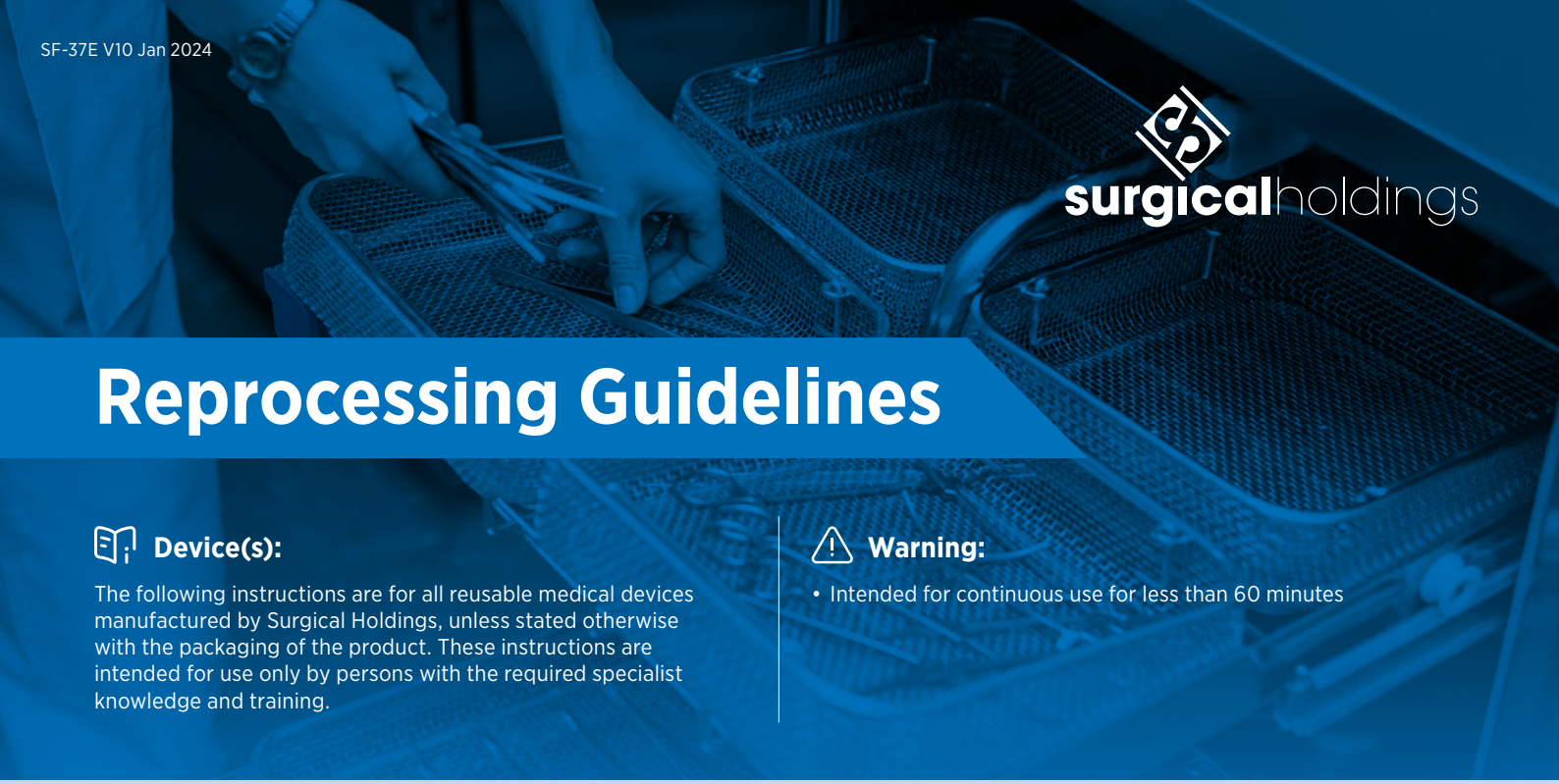

Reprocessing Guidelines

Device(s):

The following instructions are for all reusable medical devices manufactured by Surgical Holdings, unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required specialist knowledge and training.

Warning:

- Intended for continuous use for less than 60 minutes

Warnings

Note: When reprocessing medical devices, always handle with care, wearing protective clothing, gloves, and eyewear in accordance with local Health & Safety procedures.

- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid the use of mineral acids and harsh, abrasive agents.
- No part of the process shall exceed 137°C.
- Some sensitive materials (e.g. Aluminium) are damaged by alkaline solutions (pH>10).
- Devices with long, narrow cannula, hinges, and blind holes require particular attention during cleaning.
- Prolonged instrument contact with saline solution leads to pitting, stress corrosion cracking and rust formation. If devices come into contact with saline during a procedure ensure they are thoroughly rinsed as soon as possible.

Limitations on Reprocessing

- Repeated processing has minimal effect on these instruments.
- End of life is determined by wear and tear and damage in use.
- Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.

Instructions

From Point of Use

- Wherever possible, do not allow blood, debris or bodily fluids to dry on instruments; remove all coarse contamination immediately after the procedure.
- For best results, and to prolong the life of the medical device, reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help protect soil from drying.

Preparation for Decontamination

- New instruments are delivered nonsterile and require cleaning, disinfection and sterilisation prior to use.
- Reprocess all instruments as soon as it is reasonably practical following use.
- Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available through contacting Surgical Holdings.

Cleaning: Automated

Note: Automated cleaning may not be suitable for all lumens and cannula, in which case clean manually with a water jet gun, if available, and an appropriate brush (and stiletto, if provided) that reaches the depth of the feature. After routine cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.

- Instruments should be cleaned in washer disinfectors validated and maintained in accordance with EN ISO 15883 series of standards and/or national regulations.
- Use only either UKCA or CE marked, validated washer-disinfector machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.
- Load instruments carefully, with any box joints and hinges open and so that any fenestrations in instruments can drain.
- Place heavy instruments with care in the bottom of containers, taking care not to overload wash baskets.

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- Place instruments with concave surfaces facing down to prevent pooling of water.
- Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula.
- Ensure that soft, high purity water, which is controlled for bacterial endotoxins, is used in the final rinse stage.

Important instructions: We recommend following our validated washer disinfector cycles and drying processes for our reusable surgical instruments, as follows:

- **Do not use an alternative process unless you have a written concession for this or you will invalidate the warranty of your instruments.**
- **These instructions have been validated using a water-disinfector cycle validated to include a pre-wash cycle at 20°C, a wash cycle 50°C, a disinfection and final rinse cycle operating at a temperature of between 90°C and 95°C for a minimum holding time of 1 minute and a 20 minute drying cycle. No residual water should be observed on any part of the instrument following drying. The detergent for validation used was a low foaming, non-ionising enzymatic detergent cleaner (we recommend neutral pH).**

Cleaning: Manual

Note: Manual cleaning in NOT a disinfection process: when manual cleaning is used it may not be possible to disinfect the device prior to further handling.

Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process.

1 Use a double sink system (wash/rinse) dedicated for instruments cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C.

2 In the first sink, keeping the instrument submerged, with an autoclavable brush, apply UKCA or CE marked cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body and avoiding splashing. Ensure rongeurs and hinged instruments are thoroughly cleaned in both open and closed positions. If cloths are used, they must be non-linting.

3 In the second sink, rinse instruments thoroughly with soft, high purity water which is controlled for bacterial endotoxins, so that the water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet.

Cleaning: Inspection

- After cleaning, visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

Maintenance

- Apply surgical grade lubricants to hinges, joints and moving parts as per the lubricant manufacturer's instructions.

Inspection and Function Testing

Note: If an instrument is returned to the manufacturer/supplier, the instrument must be decontaminated and sterilised and be accompanied by the relevant documented evidence.

- Visually inspect and check; All instruments for damage and wear; cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.
- Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments.

Packaging

- All instruments to be packed following local protocol in accordance with ISO standards.

Sterilisation

Note: These instructions have been validated using a 134-137°C cycle for a minimum of 3 minutes. See ISO/TS 17665-2 table 1 for alternative time/temperature combinations.

- Either UKCA or CE marked, validated vacuum autoclave conforming with the requirements of EN 285 and/or national regulations validated as being capable of delivering saturated steam at a temperature and time specified by a national pharmacopoeia, as specified in ISO 17665 series of standards.
- When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.
- Ensure instruments are completely dry before sterilization.

Storage

- All instruments to be stored following local protocol in accordance with national regulations.
- Prior to instrument use, it is important to check the sterile packaging to confirm it is undamaged. Do not use if the packaging is damaged, or if there is a flaw in the sterile barrier.

Additional Information

- Other forms of cleaning (e.g., ultrasonic) and sterilisation (e.g., Low temperature steam and Formaldehyde, Ethylene Oxide and Gas Plasma) are available. However, these have not been validated by Surgical Holdings. Always follow the instructions for use as issued by the manufacturer and always consult with them if in any doubt over the suitability of any process used.
- Always follow national regulations and guidance when implementing these instructions.

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Note: It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired results. This requires validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

EC REP

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