Recommendations by the Quality Task Group (30): Packaging Systems – Part 2: Hard Packaging

When it came to processing medical devices little attention was paid for a long time to sterile supply packing. The psychological sense of security conferred by the visible presence of packaging was more important than the actual requirements and the underlying process. Neither the correct choice of packaging nor the consequences of inadequate packaging warranted much reflection.

The Quality Task Group, a working group composed of experts, is now dealing with this topic. Its goal is to give users an easily understood guide, presented in tabulated form, to enable them to assign the different types of packaging to their respective standards as well as to evaluate them in economic terms.

Safety aspects and user friendliness are also taken into consideration. Particular attention is also paid to validation. This is because in view of the markedly more stringent quality requirements (see ISO 17664), anywhere in the world, each manufacturer of medical devices, each hospital as well as anyone dealing with medical device packaging and sterilisation must focus in detail on this aspect of quality management.

In the context of standard ISO 11607, validation is understood to mean *“the provision of documented proof that all quality requirements addressed to the process are fulfilled and that the process repeatedly produces devices that meet the given specifications”*.

As far as the packing process is concerned, this means that the process must be reproducible. Processes that unfold differently on each occasion do not lend themselves to validation.

Binding procedural directives and standard operating procedures, as stipulated by a quality management system, as well as specialist personnel who undergo regular training are a prerequisite for validable processes.

These recommendations are divided into three parts:

Part 1: Soft Packaging Systems (published in *Central Service* 2/2003)
Part 2: Hard Packaging Systems and
Part 3: Comparison of the Systems

By consulting the tables, the user should be able to select the appropriate system

Sigrid Krüger
Quality Task Group Coordination

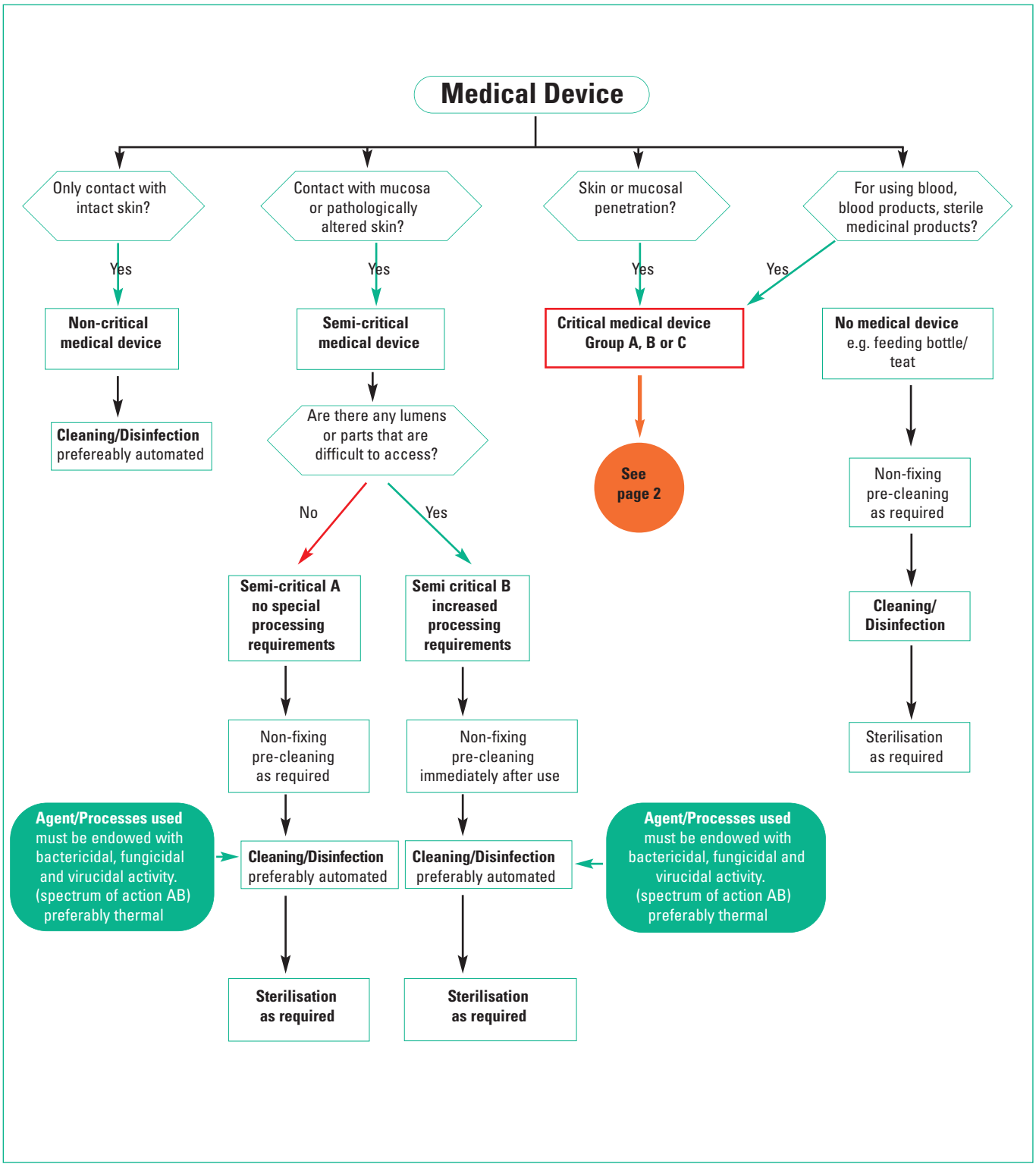
		Hard Packaging	
Packaging material			
Competent standards	DIN	EN 868-1	EN 868-8
	EN	868-1	868-8
	ISO	11607[1]	
Packing technique			
	manual automated	X[3]	
Validation			
Reproducible		yes	
Validable		yes	
Application technology			
Competent standards	DIN	58953-9	
	EN	ISO 17664 (draft)	
	ISO	11607[1]	
Sterilisation process			
Steam		yes	
Formaldehyde		no	
Ethylene oxide		yes[2]	
Gas plasma		yes[2]	
Hot air		no	
Liquid media		no	
Economic efficiency			
Material investment		high	
equipment investment		none[4]	
Labour		low[4]	

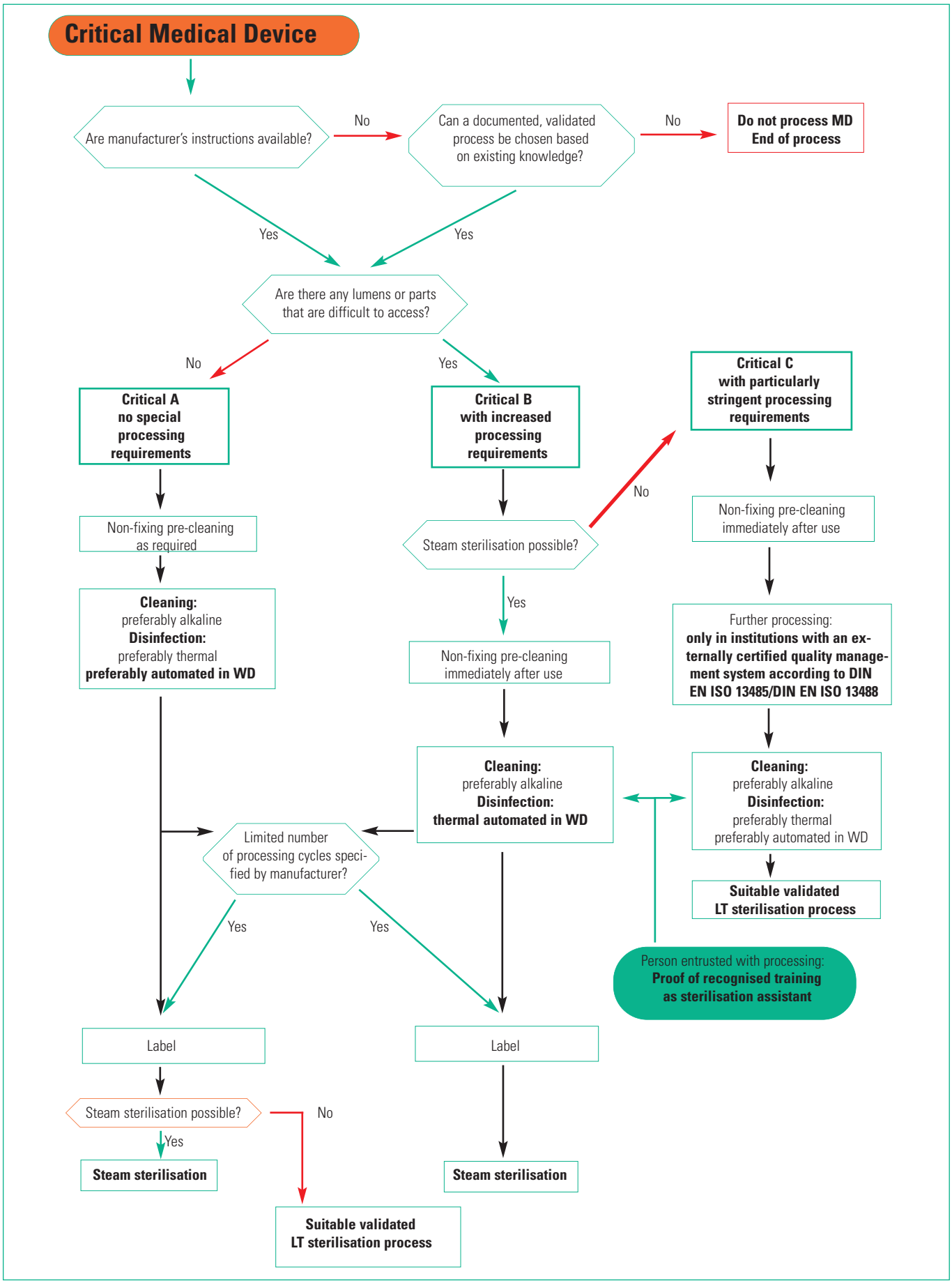
Table 2: Hard packaging systems

[1] contains no specific information for the operator
[2] the operating manual produced by the container manufacturer giving a list of the processes permitted must be observed
[3] this is determined by the design (guided control), no deviation possible
[4] depends of the type of processing

Classifying Medical Devices before Processing (as of October 2003)

based on the Recommendation (by the RKI and BfArM) *Hygienic Requirements for Processing of Medical Devices* (published in: *Bundesgesundheitsbl. 2001; 44: 1115–1126.*)




Critical Medical Device
Are manufacturer's instructions available?
No
Can a documented, validated process be chosen based on existing knowledge?
No
Do not process MD
End of process
Yes
Yes
Are there any lumens or parts that are difficult to access?
No
Yes
Critical A
no special processing requirements
Critical B
with increased processing requirements
Critical C
with particularly stringent processing requirements
Non-fixing pre-cleaning as required
Steam sterilisation possible?
No
Non-fixing pre-cleaning immediately after use
Cleaning:
preferably alkaline
Disinfection:
preferably thermal
preferably automated in WD
Yes
Non-fixing pre-cleaning immediately after use
Further processing:
only in institutions with an externally certified quality management system according to DIN EN ISO 13485/DIN EN ISO 13488
Cleaning:
preferably alkaline
Disinfection:
thermal automated in WD
Cleaning:
preferably alkaline
Disinfection:
preferably thermal
preferably automated in WD
Limited number of processing cycles specified by manufacturer?
Suitable validated
LT sterilisation process
Yes
Yes
Person entrusted with processing:
Proof of recognised training
as sterilisation assistant
Label
Label
Steam sterilisation possible?
No
Yes
Steam sterilisation
Steam sterilisation
Suitable validated
LT sterilisation process