European Alliance for
Access to Safe Medicines

→ WHEN IS A MEDICINE NOT A MEDICINE?

RE-USE OF SINGLE-USE DEVICES

In recent years, great advances in design, manufacture and use of medical devices have provided enormous patient benefit during surgery and treatment.[1] →

However, important safety, ethical and legal concerns arise when devices, originally designed and labelled for single use, are, despite the manufacturers' express instructions, refurbished, repackaged and reused.[1]

There are three reasons why single-use devices should not be reused:

1→ Serious Risks to Patient Safety

- The risks of cross-contamination and the spread of serious hospital acquired infections which are extremely debilitating and potentially fatal. This is one of the biggest public health challenges facing all European healthcare systems[2]
- The risks of device malfunction during surgery or intensive care due to it being second-hand
- There is absolutely no guarantee that a reprocessed single-use device will perform to its original standard

2→ Lack of Proven Economic Value

- Complete lack of evidence for the supposed economic value of reprocessing single-use devices[1]
- A 2008 study showing that angiography catheters were actually more expensive than the cost of new devices when reprocessed to a high standard[3]
- The European Commission (EC) has noted the lack of evidence regarding the economic value of reprocessing single-use devices and question whether it is either cost-effective or environmentally friendly when done to a high standard[4]

3→ Disturbing Ethical and Legal Concerns

- Are patients being properly and fully informed about the seriousness of the risks they are being exposed to? Would patients be happy with a reused catheter designed for single use if they knew about it?
- How are healthcare providers deciding which patients are treated with a reprocessed device or a new single-use device?
- Do healthcare providers in the theatre even know that reprocessed devices are being used?
- The EC agrees that the reprocessing of single-use devices raises serious ethical concerns, both in terms of inequalities between patients, and the necessary consideration of the issues of prior information and patients' consent[4]

There is a clear case that the very serious risks and lack of informed consent for patients far outweigh the assumed – and far from obvious – potential savings.

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Historical Background

- Historically, the vast majority of medical devices were designed to be reusable. Their design, shape and size, as well as the construction materials used – glass, metal and rubber – lent themselves to relatively straightforward cleaning and sterilisation.[5]
- However, as public awareness grew of the risk of transmission of serious blood-borne diseases such as hepatitis and HIV, the need for single-use medical devices to reduce the risk of infection became established.[4]
- The development of these single-use devices offered opportunities to use different materials and more complex designs. *They did not have to:*
  - withstand the rigours of reprocessing, such as steam sterilisation and exposure to chemical cleaning
  - many of these devices were impossible to clean or sterilise effectively, so they were labelled for 'single use'.[4]
- *In 1993, the European Union's Medical Devices Directive made a clear distinction between those medical devices that were intended by the manufacturer to be reused and those intended only for single use:*
  - manufacturers subsequently had to label their products accordingly
  - in the case of a reusable device, this meant including instructions on how to prepare for reuse and any restrictions on the number of times it may be recycled
  - those devices intended for single use needed to have this clearly indicated on the label[4]
- Despite this, an industry has grown up to refurbish, repackage and reuse (i.e. reprocess) single-use devices:
  - this is usually carried out by or on behalf of institutions, such as hospitals, in an attempt to save money
  - there is no evidence that reprocessing actually does save money
  - studies in the case of single-use angiography catheters have shown that a reprocessed device is actually more expensive than the cost of a new device to deliver equivalent levels of safety and quality[1]
- Currently, there is no EU-wide law to prevent reprocessing of single-use devices; each country has its own regulations. *For example:*
  - In France, the reuse of single-use devices is illegal;
  - In the UK, health authorities have issued guidance that warns of the potential risks and consequences when re-using a single-use device
  - Germany has guidelines in place to regulate reprocessing to a certain extent, although it makes no legal distinction between single-use and multiple-use devices[1]

These disparities highlight a clear need for legal measures to secure the highest level of safety for single-use medical devices, especially in the light of the proposed cross-border directive.
The European trade body for medical equipment, Eucomed, supported by the EAASM, is calling on the European Commission to propose suitable legal measures that will ensure the highest possible level of safety for patients and citizens in Europe.

1 → Eucomed White Paper on the reuse of single use devices:

http://www.eucomed.org/uploads/Press%20Releases/Eucomed%20White%20Paper%20on%20the%20reuse%20of%20single–use%20devices.pdf

2 → Health First Europe facts and figures on patient safety:

http://www.healthfirsteurope.org/index.php?pid=82

3 → Larmuseau David, Siok Swan Tan. The impact of reprocessing single use devices in Belgium – An economic study, Erasmus MC University Medical Center, Institute for Medical Technology Assessment, Rotterdam, Netherlands, 2008

4 → European Commission report on reprocessing of medical devices: http://ec.europa.eu/consumers/sectors/medical–devices/files/pdfdocs/reprocessing_report_en.pdf

5 → SCENIHR scientific opinion: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf