

SMTL Medical Device Adverse Incident Reporting Form

SURGICAL MATERIALS TESTING LABORATORY



Reporting Officer Ref No.	
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Has this device been in patient contact? YES/NO	Was any injury sustained during this incident? YES/NO
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PART 1 - To be completed by the User, or on behalf of the user (Reporter), and returned to your Reporting Officer with the defect and as many unused samples as possible. Keep a copy for your own records. PLEASE DO NOT INCLUDE ANY PATIENT IDENTIFIABLE INFORMATION BELOW OR ON ANY RETURNED ITEMS

Date of incident		Ward/Dept	
LHB/Trust		Hospital	
User's Name		Reporter's name:	
User's Position		Reporter's position:	
User's Tel No		Reporter's Tel No	
Users Email		Reporter's Email	

Defective Device Information

Item Name		Size	
Manufacturer and/or Distributor		Catalogue No	
Batch/Lot Number		Other Info	

Details of incident/nature of defect, including details of any injuries sustained

Please provide as much information as possible. Note that the information you supply will be included in the final report sent to the supplier and MHRA. If there is any information you would rather we did not relay then please mark it as "For SMTL Only"

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PART 2 - To be completed by the Reporting Officer

Date sent to SMTL		No of defective items sent to SMTL	
Reporting Officers Name		No of unused items sent to SMTL	
RO Tel. No & Ext		All Wales Contract No	
RO Email Address			

IMPORTANT - PLEASE READ

YOUR REPORTING OFFICER IS

PLEASE SEE REVERSE OF FORM FOR INSTRUCTIONS.

Send a copy of this form and samples to:

The Defects Section, SMTL,
Princess of Wales Hospital, Coity Road,
Bridgend, CF31 1RQ.
Tel: 01656-752820
Fax: 01656-752830
Email: smtl.defects@wales.nhs.uk

If you have downloaded this form from the SMTL web site, then you will have to determine who is your local reporting officer. The Reporting Officer acts as the coordinating contact between your Health Board/Trust and SMTL

Please contact SMTL on the number in the box opposite if you have any questions or queries about defect reporting.

IMPORTANT INFORMATION - PLEASE READ

Please obtain a copy of MDA/2004/054(Wales) for complete information on reporting defects. Also see <https://nwssp.nhs.wales/contact-us/services-we-provide-a-z/surgical-materials-testing-laboratory/i-work-for-an-nhs-wales-organisation/reporting-a-defective-product/>

Who is the User, and who is the Reporter ?

The **USER** will be the clinician actually using the device when the incident happened.

The **REPORTER** may be the user if they are filling in the form themselves, in which case these boxes may be left blank, or it may be a different person, filling in the form on behalf of the user.

The **PATIENT'S** name and other details should **NOT** be recorded on any of the material sent to SMTL as this may contravene the GDPR.

Reporting Officer

Your reporting officer will typically be based in your procurement or Risk/clinical governance department, depending on local policy. If you are unsure who your local reporting officer is, SMTL will be able to tell you who to contact within your Health Board.

Reporting Officer Reference No

Please ensure you enter a unique identifier in this box, which will ensure traceability for SMTL and the Health Board/Trust.

Sample Submission

1. Please try to send us the defective device. If possible, it should be decontaminated in line with our instructions below.
2. Where practical, please also send unused samples from the same batch of product, to enable us to compare products.

Decontamination Instructions

1. **If the device is not contaminated**, then post to SMTL with this reporting form and a decontamination certificate stating 'Not Contaminated'.
2. **If the device is contaminated and can be decontaminated locally**, decontaminate the device using a combination of pre-cleaning with detergent/enzyme followed by cold sterilant (for example, Perisafe, Cidex - seek advice locally from health and safety advisor or other appropriate personnel), package appropriately and post to SMTL with this reporting form and a completed decontamination certificate.
3. **If the device is contaminated and it is not possible for the device to be decontaminated locally** (or there are concerns that decontamination could destroy important evidence) follow one of the 4 options below:
 - a) Package appropriately and organise transfer of the package to SMTL via the hospital transport system (contact hotel services, post room or pharmacies for more details about local hospital transport arrangements).
 - b) Package appropriately and pass on to a member of SMTL staff during a meeting (SMTL staff attend regular meetings with other NHS staff throughout Wales and devices could be passed on during these occasions).
 - c) Package appropriately and send to SMTL via UN approved courier.
 - d) Label item, place in quarantine and contact SMTL for advice regarding transportation.

Please see this document for further details on dealing with contaminated devices:

http://smtl.co.uk/images/pdf/The_postage_of_contaminated_devices-2008.pdf