

Product liability and reuse of medical devices



Anne Ware

The reprocessing of medical devices has been an increasing industrial practice since the late 1970s. While reprocessing of some medical devices has taken place within hospitals for many years, the market for professional third-party reprocessing service providers has developed during the last decade due to financial pressures as well as scientific and technological advances. Anne Ware and Brian Kelly discuss the risks of reprocessing single-use medical devices and the associated product liability issues that may arise.



Brian Kelly

Before the widespread availability and use of single use devices (SUDs) in the 1980s, the reuse of some medical devices was facilitated by their shape, their size and the fact that they were usually made of glass, metal or rubber. The reprocessing of these devices was relatively straightforward and more akin to “recycling”. With technological developments, including the use of

novel plastics, instruments with smaller lumens and more intricate, delicate working mechanisms, devices are not as easy to clean or sterilize. Because of this, manufacturers label some products as “single-use”, i.e. they should be used for a single procedure on a single patient and then discarded.

...reusable devices

Reusable devices are designed in such a way that they can be disassembled, cleaned, re-assembled, sterilized, re-packaged and used again. Under the Medical Device Directive 93/42/EEC (MDD)¹ as amended, if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization must be provided. Any restrictions on the number of reuses must be specified in the labelling.²

...single-use devices

SUDs were developed in response to the need to avoid cross-infection and to improve standards of care. Common examples of SUDs include surgical drills, saw blades, biopsy forceps, laparoscopy scissors, metal orthodontic braces, balloon angioplasty catheters, and irrigating syringes.

SUDs are defined under the MDD as devices intended by their manufacturers to be used only once for a single patient and then discarded.³ Under the MDD, the manufacturer of an SUD must include an indication that the device is for single use which is consistent across the European Community.⁴

...reusing SUDs

Unlike reusable devices, SUDs are not designed to be reprocessed and reused. However, the reprocessing and reuse of SUDs has become a common practice. Users of reprocessed SUDs, for example hospitals, often justify the reprocessing of such devices on the basis that they are cheaper and reduce medical waste. These perceived benefits are questionable as many of the processes required to

ensure that the device is safe and fit for its intended purpose cannot be undertaken by the “reprocessor”, the person or company that undertakes the reprocessing of an SUD.

By definition, SUDs have not undergone extensive testing, validation and documentation by the manufacturer to ensure that they are safe to reuse. If SUDs are reprocessed, their safety and functionality cannot be guaranteed. In particular, using reprocessed SUDs poses the following risks:

- *Cleaning and decontamination:* a satisfactory cleaning process for devices must access all parts of the device to ensure complete decontamination. This process should be validated, to establish that it will consistently provide results complying with its predetermined specifications. Device features that make cleaning and decontamination difficult include: acute angles, coils, long or narrow lumens, specialist surface coatings, etc.;
- *Residues from chemical decontamination agents:* these may be absorbed by the material of the devices e.g. plastics, and leach out after reprocessing. This could result in chemical burns or a risk of sensitisation in the patient or user;
- *Material alteration:* exposure to chemical cleaning and sterilisation agents may cause corrosion and/or changes in the materials of the device. Exposure to elevated temperatures or pressure during the sterilisation process may also alter the properties or cause degradation of the device material. For example, plastics may soften, crack or become brittle;
- *Mechanical failure:* some devices may experience stress during each cycle of reuse, leading to fatigue-induced failure and fracturing e.g. single-use saw blades and craniotomy blades;
- *Reactions to endotoxins:* endotoxins are Gram-negative bacterial breakdown products and can be a significant problem if the device has a heavy bacterial load after use which cannot be adequately removed by cleaning. The sterilisation process will not inactivate the toxins, even when cleaning and sterilisation is effective in killing the bacteria⁵;
- *Cross contamination and hospital-acquired infections:* SUDs can help reduce hospital acquired infections. However, the use of reprocessed SUDs increases the risk of cross-contamination and hospital acquired infection. In many cases it is not possible to guarantee that all blood, tissue and body residues have been removed. The European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has recommended the use of SUDs to avoid cross-contamination from variant Creutzfeldt-Jakob Disease (vCJD) because there is no validated cleaning process available for instruments that might

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be contaminated with transmissible spongiform encephalopathy agents like vCJD.⁶ There are similar concerns for other viruses, such as hepatitis, and unknown viruses.

With these points in mind we turn to the potential product liability issues that may arise.

...product liability issues

1. Who is a “producer”?

The Product Liability Directive 85/374/EEC⁷ (the Directive) established the principle of strict liability, i.e. liability without fault of the “producer”, in cases of personal injury caused by a defective product. If more than one person is liable for the same damage, then those persons are jointly liable. In defining the term “producer”, the Directive seeks to ensure that an injured party will always have someone within the European Economic Area (EEA) against whom they can bring a claim. The EEA includes the EU Member States plus Norway, Iceland and Liechtenstein.

A “producer” is:

- a manufacturer or participant in the production process;
- the importer of a product;
- any person putting their name, trademark or other distinguishing feature on the product (e.g. companies selling own-brand products);
- other intermediate suppliers of products, e.g. distributors, retailers, healthcare professionals and their employers.

However, intermediate suppliers are only liable under the Directive if they fail to identify any other “producer” further up the supply chain within a reasonable period.

Under the Directive, it is necessary for the injured person to prove:

- the defect in the product;
- the actual damage;
- the causal relationship between the actual damage and the defect.

As the Directive introduces strict liability, it is not necessary to prove any negligence or fault on the part of the producer, importer or other intermediary.

2. What is a “defect”?

A product is defective if it does not have the level of safety which the general public is entitled to expect. Factors to be taken into account under Article 6(1) of the Directive include:

- the presentation of the product (e.g. packaging and labelling);
- the use to which it could reasonably be put (e.g. instructions and warnings);
- the time when the product was put into circulation (e.g. sold or made available).

The fact that a safer product is subsequently put into circulation does not render an earlier product defective.

...defences to product liability claims

A key question for manufacturers, reprocessors and users of SUDs is: who is liable under the Directive when an SUD has been

reprocessed and subsequently reused? Article 7 of the Directive contains a number of possible exemptions from liability. The most relevant defences here are:

- that the “producer” did not put the product into circulation;
- that the defect causing the damage came into being after the product was put into circulation by the “producer”.

In the first case, the defendant to a claim would need to show that they were not the “producer” of the product as defined in the Directive. For example, if a claim is against an original manufacturer of an SUD, it would be necessary to demonstrate that the reprocessor and/or user of the SUD was the “producer” and put the reprocessed SUD into circulation. If a claim is made against a reprocessor or other supplier, it would be necessary to demonstrate that the original manufacturer or end user is the “producer” for the purposes of the Directive. For example, the defendant or manufacturer might be able to prove that the product as originally designed was defective.

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“it is worth noting that if SUDs are manufactured or reprocessed in the EEA and thereafter exported outside the EEA, e.g. to a developing country, claims might still be brought against the original manufacturer and/or reprocessor in the EEA under the Directive”

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In the second case, the defendant to a claim would have to show that the defect which caused injury to the claimant was attributed to another entity in the supply chain. If an original manufacturer issued a claim, it would have to demonstrate that the defect was caused by the reprocessor or a medical professional, or their employer, misusing or mishandling the device (for example, by using the SUD contrary to the original manufacturer’s instructions). The original manufacturer’s defence would be strengthened if it has taken clear steps to prevent reuse of its products, e.g. correct labelling and warnings, use of tamper-evident packaging and providing training on the correct use of SUDs.

A reprocessor of an SUD would need to show that it did not cause the defect in the device.

Reprocessors will need to carefully consider their standard operating procedures, validation and certification procedures. Reprocessors would also need to consider whether the original manufacturer implicitly approved the processes for reusing SUDs, for example by failing to challenge or warn against inappropriate procedures or validation techniques.

It is worth noting that if SUDs are manufactured or reprocessed in the EEA and thereafter exported outside the EEA, e.g. to a developing country, claims might still be brought against the original manufacturer and/or reprocessor in the EEA under the Directive.

End users, such as hospitals and medical professionals, will face similar issues under the Directive and would seek to shift liability onto the original manufacturer or the reprocessor.

...consultation on the reuse of medical devices

Directive 2007/47/EC, which amended the MDD, provides that the European Commission must submit a report to the European Parliament by September 2010 on the issue of reprocessing medical devices.⁸ Between May and August 2007, the Commission issued a series of consultations on the reprocessing of medical devices and comments were received from manufacturers, reprocessors, hospitals and medical staff. A report on the responses received was published in May 2008 and discussed issues relating to safety, product liability, and ethics of reusing medical devices.⁹

The majority of consultees considered that liability of the original manufacturer of an SUD ends at the point when the device is not

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used for its intended purpose, i.e. the purpose specified in the accompanying documentation, labelling and the promotional materials. If an SUD is reprocessed, the consultees took the view that liability for the product sales to the reprocessing service provider. If a hospital reprocesses SUDs itself, the consultation report stated that the hospital should be subject to the same obligations as a professional reprocessing service provider.

In the case of reprocessing of “reusable” medical devices, i.e. devices where the manufacturer provides information to enable the subsequent safe reuse of a product, the consultation report stated that the original manufacturer should “bear full responsibility for the first use and the subsequent uses, provided that its instructions are correctly applied”.

...negligence

In addition to claims under the Directive, manufacturers, reprocessors, medical professionals or anyone in the supply chain of a reprocessed medical device may also be liable to an injured claimant in negligence or under the relevant civil law code of the jurisdiction where the claim is brought. Liability may arise where, for example, they fail to provide adequate warnings. This raises issues of informed consent, as patients are not likely to be informed that they will be treated with a reprocessed SUD and warned of any associated risks. In some cases, medical professionals themselves are not aware that they are treating patients with reprocessed SUDs.¹⁰

In English law, negligence is judged against what is the appropriate level of knowledge and conduct assessed against the state of the art at that time. Courts will consider whether the conduct of those involved in the supply or use of a device has fallen below what would reasonably be expected of that individual or organisation. What constitutes reasonable conduct would depend on the magnitude of the associated risk, the likelihood and consequences of any injury and the practicality and costs of taking avoiding or corrective action.

...general product safety and other issues

Under the General Product Safety Directive 2001/95/EC (GPSD),¹¹ producers and distributors of products intended for consumers or likely to be used by consumers must only place those products on the market if they are safe. The majority of the safety requirements under the GPSD are also covered by medical device legislation, e.g. the essential requirements in Annex I to the MDD. The general rule, therefore, is that the safety requirements of the GPSD are not relevant to medical devices.¹²

However, producers and distributors (including reprocessors) of medical devices intended, or likely to be used by the consumer, e.g. contact lenses, must be mindful of other duties which apply to them under the GPSD. For example, there is a general duty to notify the competent authorities and, if necessary, cooperate with them if a product is considered to be unsafe.¹³

...discussion

If a reprocessed device is supplied to a legal entity or individual and the device is defective, the reprocessor, professional user and/or their

employer may be legally liable under the Product Liability Directive and/or in negligence to a patient who suffers an adverse outcome as a result.

To reduce the risk that liability will attach to the original manufacturer of a reprocessed SUD, original manufacturers should clearly and correctly label their products for single use only and adopt the EU wide common label for SUDs on the packaging of the device. They should also consider ways to prevent reprocessing wherever possible, for example by using tamper-evident packaging and offering training on SUDs to hospitals and medical professionals. Original manufacturers should also ensure that they do not provide reprocessors or end users with guidance or technical specifications that could be viewed as encouraging or endorsing reuse of their SUDs.

Traceability of a reprocessed SUD may also be a problem if a reprocessor fails to remove the branding of the original manufacturer. Original manufacturers should seek additional safeguards from the European Commission on this. For example, the Commission could consider requiring reprocessors to remove the original manufacturer’s branding from the packaging and labelling before putting the device back into circulation for reuse. It should also require additional identification of the reprocessor to ensure traceability of the devices. This would give some protection to patients and those involved in the supply chain to detect defective products. *

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¹Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

²MDD, Annex I, paragraph 13.6.

³Article 1.2(n) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p.1), as amended (“Medical Device Directive”)

⁴Medical Device Directive, Annex I, paragraph 13.3

⁵DB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse, Medical and Health care Products Regulatory Agency.

⁶The Scientific Committee on Emerging and Newly Identified Health Risks published an Opinion on The Safety of Human-derived Products with regard to Variant Creutzfeldt-Jakob Disease, 28-29 September 2005.

⁷Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [Official Journal L 210 of 07.08.1985]

⁸Article 12a, Directive 2007/47/EC, Official Journal L 247, 21/09/2007 P. 0021 - 0055

⁹Synthesis Document, Outcome of the First Consultation on Reprocessing of Medical Devices, European Commission, May 2008.

¹⁰Supra note 8.

¹¹Directive 2001/95/EC of 3 December 2001 on General Product Safety (OJ No L 11 of 2002-01-15)

¹²Guidance Document On The Relationship Between The General Product Safety Directive And Certain Sector Directives With Provisions On Product Safety (Directives On Medical Devices, Construction Products, Machinery, Medicinal Products And Motor Vehicles), Second Chapter, Directorate General Health And Consumer Protection (DG SANCO), November 2005, paragraph 2.1.1.

¹³Supra note 12, Article 5.

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