Reprocessing / Traceability of Dentistry Reusable Medical Devices: Narrative Review

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Introduction

The reprocessing of reusable medical devices (MD) is a key-element in clinical settings infection control, being reported in several medicine fields.

Objectives

To perform a descriptive review of clinical dental instruments definition as MDs and to describe concepts of MD reprocessing and traceability processes in dentistry.

Methods

Research was performed in PubMed between the years 2000-2015, with the keywords: “cross-contamination”, “disinfection”, “sterilization”, “reusable instruments”, “reprocessing”, “traceability” and “dental medical devices”. Five hundred and sixty three papers were identified. Research methodology included narrative/systematic reviews, and observational studies of reprocessing/traceability processes; publications regarding the effects in MD resistance, efficacy of methods and equipment processing were excluded.

Results

Sixteen papers were selected. Dental instruments are included in the MD category and regulated by law (Figure 1). Depending on the nature and complexity of the MD (Figure 2), several methods can be applied, recognizing their characteristics and limitations. MD reprocessing/traceability involve several stages and may include (Figure 3): disassembly, cleaning, disinfection, inspection, testing for functionality, packaging, sterilization and storage, requiring detailed records (Figure 4), logistical capacity and appropriate training. The instructions of MD manufacturers fall short of the necessary regulatory requirements, with information gaps that may limit those processes (Roebuck E.M. et al., 2008). Literature description is scarce, being necessary further studies applied to particularities of the dentistry clinical environment.

MEDICAL DEVICE: *"(...) any instrument, apparatus, appliance, software or material used alone or in combination, intended by its manufacturer to be used to prevent, diagnose or treat a human disease (...)"*

CRITERIA	MD CLASSIFICATION
HUMAN BODY VULNERABILITY/DESIGN AND MANUFACTURING RISK	CLASS I: low risk
	CLASS IIa e IIb: medium risk
	CLASS III: high risk
INFECTION TRANSMISSION RISK	CRITICAL: penetrates sterile tissue
	SEMI-CRITICAL: contacts with intact mucous membranes or non-intact skin
	NON CRITICAL: contacts with intact skin

Figure 1 – MD definition and classification categories (Ministério da Saúde, 2009; Infarmed).

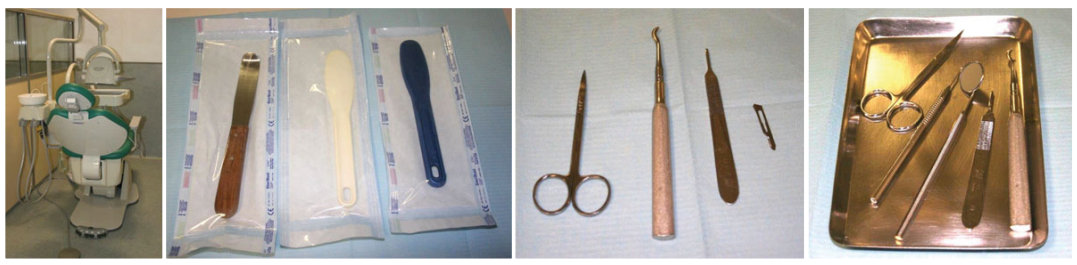


Figure 2 – Examples of MD that require reprocessing by disinfection and sterilization circuits, for reuse.

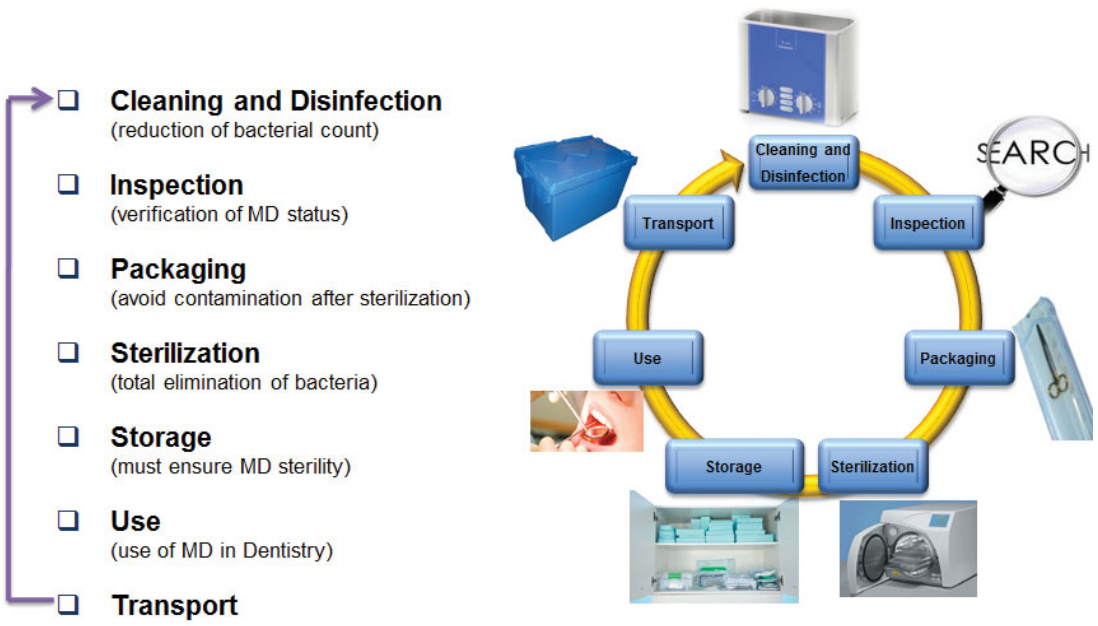
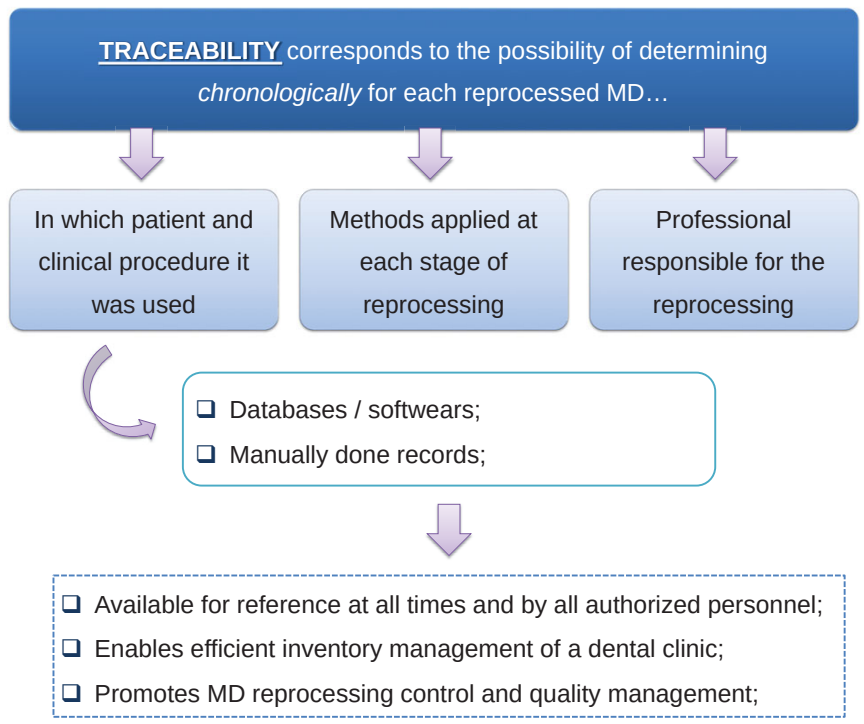


Figure 3 – Scheme of a reusable MD life cycle; Requires MD manufacturer's Directions For Use consultation (Palenik C.J., 2001; Thomas L.P. *et al.*, 2005).

Figure 4 – Traceability process and its main advantages (Rato C., 2011; Krejci I. *et al.*, 2013).



Conclusion

The reprocessing / traceability processes depend on the MD type, instructions issued by MD manufacturers, professional training and require documented and validated records, there being no standard protocol.

Clinical Implications

The possibility of reprocessing/tracing reusable MD assures resources optimization and promotes patients and dentistry team safety.

Keywords
Cross-contamination
Disinfection
Sterilization
Reprocessing
Traceability
Medical Devices

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