

Press Release

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Brussels, 3rd May 2006 - The Inaugural European Forum on Medical Device Reprocessing in Tours, France, on 11th April, brought together leading European representatives and experts from medical science, hospitals, medical device and reprocessing industry. Evidence and arguments from all sides were in unanimous favour of regulated reprocessing for medical devices labelled “single-use” or “multiple-use”. On a European level, the current revision of the Medical Devices Directive 93/42/EEC provides an excellent opportunity to regulate reprocessing.

Andrea Fischer, former German Health Minister, explained how the reform of the German regulatory framework has stamped out the practice of illegal reprocessing, and led to improved patient safety and considerable cost savings. In the five years since the reform, over six million so-called “single-use” devices have been professionally reprocessed without one single reported claim. The Managing Director of EAMDR, Nikou Ghassemieh, provided more details of the impact this has had on the medical industry. In spite of the benefits, he recognised the obstacles that such reforms face on a European level, and called for a more widespread movement to update regulations across Europe.

Ms. Fischer therefore recommended that other countries consider the German example. Other contributors supported this view. Dr. J. Fereres, of CEDEST (Club Español de Esterilización), is campaigning against the Spanish government’s position of prohibiting reprocessing. CEDEST’s own research shows that, far from protecting patient safety, the lack of regulation simply drives reprocessing underground. The consequent risks to patients have translated into some documented cases of contamination, and presumably many more unrecorded incidents. Dr. Fereres was clear that a European Guideline for Reprocessing would help solve this urgent problem by introducing transparency and accountability into the reprocessing sector.

Unlike Spain, in Denmark it is possible for hospitals to use professional reprocessing of devices labelled “single-use” under high quality standards. Elsebeth Tvenstrup Jensen, MD, of the National Center for Antimicrobials and Infection Control (Statens Serum Institut), conducted a pilot study in 2003 to follow up on the surveys of 1996 and 1998. They found that in-house, unsatisfactory reprocessing had fallen, and that third-party reprocessing was an increasingly viable alternative under Danish regulation. In those Danish hospitals which are making use of these professional services, the results are positive. The Heart Centre at Varde, a private Danish hospital, has been doing so for over two years. Dr. Håkan Walfriedsson, electrophysiology expert at the hospital, stressed the benefits of reprocessing. Reusing catheters that would cost 2,500 new substantially reduces the cost of healthcare. The risks of reprocessing, in Walfriedsson’s experience, are minimal. On the contrary – the lower the cost of using a catheter, the more readily available they are for patients’ treatment.

From a more technical perspective, Dr. Francesco Tessarolo from the Department of Material Engineering and Industrial Technologies, University of Trento, Italy, has subjected reprocessed catheters (both EP and PTCA) to rigorous chemical and physical examinations. Although the data demonstrated that the devices examined could safely be reprocessed a certain number of times, Tessarolo’s team determined that, once

again, national regulation fails to provide an adequate framework. In most European Member States there is no way to trace how many times a device has been reprocessed, nor any provision for the reprocessor's liability. Therefore, Tessarolo stressed the need for a European harmonisation on the issue.

Widespread, regulated reprocessing would not only provide the framework to achieve cost reduction in the medical sector, but also to reduce the two environmental burdens of unnecessary waste generation and new device production. Additionally, Europe has the potential to be a globally competitive provider of reprocessing services.

The EAMDR calls on the European Council and the European Parliament to address the issue of medical device re-use in the current review of the Medical Device Directive. Furthermore, the European Union should set this issue on the agenda of the different bodies that deal with medical devices. This is a window of opportunity to provide the legislation framework that is necessary if all European countries are to enjoy the potential benefits of reprocessing.

About EAMDR:

The European Association for Medical Device Reprocessing (EAMDR) represents associations, research institutes, companies and opinion leaders in the fields of hygiene and microbiology, as well as the medical device industry involved in the reprocessing of medical devices throughout Europe. EAMDR seeks to professionalise the medical device reprocessing industry in Europe by fostering the exchange of expertise and the dissemination of information on state-of-the-art reprocessing activities, and by supporting European institutions in developing a level playing field for medical device reprocessing. EAMDR consults with its stakeholders to identify win-win strategies that raise the level of patients' safety while facilitating cost reductions in the health sector. For more information see: www.eamdr.com