Falcon®
Your Instruments since 1975
PREMIUM QUALITY

CE UK CA MD

INSTRUCTIONS FOR USE

Reusable Instruments – Cleaning, Disinfection and Sterilization

NON STERILE

All non-sterile instruments must be cleaned, disinfected, and sterilized prior to first use as well as before every subsequent use.

MD Dental and Surgical Instruments (Non-Sterile and Reusable)

Intended Use: The instruments are intended for transient invasive surgical and dental procedures and are designed to be used exclusively by trained and qualified healthcare professionals.
Note: This IFU applies to reusable non-sterile surgical and dental instruments including forceps, scissors, needle holders, elevators, etc

MATERIALS: Stainless Steel used for manufacturing, which is in conforming with ASTM F899-23, EN ISO 7153-1:2016 and EN ISO 21850-1:2020 respectively, which are recommended for non-active Surgical and Dental Instruments

WARNINGS

- Instruments are supplied in a non-sterile condition and must be cleaned and sterilized before first use and reuse. Use of non-sterile can pose a serious risk to patient safety.
- These instruments must be handled with care as they are sharp and can cause injury to both the patient and the user. Always avoid holding the instruments by their working ends. Additionally, handle the instruments gently to prevent damage.
- Never place heavy instruments on top of lighter ones. heavy instruments should always be placed at the bottom, with lighter instruments on top.
- Residual risks remain despite compliance; proper training and handling reduce risk.

Avoid Contact With:

- Strong acids such as hydrochloric acid, aqua regia, and sulphuric acid.
- Salt solutions like ammonium chloride, mercury salts, and stannous chloride.
- Potassium thiocyanate and potassium permanganate.
- Iodine solutions.

Material and Equipment:

- Never use abrasives on instruments, as this will damage the surface finish, potentially leading to discoloration, rusting, or pitting.
- Do not use abrasive cleaners or brushes with hard bristles.
- Always use validated medical device detergents, cleaning materials, and equipment specifically designed for processing medical devices made from stainless steel.

IMITATIONS ON PROCESSING:

Due to the product design and materials used, no specific limit on the number of reprocessing cycles can be defined. Repeated reprocessing has minimal effect when validated procedures are followed. The end of service life is determined by wear or damage, such as cracks, misalignment, corrosion, deformation, or loss of function. After each reprocessing cycle, instruments shall be visually inspected and functionally checked. Damaged or malfunctioning instruments must be removed from use and disposed of in accordance with hospital procedures and applicable regulations.

ADDITIONAL INFORMATION:

- The cleaning and sterilization information is provided in accordance with ISO 17664-1.
- The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile medical device. It remains the responsibility of the processor and/or hospital to ensure that the processing is actually performed when using equipment, materials, and personnel in the reprocessing facility in order to achieve the desired result. This requires validations and routine monitoring of the process.

- These should be used only for the intended purpose for which they are designed.
- These devices should not be used without sterilization and when damaged or rusty.
- No age-specific limitation unless defined by the clinical procedure
- Users must wear appropriate personal protective equipment (PPE) when processing devices.
- During transport, device(s) should be handled with maximum care.
- No special decomposition or disposal required for pertinent product(s) as they don't contain any toxic or hazardous material; when recycling medical device(s) please follow your local government Health & Safety procedures and regulatory requirements.
- All users should be qualified personnel with documented expertise, competency, and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.
- This product is guaranteed to be free from defects in material or workmanship. The warranty becomes null and void if the product is damaged due to mishandling or misuse. Any modifications made to the device may also void the warranty. Proper care must be taken in the handling and use of this product to maintain warranty rights.
- In case of damage or faulty instrument, please return to us with same packaging and event description.
- If the device fails any of the quality inspection, it should be segregated, identified accordingly and decontaminated. It should then be either sent back to us along with the signed Decontamination Certificate, or disposed of following hospital approved procedures, e.g. Sharps Bin or Clinical Waste etc.
- In case of any incident, report it to manufacturer, EU authorized representative. and the competent authority of the member state where the user and/or patient is located. This includes reporting any serious incident related to the device. Serious incidents shall be reported without undue delay.
- In case of any incident, report it to manufacturer, EU authorized representative. and the competent authority of the member state where the user and/or patient is located. This includes reporting any serious incident related to the device. Serious incidents shall be reported without undue delay.
- Users are encouraged to provide feedback on the performance and safety of the device to the manufacturer to support post-market surveillance activities.
- Complications related to the use of the instruments depend on the procedure adopted. No specific complications are directly associated with the instruments themselves.
- UDI, catalogue number, and importer details are provided on the device label in accordance with Regulation (EU) 2017/745.
- Reusable surgical instruments do not require calibration.
- The instructions provided are based on validation performed on worst-case instruments (Surgical scissors, hemostatic forceps, rongeurs) by FALCON SURGICAL CO. (PVT) LTD. for reusable surgical instruments, confirming their capability to prepare the medical device for reuse. The healthcare facility is responsible for ensuring that reprocessing is performed using validated equipment, materials, and trained personnel.

INITIAL TREATMENT AT THE POINT OF USE:

For reusable surgical instruments, the following initial treatment steps are required at the point of use to ensure effective reprocessing:

I. Initial Treatment Techniques:
After use, the instruments should be rinsed immediately with water to prevent the drying of contaminants. This helps facilitate the cleaning process later.

2. Visual Checks:
A preliminary check should be performed to ensure that there are no visible signs of damage or contamination that could affect the reprocessing or reuse of the device.

3. Time Considerations: The time between use and reprocessing should be minimized to reduce the risk of contaminants drying on the surface of the instrument, which could make cleaning more difficult. Instruments reprocessing within 2 hours of use is an ideal target, not a strict limit. Explicitly allow delayed reprocessing (e.g. up to 24 hours) provided drying of soil is prevented and instruments are protected from damage and contamination. If reprocessing is delayed, instruments shall be rinsed after use and kept moist, e.g. covered, placed in a closed container, or using a validated holding/pre-cleaning solution compatible with stainless steel instruments.

4. Support System:
The instruments should be supported on trays or in containers that allow them to be transported without risk of damage or contamination.

5. Transportation:
The instruments should be transported in sealed, puncture-resistant containers to the reprocessing area. During transportation, care should be taken to ensure that the instruments are protected from damage and that contamination is contained. 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 at the bottom of containers, taking care not to overload wash baskets.
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.

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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 stilette if provided) that reaches the depth of the feature. After manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.

PREPARATION BEFORE CLEANING:

- A preliminary check should be performed to ensure that there are no visible signs of damage or contamination that could affect the reprocessing or reuse of the device.
- Presoak and/or rinse heavily soiled devices prior to cleaning to loosen dried soil or debris.

MANUAL CLEANING:

Equipment:

- Soft-bristled brushes (Spectrum M16)
- Pipettes, and/or water jet
- 4% Sekusept Active solution detergent
- Clean dust and lint-free cloths & filtered pressurized air

Step 1: Soak the device in a 4% Sekusept Active solution for 15 minutes at 30-35°C.
Step 2: Using a soft bristle brush (Spectrum M16), while keeping the device inside the soaking solution, apply the washing/disinfecting solution to all surfaces. Ensure all visible (gross) contamination is removed. Rinse the device with tap water (<40°C) for at least 3 minutes, or until all signs of blood or soil are removed from both the device and the rinse stream.
Step 3: Dry the device using dust-free cloths.
Step 4: Place the device in an ultrasonic washer with a 4% Sekusept Active solution for 3 minutes at 35 kHz and 40±1°C.
Step 5: Rinse the device with RO (reverse osmosis) water for 3 minutes.
Step 6: Dry the device thoroughly for 3 minutes.
Note: Visually inspect instruments. Repeat the cleaning process if visible soil remains

AUTOMATED CLEANING:

Prewash:

Instruments should be immersed in a 4% Sekusept Active solution at a temperature of 30°C to 35°C for 15 minutes ± 3 minutes. Following immersion, the devices should be placed in an ultrasonic cleaner filled with 4% Sekusept Active. Ultrasonic cleaning should be performed under the following conditions: 3 minutes, 40°C, and 35 kHz. If necessary, any remaining soil should be gently removed using a soft brush.
Note: In cases of heavy contamination, the steps outlined in the "Pre-wash" section may be repeated multiple times to ensure sufficient pre-cleaning of the device. Instruments should be cleaned in an open position, where applicable.
Automated Cleaning:
The automated cleaning process will include the following steps as outlined below:
Note: In cases of heavy contamination, the steps outlined in the "Pre-wash" section may be repeated multiple times to ensure sufficient pre-cleaning of the device. Instruments should be cleaned in an open position, where applicable.
Automated Cleaning:
The automated cleaning process will include the following steps as outlined below:

Process	Parameters
Cold pre-wash	1 min, water temperature <40°C
Washing	10 min, 55°C, 0,7% Thermoset RKF
Neutralization	2 min, >30°C, 0,15% Thermoset NKZ
Rinsing	1 min, water temperature <40°C
Thermal disinfection	>2,5 min, >93°C
Drying	6 min, 110°C

Note: Washer-disinfectors shall comply with ISO 15883.
Water quality used in automated cleaning shall comply with ISO 15883.
Reverse osmosis (RO) water may be used where required by local regulations or local decontamination protocols.

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CLEANING AGENTS:

The cleaning process has been validated using a 4% Sekusept Active® solution. Alternative enzymatic or alkaline detergents ((typically pH 6–10)suitable for stainless steel medical devices may be used, provided they are validated by the user's reprocessing facility.
MAINTENANCE:

- Instruments with metallic sliding surfaces or connection parts must be lubricated with biocompatible, steam-sterilizable agents (e.g., paraffin oil) after cleaning and before sterilization.
- Instruments should be regularly inspected, lubricated, and maintained after each cleaning to ensure smooth operation and extend their lifespan.
- Damaged or worn or rusty instruments should be replaced promptly to prevent any risk of injury or malfunction during surgery.

INSPECTION AND TESTING: Inspection shall confirm cleanliness, integrity of surfaces, proper alignment, and functional performance prior to sterilization in order to ensure proper function.
PACKAGING: After cleaning, pack the instruments into sterilization pouches that comply with ISO 11607 standards. Each instrument should be individually placed in a separate paper/foil sterilization pouch.

STERILIZATION METHOD:

Sterilization must be performed in a validated steam sterilization process according to relevant ISO 17665 standards.
Product must be sterilized and inspected for damage prior to use. The following recommendations are for the sterilization (pre vacuum steam sterilizer) of FALCON SURGICAL CO. (PVT) LTD. devices Steam sterilization parameters.

Temperature	Pressure	Exposure time	Drying
°C	bar	min	min
134	3.11	5	10

Note:

- **It is recommended that sterilization temperatures should not exceed 134°C.**
- **Higher temperatures may affect material properties and surface finish.**
- **Do not overload sterilizer; ensure steam penetration to all surfaces.**

STORAGE: Store reusable surgical instruments in a dry, clean, and dust-free place to keep them in good condition for future use.

Contraindications: No known contraindications when used as intended.

Symbols Glossary

REF — **Article number** (ISO 15223-1, Clause 5.1.6)
Indicates the manufacturer's catalogue number so that the medical device can be identified.

LOT — **Batch number** ISO 15223-1, Clause 5.1.5
Indicates the manufacturer's batch code so that the batch or lot can be identified.

QTY — **Number of units in the package**
Quantity of devices.

Date of manufacture YYYY-MM ISO 15223-1, Clause 5.1.3
Indicates the date when the medical device was manufactured.

Use by ISO 15223-1, Clause 5.1.4
IIndicates the date after which the medical device is not to be used.

NON STERILE — **Non-sterile** ISO 15223-1, Clause 5.2.7
Indicates a medical device that has not been subjected to a sterilization process.

MD — **Medical Device** ISO/DIS 15223-1:2020(E) DRAFT, Reference no. 5.7.7
Indicates the item is a medical device.

Consult instructions for use ISO 15223-1, Clause 5.4.3
Indicates the need for the user to consult the instructions for use.

CE — **CE marking** 765/2008/EC; 768/2008/EC; MDR EU 2017/745, Article 20; MDD 93/42/EEC, Articles 4,11,12,17, Annex II)
The product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.

UK CA — **UK Conformity Assessed.** This product is in conformity with the applicable requirements for products sold within Great Britain.

Keep dry ISO 15223-1, Clause 5.3.4
Indicates a medical device that needs to be protected from moisture.

Caution ISO 15223-1, Clause 5.4.4
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

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