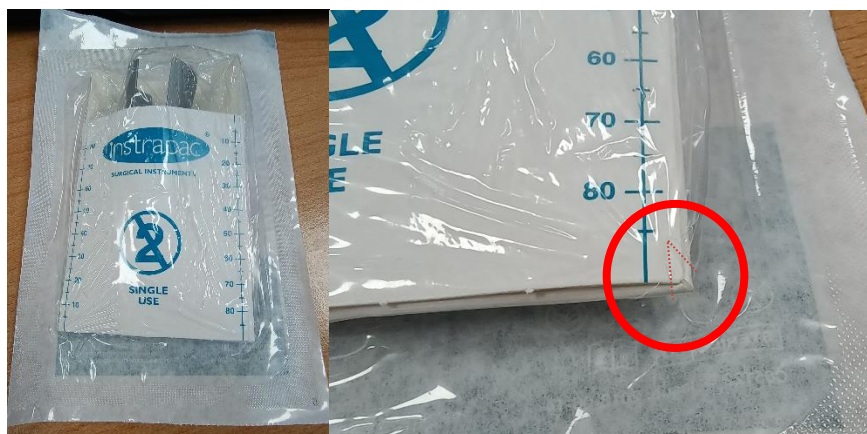


Figure 1. Image of faulty packaging showing breach to sterile barrier

As Robinson Healthcare is dedicated to delivering high standards of product quality and safety, we have taken the decision to voluntarily recall all batches of potentially affected products which are still within their useable shelf life (Expiry to January 2025)

A complete list of potentially affected products and manufacturing lot (batch) numbers is provided on the attached response form for your convenience.

Requested action to be taken by the end user (Healthcare Facilities):

Please check your stock of product:

1. Identify if you have any of the affected products and batches in stock.

The affected products and a list of product codes (**REF**) and batches (**LOT**) are listed on the response form (attached). Please refer to Appendix 1 for a guide to checking our labels.

2. Segregate and quarantine affected batches of products to prevent them from being used clinically.

3. Complete the Response Form (attached)

Please indicate the quantity of individual packs per product and batch (LOT) number.

4. Scan and email the completed form to product.safety@vernagroup.com

5. Return the affected batches of products to Robinson Healthcare Ltd (the manufacturer)

Please secure the box with standard packaging tape and return to Robinson Healthcare via your chosen courier (Postal address and return reference below). Alternatively, you can contact Robinson Healthcare who will arrange for your goods to be collected. Robinson will issue a credit for all returned goods.

F.A.O. Quality REC007-23
Robinson Healthcare Ltd
Lawn Road Industrial Estate
Carlton-In-Lindrick
Worksop
Nottinghamshire
S81 9LB
United Kingdom

Transmission of this field safety notice:

Forward this notice to all departments/teams within your organisation who may have received the affected batches of products and ask that they complete the attached form.

Requested action to be taken by Distributors:

Goods in stock

1. Identify if you have any of the affected products and batches in stock.

The affected products and a list of product codes (**REF**) and batches (**LOT**) are listed on the response form (attached) for convenience. Please refer to Appendix 1 for a guide to checking our labels.

2. Segregate and quarantine affected batches of products to prevent them from being delivered to customers and end-users.

3. Complete the Response Form (attached)

Please indicate the quantity of individual packs per product and batch (LOT) number.

4. Scan and email the completed form to product.safety@vernagroup.com

5. Return the affected batches of products to Robinson Healthcare Ltd (the manufacturer)

Please contact Robinson Healthcare who will arrange for your goods to be collected. Robinson will issue a credit for all returned goods.

Goods already distributed:

Distributors are requested to contact their customers and forward this notice on to them.

If you have already distributed the affected batches of products, please consult your delivery records and identify all recipients to whom you have supplied the affected batches of products.

If you are unable to identify what has been supplied by lot number, please identify all recipients to whom you have supplied the products during the period 2020-01-01 and 2023-01-10.

We apologise for any inconvenience caused by this matter and thank you for your cooperation.

If you are unsure what to do or need further information, please call us quoting "Tubegauze Recall" on 01909 735000 or email us at product.safety@vernagroup.com

Kind regards



Stephanie Hewitt
Quality Manager

Response form

Field Safety Corrective Action 10th January 2023
Tubegauze Applicators, Thudicums, Backhaus Towel Clips

Customer name	
Department	
Organisation	
Address	
Tel. Number	
E-mail Address	

Please tick the boxes below which apply:

We have none of the affected batches of products listed below in stock and have not sold or transferred them (no further action required).

We have sold or transferred our stock of the affected product and lots. We have identified the recipients and undertake to forward a copy of this Field Safety Notice and response form to them.

We have identified and quarantined stock of the product in the lots listed below. We have completed the table above.

Please complete the table below if you have stock.

Please indicate the quantity of individual packs you have in the appropriate box against each LOT

If you do not have stock of these items, you do not need to complete this table.

Tubegauze Applicators (Small) – REF 8169					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57672		58019		60201	
60494		69696			
Tubegauze Applicators (Medium) – REF 7929					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57068		68340		63029	
58024		69988		64275	
58591		71519		66463	
60208		72743		67940	
62208		57612		68682	
63063		58291		70817	
65476		59675		72208	
67086		60473		73112	
Tubegauze Applicators (Large) – REF 7930					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57069		66267		58592	
58293		69718		65477	
62945		57613		67015	
Thudicum Nasal Specula (Size 0) – Ref 7860					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
58013		67570		70812	
60492		68320		72293	
66152		69060		72816	
66959		70240		73204	
67314		70392		73225	
Thudicum Nasal Specula (Size 1) – Ref 7861					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57052		65543		70393	
57655		67818		70839	
58582		68405		71512	
59667		68570		72295	
60196		69090		72898	
62199		69694		73226	
64267		70045			
Thudicum Nasal Specula (Size 2) – Ref 7862					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57053		66214		69000	
57596		66234		69300	
58014		66388		69695	
58287		66576		69956	
58583		66715		70035	
59624		67315		70394	
60197		67752		71513	
62200		67869		72202	
63062		68015		72600	
63691		68272		72740	
64268		68592		72817	
65471					

Thudicum Nasal Specula (Size 3) – Ref 7863					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57054		66215		69728	
57597		66235		69921	
57908		66577		70241	
58015		66716		70395	
58288		66960		70813	
58584		67385		71514	
59625		67895		72203	
60198		68128		72443	
62201		68260		72542	
62941		68571		72818	
63692		68651		73110	
64269		69290		73291	
65472		69546			
Thudicum Nasal Specula (Size 4) – Ref 7864					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57055		62942		69263	
57598		64270		69410	
58016		65473		69729	
58289		66216		69922	
58585		66615		70396	
58638		66717		70814	
59668		67890		71515	
60221		68016		72204	
60305		68593		72741	
62202					
Thudicum Nasal Specula (Size 5) – Ref 7865					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57056		63269		70046	
57599		65474		70397	
57656		66448		71516	
57966		66578		72205	
58616		67938		72543	
59669		68129		72819	
60199		68679		73206	
62203					
Thudicum Nasal Specula (Size 6) – Ref 7866					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57600		62943		67896	
59670		66217		68680	
60493					
Thudicum Nasal Specula (Size 7) – Ref 7867					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57601		60469			
Backhaus Towel Clip 10cm – REF 8260					
LOT	QTY Return	LOT	QTY Return	LOT	QTY Return
57700		60204		65501	
57748					

Can you please sign below, even if you do not have any stock and have not completed the table above to acknowledge receipt of this Field Safety Notice.

Signed Print

Position Date

Thank you.

Please scan and e mail this form to; product.safety@vernagroup.com

For help in completing this form, please call 01909 735000 or e-mail us at the above address quoting "Tubegauze Recall".

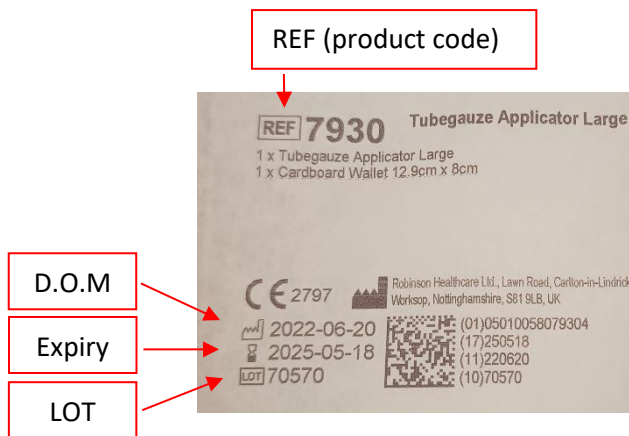
Appendix 1.

Guide to identifying the product REF, the LOT (batch) code and Date of Manufacture (DOM)

The individual packs of affected stock have the part REF, LOT and Date of Manufacture printed in black ink directly onto the front of the instrapac branded packaging, and on the case label

This printed area can be at the top of the pack below the instrapac logo or the bottom of the pack, as per the examples below:

Pack Label



Case Label

