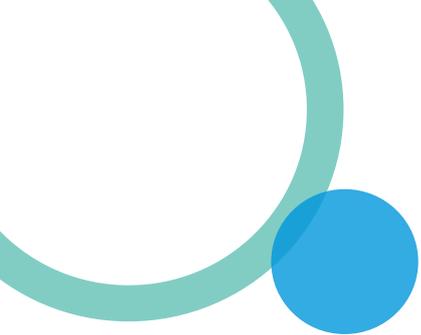


Lección Aprendida de Incidentes de Descontaminación- Problema y Desafíos

Health
Facilities
Scotland

Dr. Sulisti Holmes
Head of Decontamination & Incident
Reporting Investigation Centre

Contorno



¿Porqué?

Cómo?

**¿Qué
hemos
aprendido
?**

**¿Mis
preguntas
?**

¿Porqué?

Ortopédicos

- 15 pacientes infectados
- mujer de 78 años de edad murió

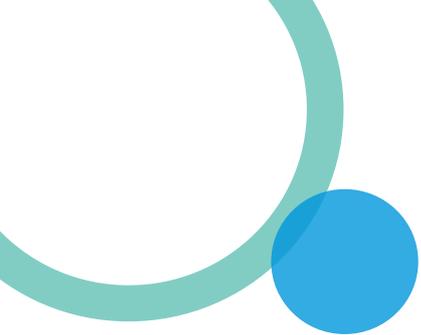
2009

Oftálmica

- 5 pacientes-endoftalmía
- señora de 75 años de edad con déficit visual permanente

Surgical site infections linked to contaminated surgical instruments

S.J. Dancer^{a,*}, M. Stewart^a, C. Coulombe^a, A. Gregori^b, M. Viridi^c



Cómo?

1. Taller de aseguramiento de calidad
2. Sistema de informes
3. Investigaciones
4. Compartir y colaborar

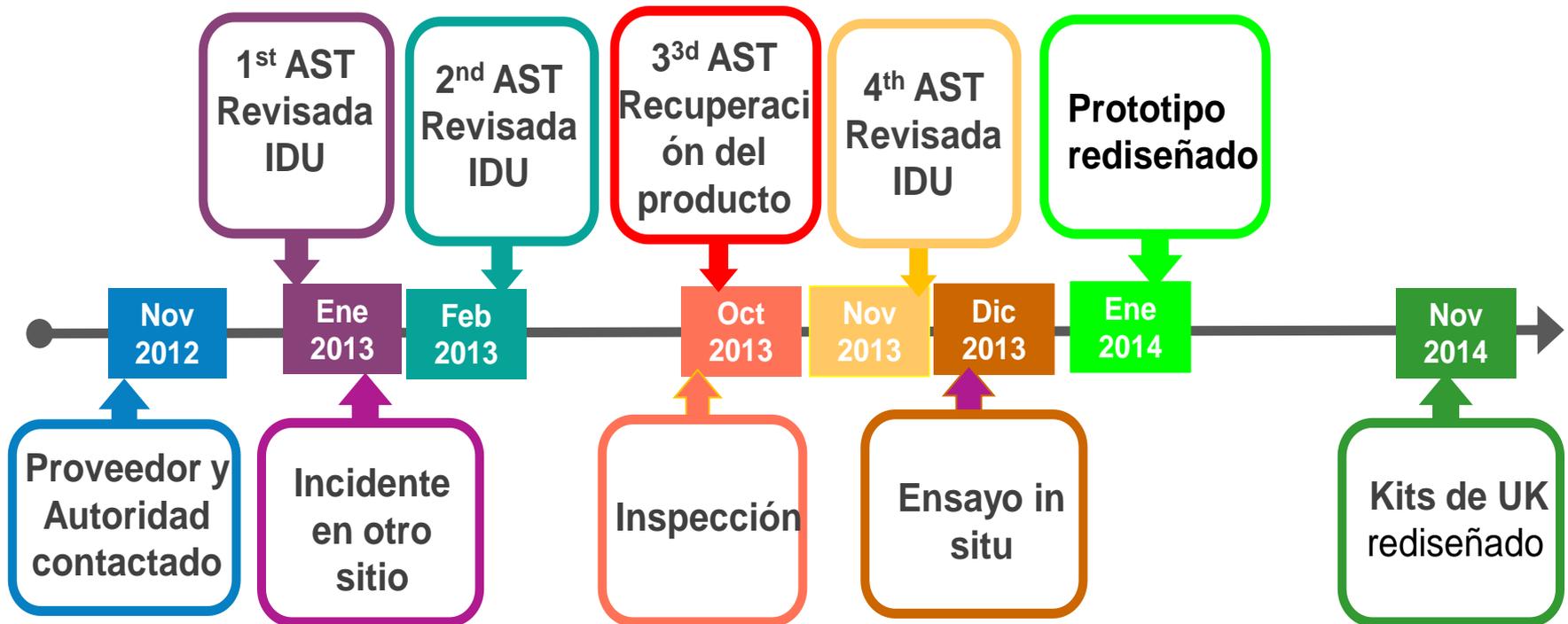
Retractor



**Un Ejemplo
de
Investigación**

Cronología de la Investigación

AST: Aviso de Seguridad en el Terreno
IDU: Instrucciones De Uso



Primero Aviso de Seguridad en el Terreno - 14 Enero 2013

- Todos los componentes – cesta en la lavadora desinfectadora
- Limpieza manual

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, 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.

Comprobar en Otro Sitio

22 Ene 2013

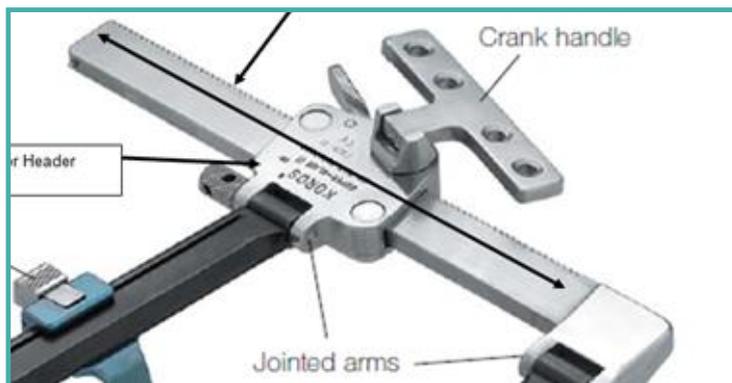


Segundo Aviso de Seguridad en el Terreno - 22 Feb 2013

- Ignorar IDU anterior
- Utilice el nuevo IDU validado

Surgical Instruments of Excellence	
Field Safety Notice	
Revised washing & cleaning Instructions	
Super-Slide Laminectomy Retractor	
Immediate Action Required	
Ref;	FSCA 27.02.2013
Date Issued;	February 27th, 2013
Product.;	Super-Slide Laminectomy Retractor Set, Code Numbers; 7329-00, 7329-05, 7329-05M, 7329-06 & 7329-99
Explanation;	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.
Necessary Actions;	Disregard the previously issued instructions and use the validated Cleaning & Washing Instructions provided with this notice.

Revisado IDU – Feb 2013



Pre limpieza: Cabeza del retractor -mueva hacia adelante y hacia atrás a lo largo de la longitud completa del estante, limpie el estante con el paño cada vez (x 3)

Servicio: cada 12 meses o 300 utiliza



Inspección 8 Oct 2013

13 usos después de
servicios

IDU (Ene 2013)

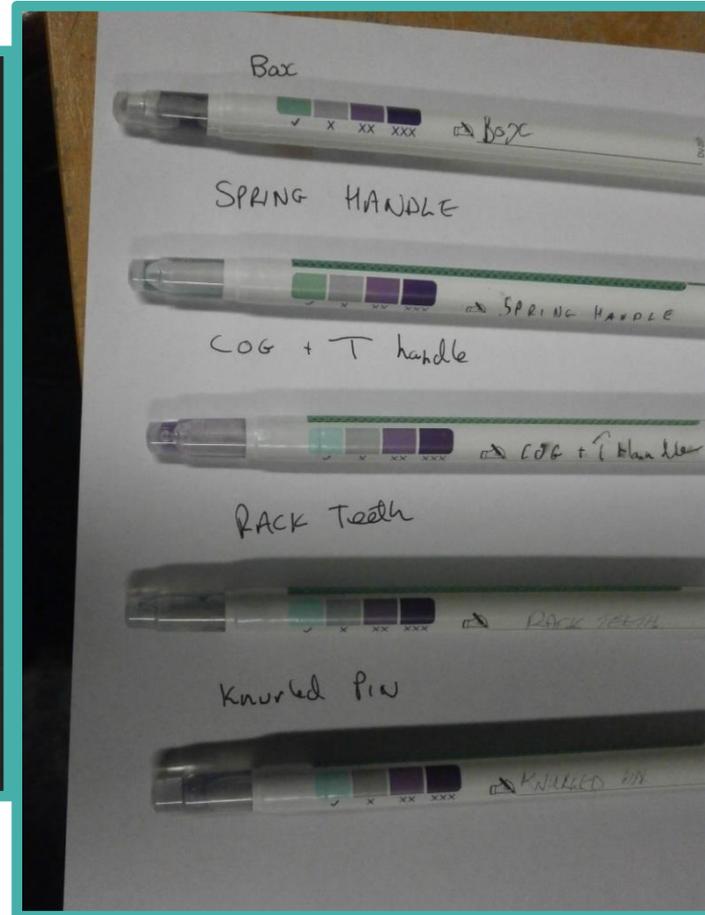
Contaminantes
detectados



Resultados de la prueba de proteína



ProReveal



Clean Trace

Recuperación del Producto

Tercer Aviso de Seguridad en el Terreno -10 Oct 2013

No puede
garantizar
la eliminación de
la contaminación
cuando se sigue
el IDU

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.

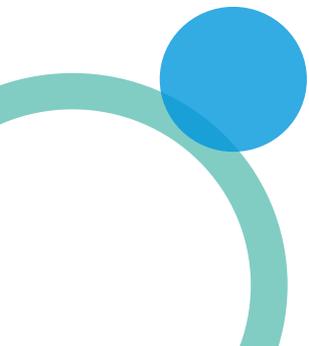
Televisión Escocesa

21 Nov 2013



Pacientes dejados en el limbo por retiro del equipo usado en cirugía trasera

Cinco consejos de salud han sido afectados después de que los fabricantes retiraron un dispositivo debido a la preocupación por la esterilización



Cuatro Aviso de Seguridad en el Terreno - 4 Nov 2013

- Nuevo IDU validado con desmontaje y reensamblaje
- Resume el uso clínico
- No hay necesidad de devolver el dispositivo al proveedor

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:

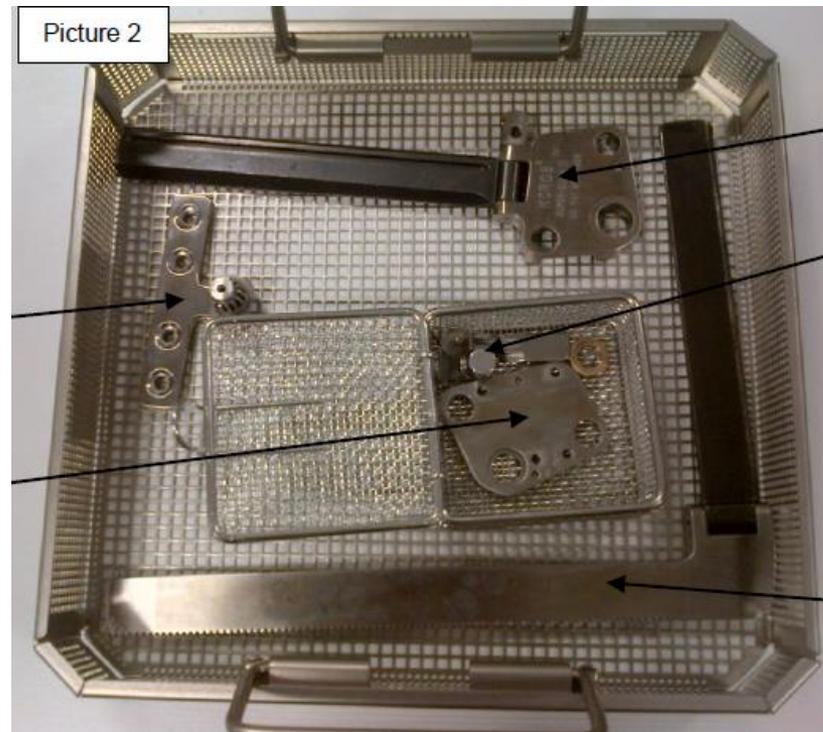
Please follow the new cleaning and sterilising instructions supplied with this notice. Using these instructions, you can now resume clinical use of the device and there is no longer a requirement for the device to be returned to us.

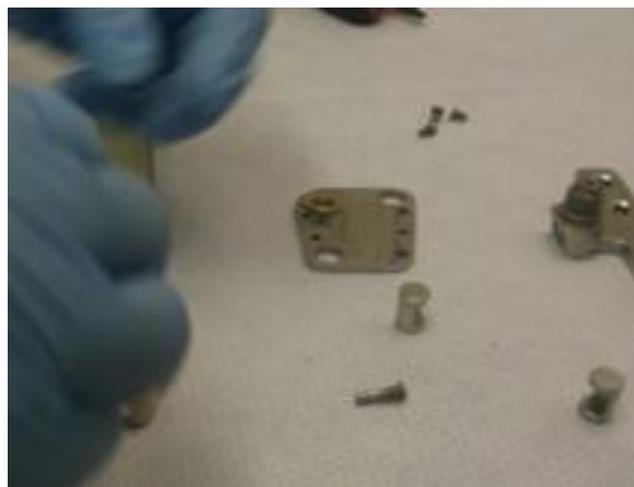
Revisado IDU - Nov 2013

Desmantele el cabezal completamente del marco del retractor:

- a. Vea Apendice 1 para mas detalles sobre el desmantelamiento del cabezal

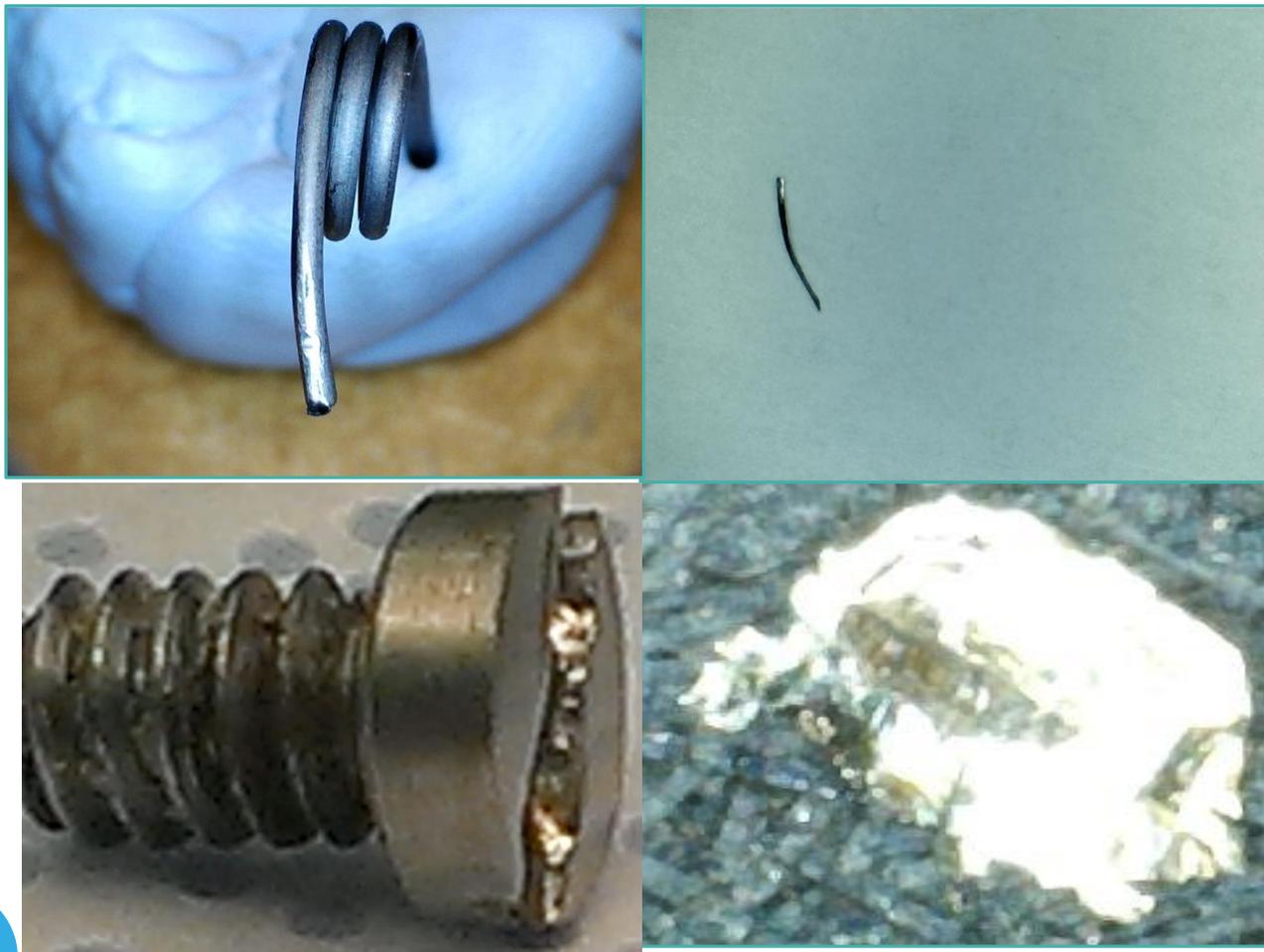
Utilice los
destornillador
es ranurados





**La Prueba de
reensamblaje
7 minutos**





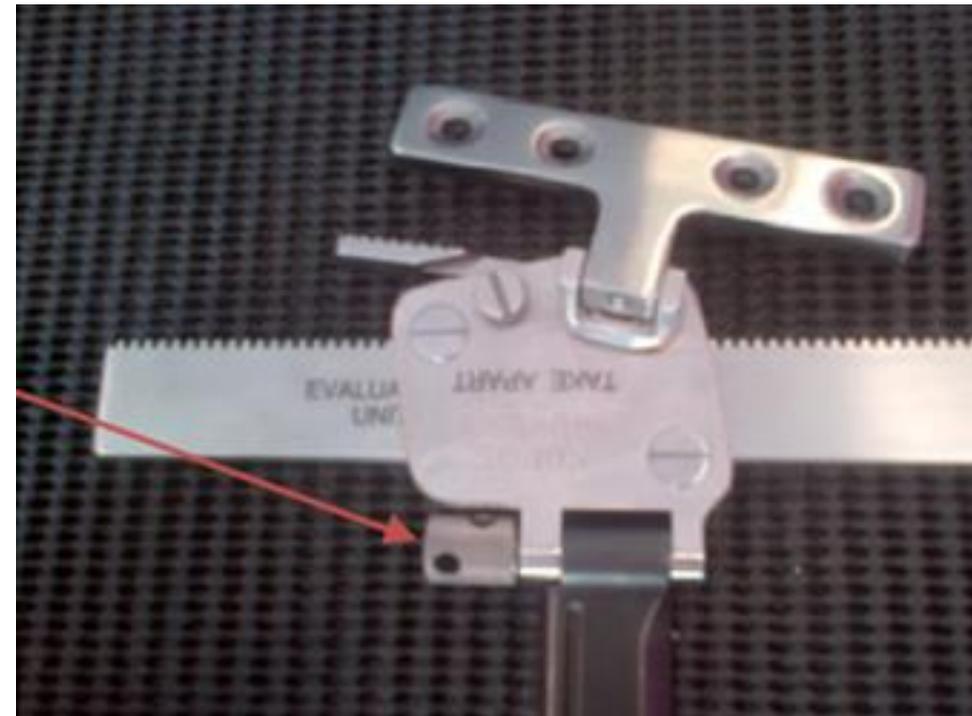
Hallazgos: Daños y Fragmentación de Componentes

Prototipo Rediseñado

Ene 2014

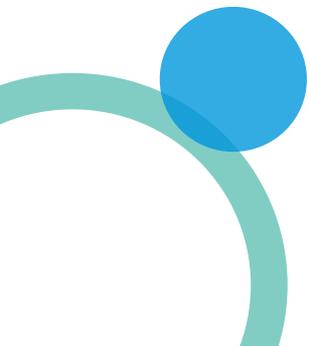
Marco rediseñado:

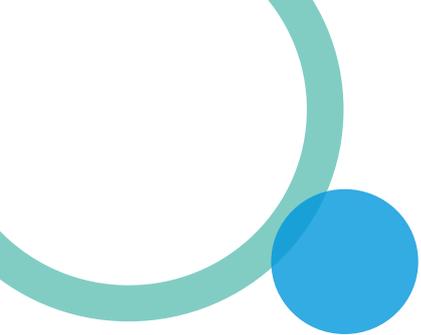
- 2 tornillos
- No más de herramienta
- Resorte – una parte de la palanca



18 Nov 2014

**La mayoría de los
dispositivos británicos
fueron convertidos.**





¿Qué hemos aprendido?

1. ¿no puede desmantelar completamente? ¡Arriesgado!
2. Evaluación de riesgos
3. Validación
4. Ensayo clínico
5. Programa de mantenimiento/servicio
6. Comunicación y colaboración



¿Mis preguntas?