V.05/07

# Report Form
# Field Safety Corrective Action

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 5)

| **1. Administrative information**<br>**Destination** |
|---|
| Name of national competent authority (NCA)<br>Irish Medicines Board |
| Address of national competent authority<br>Earlsfort Centre<br>Earlsfort Terrace<br>Dublin 2<br>Ireland |
| Date of this report |
| Reference number assigned by the manufacturer<br>Shiley 07-12 |
| Incidence reference number and name of the co-ordinating national competent authority (if applicable) |
| Identify to what other national competent authorities this report was also sent |

| **2 Information on submitter of the report** |
|---|
| Status of submitter<br>☐ Manufacturer<br>☐ Authorised representative within EEA<br>☒ Others (identify the role): Recall coordinator |

| **3 Manufacturer information** | |
|---|---|
| Manufacturer name<br>Covidien llc | |
| Manufacturer's contact person<br>Jean Simon | |
| Address<br>15 Hampshire Street | |
| Postal code<br>MA 02048 | City<br>Mansfield |
| Phone | Fax |
| E-mail<br>jean.simon@covidien.com | Country<br>US |

| **4 Authorised representative information** | |
|---|---|
| Name of the authorised representative<br>Covidien Ireland Limited | |
| The authorised representative's contact person<br>Thomas Breslin | |
| Address<br>IDA Business & Technology Park | |
| Postal code | City<br>Tullamore |
| Phone<br>+353 57 93 27269 | Fax<br>+353 57 93 27210 |
| E-mail | Country |

| | |
|---|---|
| thomas.breslin@covidien.com | Ireland |

| **5 National contact point information** | |
|---|---|
| National contact point name | |
| Name of the contact person<br>submitter: Isabelle De Pauw | |
| Address<br>Generaal de Wittelaan 9/5 | |
| Postal code<br>2800 | City<br>Mechelen |
| Phone<br>+32 15 29 81 48 | Fax<br>+32 15 29 81 98 |
| E-mail<br>isabelle.depauw@covidien.com | Country<br>Belgium |

**6 Medical device information**

Class

☐ AIMD Active implants

☐ MDD Class III

☒ MDD Class IIb

☐ MDD Class IIa

☐ MDD Class I

☐ IVD Annex II List A

☐ IVD Annex II List B

☐ IVD Devices for self-testing

☐ IVD General

Nomenclature system (preferable GMDN)
GMDN

Nomenclature code
35404

Nomenclature text
Basic tracheostomy tube, single use

Commercial name/brand name/make
Shiley Reusable Cannula cuffed tracheostomy tubes

Model number
8FEN, 8LPC, 8FENJ, 8FEN-S, 8FENJ-S, 8LPC-S

Serial number(s) and/or lot/batch number(s)
see customer letter

Software version number (if applicable)
n/a

Manufacturing date/expiry date (if applicable)

Accessories/associated device (if applicable)
n/a

Notified body (NB) ID- number
0123

**7 Description of FSCA**

Background information and reason for the FSCA

The field action is related to certain models of size 8 Shiley Reusable Cannula Cuffed Tracheostomy Tubes. Volume leakage between the inner and outer cannulea and disconnection between the inner and out cannulea had been observed. When this was event observed, it was typially during mechanical ventilation.

Description and justification of the action (corrective/preventive)

A comprehensive review of this issue is currently underway and being tracked through the CAPA system. Review of the manufacturing process controls, component specifications, assembly specifications, and quality control has been performed. In addition to testing to verify proper

connections, the investigation identified where specifications can be controlled to reduce tolerances closer to mean values and reduce variation. The investigation has also identified where monitoring of torque will ensure the proper locking of the inner and outer cannula. Improved monitoring of torque as part of quality control is being established as part of the manufacturing process and will be required for product release.

Advice on actions to be taken by the distributor and the user

Distributors will be requested to forward the notification to their customers.
End users are requested to quarantine and return their stock as requested.

Attached please find

☒ Field Safety Notice (FSN) in English
☐ FSN in national language
☐ Others (please specify):

Time schedule for the implementation of the different actions

These countries within the EEA and Switzerland are affected by this FSCA

Within EEA and Switzerland:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| ☒ AT | ☒ BE | ☐ BU | ☒ CH | ☒ CY | ☒ CZ | ☒ DE | ☒ DK | ☒ EE | ☒ ES |
| ☒ FI | ☒ FR | ☒ GB | ☒ GR | ☒ HU | ☒ IE | ☐ IS | ☒ IT | ☐ LI | ☒ LT |
| ☐ LU | ☒ LV | ☒ MT | ☒ NL | ☒ NO | ☒ PL | ☒ PT | ☒ RO | ☒ SE | ☒ SI |
| ☒ SK | | | | | | | | | |

Candidate Countries:

☒ CR ☒ TR

☐ All EEA, Candidate Countries and Switzerland

Others:

These countries outside the EEA and Switzerland are affected by this FSCA

US, Latin America, Asia, Africa, Europe

**8 Comments**

I affirm that the information given above is correct to the best of my knowledge.

.....
Signature

| Isabelle De Pauw | Mechelen | 23/07/2012 |
|---|---|---|
| Name | City | Date |

*Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.*

COVIDIEN

# URGENT FIELD SAFETY NOTICE
## Shiley™ Reusable Cannula Cuffed Tracheostomy Tubes

July 23, 2012

Dear Valued Customer,

We have received customer reports on certain size 8 Shiley™ reusable cannula, cuffed tracheostomy tubes that have had volume leakage and/or disconnection between the inner and outer cannulae. These events were typically observed during mechanical ventilation and represent a small fraction of the tubes distributed. If a leak and/or disconnection occur, ventilation may be adversely affected and the tracheostomy tube might require immediate replacement. Accordingly, we are recalling affected product codes and lot numbers.

We are requesting your assistance in conducting this activity. Please review your inventory and immediately quarantine affected product codes and lot numbers, shown in the table below. Unused products from the affected product codes and lots should be returned as described below.

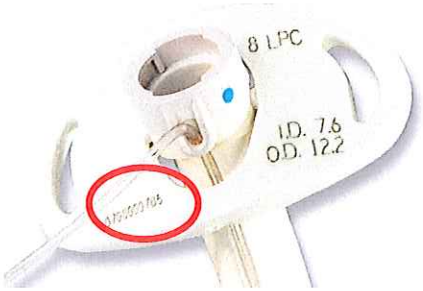
If one of the recalled tubes is already in use in a patient, we recommend that the tube be replaced as soon as clinically appropriate, as determined by the patient's physician. If the physician advises leaving the tracheostomy tube in place, we strongly encourage that the frequency of direct patient observation be increased.

This FSCA is limited to the six product codes and associated lot numbers listed in the table below. Lot numbers are configured as follows – YYMMXXXXXX where YY is the year, MM is the month, XXXXXX is a sequentially assigned number.

**Shiley Reusable Cannula Low-Pressure Cuffed Tracheostomy Tubes**

| Worldwide Product Codes | | |
|---|---|---|
| **Product** | **Starting Lot Number** | **Ending Lot Number** |
| 8FEN | 0910000342 | 1101001558 |
| 8FEN | 110201893X | 120600700X |
| | | |
| 8LPC | 0910000346 | 1101001823 |
| 8LPC | 110200327X | 120600351X |

| These Codes are affected but not sold in Europe, Middle East and Africa | | |
|---|---|---|
| Product Code | Starting Lot Number | Ending Lot Number |
| 8FENJ | 1003002176 | n/a |
| 8FENJ | 1004000412 | n/a |
| 8FENJ | 120100443X | n/a |
| 8FEN-S | 0910001010 | n/a |
| 8FENJ-S | 0910002075 | 1103002299 |
| 8FENJ-S | 110601803X | 120402125X |
| 8LPC-S | 0910001002 | 1103002052 |
| 8LPC-S | 111000400X | 120600014X |




The lot number for all Shiley reusable cannula tracheostomy tubes is clearly printed on the left side of the soft swivel flange (see picture).

It is also shown on the carton and pouch in which the product was shipped.

If you are unable to determine the lot number then those products should be treated as if they are affected and you should proceed as directed below.

Even if you do not have affected product, complete the enclosed verification form and return it to verify that you have received this letter and inspected your inventory.

If you purchased product from a distributor, please contact your distributor for their return process.

If you or your company has distributed the product codes listed above, to other persons or facilities on or after October 1, 2009, please promptly forward a copy of this letter and provide the recipients with any additional information related to your return process. Please complete the attached verification form, even if you do not have product to return. Your customers should notify you directly of any affected product they have in stock.

If you are a patient, or non-clinician, caregiver receiving this letter, it is because you *may* have received a size 8, reusable cannula cuffed tracheostomy tube from one of the affected product codes and lot numbers.
If your tracheostomy tube(s) are among the affected product codes and sizes, then check as described above to identify the lot number(s). If you cannot identify the lot number(s), please contact your home-care provider for assistance.
If you determine that the tracheostomy tube being used by you or your patient may be in one of the affected product codes and lot numbers, call your physician (or the patient's physician, as applicable) for advice.
If you determine that you have any unused tracheostomy tubes from the affected product codes and lot numbers, please contact your home-care provider to arrange return of the product.

This letter is being sent with the knowledge of '**add local C.A. details**'.

We expect to have the Shiley 8LPC, 8FEN, replacement product available in our region within approximately 2 months. Contact **add local contact details** to determine if there is an alternative product you can use while you wait for the new lots of Shiley product to become available. We will work diligently to resolve any supply challenges you may experience as a result of this action.

Meanwhile, please Report any issues with Shiley reusable cannula low-pressure cuffed tracheostomy tubes to **add local contact details** to ensure proper device reporting procedures are followed.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause and appreciate your prompt attention to this matter.

Sincerely,

Michael A. Ronningen
Vice President, Regulatory Affairs
Respiratory and Monitoring Solutions
Covidien

COVIDIEN

[*Please insert date the form was sent*]

# URGENT MEDICAL DEVICE FSCA –
# Shiley™ Reusable Cannula Cuffed Tracheostomy Tubes
# VERIFICATION FORM

| Customer Contact Details | Covidien Contact Details |
|---|---|
| **Hospital/HCP Name:**<br>**Covidien Account Number:** | **To:** [*please insert name Covidien commercial office*] |
| **Collection Address:**<br>**Department:**<br>Street:<br>City:<br>Postal Code:<br>Contact Person at Point of Collection:<br>Opening Hours: | **Address:** [*please insert Covidien address*] |
| **Telephone n°:** | **Telephone n°:** [*please insert Covidien telephone number*] |
| **Fax n°:** | **Fax n°:** [*please insert Covidien fax number]* |
| **E-mail:** | **E-mail:** [*please insert contact e-mail address*] |

Please list the quantity of affected product at your facility, if you have **no** stock, please indicate **'0'**.

| Product code | Invoice or Despatch Note | Lot number | Qty |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

Information for the courier:

Number of parcels to collect: _____

Weight: ☐ < 45kg ☐ > 45kg

Name:
(please print)

Signature:

Date:

_____ _____ _____

- Please fax this form to the fax number referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit for these products.
- Please don't send the goods back before having received the return documentation.
- **Even if you have no affected stock, please complete this form and return it to Covidien.**