



# **Lesson Learned from Decontamination Incidents - Challenging Design of Instruments**

**Health  
Facilities  
Scotland**

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# Outline

**Why?**

**How?**

**What've  
we  
learned?**

**My  
questions  
to you?**

**WHY?**

**Orthopaedic**

- 15 patients infected
- 78 years old female died

**2009**

**Ophthalmic**

- 5 patients -  
endophthalmitis
- 75 years old female  
permanent visual deficit

**Surgical site infections linked to contaminated surgical instruments**

S.J. Dancer <sup>a,\*</sup>, M. Stewart <sup>a</sup>, C. Coulombe <sup>a</sup>, A. Gregori <sup>b</sup>, M. Viridi <sup>c</sup>

# HOW?

1. Quality Assurance Workshop
2. Reporting system
3. Investigations
4. Sharing & Collaborations

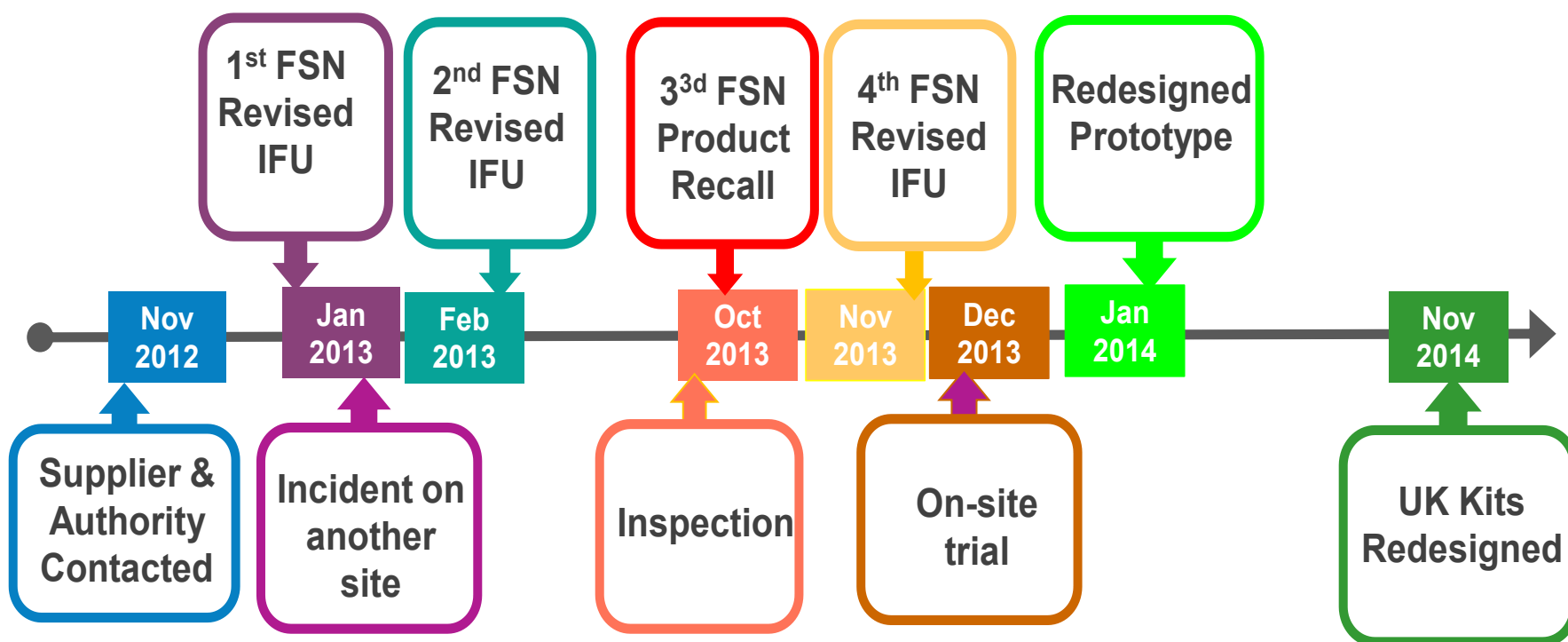
# Retractor



**An Example  
of  
Investigation**

# Investigation Timeline

FSN: Field Safety Notice  
IFU: Instructions for Use



# First Field Safety Notice

## 14 Jan 2013

- All components – basket - WD
- Manual cleaning

Surgical Instruments of Excellence

### Field Safety Notice

Revised washing & cleaning Instructions

Super-Slide Laminectomy Retractor

#### Immediate Action Required

|                    |   |
|--------------------|---|
| Date Issued;       | January 14th, 2013  |
| Product ;          | Super-Slide Laminectomy Retractor Set,<br>Code Numbers; 7329-00, 7329-05, 7329-05M, 7329-06 & 7329-99   |
| Explanation;       | <p>The purpose of this communication is to inform you of a risk of inadequate decontamination with the Super-Slide Retractor Blades and issue modified cleaning instructions.</p> <p>We have found that if the Retractor Blades remain mounted in the Container supplied during the decontamination process there is the risk of contamination remaining in the area of the Retractor Blades which are in contact with the Container.</p> |
| Necessary Actions; | In order to effectively decontaminate the Retractor remove all the Retractor components from the sterilizing Container and place them into a standard wire basket. Manual washing of the Retractor Blades is recommended to ensure effective decontamination of the Retractor.  |

# Check on Another Site

## 22 Jan 2013





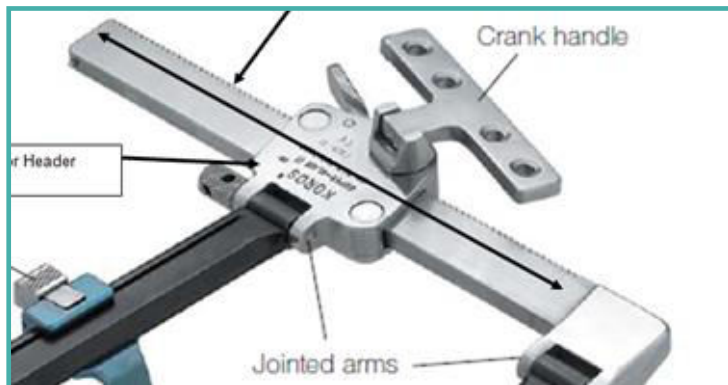
# Second Field Safety Notice

## 22 Feb 2013

- Disregard previous IFU
- Use the new validated IFU

|   |  |                            |
|---|--|----------------------------|
| <small>Surgical Instruments of Excellence</small> |  | <b>Field Safety Notice</b> |
| Revised washing & cleaning Instructions           |  |                            |
| Super-Slide Laminectomy Retractor                 |  |                            |
| Immediate Action Required                         |  |                            |
| <b>Ref;</b>                                       | FSCA 27.02.2013  |                            |
| <b>Date Issued;</b>                               | February 27th, 2013  |                            |
| <b>Product.;</b>                                  | Super-Slide Laminectomy Retractor Set,<br>Code Numbers; 7329-00, 7329-05, 7329-05M, 7329-06 & 7329-99  |                            |
| <b>Explanation;</b>                               | This is a revision to our previous released FSN relating to our Super-Slide II Retractor, we are now able to issue clinically validated cleaning & sterilizing Instructions. |                            |
| <b>Necessary Actions;</b>                         | Disregard the previously issued instructions and use the validated Cleaning & Washing Instructions provided with this notice.  |                            |

# Revised IFU – Feb 2013



Pre Cleaning: Retractor head - move back and forth along the full length of the rack, wipe the rack with cloth each time (x 3)

Service: Every 12 months or 300 uses



## Inspection 8 Oct 2013

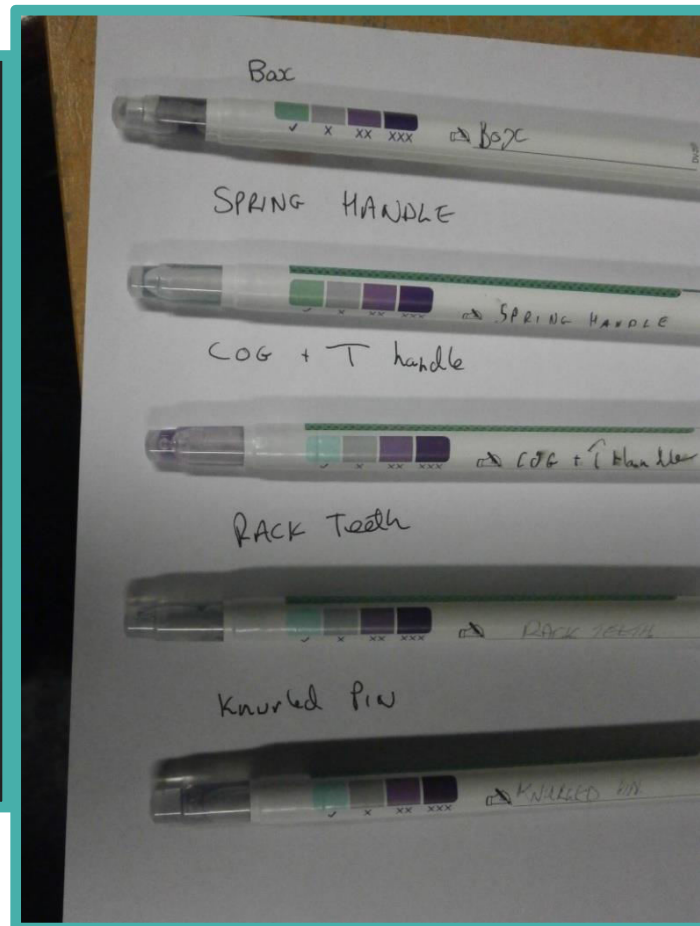
13 uses after services  
IFU (Jan 2013)  
Contaminants detected



# Residual Protein Test Results



**ProReveal**



**Clean Trace**



# Product Recall

## Third Field Safety Notice

### 10 Oct 2013

Cannot guarantee  
the removal of  
contamination  
when IFU is  
followed

#### Urgent Field Safety Notice

Mercian Super Slide Laminectomy Retractor System

FSCA 10/10/13

Action to reduce risk of serious deterioration in state of health.

Date: 10/10/13

Attention: Owners and users of Mercian Super Slide Laminectomy Retractor System

#### Details on affected devices:

*Mercian Super Slide Laminectomy Retractor System – part number refs 7329-00, 7329-05, 7329-05M, 7329-06, 7329-09, 7329-99*

#### Description of the problem:

*Mercian Super Slide Laminectomy Retractor System Cleaning and Sterilising Instructions cannot guarantee complete removal of contaminants from instrument when instructions are followed.*

*Potential hazard regarding contaminants remaining on instrument between head plates on retractor head.*

*Potential risk of transfer of contaminants between patients.*

*Previous use of affected devices may potentially have transferred contaminants between patients.*

#### Advise on action to be taken by the user:

*Mercian Surgical Supply Company Limited are unable to supply Cleaning and Sterilising Instructions which are guaranteed to completely remove contaminants from area between head plates on the retractor head. Because of this, we have determined that the device does not meet the Essential Requirements of 93/42/EEC and we are recalling the device. Please return the devices to Mercian Surgical Supply Company Ltd for the attention of the contacts given below.*

*Please do not use the device, and follow usual procedures for monitoring and recording post-operative infection in patients on whom the device has been used.*

# Scottish Television

21 Nov 2013



**News**

## **Patients left in limbo by recall of equipment used in back surgery**

Five health boards have been affected after the manufacturers withdrew a device because of concerns about sterilisation.

# Fourth Field Safety Notice

## 4 Nov 2013

- New validated IFU with dismantling & reassembly
- Resume clinical use
- No need to return device to supplier

### Urgent Field Safety Notice

**Mercian Super Slide Laminectomy Retractor**

**FSN 08/11/13**

**Action to reduce risk of serious deterioration in state of health.**

Date: 08/11/13

Attention: Owners and users of the Mercian Super Slide Laminectomy Retractor System

#### Details on affected devices:

Mercian Super Slide Laminectomy Retractor System – Model numbers 7329-00, 7329-05, 7329-09, 7329-10, 7329-05M, 7329-06 and 7329-99

#### Description of the problem:

We have previously advised that our cleaning and sterilising instructions could not guarantee the complete removal of contaminants from the instrument, that there was a potential hazard of contaminants remaining between the plates on the retractor head and a potential risk of transfer of contaminants between patients.

We now have new instructions for cleaning and sterilising the retractor, with instructions for the dismantling and reassembly of the retractor frame. These allow the frame head to be effectively decontaminated and remove the hazards referred to on our previous communication. The efficacy of the new cleaning and sterilising instructions has been validated by laboratory testing.

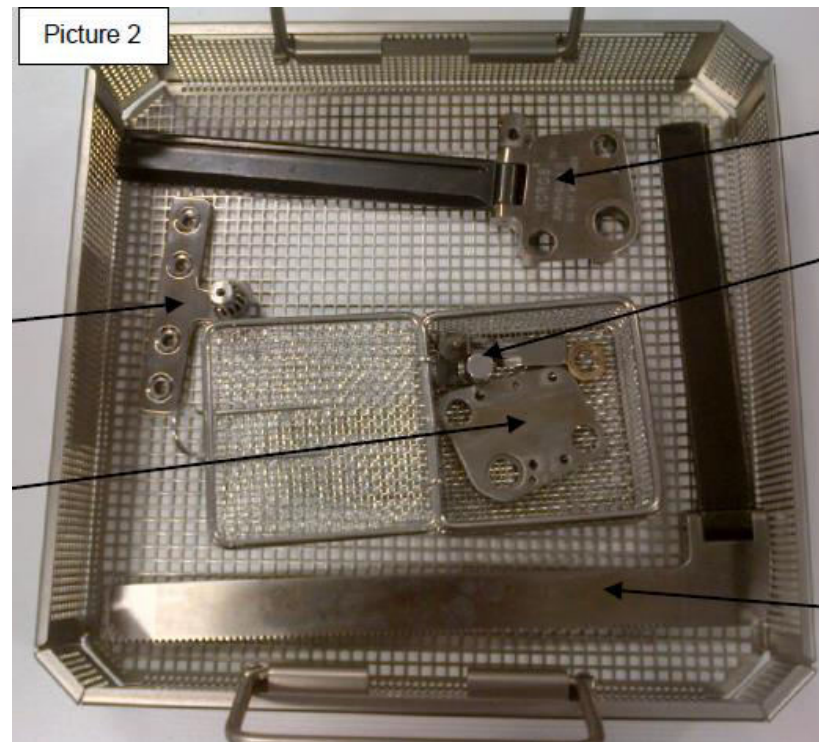
#### Advice on action to be taken by the user:

Please follow the new cleaning and sterilising instructions supplied with this notice. Using these instructions, you can now resume clinical use of the device and there is no longer a requirement for the device to be returned to us.

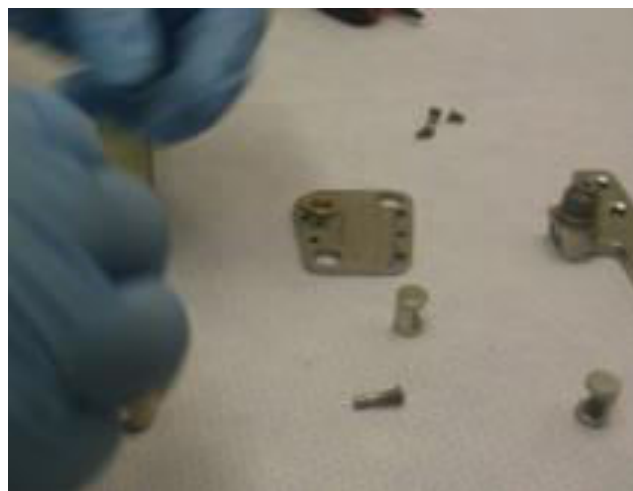
# Revised IFU - Nov 2013

2. Fully dismantle the head unit of the Retractor Frame;
  - a. See appendix 1 for detailed instructions on dismantling the Retractor head.

Use slotted  
screw drivers







**The Trial  
Reassembly  
7 minutes**





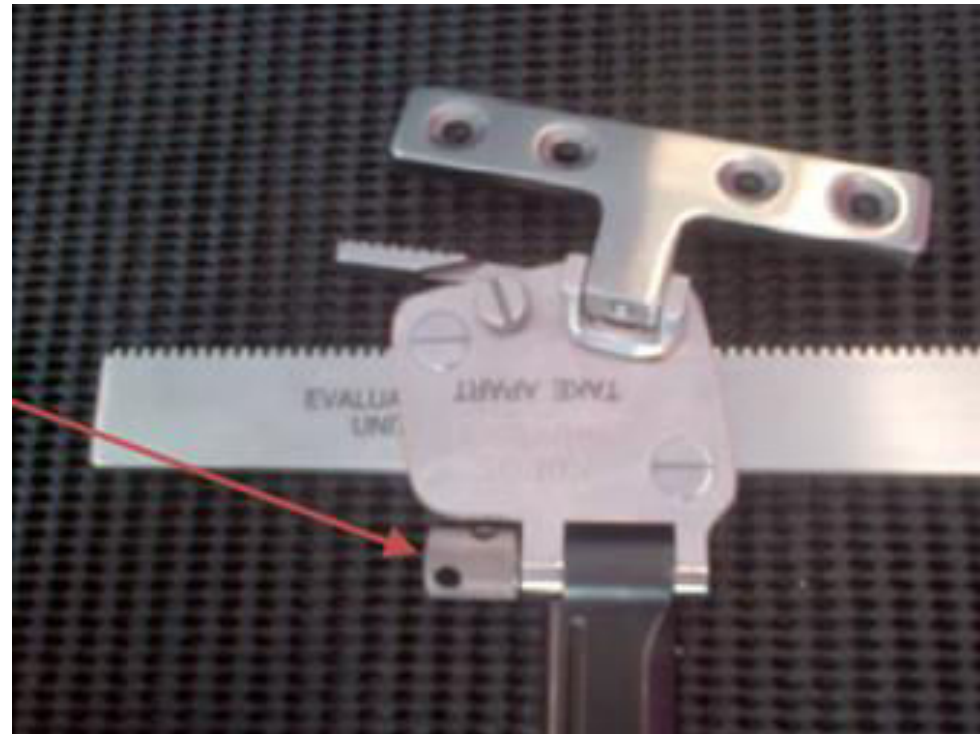
**Findings: Damage and Fragmentation of Components**

# Redesigned Prototype

## Jan 2014

### Redesigned Frame

- 2 Screws
- No more tool
- Spring – a part of the lever



**18 Nov 2014**

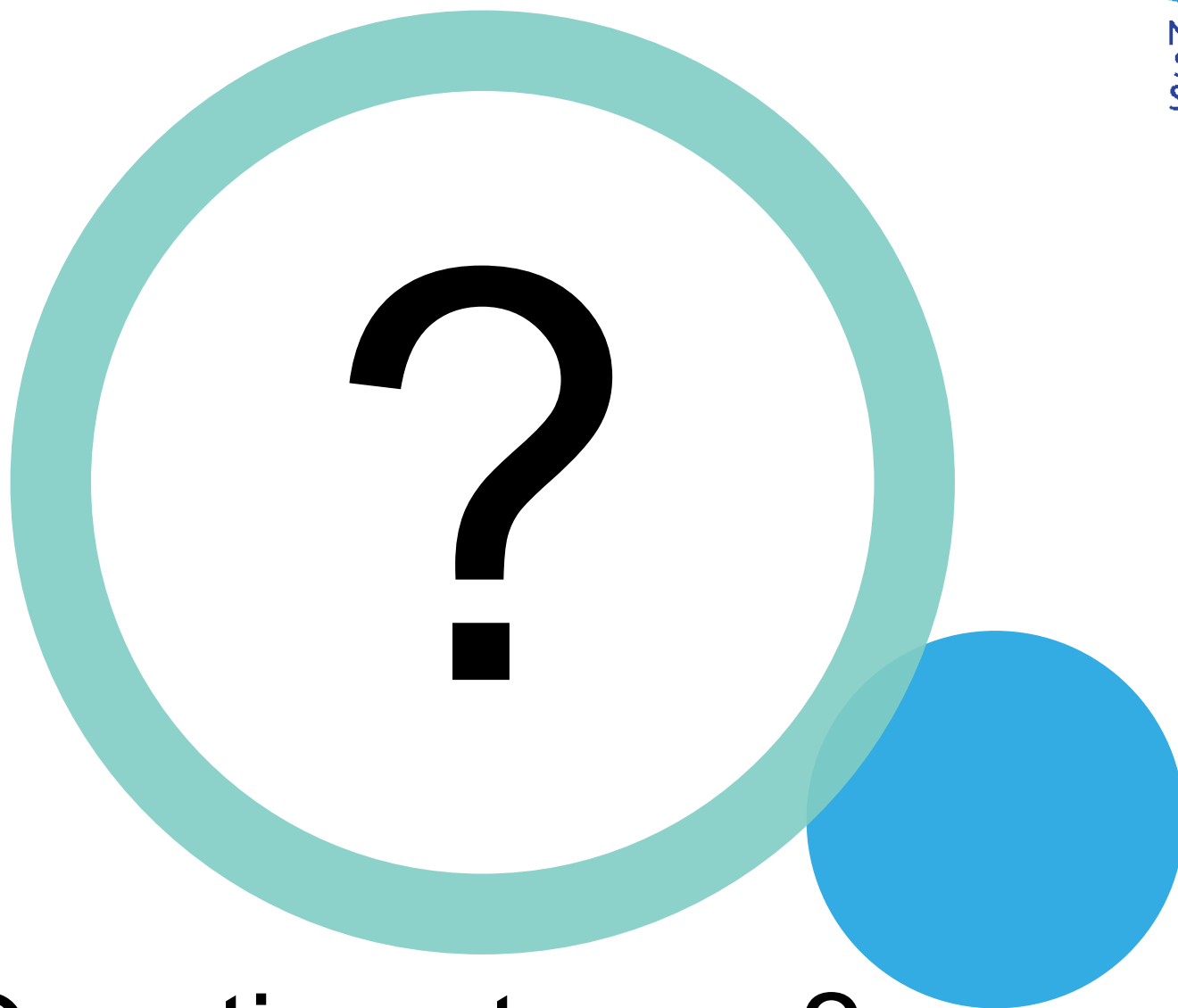
**Majority of UK devices  
were converted.**





# What've We Learned?

1. Can't fully dismantle? Risky!
2. Risk assessment
3. Validation
4. Clinical trial
5. Maintenance/service programme
6. Communication & Collaboration



My Questions to you?