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Operating specification for cleaning, disinfection, and sterilization of 3D-Printed orthopedic surgical guides

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Preface

This document is drafted in accordance with the *Directives for standardization — Part 1: Rules for the structure and drafting of standardizing documents* (GB/T 1.1—2020).

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Operating specification for cleaning, disinfection, and sterilization of 3D-Printed orthopedic surgical guides

Chinese Research Hospital Association

1 Scope of Application

This document specifies the basic requirements, equipment and facilities, consumables and tools, operating procedures, and quality control and traceability requirements for the cleaning, disinfection, and sterilization of 3D-printed orthopedic surgical guides.

This document is applicable to the cleaning, disinfection, and sterilization of 3D-printed orthopedic surgical guides made of polymer materials in the Central Sterile Supply Department (CSSD) of medical institutions.

2 Normative References

The following normative documents contain provisions, which, through reference in this text, constitute provisions of this document. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated references, the latest edition of the normative document (including any amendments) referred to applies.

Standards for drinking water quality (GB 5749)

Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems (GB/T 19633.1)

Central sterile supply department (CSSD) - Part 1: Management standard (WS 310.1—2016)

Central sterile supply department (CSSD) - Part 2: Standard for operating procedure of cleaning, disinfection and sterilization (WS 310.2—2016)

Central sterile supply department (CSSD) - Part 3: Surveillance standard for cleaning, disinfection and sterilization (WS 310.3—2016)

General requirements of guides for orthopaedic surgery (YY/T 1845)

Packaging materials for terminal sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods (YY/T 0698.2)

Processing of health care products - Information

to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Easily detachable particles

Loose micro-particles on the surface or inside a surgical guide that may detach during or after surgery, which are caused by insufficient material curing, weak interlayer bonding, or improper handling.

3.2 Glass transition temperature; T_g

The critical temperature at which a polymer material transitions from a rigid glassy state to a viscoelastic rubbery state.

Note: Within this temperature range, the mechanical properties of the material change abruptly, directly affecting the dimensional stability, load-bearing capacity, and biomechanical compatibility of the surgical guide.

3.3 Rockwell hardness; HRC

A quantitative indicator of the material's ability to resist plastic deformation under external force.

3.4 Sharp edge

Sharp or angular protrusions formed on the surface or edges of a surgical guide due to material stacking, poor interlayer bonding, or improper processing during 3D printing or post-processing.

3.5 3D-printed orthopedic surgical guides

Personalized auxiliary instruments fabricated using three-dimensional reconstruction based on patient medical imaging data, computer-aided design, and additive manufacturing techniques. They are primarily used in orthopedic surgeries to precisely determine spatial distances, angular relationships, directions, and depths, and to guide osteotomy, drilling, or implant positioning.

4 Abbreviations

The abbreviations defined as follows apply to this document.

ABS: Acrylonitrile-butadiene-styrene copolymer

PA: Polyamide

PA 6: Polyamide 6

PA 11: Polyamide 11

PA 12: Polyamide 12

PA 46: Polyamide 46

PA 66: Polyamide 66

PA 1212: Polyamide 1212

PEEK: Polyether ether ketone

PLA: Polylactic acid

5 Basic Requirements

5.1 Appropriate cleaning, disinfection, drying, and sterilization procedures shall be selected according to the instructions for use provided by the surgical guide manufacturer. The basic performance and safety requirements of surgical guides shall comply with the standard YY/T 1845. The manufacturer shall provide clear processing information in accordance with the standard ISO 17664.

5.2 For surgical guides arriving at CSSD for the first time, the upper limit of processing temperature shall be selected based on the glass transition temperature (T_g) of the material.

5.3 During processing, close observation shall be made for structural changes in the surgical guide to avoid mechanical damage (e.g., scratches, impacts). If damage (e.g., cracks, deformation) is found, the medical device user department shall be contacted promptly.

6 Requirements for Equipment, Facilities, Consumables, and Tools

6.1 Equipment and Facilities Requirements

6.1.1 Water treatment equipment, medical drying cabinets, medical low-temperature vacuum drying cabinets, steam sterilizers, hydrogen peroxide low-temperature sterilizers, and ethylene oxide

sterilizers shall be provided.

6.1.2 Manual cleaning sinks, pressure water/air guns, etc., shall be provided.

6.2 Consumables and Tools Requirements

6.2.1 Medical cleaning agents compatible with the surgical guide materials shall be selected and shall comply with the standard *Hygienic requirements for medical detergents* (T/WSJD 002).

6.2.2 75% ethanol shall be provided.

6.2.3 Sterilization packaging materials shall be selected according to the sterilization method and shall comply with the standards GB/T 19633.1 and YY/T 0698.2.

6.2.4 Low-lint cleaning cloths, cleaning brushes (brush bristles shall be compatible with the surgical guide materials), cleaning baskets, and transport tools shall be provided.

6.3 Cleaning Water Requirements

Cleaning water shall comply with the standard WS 310.1. Supply of tap water, hot water, softened water, and purified water shall be available. Tap water quality shall comply with the standard GB 5749. The conductivity of final rinse water shall be $\leq 15 \mu\text{S}/\text{cm}$ at 25 °C.

7 Operating Procedures

7.1 Receiving

7.1.1 The medical device user department shall deliver the surgical guides to CSSD in advance to ensure sufficient processing time.

7.1.2 Upon receipt, the surgical guides shall be inspected to confirm structural integrity, with no defects, burrs, sharp edges, cracks, or indentations.

7.2 Classification

Surgical guides shall be classified according to material properties, in accordance with Appendix A.

7.3 Cleaning

7.3.1 Surgical guides should preferably be cleaned manually.

7.3.2 Cleaning steps include rinsing, washing, rinsing, and final rinsing. A pressure water gun (pressure $\leq 0.2 \text{ MPa}$) shall be used to flush the sur-

face and pores of the guide to remove contaminants, including easily detachable particles. Moisture-resistant surgical guides shall be completely immersed in a solution containing medical cleaning agent for cleaning; moisture-sensitive surgical guides (e. g., PA 6, PA 46, PA 66, etc.) shall be wiped with a low-lint cleaning cloth. The cleaning procedure shall be carried out in accordance with Appendix B.

7.4 Disinfection

7.4.1 For moisture-heat-resistant surgical guides such as PA 46, PEEK, ABS, etc., thermal disinfection is the preferred method. Thermal disinfection methods shall comply with the provisions in Section 5.4.3, WS 310.2—2016.

7.4.2 For surgical guides that are not moisture-heat-resistant, such as photopolymer resins and PLA (nylon materials excluded), 75% ethanol wiping disinfection should be used.

7.5 Drying

7.5.1 For surgical guides made of photopolymer resins, PA (PA 6, PA 66, PA 11, PA 12, PA 1212), PLA, etc., medical low-temperature vacuum drying cabinets should be used for drying. The drying temperature shall be ≤ 60 °C for at least 20 min, and shall ensure thorough drying. For heat-sensitive surgical guides, low-lint cloth wiping or pressure air guns may also be used for drying.

7.5.2 For surgical guides made of PA 46, PEEK, ABS, etc., medical drying cabinets or other drying equipment should be used. The drying temperature shall be 70 °C to 90 °C for at least 20 min, and shall ensure thorough drying.

7.5.3 Appropriate drying temperature and method shall be selected based on the material of the surgical guide. Natural drying methods shall not be used.

7.6 Functional Inspection

7.6.1 Visual inspection and inspection using a magnifying lamp with illumination shall be performed to check the cleaning quality and func-

tionality of the surgical guides.

7.6.2 Surgical guides shall be thoroughly cleaned and dried, fully functional, with no loosening or deformation. The surface and edges shall be free of contaminants, easily detachable particles, defects, cracks, or indentations.

7.7 Packaging

7.7.1 Packaging shall comply with the standard WS 310.2—2016, including packaging, sealing, and labeling. Before packaging, the type, specifications, and quantity of surgical guides shall be verified.

7.7.2 Packaging materials shall follow the product instructions, and sterilization packaging materials that allow visual inspection of the surgical guide are preferred.

7.7.3 Before packaging, it shall be reconfirmed that the surgical guide is thoroughly dried and fully functional.

7.7.4 The sealing width of paper-plastic pouches and paper bags shall be ≥ 6 mm, and the distance from the instrument to the seal edge shall be ≥ 2.5 cm.

7.7.5 The sterilization package label shall be traceable and include the item name, inspector/packager name or code, sterilizer number, lot number, sterilization date, and expiration date.

7.8 Sterilization

7.8.1 Effective sterilization methods shall be selected according to the material properties of the surgical guides. For PA 46, PEEK, etc., steam sterilization should be selected; for photopolymer resins, PLA, PA 6, ABS, etc., hydrogen peroxide low-temperature sterilization or ethylene oxide sterilization should be selected, in accordance with Appendix A.

7.8.2 Sterilization operating requirements

- a) Sterilization parameters shall comply with the standard WS 310.2—2016 and shall follow the product instructions;
- b) Sterilization cycles shall be selected according to material properties as specified in Appendix A;

- c) Dedicated sterilization racks or baskets shall be used for loading sterilized items, and gaps shall be maintained between sterilization packages;
 - d) During sterilization, critical parameters such as temperature, pressure, and time shall be monitored, and equipment operating status shall be observed.
- 7.8.3 The temperature, pressure, and time of the steam sterilizer cycles shall be verified annually; low-temperature sterilizers shall be verified in accordance with the product instructions or operator manuals.
- 7.9 Storage and Issuance
- 7.9.1 After sterilization, the effectiveness of sterile items shall be confirmed, with no wet packs, and they shall be placed in designated locations. Shelves shall be at least 20 cm above the floor, 5 cm from the wall, and 50 cm from the ceiling.
- 7.9.2 Before issuance, information shall be verified and packaging integrity confirmed.
- 7.9.3 Once issued, sterile items shall not be returned to the sterile storage area.
- 7.10 Precautions
- 7.10.1 Manual cleaning sinks and cleaning tools shall be dedicated for this purpose, cleaned and disinfected after each use, and cleaning solution shall be changed after each use.
- 7.10.2 Nylon surgical guides should not be immersed in water for prolonged cleaning and disinfection. PA 6 and PA 66 surgical guides shall not be immersed in water for cleaning. All nylon surgical guides shall not be disinfected with 75% ethanol.
- 7.10.3 Abrasive cleaning materials and tools shall not be used for processing surgical guides.
- 7.10.4 After cleaning, a low-lint cleaning cloth of a color different from the guide should be used to wipe the surface of the surgical guide to check for removal of easily detachable particles.
- 7.10.5 Surgical guides should be individually packaged. Damaged packaging or wet packs shall

be reprocessed.

- 7.10.6 Opened but unused surgical guides shall be considered contaminated and shall be re-cleaned and re-disinfected.
- 7.10.7 Throughout the entire processing workflow, surgical guides shall be loaded properly, and stacking, squeezing, or collision is strictly prohibited.
- 7.10.8 After steam sterilization, surgical guides shall be placed away from the air outlet for cooling, with a cooling time of not less than 30 min.
- 7.10.9 After sterilization and before issuance, the structural and functional integrity of the surgical guides shall be inspected.

8 Quality Control and Traceability

- 8.1 Quality inspection standards for cleaning, disinfection, and sterilization of surgical guides shall be established.
- 8.2 A feedback system for quality inspection of surgical guides shall be established for continuous quality improvement.
- 8.3 Communication with the medical device user department shall be maintained to ensure correct processing techniques for surgical guides.
- 8.4 A quality management traceability system shall be established, and records related to quality control processes shall be maintained to ensure traceability. Monitoring of cleaning, disinfection, and sterilization effectiveness shall comply with the standard WS 310.3.

Appendix A

(Normative)

Material Properties and Recommended Sterilization Methods for 3D-Printed Orthopedic Surgical Guides

The material properties and recommended sterilization methods for 3D-printed orthopedic surgical guides shall be selected according to Table A.1.

Table A.1 Material properties and recommended sterilization methods for 3D-printed orthopedic surgical guides

Material Name	Rockwell Hardness (HR)	Glass Transition Temperature (T _g , °C)	Comprehensive Performance	Recommended Sterilization Methods
Polylactic Acid (PLA)	88	60~65	Moderate mechanical properties, low heat resistance, biodegradable	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization
Photopolymer Resins	50~90	45~80	Moderate mechanical properties, significant brittleness, poor heat resistance	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization
Polyamide (PA)	95~115	PA 6 50~60	Excellent mechanical properties, good flexibility, high moisture absorption; ethanol has corrosive and dissolving effects	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization
		PA 11 46~55	Excellent mechanical properties, good wear resistance, low moisture absorption; ethanol has corrosive and dissolving effects	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization
		PA 12 50~60	Excellent mechanical properties, good wear resistance, low moisture absorption; ethanol has corrosive and dissolving effects	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization
		PA 46 78~85	High heat resistance, excellent mechanical strength, good chemical resistance; ethanol has corrosive and dissolving effects	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization; Steam sterilization
		PA 66 60~70	Excellent mechanical properties, good wear resistance, relatively high moisture absorption; ethanol has corrosive and dissolving effects	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization
Polyether Ether Ketone (PEEK)	85~100	PA 1212 40~50	Excellent mechanical properties, good wear resistance, relatively low moisture absorption; ethanol has corrosive and dissolving effects	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization
		143~145	Excellent impact resistance, high heat resistance, can be sterilized multiple times	Hydrogen peroxide low-temperature sterilization; Ethylene oxide sterilization; Steam sterilization
Acrylonitrile-Butadiene-Styrene Copolymer (ABS)	113	105~110	Moderate mechanical properties, good chemical resistance, moderate heat resistance	Ethylene oxide sterilization; Hydrogen peroxide low-temperature sterilization

Note:

- 1: The recommended sterilization methods are for reference only. The specific sterilization method shall follow the product instructions and be validated.
- 2: The glass transition temperatures (T_g) listed in this table are typical ranges or common values. Specific values may vary among different manufacturers, brands, and post-processing techniques. The parameters provided in the product instructions shall prevail.

Appendix B

(Normative)

Manual Cleaning Procedure for 3D-Printed Orthopedic Surgical Guides

The manual cleaning procedure for 3D-printed orthopedic surgical guides shall be carried out according to Table B.1.

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Table B.1 Manual cleaning procedure for 3D-printed orthopedic surgical guides

Procedure	Specific Steps
Equipment and Tool Inspection	a) Confirm that manual cleaning sinks, pressure water/air guns, steam cleaners, and other equipment are functioning properly;
	b) Medical cleaning agents compatible with the surgical guide material and 75% ethanol shall be provided, and the expiration date and quality of medical cleaning agents and disinfectants shall be inspected;
	c) Final rinse water quality shall be checked, with conductivity ≤ 15μS/cm (25 °C);
	d) Low-lint cleaning cloths, soft-bristled brushes, cleaning baskets, and dedicated transport containers shall be provided, and the cleaning baskets shall be inspected for integrity to ensure no sharp edges or burrs.
Personnel Protection	Wear caps, masks, gloves, and goggles or eye shields; wear dedicated footwear and protective clothing or waterproof aprons.
Manual Cleaning	Rinsing Use a pressure water gun (pressure ≤0. 2 MPa) to flush the surface and pores of the guide to remove visible contaminants such as easily detachable particles.
	a) Prepare the appropriate cleaning solution according to the medical cleaning agent and surgical guide product instructions;
	b) Moisture-resistant surgical guides shall be completely immersed in the medical cleaning agent solution for cleaning; moisture-sensitive guides (e. g. , PA 6, PA 46, PA 66, etc.) shall be wiped with a low-lint cleaning cloth;
	c) Use a soft-bristled brush to gently scrub (for moisture-resistant materials) the guide surface and complex structural areas beneath the liquid surface.
	Rinsing Rinse the surgical guide with running water to remove cleaning agent residues.
	a) Use water with conductivity ≤15 μS/cm (25 °C) for final rinsing;
	Final Rinsing b) If the guide has a complex structure, rinsing time may be appropriately extended;
	c) After final rinsing, cleaning quality and functional integrity shall be inspected.

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