IRISH MEDICINES BOARD

Notice Information: Medical Devices - Recall
10 May 2007

Part 1. Product Information

a)	Title:	Shelhigh Implantable Devices
b)	Product Name/Type:	Shelhigh Implantable Devices
c)	Reference:	SN2007(01)
d)	Manufacturer/Supplier:	Shelhigh Incorporated, New Jersey, USA UK Medical Limited, Sheffield, United Kingdom (Distributor) Krijnen Medical, The Netherlands (Authorised Representative)

Part 2. Target Audience

a)	Target Audience:	Hospital Chief Executive Officers; Hospital Risk Managers; Cardiothoracic Surgeons; Cardiologists Vascular Surgeons; Neurosurgeons; Gastrointestinal Surgeons; Urological Surgeons; Gynaecological Surgeons; General Surgeons

Part 3. Problem/Issue

a)	Problem/Issue:	The Food & Drug Administration (FDA) issued a formal written request to Shelhigh Inc. to recall all its medical devices.

Part 4. Background Information

a)	Background Information:	On 17th April 2007, US Marshalls at the request of the FDA ordered the seizure of all implantable medical devices manufactured by Shelhigh Inc. as they had determined that significant deficiencies in Shelhigh''s manufacturing procedures exist. The FDA indicated that these deficiencies may compromise the safety and effectiveness of the device, especially their sterility. On 2nd May 2007, the FDA issued a formal written request to Shelhigh Inc. to recall all its medical devices remaining in the market place, including end users and distribution outlets. Discussions are ongoing at a European level to determine any necessary action in the EU. The IMB has confirmed through communication with the manufacturer's United Kingdom distributor, UK Medical, that none of Shelhigh''s devices have been implanted in the Republic of Ireland since 2002. However there is a possibility that patients may have had Shelhigh devices implanted abroad.

Part 5. Action to be taken

a)	Action to be taken:	Please ensure that all appropriate staff who are involved in the implantation / follow up of patients with this type of device are advised of the issue. The FDA press releases and further information are available on www.fda.gov .

Part 6. Enquiries

a)	All enquiries should be made to:	All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Medical Devices Department Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6764971 Fax: +353-1-6344033 Email: vigilance@imb.ie Website: www.imb.ie SN2007(01): Shelhigh Implantable Devices SN2007(01): Shelhigh Implantable Devices - Attachment 1 SN2007(01): Shelhigh Implantable Devices - Attachment 2

Part 7. Keywords

a)	Keywords:	Shelhigh Implantable Devices