FRESENIUS KABI

Fresenius Kabi AG **08. December 2010**

Information on known risks associated with the re-use of designated single-use medical devices manufactured by Fresenius Kabi

Dear customer,

According to the requirements of the Council's Directive 93/42/EEC (Appendix I 13.6 (h)) as amended by Council Directive 2007/47/EC, we would like to inform you that medical devices designated for single-use shall be used once only for the same patient. In case of reprocessing and/or re-use of medical devices, different risks may occur which might compromise the health of the patient and the user.

The known risks can be assigned to the following categories:

- **Hygiene**
  Medical devices designated of single-use are not designed for being cleaned, decontaminated, dried and sterilized. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.

- **Functionality**
  After the first use as well as after the reprocessing of a medical device which is designated for single-use, the structural integrity as well as the efficiency of the device might be compromised. Important material and construction characteristics might be changed as a consequence of cleaning, disinfection and sterilization and, in consequence, lead to a malfunction of the device. Consequently, the compatibility with other medical devices may be affected. Furthermore, important safety characteristics might be negatively influenced.

- **Material affects** (Interaction and aging)
  Many medical devices designated for single-use are made from materials specifically chosen for the intended single-use. Those materials may degrade or change their characteristics when being repetitively used or sterilized, or when coming into contact with chemicals or being exposed to high temperatures during reprocessing. As a consequence, corrosion of the material may occur and any coatings may be removed. In addition, the biocompatibility may be changed. As a result of material fatigue, device failures may occur.

- **Packaging and labeling**
  Packaging and labeling are an integral part of medical devices which are designated for single-use and often go beyond a sole function to ensure sterility. Packaging prevents contamination and protects the device against damage. The labeling of such devices provides important information to the user regarding the proper intended use as well as information on the specific device such as the shelf life and manufacturing details for the given batch. Not maintaining information on the packaging may pose the usage beyond the shelf life and loss of traceability. Furthermore, the product may be damaged, may pose a risk of injury and the sterility of the product may be lost.

According to their intended use, medical devices which are manufactured by Fresenius Kabi AG and which are designated for single-use only shall not be reprocessed nor re-used in order to avoid the above mentioned risks.

Yours sincerely,

Fresenius Kabi AG

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