

Definition Reprocessing

Reprocessing of Medical Devices – Terms & Definition

Controlled Reprocessing

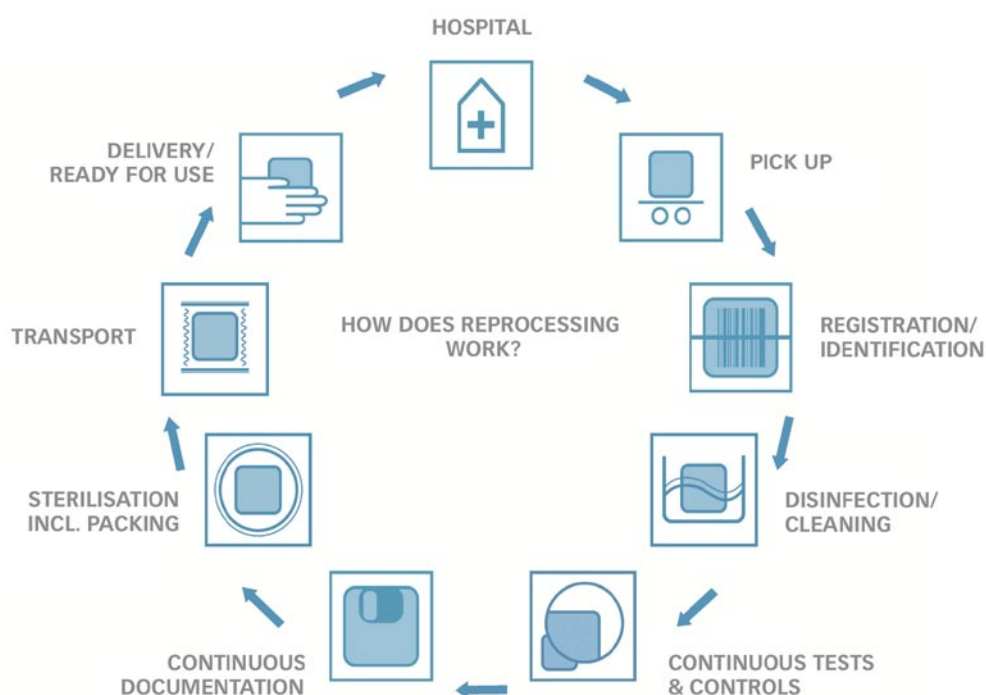
The EAMDR strongly supports and promotes the application of controlled and professional reprocessing according to validated procedural rules, complying to highest quality criteria and taking place within an accredited quality management system.

Reprocessing, in this context, includes the cleaning, disinfection and sterilisation of a used medical device and the related steps in these procedures as well as reinstating and testing the technical and functional safety of the device.

Reprocessing takes place in a hygienically monitored environment. Reprocessing is subject to validation rules that are backed by scientific evidence and subject to the control and supervision of the public authorities. The validation ensures that the reprocessed device has identical hygiene and functional properties as the original product.

Reprocessing takes place in a closed loop where all steps are hygienically monitored. Medical devices that are reprocessed for third parties are returned to the same people and places where they were picked up. Therefore, reprocessing does not constitute the “placing on the market” of the medical device.

The different steps of a safe and professional reprocessing process:



Professional reprocessors shall comply to statutes that require them to:

- Apply validated procedures that are backed by scientific evidence and ensure that the reprocessed device has identical hygiene and functional properties as the original product
- Officially indicate their activities and are subject to the control and supervision of public authorities
- Have implemented total quality management systems to guarantee a consistently high and transparent level of quality

Distinction from Refurbishing

Reprocessing does not equal refurbishing. Refurbishing includes the removal and the re-manufacturing of a device and might also include some upgrades, e.g. fixing panels, switches, readouts etc. While reprocessing essentially consists of cleaning, disinfecting, sterilising and testing devices, refurbishing additionally includes the regeneration or the exchange of parts of the device.

Distinction from Remarketing

Reprocessing does not equal remarketing of used medical devices. Remarketing of used medical devices consists of activities that are deemed to significantly change the finished device's performance and safety specifications and those that do not include refurbishing, reconditioning, rebuilding or servicing.

Distinction from Recycling

Reprocessing does not equal recycling. Recycling is the act of processing used or abandoned materials for use in creating new products. Recycling involves altering the physical form of an object or material and making a new object from the altered material. It thereby distinguishes itself from re-use, which does not alter the physical form of an object. By-products and residual material accrued during production and consumption are thereby re-introduced into the production-consumption-cycle. Three types of recycling can be distinguished:

- 1) Reuse – the repeated use of a product or material for the same purpose
- 2) Further application – by-products and residual material for new purposes after suitable physical, chemical or biological pre-treatment
- 3) Further utilization – basic chemical elements are retrieved out of by-products and residual material and re-introduced into the production process