1. PURPOSE

The following instructions are for reusable surgical instruments, unless indicated otherwise by specific product labelling. **These reusable devices are supplied non-sterile and must be cleaned and sterilized before first use and after each subsequent use.** These instructions are intended for use only by persons with the required specialist knowledge and training.

2. SCOPE OF APPLICATION

*These instructions apply to the below listed items here, distributed by Premier:

Instrument Description	Applicable SKUS
Rubber Dam Clamp Forceps	9065131
Forceps – Mandibular	9065008, 9065011, 9065018, 9065021, 9065031, 9065035, 9065039, 9065051, 9065052, 9065053, 9065058, 9065064, 9065077, 9065079.
Forceps – Maxillary	9065009, 9065010, 9065015, 9065016, 9065024, 9065025, 9065027, 9065028, 9065030, 9065032, 9065034, 9065054, 9065057, 9065078.
Root Forceps	9065019, 9065043, 9065044, 9065045, 9065063
Rongeurs	9065070, 9065071, 9065073, 9065076

3. WARNINGS

Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.

- Do not use chemical sterilants with caustic ingredients such as: surgical scrub solutions, povidone-iodine solutions, bleach, peroxide solutions, Virox 3, Sporox and Cidex PA. Do not use garment or surface disinfectants.
- Do not autoclave with substandard stainless steel surgical instruments as this may cause a reaction and lead to rust or discolorization.
- No part of the process shall exceed 140° C.
- When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles where appropriate.

4. LIMITATIONS ON REPROCESSING

- Do not flash autoclave.
- Devices may continue to be used if inspected and determined to be in a safe and good condition for its intended use.

5. INSTRUCTIONS AFTER POINT OF USE

- If possible, soiled devices should be placed in a holding solution (combined disinfectant / enzyme solution) immediately after use and prior to cleaning.

6. PREPARATION BEFORE CLEANING

- Reprocess all devices as soon as it is reasonably practical to do so.
- Where necessary, disassemble devices that require disassembly for adequate cleaning and reprocessing.

7. CLEANING/DISINFECTION

Manual cleaning/disinfection:
Some devices cannot be effectively cleaned by a washer-disinfector, those items should be manually cleaned as follows and then cleaned in a washer-disinfector as below:

- Using a sink dedicated for instrument cleaning (not used for hand washing), rinse excess soil from the device (water temp<35°C).
- Keeping the device submerged, with a brush, apply CE marked cleaning solution to all surfaces. Pay particular attention to underside and any jointed part of the device. Always brush away from the body. Do not use a wire brush.
- Rinse the device thoroughly with clean water, so that the water reaches all parts of the device, then carefully hand dry with lint-free gauze or use a drying cabinet.

Automated cleaning/disinfection:

- Use only CE marked and validated washer-disinfector machines and cleaning agents, following the manufacturers' instructions for use, warnings and recommended cycles.
- Load devices carefully, ensure any delicate parts of the device are not liable to damage during the loading procedure.

Surgical instruments have been validated to the following automatic washer-disinfector cycle:
Pre-wash 28 °C for 4 minutes, Wash at 50 °C for 8 minutes, Rinse at 50°C for 4 minutes.
Thermal Disinfection at 90°C – 95°C for 1 minute, Drying for 25 minutes.
Validated detergents: Instro-Klenz, Enzycare, Olympic Spraydry 1000 and Sprayclean 2000.

8. INSPECTION, MAINTENANCE, AND TESTING

- Visually inspect and functionally check all devices. Dispose damaged devices or if contaminants cannot be removed. If any soil is still visible, return the device for repeat decontamination.
- If any devices have been disassembled, reassemble in accordance with any product specific instructions for use and test.

9. PACKAGING

All devices should to be packed following local protocol in accordance with BS standards.

10. STERILIZATION

Use CE marked and validated vacuum autoclave operating at 134–137°C 2.25 bar for a minimum holding time of 3 minutes - always following the instructions of the machine manufacturer.

- When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer manufacturer's stated maximum load is not exceeded.
- Ensure all devices are dry before sterilization. If the devices cannot be dried prior to sterilization, then use distilled/de-ionized water in the final-rinse stage of cleaning.
- Surgical instruments have been validated to the following sterilizer cycle:
  Sterilizing temperature 134 – 137°C, Sterilizing time 3 minutes,
  Normal drying time 5 minutes, Extended Drying time 15 minutes.

11. STORAGE

Ensure all devices are dry before storage, and stored in dry, clean conditions at an ambient room temperature.

12. ADDITIONAL INFORMATION

- Other forms of cleaning (alkaline and neutral) and sterilization (Cidex OPA, Ethylene oxide up to 65ºC for anaesthetic devices) are permitted. However, always follow the reprocessing instructions provided by Premier and always consult with us if in any doubt over the suitability of any process used.
- Follow cleaning and sterilizing guidelines as per HTM 01-01.
- These instructions have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

For Your Information - HTM (Health Technical Memorandum) series provides guidance on various aspects of healthcare facility management, and HTM 01-01 focuses on the decontamination of reusable medical devices.

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