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Dr Jennifer Armstrong  
Dr Tracey Gillies  
Dr Iain Wallace

All other NHS Board Medical Directors – please cascade to GP leads

Dear Colleague

On Tuesday 4 April 2017 the Medicines and Healthcare products Regulatory Agency (MHRA) issued a Medical Device Alert for the “Comprehensive Reserve Titanium Shoulder Tray (specific lots) – risk of device fracture”

<https://www.gov.uk/drug-device-alerts/comprehensive-reverse-titanium-shoulder-tray-specific-lots-risk-of-device-fracture>

This alert must be followed and the actions are to :

- Do not implant
- Locate and return all affected implants
- Identify all patients implanted with the affected device and inform them of this issue
- Advise patients to contact their orthopaedic surgeon if they have symptoms
- Investigate symptomatic patients
- Report adverse events

I append a table of the information available from National Procurement based on invoice data which highlights the potential use in three Boards.

(2010-2017 National Procurement data )

Hospital & Health Board	2011	2013	2014	2015	2016	Grand Total
NHS GG&C- INVERCLYDE ROYAL HOSPITAL	1					1
NHS Lanarkshire- WISHAW HOSPITAL	1					1
NHS Lothian- Edinburgh Royal Infirmary		4	9	20	5	38
Grand Total	2	4	9	20	5	40

It will be necessary to verify if any of the above are included in the affected lot numbers in the manufacturer’s Field Safety Notice (FSN)

<https://mhra.filecamp.com/public/file/2k7i-fm75dc0c>

**From the Chief Medical Officer  
Dr Catherine Calderwood MA  
FRCOG FRCP (Edin)**

Date 7 April 2017

SGHD/CMO(2017) 5

For action  
Medical Directors, NHS Boards

**Further Enquiries to:**

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I trust you will check the information and provide all necessary care to your patients.

Yours sincerely

*Catherine Calderwood*

**DR CATHERINE CALDERWOOD**