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## Specification for Reusable Surgical Instruments Management in Hospital

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## Preface

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The organizations responsible for drafting this document include Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Beijing Clean Park Environmental Technology Co., Ltd., Nanjing Blue Night Tech Ltd., Shanxi Provincial People's Hospital, Beijing Shijitan Hospital, the First Hospital of Jilin University, Renmin Hospital of Wuhan University, Wuhan No.1 Hospital, Tongji Hospital affiliated to Tongji Medical College of Huazhong University of Science & Technology, Xiangyang General Hospital, Zhongnan Hospital of Wuhan University, the First Affiliated Hospital of Zhengzhou University, Tianjin Medical University Cancer Institute & Hospital, Jingzhou Central Hospital, Yancheng No.1 People's Hospital, Yichang Central People's Hospital, and Shandong Provincial Third Hospital.

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# Specification for Reusable Surgical Instruments Management in Hospitals

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## 1 Scope of application

This document specifies the classification, basic requirements, process management (including procurement and acceptance, storage, activation of newly purchased instruments, clinical use, cleaning, disinfection, sterilization, maintenance, disposal, etc.), informatization construction, intelligent management, and quality management of reusable surgical instruments in hospitals.

This document applies to the surgical department (operating room) and the central sterile supply department (abbr. CSSD) of hospitals at all levels, including inpatient surgical department, outpatient operating room, day surgery room, and specialized operating room (interventional operating room, endoscopy center, etc.). Other medical institutions may refer to this document for implementation.

## 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.

*Packaging for terminally sterilized medical devices* (GB/T 19633)

*Medical devices —— Quality management systems —— Requirements for regulatory purposes* (ISO 13485)

*Central sterile supply department (CSSD) — Part I: Management standard* (WS 310.1)

*Central sterile supply department (CSSD) — Part II: standard for operating procedure of c1eaning, disinfection and sterilization* (WS 310.2)

*Central sterile supply department (CSSD) — Part III: surveillance standard for cleaning, disinfection and sterilization* (WS 310.3)

*Regulation of disinfection technique in healthcare settings* (WS/T 367)

*Medical suture needle* (YY/T 0043)

*Surgical instrument standards and scope of application* (YY/T 0076)

*Medical Instruments of Stainless Steel-Test Methods of Corrosion Resistance* (YY/T 0149)

*Surgical instruments — Packaging, marking and instructions* (YY/T 0171)

*Artificial intelligence medical device* (YY/T 1833.1)

*Requirements for the information traceability system of center sterile supply department items in medical institutions* (TWSJD 39—2023)

*Regulation on the Supervision and Administration of Medical Devices* (SCA/TC 221)

*Materials, Processing and Testing Medical Device Tweezers* (DIN 58298)

Management Measures for Clinical Use of Medical Devices

## 3 Terms and definitions

The terms and definitions defined as follows apply to this document.

3.1 Reusable surgical instrument

A surgical instrument used for cutting, drilling, sawing, scratching, scraping, clamping, shrinking, shearing, or similar purposes, which do not involve active devices and are explicitly stated by the manufacturer to be reusable after appropriate cleaning, disinfection, and sterilization procedures.

3.2 Basic surgical instrument

A general surgical instrument, which is divided into various types and models based on different structural characteristics.

3.3 Microsurgery instrument

A fine surgical instrument specifically designed and developed for microsurgery, including microsurgical forceps, microsurgical scissors, micro needle holder, microvascular clamp, vascular approximator,

vascular dilator, micro irrigation flat needle, etc.

3.4 Specialized surgical instrument

A surgical instrument used for specialized purposes beyond the basic surgical instruments used in clinical practice. These include specialized surgical instruments for neurology, cardiovascular surgery, orthopedics, ophthalmology, dentistry, obstetrics and gynecology, etc.

3.5 Endoscope instrument

A surgical instrument that enters the body cavity through a natural or surgically created channel, using optical or non-optical methods for examination, diagnosis, and treatment.

Note: This refers to the passive surgical instrument part of endoscopes.

3.6 Loaner instrumentation

A reusable surgical instrument leased to hospitals by instrument suppliers, primarily used in surgeries involving implants.

3.7 Robot surgical instrument

A passive surgical instrument that is compatible with surgical control systems and equipment, reusable, and used for surgical diagnosis and treatment in robotic surgeries.

3.8 Artificial intelligence medical device; AIMD

A medical device that utilizes artificial intelligence (AI) to achieve intended purposes.

Note[1]: Such as independent software that uses machine learning, pattern recognition, rule-based reasoning, etc., to achieve medical purposes.

Note[2]: Such as medical devices that use embedded AI algorithms or AI chips to achieve medical purposes.

3.9 Traceability system

Modern information management based on traceability codes, documentation, related hardware and software, and communication networks, enabling the retrieval of relevant data during the product traceability process.

## 4 Classification

According to the classification principles of the Catalogue of Medical Devices and the common terminology and management needs of reusable surgical instruments in clinical practice, they are divided into the following six categories.

4.1 Basic surgical instrument

4.2 Microsurgical instrument

4.3 Specialized surgical instrument

4.4 Endoscope instrument

4.5 Loaner instrumentation (including instruments leased from manufacturers and instruments from other hospitals)

4.6 Robot surgical instrument

Note: The serial numbers, categories, product descriptions, uses, names, and management categories of surgical instruments are detailed in the *Catalogue of Medical Devices* (2017 Edition).

## 5 Basic requirements

5.1 The hospital shall establish a medical device clinical use management committee which is charged by relevant functional departments. The committee shall adopt a multidisciplinary team management model, formulate clinical use management and adverse event reporting systems for surgical instruments, and conduct regular self-inspections, assessments, and evaluations to ensure the safe and effective clinical use of surgical instruments.

5.2 Information archives shall be established for reusable surgical instruments throughout the entire process; appropriate packaging materials such as sterilization boxes, non-woven fabrics, and paper-plastic shall be used based on the instruments' delicacy, bacterial barrier rate, and transportation safety requirements.

5.3 The use of surgical instruments shall strictly adhere to the core system of surgical item counting by implementing four counts: before surgery, before cavity closure, after cavity closure, and after skin suturing. An emergency response process for intraoperative foreign body retention shall be established to prevent safety incidents of foreign body retention during surgery.

5.4 The recovery, cleaning, inspection, packaging, disinfection, storage, and distribution of surgical in-

struments shall comply with the requirements in the standard (file No. WS310.2).

5.5 Microsurgical instruments shall prevent from stacking damage; low-temperature sterilized passive endoscope instruments shall be disassembled to the smallest unit; the management of loaner instrumentations shall follow the requirements in the standard (file No. WS310.2), and specialized surgical instruments brought in from other hospitals must be processed in a qualified medical institution's CSSD before use; the quantity of uses of robot surgical instruments shall be recorded after each use.

5.6 Surgical instruments contaminated by prions, gas gangrene, or unknown infectious pathogens shall be processed in accordance with the regulations in the standard (file No. WS/T 367).

5.7 Professional training shall be provided by professionals or manufacturers before the use of surgical instruments, including the composition and characteristics of the instruments, installation and usage methods, re-processing, maintenance methods and precautions, warranty principles, user manuals, or instructions.

## 6 Process management

6.1 Procurement and acceptance

6.1.1 Procurement of surgical instrument

6.1.1.1 The procurement and planning of surgical instruments shall be scientifically formulated, considering the development plans and functional positioning of the surgical departments, with priority given to configuring functionally suitable and technically appropriate surgical instruments.

6.1.1.2 The Medical Device Management Committee shall discuss the procurement plan. If it is an issue under the "Triple-one rule for proceeding with discussions", it shall follow the relevant procedures, and an annual budget and procurement implementation plan for surgical instruments shall be prepared.

6.1.1.3 The procurement process shall comply with policy and regulatory requirements, adhering to the principles of openness, fairness, justice, and integrity. Emergency procurement beyond the plan shall follow the hospital's pre-arranged emergency procurement plan.

6.1.2 Acceptance of surgical instrument

6.1.2.1 The medical device management department shall establish an acceptance inspection management system for surgical instruments which is responsible for scientifically and reasonably assessing the procurement needs of surgical instruments; the department is responsible for the entire process management of surgical instrument procurement, acceptance, quality control, operation and maintenance, fault repair, and disposal.

6.1.2.2 Purchased surgical instruments shall be strictly accepted according to the acceptance procedures, and only those that pass the acceptance shall be stored; those that fail the acceptance shall be returned or replaced within the contractually agreed claim period.

6.1.2.3 When accepting surgical instruments, the management personnel shall require the supplier to provide the supplier and product qualifications, medical device registration certificates, registration forms, instrument qualification certificates, user manuals, and other relevant documents, which shall be archived.

6.2 Storage

6.2.1 The backup surgical instrument warehouse shall be clean and free from contamination, and protected from moisture. Surgical instruments shall be stored on shelves or in cabinets, clearly labeled.

6.2.2 The disinfection and sterilization of surgical instruments shall comply with the sterile surgical instrument storage requirements in the standard (file No. WS310.1) (temperature <24℃, humidity < 70%; storage shelves shall be ⩾20 cm from the ground, ⩾50 cm from the ceiling, and ⩾5 cm from the wall).

6.3 Activation of newly purchased instrument

A newly purchased reusable surgical instrument shall undergo initial cleaning before its first use. The initial cleaning method may follow the manufacturer's instructions or refer to Appendix A.

6.4 Clinical use

6.4.1 Before surgery

6.4.1.1 Before using sterile surgical instruments,

the cleanliness and environmental indicators of the operating room shall be inspected.

6.4.1.2 The scrub nurse shall inspect the quantity and integrity of items and instruments in the sterile surgical instrument pack and test the functionality of the surgical instruments.

6.4.1.3 Before surgery, the surgeon, scrub nurse, and circulating nurse shall jointly count the instruments, preferably using the in-situ counting method, confirming one by one to ensure the quantity and integrity of the surgical instruments match the original data, and record promptly.

6.4.1.4 Loaner instrumentations shall have their names, specifications, and quantities clearly listed in the surgical count sheet.

6.4.2 Before cavity closure

6.4.2.1 During surgery, surgical instruments shall be handled and passed gently, sharp instruments shall not be passed hand-to-hand directly, and a tray shall be used for non-contact horizontal passing to prevent collisions, drops, and occupational exposure.

6.4.2.2 Surgical instruments in use shall be kept clean. After use, they shall be wiped with sterile water-soaked gauze or pads to remove surface stains and blood. Do not soak them in sterile saline or wiping with wet saline gauze.

6.4.2.3 Specialized or sub-specialized surgical instrument packs shall be set up to meet clinical surgical needs; microsurgical instruments shall be stored separately from basic and specialized surgical instruments to prevent from collisions and compression damage, and protective covers shall be used when not in use to protect the tips and edges; the quantity and integrity of caps, air holes, and blade pads of endoscope and robot instruments shall be inspected.

6.4.2.4 When additional surgical instruments are added during surgery, the circulating nurse shall promptly record the quantity in the corresponding section.

6.4.2.5 Surgical instruments that fall or pop out during surgery shall be promptly retrieved, placed in a fixed location in the operating room, and included in the handover content so as to facilitate instrument counting and prevent unnecessary searching.

6.4.2.6 During surgery, the surgeon's operation of surgical instruments shall be monitored, ensuring the proper use of instrument functions to prevent damage from overuse, such as using surgical forceps, needle holders, or scissors to twist or cut wires.

6.4.2.7 If the performance of an instrument used during surgery becomes abnormal, it shall be replaced promptly to ensure the normal progress of the surgery.

6.4.2.8 Before cavity closure, the surgeon, scrub nurse, and circulating nurse shall jointly count the quantity and integrity of surgical instruments, confirming no discrepancies before closing the cavity.

6.4.3 After cavity closure

6.4.3.1 The management of surgical instruments in use shall be the same as before cavity closure. Surgical instruments shall be promptly collected and placed on the instrument cart to prevent them from slipping.

6.4.3.2 The instrument counting method shall be the same as before cavity closure. After confirming the count, instruments for suturing subcutaneous tissue and skin shall be left for the surgeon's use.

6.4.4 After skin suturing

6.4.4.1 The instrument counting method shall be the same as before cavity closure. When removing surgical drapes, surgical instruments, including suturing needles, needle holders, toothed forceps, and tissue forceps, shall be promptly collected to prevent sharp instruments from causing occupational exposure to other staff.

6.4.4.2 The quantity and integrity of surgical instruments shall be inspected and counted, and promptly handed over to CSSD.

6.4.5 Emergency treatment

6.4.5.1 If there is a discrepancy in the count or integrity of surgical instruments, the surgeon shall be immediately informed to search jointly; if necessary, auxiliary measures shall be taken to prevent foreign body retention in the patient.

6.4.5.2 If the missing part of the surgical instrument is found, the scrub nurse and circulating nurse shall confirm its integrity and place it in a designated lo-

cation for proper storage, ready for counting verification.

6.4.5.3 If the missing part cannot be found after various efforts, the surgeon and head nurse shall be immediately informed, and X-ray anteroposterior and lateral views shall be taken to confirm that the surgical instrument or missing part is not in the patient's body. The report shall be signed by the surgeon, circulating nurse, and scrub nurse and be archived, and a report on the adverse event and emergency response of the surgical instrument shall be submitted.

6.4.6 Pre-processing in operating room

6.4.6.1 Surgical instruments shall be pre-processed promptly during use. Wipe visible stains and blood using non-linting wet gauze. After surgery, visible stains and blood shall be removed using water, and contaminants shall be removed from the lumens of instruments. If a timely handover is not possible, moisturizers shall be used.

6.4.6.2 After pre-processing, microsurgical, endoscope, and robot surgical instruments shall be placed in dedicated containers for transport to prevent stacking and collision damage.

6.4.6.3 The pre-processing of flexible endoscopes shall comply with the requirements in the standard (file No. WS 507). The pre-processing and cleaning of robot surgical instruments shall be performed by designated personnel.

6.4.6.4 The processing of surgical instruments for special infections shall comply with the relevant requirements in the standard (file No. WS310.2).

6.5 Cleaning, disinfection, and sterilization (WS310 standard are not repeated in this document)

6.5.1 Pre-processing

6.5.1.1 Routine surgical instrument Surgical instruments with visible contaminants or in a moisturizing state shall be pre-processed promptly. The operation method may refer to related document (file No. T/CRHA 079-2024).

6.5.1.2 Surgical instruments for special infections (prions, gas gangrene, unknown infections, etc.) shall follow the principle of "disinfection first, then cleaning, and finally sterilization", complying with the standard (file No. WS/T 367).

6.5.2 The management of surgical instruments shall comply with the standard (file No. WS310.1).

6.5.3 The technical specifications for cleaning, disinfection, and sterilization of surgical instruments shall comply with the standard (file No. WS310.2).

6.5.3.1 Cleaning, disinfection, and sterilization of ophthalmic instruments

1) Ophthalmic instruments shall follow the instrument instructions; cleaning agents shall be reasonably selected and used, preferably those without surfactants, and be prepared according to the cleaning agent instructions.
2) Intraocular surgical instruments shall preferably apply mechanical cleaning by using dedicated ophthalmic instrument cleaning racks and programs; manual cleaning shall apply purified water for thorough rinsing, and ultrasonic cleaners shall be used periodically to vibrate, cavitate, and dissolve contaminants on the instruments.
3) Heat and moisture-resistant instruments shall preferably apply steam sterilization, and lumen instruments shall not apply downward displacement steam sterilization; ophthalmic instruments shall not apply chemical immersion sterilization to prevent toxic anterior segment syndrome (abbr. TASS). And
4) Materials without lint shedding shall be used for packaging ophthalmic instruments to prevent cotton fiber retention in the eye.

6.5.3.2 Cleaning, disinfection, and sterilization of microsurgical instruments

1) The cleaning, disinfection, and sterilization process shall prioritize protecting microsurgical instruments, using dedicated containers for recovery, dedicated baskets or fixed boxes for protection, and preventing damage from stacking.
2) Manual cleaning shall apply soft brushes and be performed gently. Ultrasonic cleaners shall be applied periodically to vibrate, cavitate, and dissolve contaminants; mechanical cleaning shall apply dedicated cleaning racks

and programs for effective cleaning, and purified water be applied for final rinsing.

3) When a small number of instruments are urgently needed during surgery, steam sterilization shall be preferred by using small steam sterilizers and rapid sterilization programs. And

4) The cleaning, disinfection, functional inspection, and sterilization methods shall follow the instrument instructions and user manuals.

6.5.3.3 Cleaning, disinfection, and sterilization of endoscope instruments

1) The cleaning, disinfection, and sterilization of flexible endoscope instruments shall comply with the requirements in the standard (file No. WS507).

2) Due to the complex structure and materials of rigid endoscope instruments, the cleaning methods and products shall follow the manufacturer's instructions.

3) Manual cleaning of rigid endoscope instruments shall follow the pre-processing, initial cleaning, ultrasonic cleaning, washing, rinsing, and drying steps. Lumen instruments shall be brushed with appropriate tools. When using ultrasonic cleaning, instruments shall be disassembled to the smallest unit and soaked in enzymatic cleaning agents for thorough cleaning. Final rinsing shall apply distilled or purified water, and drying shall apply gas drying methods.

4) Optical lenses shall be placed in dedicated boxes to prevent bending the lens axis, drops, or collisions and shall not be ultrasonically cleaned. Manual cleaning may be applied for endoscopic lenses.

5) Before cleaning, a leak test shall be performed using leak testing equipment and following the "leak test" process in the standard (file No. WS507). If any leak is found, the instrument shall be sent for repair and recorded.

6) Semi-rigid endoscope instruments, including ureteroscopes and percutaneous nephroscopes, shall comply with the requirements in the standard (file No. WS507) for the flexible endoscope part; the rigid endoscope part shall follow the above methods for cleaning, disinfection, and sterilization. And

7) The disinfection and sterilization methods for rigid and semi-rigid endoscope instruments shall follow the product instructions.

6.5.3.4 Cleaning, disinfection, and sterilization of robot surgical instruments

1) Cleaning operations shall be performed by designated personnel who have undergone professional training and assessment to ensure standardized, safe, and effective processing of instruments after a surgery.

2) Before cleaning, instruments shall be placed in dedicated boxes to prevent stacking and collisions and safely transported to the cleaning room to prevent damage.

3) Manual cleaning shall follow the pre-processing, initial cleaning, ultrasonic cleaning, washing, rinsing, and drying steps, in which lumen instruments shall be flushed with running water through the main and secondary holes, then soaked in neutral or weakly alkaline enzymatic cleaning agents (pH ⩽11), with ultrasonic cleaning time not exceeding 15 minutes.

4) Mechanical cleaning shall apply dedicated robot instrument cleaning racks and endoscope instrument cleaning programs. Instrument drying may apply gas drying methods or follow the robot instrument instructions.

5) The integrity of robot surgical instruments shall be inspected and evaluated that the lens body shall not be deformed, the lens surface shall not have shadows, the field of view shall not be missing, the rotation gears shall be flexible, the front end shall have sufficient angles, etc. The quantity of uses shall be recorded. And

6) Steam sterilization shall be preferred for disinfection and sterilization, using sterilization boxes dedicated for robot surgical in-

struments, with the weight complying with the requirement in the standard (file No. WS310); the sterilization loading process shall avoid stacking and collisions to prevent instrument damage.

6.5.4 The effect monitoring standards for cleaning, disinfection, and sterilization of surgical instruments shall comply with the standard (file No. WS310.3).

6.6 Maintenance

6.6.1 CSSD and the surgical department (operating room) shall regularly conduct functional inspections and maintenance of surgical instruments, including cutting, elasticity, and clamping inspections. Specific methods and testing tools are detailed in **Appendix B**.

6.6.2 Regular maintenance of surgical instruments shall be performed according to the manufacturer's instructions, using medical device-specific lubricants for manual lubrication of hinge and friction areas. Instruments that cannot be used after repair shall be disposed of.

6.7 Disposal

The hospital shall establish a surgical instrument disposal management system and process, where professionals comprehensively evaluate the performance, precision, safety, and repair costs before centralized destruction and disposal, and promptly update the hospital's asset management records.

6.8 Informatization construction and intelligent management

6.8.1 Based on IoT technology, a unique device identifier (UDI) for medical devices shall be established, preferably using barcodes, QR codes, RFID, etc., to present forms, text, and images, enabling full-process informatization construction from procurement and acceptance, storage, activation of newly purchased instruments, clinical use, cleaning, disinfection, sterilization, maintenance, to disposal, thus forming a closed-loop management of the entire lifecycle of surgical instruments.

6.8.2 The equipment department shall implement informatization construction from procurement and acceptance, maintenance, to disposal, forming a closed-loop information management with clinical departments.

6.8.3 The informatization construction and item tracking in CSSD shall comply with the requirements in the standard (file No. T/WSJD 39—2023), including modules for personnel, materials and equipment, item process tracking, quality, and financial reports. The monitoring and inspection data for cleaning, disinfection, and sterilization shall be systematically recorded in compliance with the requirements in the standard (file No. WS 310.3).

6.8.4 The informatization construction of surgical instruments in the surgical department (operating room) shall refer to the standards (files No. WS310 and T/WSJD 39—2023) and shall preferably use IoT technology and mobile nursing technology to extend information module construction, including personnel categories, operation records, electronic archiving, storage, retrieval, inventory, use, verification, handover, and cost-benefit analysis.

6.8.5 The instrument pack database in the surgical department (operating room) shall include detailed lists of basic, specialized, microsurgical, endoscope, and robot surgical instruments, including names, specifications, and quantities. Loaner instrumentations shall follow the relevant standards.

6.8.6 The information management of sterile instruments in the surgical department (operating room) shall include batch storage, classification recognition, room-specific storage, expiration warnings, online queries, one-click inventory checks, usage prompts, and electronic item count sheets.

6.8.7 An intelligent management model for surgical instruments shall be established. It intends to scan, recognize, and record the integrity of surgical instruments using IoT and AI technology and quickly obtain the quantity of instruments in a pack through RFID. The equipment shall support remote monitoring and mobile operations for real-time full-process visual management.

6.8.8 Intelligent recognition of surgical instrument quality and safety Through AI scanning and UDI quantity retrieval, the system shall intelligently recognize and prompt missing parts or incorrect instrument counts during surgery to prevent adverse

events of surgical foreign body retention.

6.8.9 RFID can be used to recognize the UDI of a surgical instrument pack, enabling full lifecycle traceability and management of each instrument, providing data on instrument quality, safety, and cost-benefit analysis.

## 7 Quality management

The quality management of surgical instruments is conducted by two departments, the operating room and CSSD. The quality management of surgical instruments in the operating room includes the sterilization qualification rate, functional integrity rate, count consistency before surgery, correct count rate during surgery, timely pre-processing after surgery, and the incidence of foreign body retention risks. See **Appendix C**.

The quality management of surgical instruments in CSSD includes the correct rate of recovery counting, timely pre-processing, visual inspection accuracy of cleaning quality, correct rate of packaging, and sterilization monitoring qualification rate. See Appendix D, and the quality control indicators for central sterile supply published by the National Institute of Hospital Administration, NHC are not repeated in this appendix.

## 8 Appendices A, B, C, and D

### Appendix A

### (Informative)

### Initial treatment methods for newly purchased stainless steel surgical instruments

**A. 1** The operation methods in this appendix apply to newly purchased stainless steel surgical instruments. Non-stainless steel or partially non-stainless steel surgical instruments shall follow the manufacturer's instructions for initial treatment.

### A. 2 Operating procedure

A.2.1 Use medical device degreasers or medical alkaline cleaners with degreasing effects.

A.2.2 Dilute with hot water following the instructions. The higher the water temperature within the specified range, the better the effect.

A. 2.3 Fully open the instrument joints and completely soak them in the solution. The soaking time shall follow the instructions, and for harder-to-clean instruments (e. g., stainless steel containers), the soaking time may be appropriately extended.

A. 2.4 After soaking, use appropriate tools to thoroughly clean the instruments' joints, lumens, external surfaces, and flanges. An ultrasonic cleaner may be available for instruments with complex structures that are difficult to clean manually.

A.2.5 After cleaning, rinse thoroughly with running water, then conduct routine cleaning.

### Appendix B

### (Informative)

### Functional inspection methods for reusable surgical instruments

**B. 1** This appendix specifies the functional inspection methods for some reusable surgical instruments, including scissors, bone rongeurs (bone cutters), nasal rongeurs, cervical biopsy forceps, osteotomes (bone chisels), knives (mucosa knives, microtech knives), hemostats, needle holders, and atraumatic forceps (tweezers).

### B. 2 Cutting performance inspection

B.2.1 Scissors Use the front 2/3 of the blade to cut one layer of test material. The cut shall be smooth and clean without dragging. Ring-handle scissors and endoscopic scissors shall use red silicone film with a thickness of 0.19±0.02 mm, and spring-handle scissors shall use yellow silicone film with a thickness of 0.15±0.02 mm.

B. 2.2 Bone rongeur (bone cutter) Use at least the front 1/3 of the blade to cut hardboard (250 $g/m^2$) three times consecutively. Each cut shall be smooth and clean.

B. 2.3 Nasal rongeur Use the instrument to cut test paper (70 $g/m^2$) three times consecutively. Each cut shall be smooth and clean.

B.2.4 Cervical biopsy forceps Use at least the front

2/3 of the blade to cut test paper (17 g/m$^2$). The cut shall be smooth and clean.

B.2.5 Osteotome (bone chisel) Use the blade to cut an acrylic cylinder. The instrument shall not slip and shall cut the test material.

B. 2.6 Knife (mucosa knife and microtech knife) Use at least the front 1/2 of the blade to cut 0.06~0.08 mm thick PTFE film. The cut shall be smooth or penetrate the film.

## B. 3 Elasticity performance inspection

B.3.1 Hemostat

According to Table 1, place the corresponding thickness of acrylic plate at approximately the front 1/3 of the hemostat's functional part, then fully lock and unlock the hemostat three times. After unlocking, the functional part shall not fail to align, and the joint shall not crack. Lock the first tooth of the hemostat, simulate the passing action, and lightly tap the ring handle in the palm, once on each side. The locking teeth shall not pop open.

**Table 1 Elasticity performance inspection of hemostat**

| Total length of hemostat (mm) | Thickness of acrylic plate (mm) |
|---|---|
| ≤125 | 1. 0 |
| 140~160 | 2. 0 |
| 180~200 | 3. 0 |
| 220~260 | 4. 0 |

B.3.2 Needle holder

According to Table 2, place the corresponding diameter of stainless-steel rod at approximately the front 1/4 of the needle holder's functional part, then fully lock and unlock the needle holder three times. After unlocking, the functional part shall not fail to align, and the joint shall not crack. Lock the first tooth of the needle holder, simulate the passing action, and lightly tap the ring handle in the palm, once on each side. The locking teeth shall not pop open.

**Table 2 Elasticity performance inspection of needle holder**

| Total length of needle holder (mm) | Diameter of stainless-steel rod (mm) |
|---|---|
| ≤160 | 0. 8 |
| >160 | 1. 0 |

## B. 4 Clamping performance inspection

B.4.1 Needle holder

According to Table 3, place different specifications of plastic fiber suture threads at 1/3 from the tip of the instrument's jaws, fully lock the instrument, and apply the corresponding pulling force. The suture thread shall not be pulled out from the jaws.

B.4.2 Hemostat

Use the functional part of the instrument to clamp test paper (28 g/m$^2$), fully lock for two seconds, and release. The test paper shall show tooth marks.

B.4.3 Atraumatic forceps (tweezers)

Use the functional part of the test instrument to clamp test paper (28 g/m$^2$), fully lock for two seconds, and release. The test paper shall show tooth marks without damage.

## Appendix C

## （Informative）

## Quality indicators and evaluation methods for clinical use of surgical instruments

## Appendix D

## （Informative）

## Quality indicators and evaluation methods for cleaning，disinfection，and sterilization of surgical instruments

**Table 3 Clamping performance inspection of needle holder**

| Type | Specification of plastic fiber suture thread | Applied pulling force (N) |
|---|---|---|
| Regular fine needle holder | 6/0 | 10 |
| Inlaid fine needle holder | | |
| Inlaid atraumatic needle holder | | |
| Regular coarse needle holder | 4/0 | 20 |
| Inlaid coarse needle holder | | |

| Timing | Indicator | Formula | Evaluation method |
|---|---|---|---|
| Before surgery | Sterilization qualification rate | $\frac{\text{Quantity of sterilized instrument packs meeting standards}}{\text{Total number of sampled instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, inspect whether the external packaging sterilization indicator changes color correctly, whether there is moisture, damage, or looseness, and whether the internal chemical indicators meet standards. |
| | Count consistency before surgery | $\frac{\text{Quantity of instrument packs with consistent counts}}{\text{Total number of sampled instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, the actual count shall match the instrument pack list. |
| | Qualification rate of instrument quality inspection | $\frac{\text{Quantity of instrument packs with qualified quality}}{\text{Total number of sampled instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, inspect the integrity of tips, teeth, caps, etc. , and evaluate the functionality of reusable surgical instruments. The inspection methods refer to Appendix B. |
| | Foreign body retention rate | $\frac{\text{Quantity of cases with surgical foreign body retention}}{\text{Total quantity of surgical patients discharged}} \times 100\%$ | Regularly count the quantity of patients with foreign bodies accidentally retained in the body cavity or surgical wound after surgery; or the quantity of patients with acute reactions to accidentally retained foreign bodies during surgery. |
| | Correct count rate | $\frac{\text{Quantity of correct surgical item counts}}{\text{Total quantity of sampled surgical item counts}} \times 100\%$ | Regularly sample 5% of surgical patients' item counts, randomly select one of the four counts (before skin incision, before cavity closure, after cavity closure, and after skin suturing) as the inspection result. Evaluate whether the quantity of surgical instruments used for the patient is consistent and whether the instruments are complete. |
| After surgery | Correct pre-processing rate after surgery | $\frac{\text{Quantity of correct processings after surgery}}{\text{Total quantity of processings after surgery}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, evaluate whether the instrument nurse processes them correctly: surgical instruments and other items are processed separately, reusable basic surgical instruments are placed in closed containers; microsurgical, endoscope, and robot instruments shall have protective measures. Surgical instruments for special infections shall follow the standard (file No. WS310). |

| Timing | Indicator | Formula | Evaluation method |
|---|---|---|---|
| Recovery | Correct rate of standardized transport execution | $\frac{\text{Quantity of corresponding instrument packs}}{\text{Total quantity of corresponding instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs and evaluate whether the recovery personnel process them correctly: reusable basic surgical instruments shall be placed in closed containers; microsurgical, endoscope, and robot surgical instruments shall have protective measures to prevent stacking; external instruments shall be returned to CSSD for processing before being handed over to the supplier; surgical instruments for special infections shall follow the standard (file No. WS310). |
| | Correct rate of recovery counting | $\frac{\text{Quantity of corresponding instrument packs}}{\text{Total quantity of corresponding instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, evaluate whether the counting personnel process them correctly: visually inspect for sharp instruments and disposable items; the quantity of instruments shall match the pack list; the quantity of instrument packs shall be counted correctly. |
| Cleaning | Correct rate of classified processing | $\frac{\text{Quantity of corresponding instrument packs}}{\text{Total quantity of corresponding instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, and evaluate whether the cleaning personnel process them correctly: classify based on material, contamination level, and delicacy; delicate instruments shall be placed in fine-mesh baskets, not mixed with heavy instruments or have heavy items placed on top; puncture needles, suction tubes, lumen instruments, orthopedic instruments, ophthalmic instruments, power systems, and endoscopes shall be processed separately. |
| | Correct rate of pre-processing | $\frac{\text{Quantity of corresponding instrument packs}}{\text{Total quantity of corresponding instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, and evaluate whether the cleaning personnel process them correctly: instrument joints and moving parts shall be opened, detachable instruments shall be disassembled to the smallest unit, all surgical instruments shall be free of visible blood and biological tissue before cleaning; lumen instruments shall be brushed under water; flexible endoscopes shall undergo “leak test” and pass; surgical instruments for special infections shall comply with the standard (file No. WS310). |
| | Correct rate of manual cleaning | $\frac{\text{Quantity of corresponding instrument packs}}{\text{Total quantity of corresponding instrument packs}} \times 100\%$ | Regularly sample 5% of surgical instrument packs, and evaluate whether the cleaning personnel processes them correctly: endoscope instruments shall be disassembled to the smallest unit, use an ultrasonic cleaner to vibrate, cavitate, and dissolve contaminants, rinse with distilled or purified water, dry with a low-lint soft cloth, endoscopic lenses shall be placed in safe lens boxes after cleaning, and do not ultrasonically clean. |

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| Timing | Indicator | Formula | Evaluation method |
|---|---|---|---|
| Disinfection and sterilization | Correct rate of mechanical cleaning | $\frac{\text{Quantity of correctly used cycles}}{\text{Total quantity of cycles}}\times 100\%$ | Regularly sample 5% of mechanically cleaned surgical instrument packs, and evaluate whether the cleaning personnel process them correctly: basic surgical instruments, specialized surgical (ophthalmic) instruments, endoscope and robot instruments shall have dedicated cleaning racks, no stacking, no obstruction of the cleaning machine's spray. External instruments shall have the corresponding programs. |
| | Qualification rate of quantitative inspection | $\frac{\text{Quantity of qualified instruments}}{\text{Total quantity of sampled instruments}}\times 100\%$ | Sample various instruments for quantitative inspection from visually inspected qualified instruments, including complex structures, difficult-to-clean instruments, such as complex lumen instruments, rigid endoscopic forceps, power tools, orthopedic reamers, ophthalmic instruments (phacoemulsification handpieces), etc. , each type for 1~2 pieces. Inspect the cleaning effect of instruments after cleaning using semi-quantitative or quantitative methods, such as protein residue testing and ATP bioluminescence testing. The operation methods and result determination shall follow the manufacturer's instructions. |
| | Qualification rate of physical monitoring by high-pressure thermal sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches of physical monitoring results within the week to ensure they meet standards. The sterilization temperature fluctuation range shall be within +3℃, the time shall meet the minimum sterilization time requirement, all critical point times, temperatures, and pressure values shall be recorded, and the results shall meet sterilization requirements; the sterilization program for instruments contaminated by prions shall comply with the standard (file No. WS/T 367). |
| | Qualification rate of biological monitoring by high-pressure thermal sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches of biological monitoring results by high-pressure thermal sterilization within the cycle to ensure they meet standards. Perform biological monitoring per sterilizer per week at least, the monitoring product shall be placed in the most difficult-to-sterilize location in the sterilizer, and the biological monitoring results shall be qualified. |
| | Qualification rate of physical monitoring by low temperature hydrogen peroxide plasma sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches of physical monitoring results within the cycle to ensure they meet standards. The monitoring records of each sterilization cycle's critical parameters, sterilization time, etc. , shall comply with the sterilizer's instructions or operation manual. |

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| Timing | Indicator | Formula | Evaluation method |
|---|---|---|---|
| | Qualification rate of biological monitoring by low temperature hydrogen peroxide plasma sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches within the cycle to ensure they meet standards. Perform biological monitoring in each sterilization program of low temperature hydrogen peroxide plasma sterilization at least one sterilization cycle. When sterilizing lumen instruments, monitor them using lumen biological PCD; the biological monitoring product shall be placed in the most difficult-to-sterilize location in the sterilizer, and the biological monitoring results shall be qualified. |
| | Qualification rate of physical monitoring by ethylene oxide sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches of physical monitoring results by ethylene oxide sterilization within the cycle to ensure they meet standards. Monitor each sterilization continuously and record the sterilization temperature, pressure, time, and relative humidity, etc. , which shall comply with the sterilizer's instructions or operation manual. |
| | Qualification rate of biological monitoring by ethylene oxide sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches of biological monitoring results within the cycle to ensure they meet standards. Perform biological monitoring in each batch, and the biological monitoring results shall be qualified. The biological monitoring product shall be placed in the most difficult-to-sterilize location in the sterilizer. |
| | Qualification rate of physical monitoring by low-temperature steam formaldehyde sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches of physical monitoring results within the cycle to ensure they meet standards. Monitor each sterilization continuously and record the sterilization temperature, pressure, time, and relative humidity, etc. , which shall comply with the sterilizer's instructions or operation manual. |
| | Qualification rate of biological monitoring by low-temperature steam formaldehyde sterilization | $\frac{\text{Quantity of corresponding qualified batches}}{\text{Total quantity of corresponding batches}}\times 100\%$ | Regularly inspect all batches of biological monitoring results by low-temperature steam formaldehyde sterilization within the cycle to ensure they meet standards. Monitor once per week, the biological monitoring product shall be placed in the most difficult-to-sterilize location in the sterilizer, and the monitoring results shall be qualified. |