

Appendix V

Instruments in polypropylene with through-holes

39 Maximum attainable temperature 134°C.

Products	Max number of cycles
Surgical saliva ejectors	100

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments under abundant running water before placing them inside the thermal disinfecter, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air.

Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

If performed completely automatically, manually rinse the instruments, letting the water enter from an opening in the hole using a syringe, and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air.

Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, proceed with regular manual cleaning.

Sterilization

Do not exceed max temperature of 134°C.

International Regulations and References

AAMI TIR 12

Design, testing and labelling reusable medical devices for reprocessing in healthcare facilities: A guide for medical device manufacturers

AAMI TIR 30

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

AAMI TIR 34

Water for reprocessing of medical devices

AAMI TIR 55

Human factors engineering for processing medical devices

ANSI/AAMI ST 77

Containment devices for reusable medical device sterilization

ANSI/AAMI ST 79

Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities

EN 285

Sterilization - Steam sterilizers - Large sterilizers

EN 13060

Small steam sterilizers

ISO 11138-3

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes

ISO 11140-1

Sterilization of healthcare products - Chemical indicators - Part 1: General requirements

ISO 1607-1

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 15883-1

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests

ISO 17664

Sterilization of re-usable instruments - Information to be provided by the manufacturer for the processing of re-usable instruments

ISO 17665-1

Sterilization of healthcare products, moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 17665-2

Sterilization of health care products, moist heat - Part 2: Guidance on the application of ISO 17665-1

United States Pharmacopoeia (USP)

European Pharmacopoeia (EP)

Japanese Pharmacopoeia (JP)

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Decontamination of surgical instruments