PHOENIX
SURGICAL INSTRUMENTS
LIMITED

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Urgent - Field Safety Notice

Instructions For Use - Silver Tracheostomy Tubes – All styles produced by Phoenix Surgical Instruments Ltd

9th November 2015

Dear Customer,

Phoenix Surgical Instruments Ltd are advising all customers of a new update to the IFU for all styles and sizes of Silver Tracheostomy Tubes.

Description of the problem:

During a recent review we became aware that some previous updated information may not have been passed on to all of our customers / end users.

This Field Safety Notice is intended to draw your attention to specific information within this, and previous versions of the IFU, to assist you in informing your customers / end users:

August 2012 (Batch 5048, 5074 onwards)

In this update:
The note of "parts are not interchangeable between units" was added
The note of "stored for 3 years" was added
The note of "refurbishment is recommended after 2 years, or in the event of any signs of damage, fault or heavy tarnishing" was added

January 2014 (Batch 6155 onwards)

In this update:
A note was added regarding damage that can occur if the tubes are allowed to boil dry whilst home cleaning.

April 2014 (Batch 6338 onwards)

In this update:
Images added with notes as an aid to the patient for checking the tubes during cleaning for any damage or wear.

This latest update (Batch 7600 onwards, excluding batch 7674)

The IFU has been given its own "standalone" document number and issue, 6_6_1 and 6_9_1, which means document 6_6 issue 1 and document 6_9 issue 1. The statement regarding "boiling dry" during home cleaning has been reworded to avoid any confusion for the hospital sterilisation departments with the temperatures used during hospital sterilisation. **This is NOT a safety or end user issue.**

Action to be taken by the customer

Please review the details above, all customers / end users who are still using a silver tracheostomy tube with a batch number **lower than 6338** should be contacted and sent a copy of the latest IFU. (Silver tracheostomy tubes with a batch number of 6338 and higher will already have the latest end user guidance). Please also ensure that any tracheostomy tubes that you are holding in stock have the latest version with them. This will ensure that the end user is fully aware of best practice when it comes to caring for their tracheostomy tubes.

Tracheostomy Tubes manufactured by Phoenix Surgical are extremely well made and safe with a 0.044% fault rate based on over 15 years sales, with this in mind, there is no evidence to suggest there is any risk to patients and therefore a recall is not required.

Attached to this notice are copies of the latest IFU's for silver tracheostomy tubes:

- 6_6_1 – Tracheostomy Tubes Cleaning and User Instructions.
- 6_9_1 – Custom Tracheostomy Tubes Cleaning and User Instructions.

Both of these documents contain exactly the same user information.

After your review, we would be grateful if you could complete the attached feedback form and return it to Phoenix Surgical Instruments.

Actions being taken by Phoenix Surgical Instruments

- For some time now, Phoenix Surgical Instruments have been including the latest IFU with all refurbished or repaired Phoenix silver tracheostomy tubes. This will continue to ensure the end users have the latest information.
- Future IFU updates will be transmitted at the time of issue to our customer base.
- Phoenix Surgical Instruments have notified MHRA of this FSN.

Further information and support:

If you require any further information or support concerning this issue, please contact us as follows quoting ref **CAR00031**.

Contact Person: Peter Fairhurst, Quality Manager.
Telephone: +44 (0)1992 479444
Fax: +44 (0)1992 478878
E-Mail: peter.fairhurst@phoenixsurgical.co.uk

Sincerely

Peter Fairhurst MCMI MInstLM
Quality Manager

FSN Feedback Form – Ref CAR00031

Customer / Company Name:

We have reviewed the information within the FSN and attachments and: *(please tick as appropriate)*

☐ We understand the contents and have notified our customers / end users as appropriate.

Number of end users of affected silver tracheostomy tubes: _____

Number of end users above that have been successfully advised: _____

☐ We have checked our stock and replaced the IFU where necessary.

Number held in stock:_____

☐ We understand the contents and feel no further action by us is required.

We have kept the attached copies of the IFU's in our files for future use. ☐ YES / ☐ No

Signed on behalf of the Customer / Company above by: *(Please print name)*
Position / Job Title:
Signature:
Date:

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Telephone No. 01992 479444 Fax No. 01992 478878 Email. info@phoenixsurgical.co.uk
Tracheostomy Tubes - Cleaning and User Instructions – 6/6 iss 1

WARNING: **This device is supplied NON-STERILE: To be sterilised before use.**

Application & Use
A tracheostomy tube is inserted through a stoma in the trachea to facilitate breathing.

Cleaning & use of this device is to be defined and demonstrated by medical professionals, with the required specialist knowledge and training, nominated by the organisation prescribing its use. The following instructions are for guidance only.

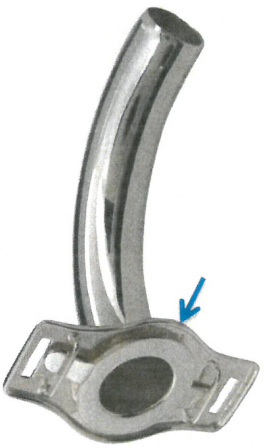
These devices are supplied in various types; the Phoenix Surgical Instruments Limited Instrument Catalogue includes images to enable types & sizes to be identified.

Handling & General Care
The device is made from a relatively soft metal and can be damaged by dropping or exerting abnormal physical force during storage & handling. The device should by adequately packed for storage or transportation. Normal use will not impose forces that are likely to damage the device.
WARNING:
Parts are not interchangeable between units. Spare inner tubes should be ordered with the original device.

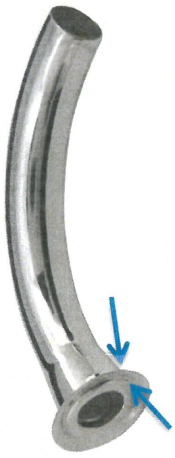
Materials
The device is made from Silver 925 except for the introducer; this is made from brass with silver plating.
WARNING: ***A soldering process is used in the manufacturing and joints may deteriorate with excessive heat.***

Check the device when cleaning

Outer Tube with Shield



Inner Tube with Speaking Valve



Inner Tube

Outer Tube Introducer

Check joints (blue arrows), the finish should be smooth with no pits or holes

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Check for

- General wear and damage caused by tube cleaning brushes etc.
- Inner tube should slide easily into outer and extend no more than 2 mm beyond the outer. The inner should not be loose in the outer.
- Sharp edges and damage, particularly to tube ends.
- Free movement of the speaking valve.
- Silver plating wear on the Introducer.
- Dents or ovality in the tubes.

Return to the manufacturer for repair and refurbishment if deterioration is evident.

Consult your health care professional if there is any discomfort when inserting or using the device.

Connecting to a respirator (non standard product)
Device is intended to connect to a respirator using a 15mm tapered connection adaptor. Intended for use with plastic connectors only. Carefully push the respirator connecting tube on the device connector, ensuring that it is secure. The connector should be approximately half way in the connecting tube.

Hospital Cleaning

1) The silver tubes can be autoclaved at 134°C for 3 minutes. Please clean before autoclaving.
2) Avoid using the product when it is tarnished. Please return the device to the manufactures for refurbishment when heavily tarnished. Tarnish may cause skin discolouration.

WARNING: **The use of hypochlorite (bleach or chlorine) is *not recommended*; it has a corrosive effect on some parts of the device. Please contact your infection control officer for sterilisation recommendations.**

Home Use Cleaning & Sterilising

1) Remove tubes from patient.
2) Clean tubes by using a tracheostomy cleaning brush, if necessary, to clean away debris. Clean device with warm soapy water then rinse in cold water after cleaning, this will ensure a fresh clean tube.
3) Sterilise in simmering water for 2 to 3 minutes maximum. Device must be fully immersed in water for the duration of sterilisation. Ensure tubes are cool before use.
4) The tubes may tarnish over time. Please return device for refurbishment when tarnished.
5) Frequency of cleaning varies from patient to patient. A medical professional should be consulted for guidance.
6) Avoid using the product when it is tarnished.
7) The use of disinfectant solutions (e.g. hypochlorite, bleach or chlorine) is ***not recommended***; it has a corrosive effect on some parts of the device.

WARNING: **If the device is subject to high temperatures (e.g. if the device has been boiled dry during sterilisation), the device *must* be returned to the manufacturer for inspection.**

Shelf life
The devices can be stored for 3 years, kept in its original packaging. The surface may tarnish and require cleaning and should by checked for damage & function before use, after storage.

Expected usage life
Life of the device will depend on usage, care and handling. Life should be at least 2 years if carefully handled and with regular cleaning. Refurbishment is recommended after 2 years, or in the event of any signs of damage, fault or heavy tarnishing. It is recommended that the device be used for one patient only, and then disposed.

Disposal after use
The device itself does not require special disposal instructions. The device should be cleaned and autoclaved to remove any possibility of infection. The device can be recycled; the introducer is made of brass, the speaking valve hinge pin is stainless steel, the remainder of the device is Silver 925.

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Tracheostomy Tubes - Cleaning and User Instructions – 6/9 iss 1

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Materials

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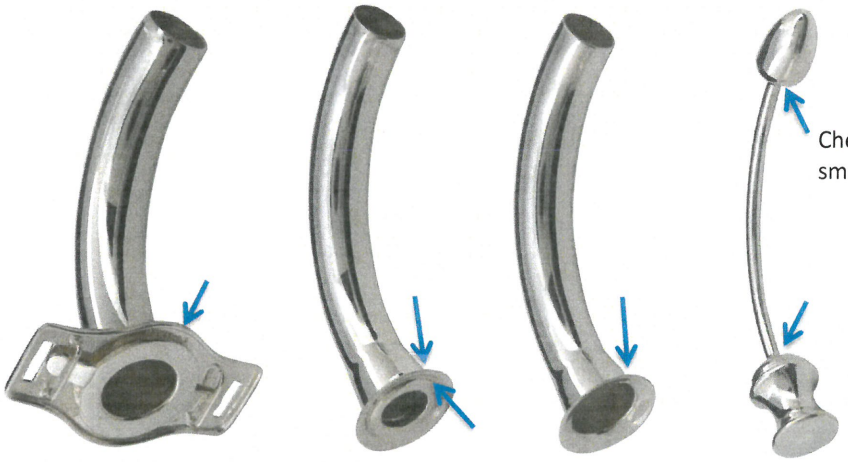
Check the device when cleaning

Outer Tube with Shield | Inner Tube with Speaking Valve | Inner Tube | Outer Tube Introducer



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