



**IRISH MEDICINES BOARD  
MEDICAL DEVICE INCIDENT USER REPORT FORM**

If you have experienced problems with a medical device, please complete this form and send it to the Irish Medicines Board, Medical Devices Department, Earlsfort Centre, Earlsfort Terrace, Dublin 2 or contact us by telephone at 01-6764971 or by email [vigilance@imb.ie](mailto:vigilance@imb.ie)

<b>SECTION 1: CONTACT DETAILS OF REPORTING ORGANISATION</b>	
<b>Name of Organisation:</b>	<b>Fax Number:</b>
<b>Address of Organisation:</b>	<b>Contact Name:</b>
	<b>Position:</b>
<b>Telephone Number:</b>	<b>Email Address:</b>
Can the Irish Medicines Board provide your contact details to the manufacturer, as they may need to contact you in order to carry out an investigation <input type="checkbox"/> Yes <input type="checkbox"/> No	

<b>SECTION 2: DEVICE DETAILS</b>	
<b>Name of device and model number:</b>	
<b>Kind of device (e.g. pacemaker):</b>	
<b>Serial number / batch number / lot number:</b>	
<b>Where did you get the device?</b>	<b>Name of the person who supplied the device:</b>
<b>Name and address of the manufacturer:</b>	<b>Name and address of the distributor:</b>

<b>SECTION 3: INCIDENT DETAILS</b>
<b>What went wrong with the device?</b>

**Was an injury suffered?** Yes  No

**If yes, specify who and what injuries were suffered?**

**Have you contacted the manufacturer?** Yes  No

**Signature:**

**Date of Report:**