

## Technical Support for Medical Device Products

### On-site support:

Blood bank refrigerators; Plasma freezers; Platelet incubators and agitators; and Barkey plasma thawers manufactured and/or supplied by Labcold since 2007 are independently audited and verified Class IIa Medical Devices in accordance with Directive 93/42/EC and revisions, plus the relevant supporting Regulations. These Regulations place significant responsibilities on the manufacturer both in terms of the design and manufacture, but also any ongoing risk associated with the product in use both to the user and the patient. In addition there are further important requirements imposed on the manufacturer to maintain ongoing surveillance and monitoring of these products throughout their working lives.

In order to fulfil these obligations Labcold employs a team of fully trained engineers supported by selected authorised repair agents\*, and a stock of original spare parts to ensure continuing compliance in terms of both performance and safety. Only original, or manufacturer-approved replacement parts may be fitted to a medical device to ensure it continues to comply with its medical device approval, and Labcold strongly recommends using only Labcold authorised engineers or contractors\* to work on their Medical Device products. Should users or those persons responsible for a Medical Device product choose to make use of a non-authorised agent for repair or maintenance it is incumbent upon them to ensure that the personnel employed possess the necessary competence, training and equipment for the work to be undertaken and, where fitted, appropriate parts are supplied and the faulty parts returned to Labcold for analysis.

\*In addition to Labcold's own employed engineers the following are authorised Labcold Contractors:

#### In the UK:

- Network Cooling Ltd
- Coolcrest Refrigeration Ltd

#### In ROI:

- Brennan and Company

### Remote telephone/email support:

Labcold has a team of technical support advisors, based at our Basingstoke head office, to provide advice and support over the phone or by email for your Labcold device. However because of the obligations imposed by the Medical Device Regulations and the risks involved we regret that they will be unable to provide advice of a highly technical nature relating to Medical Device products to non-authorised contractors or personnel.