IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

Shelhigh Implantable Devices
IMB Safety Notice: SN2007(01)

SAFETY NOTICE

MANUFACTURER/SUPPLIER

Shelhigh Incorporated, New Jersey, USA
UK Medical Limited, Sheffield, United Kingdom (Distributor)
Krijnen Medical, The Netherlands (Authorised Representative)

TARGET GROUPS

Hospital Chief Executive Officers
Hospital Risk Managers
Cardiothoracic Surgeons
Cardiologists
Vascular Surgeons
Neurosurgeons
Gastrointestinal Surgeons
Urological Surgeons
Gynaecological Surgeons
General Surgeons

ISSUE

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

BACKGROUND

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.

ACTION OR RECOMMENDATIONS

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

ENQUIRIES

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

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