Letters

Reprocessing of single-use products in endoscopy?

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The increasing use of disposable products is a current trend in endoscopy. This not only applies to endoscopic accessories and components, but also increasingly to the endoscopes themselves. By definition (according to Commission Implementing Regulation (EU) 2017/745, also known as Medical Device Regulation, MDR, article 2, point 8), single-use products should only be used once on a single patient [1].

Therefore, the instructions for use for single-use products do not contain any information on safe reprocessing practices or functional checks after reprocessing. To ensure these devices are utilized only once, some manufacturers have designed their single-use products in such a way that reprocessing is not possible after use ("single-use by design" principle).

Surprisingly, reprocessing of single-use products is generally not prohibited even if it contradicts the intended use as defined by the manufacturer. §17 MDR regulates the reprocessing of single-use products, but national regulations must be used as a prerequisite for the permissibility of this practice. In these cases, the reprocessing entity becomes the "new manufacturer" and must assume the responsibility of the original manufacturer according to §17 MDR. This includes preparation of the technical documentation. For example, required risk management practices must include an evaluation of the following product characteristics:

- *materials,*
- *design,*
- *properties and*
- *intended use.*

In this context, the reprocessability must also be considered. This should include assessments of:

- *the microbiological contamination to be expected during normal use of the product,*
- *how reprocessing may affect the material changing of the product, in particular regarding the soluble or chemically reactive components of these materials and*
- *remnants of reprocessing, that may cause pyrogenic, allergic, or toxic reactions.*

The Commission Implementing Regulation (EU) 2020-1207 further explains that single-use products must not be reprocessed where severe incidents have occurred, such as patient infections related to improper reprocessing [2].

If successful reprocessing of a single-use device seems possible through risk management, then all steps of the reprocessing process, including initial treatment at the point of use, must be validated. This also includes a determination of the maximum possible reprocessing cycles. Furthermore, procedures for performance testing and product lot releases must be defined and included in a quality management system.

The manufacturer's responsibility does not end with the product release but extends to the obligation to report incidents and to ensure the traceability of all disposable products that have been reprocessed and brought into use.

In summary, from the point of view of the Instrument Reprocessing Working Group (AKI), the only endoscopes, accessories and components that should be reprocessed are those intended to be reprocessed by the respective manufacturer and for which there are corresponding instructions for use.

References

1 Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)

2 Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices (Text with EEA relevance)