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User Guide

	Consult user manual		Unique device identifier
	Manufacturer		CE compliance marking
	Quantity		Date of manufacture
	Use by date		LOT no.
	Keep dry		Single use product (no reuse)
	Caution		Non-sterile
	Medical device		Customised product – not in its standard form

Directions

Only trained professionals must use these instruments and only for their intended purpose. This applies to reconditioning instruments. New instruments must always pass through a complete cycle of instruments reprocessing at least once prior to first use. All instruments must be cleaned, disinfected, and sterilised before each usage. All new non-sterile instruments must be cleaned, disinfected, and sterilised following the removal of protective packaging before the first use. The user bears full responsibility of the sterility of the instruments. Only manufacturer recommended methods must be used for cleaning, disinfection, and sterilisation. Sterilisation equipment must also be checked and serviced regularly as recommended by the manufacturer. The validated parameters for the cleaning and sterilisation cycles must also be checked regularly. User must comply with the exceptions applying to cleaning, disinfection, and sterilisation of certain instruments & customised instruments described in the instrument specific instructions (comes with every instrument's packaging). User must comply with the legal requirements enforced in user's country, medical practice, or hospital regarding hygiene of the instruments. Incorrect handling, care, and use of the instruments which they are not intended for may result in damage and premature wearing out of the instruments whose responsibility will fall completely on the user. Users must be trained and familiar with the use and handling of medical instruments and accessories.

INSPECTION AND FUNTIONS CHECK

It is vital to inspect every instrument for any defect and malfunction before each use. Areas like cutting edges, tips, closures, locks, catches, hinges, and all moving parts must be checked. Never use damaged products. Do not repair yourself. Services and repairs must only be carried out by Fedior or an authorised company appointed by Fedior. Please refer to the manufacturer or your technical medical department for any questions.

PERSONAL PROTECTION

Approperiate PPE (personal protective equipment) which comply with the user's country, medical practice or hospital must be worn while handling used and contaminated instruments to maximize the safety of people involved. All contaminated instruments must be cleaned and disinfected no later than 6 hours.

PRE-TREATMENT

Remove any soiling from instruments no later than 2 hours (recommended to remove it immediately) before further processing in a tray/cassette system. Contaminated instruments must be pre-treated within 2 hours after use. Do not overfill instruments sieves and washing trays. Always clean and disinfect jointed instruments in open position. Use only a soft brush (we recommend brushes with nylon bristles), with long handles as needed. Never use metal brush or steel wool as they wreck passive layer of the instrument's surface.
As applicable: Manual precleaning of hollow areas must be conducted. Pre-treatment is for personal safety only and cannot replace the following disinfection step.

AUTOMATIC CLEANING

Equipment: Cleaning / disinfection device / cleaning agent

1. Disassemble dismountable instruments.
2. Place instruments in the disinfection device.
3. Placed jointed instruments in the device in open position so the water can drain out of cannulas and blind holes.
4. Start cycle, wash for at least X minutes* and rinse for at least X minutes* (*see each instrument's instructions which comes in their individual packaging)
5. While removing the instruments, check cannulas, blind holes, etc. for any soiling. Repeat cycle or clean manually if necessary.
6. Must dry the instruments fully before sterilisation.
7. Reassemble the dismounted instruments after sterilisation process.

MANUAL CLEANING

Equipment: Cleaning solution / detergent, brush, running water

1. Disassemble dismountable instruments.
2. Rinse off surface soiling thoroughly.
3. Use brush to apply cleaning solution on all surfaces. Clean jointed instruments in both open and closed positions.
4. Hold instruments under running water. Running water must flow through the cannulas. Blind holes must be filled and drained frequently.
5. Must dry the instruments fully before sterilisation.
6. Reassemble the dismounted instruments after sterilisation process.

DISINFECTION AGENTS / SOLUTIONS

Both neutral pH and alkaline cleaning agents can be used. Follow instructions of disinfectant solutions provided by their manufacturer (mostly on the label). Use deionized water for last rinse if possible. This will avoid spots, deposits and corrosion on the rinsed instruments.

DRYING

Temperature must not exceed 93° C / 200° F in drying phase which is a part of cleaning and disinfection cycle.

MAINTENANCE

Apply a tiny amount of high quality silicon spray or medical white mineral oil to the joints and movable parts. Set aside dull or old instruments and look for cracks and damage. Ensure proper functionality before every use.

QUALITY AND FUNCTIONALITY TEST

Check jointed instruments for ease of movement (avoid excessive play). Check locking mechanisms on applicable instruments and make sure their correct funtionality. Conduct visual inspection for wear and damage. Cutting edges must be uniform and free of notching. Instruments that are part of a larger assembly or other instruments must be checked and tested together with the respective parts/instruments.

PACKAGING

Individual: Standardised packaging material can be used. The bag must be big enough that it does not pressure the instrument inside.
Sets: Sort instruments into approperiate trays or place on suitable sterilisation trays. Cutting edges must be protected. Trays must be fit to use as per manufacturer's instructions.

STERILISATION

Refer to product specific instructions (packed & shipped with each product)

Rapid sterilisation causes high instrument wear levels.
Additional information: When sterilizing multiple instruments in a sterilisation cycle, the maximum steriliser charge must not be exceeded. Refer to manufactuer information

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STORAGE

Store in dry and dust-free place.

EXCEPTIONS

Instruments listed below are made entirely or in part from chrome-plated, aluminium and/or titanium parts for technical and/or aesthetic reasons and must not be placed in the thermal disinfector or ultrasound bath.

- Cylinder ampoule syringe thumb ring
- Aluminium instruments
- Titanium instruments
- Mouth mirror
- Resection mirror
- Chrome-plated instruments/parts

CUSTOMISED INSTRUMENTS

Fedior develops and manufactures customised instruments matching customers' own specifications and demands. Information for customised instruments depends on what customisation has been applied to the instruments. Instructions for such instruments varies case-by-case and must be consulted from Fedior.

GUARANTEE

Fedior supplies only defect-free and tested products. All our products are designed and manufactured to fulfil the toughest quality requirements. Thus our products generally come with up to 3 years of guarantee (see individual product's user guide for exact information relevant to that specific product).
Important: We assume no liability for the instruments that have been tempered with, altered, modified, customised (except customised by Fedior), used improperly or used by someone not professional to do so, or used for purposes not originally intended from the instruments. Instruments which are repaired, serviced, or altered by any other company than Fedior or a company authorised by Fedior for these purposes are also no longer covered by Fedior and are solely the liability of the user.

RETURNS

Returns must be submitted within 14 days of receiving instruments. Return items must be unused, undamaged, in their original form and packaging.
Full return policy: fedior.com/orders-and-shipping/

The above given guidelines have been proven as suitable for preparation of a medical device or its first use and reuse. These guidelines are generic only and are not tailored for any specific product (please refer to product specific user guides which come with every product). The user bears full responsibility for achieving the desired outcomes of the actual processing with the equipment, materials, and personnel used in the processing facility for that purpose. Any deflection from these instructions must be excpected with negative effects.

SUPPORT SERVICE

Please contact us should you wish to speak to us regarding anything given in this user guide or any other matter.
Contact: fedior.com/contact/

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