

Notice Information: - Advisory
06 May 2014

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

a) Background Information:

Planer plc has issued a field safety notice relating to certain models of the Kryo range of controlled rate freezers. Such freezers are used to gradually freeze tissues and cells in the presence of cryoprotectants, in accordance with a programmed protocol. The models identified in the field safety notice are as follows:

- Kryo 1060-180
- Kryo1060-380
- Kryo3xx-1.7
- Kryo5xx-16
- Kryo750Plus
- MRV Controller, and
- Kryo-250

The IMB is working to ensure that all establishments which may cryopreserve tissues and cells using a controlled rate freezer are aware of the field safety notice.

Part 5. Action to be taken

a) Action to be taken:

The IMB advise that users:

(1) Follow the instructions outlined by the manufacturer in the field safety notice (FSN) attached.

(2) Forward this IMB Safety Notice to all those within your organisation that need to be aware of this information. Please also pass this Safety Notice and the attached FSN on to any end users or organisations where these devices may have been distributed.

Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries to the manufacturer should be addressed to:

Service Manager

Planer plc,

110 Windmill Road,

Sunbury on Thames

Middlesex, TW167HD

UK

Telephone: +44 1932 755036

Fax: N/A

E-mail: service@planer.com

Website: N/A

Enquiries to the manufacturer should be addressed to:

(alternative contact details)

Quality Manager

Planer plc,

110 Windmill Road,

Sunbury on Thames

Middlesex, TW167HD

UK

Telephone: +44 1932 755072

Fax: N/A

E-mail: quality@planer.com

Website: N/A

IMB CONTACT INFORMATION

All adverse incidents relating to a medical

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All adverse incidents relating to a medical device should be reported to:

Irish Medicines Board

Human Products Monitoring

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

[Please click here to download a copy of this safety notice](#)

[Please click here to download copy of the field safety notice](#)