Rigicon Reusable Surgical Instruments

Recommended Care, Cleaning and Sterilization Instructions

Rigicon®
Innovative Urological Solutions

www.rigicon.com

DESCRIPTION

These instructions provide information on the use, care, cleaning, maintenance, and sterilization of reusable surgical instruments supplied by Rigicon intended for reprocessing in a health care facility.

Rigicon reusable surgical instruments may be safely and effectively reprocessed using the manual cleaning instructions and sterilization parameters provided.

Equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing. The healthcare facility should ensure that the selected reprocessing steps are safe and effective. Alternative methods of reprocessing outside the scope of these instructions may be suitable for reprocessing; however, those must be validated by the end user.

In states or countries where reprocessing requirements are more stringent than those provided in this document it is the responsibility of the user/processor to comply with those prevailing laws and ordinances.

These reprocessing instructions apply to:

i. Reusable Non-Sterile surgical instruments supplied by Rigicon (See Table 1 – Rigicon Reusable Non-Sterile Surgical Instruments)
ii. Instruments intended for reprocessing in a health care facility setting
iii. and do not apply to single-use devices.

Table 1 - Rigicon Reusable Non-Sterile Surgical Instruments

RIGICON SURGICAL TOOL NAME	MODELS	
Rigicon Furlow Insertion Tool	RSSF-1000	
Rigicon HL Dilators	RSSD-0910 RSSD-1112 RSSD-1314 RSSD-1012	

WARNINGS

- Rigicon reusable surgical instruments are provided NON-STERILE and must be cleaned and sterilized according to these instructions prior to use.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments.
- Caution should be exercised while handling, cleaning, or wiping instruments with sharp cutting edges, tips, and teeth.
- Do not allow biologic soil to dry on contaminated devices. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on used instruments.
- Metal brushes and scouring pads must not be used during manual cleaning. These materials will damage the surface and finish of the instruments. Use only soft bristle nylon brushes with different shapes, lengths, and sizes to aid with manual cleaning.

- Use of hard water should be avoided. Softened tap water may be used for most rinsing however purified water should be used for final rinsing to prevent mineral deposits.
- Do not use saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, or iodide. These are corrosive and should not be used.
- Do not place or soak instruments in Ringers Solution.
- Do not use oil-lubricants. Because these may:
    i. coat microorganisms,
    ii. prevent direct contact of the surface with steam
    iii. and are difficult to remove.
- When processing instruments do not place heavy devices on top of delicate instruments.
- Steam (moist heat) is the recommended method.
- Do not use the product if the package has been previously opened or if there is visual damage to the package or product.
- Devices that fail functional checks, have identification markings that are not legible, and/or have visible wear, rust, or pitting should be safely disposed of in accordance with standard biohazard practices. Devices that have visible soil after repeated cleaning should be disposed of in accordance with standard biohazard practices.
- Articulating devices such as the Furlow Inserter Tool) should be disassembled when being cleaned. Failure to disassemble devices could result in the retention of tissues or fluids that will prevent the device from being used as intended.
- Any physician using the surgical instruments should be thoroughly familiar with and trained in the surgical procedure being performed prior to using these tools.

DISASSEMBLY AND REASSEMBLY OF THE FURLOW INSERTION TOOL

To disassemble the Rigicon Furlow Insertion Tool, manually pull the "obturator" (round handle) (marked as "a") completely out of the "cylinder handle" (marked as "b"). Refer to Figure 1.

To reassemble the Rigicon Furlow Insertion Tool manually insert the obturator into the cylinder handle.

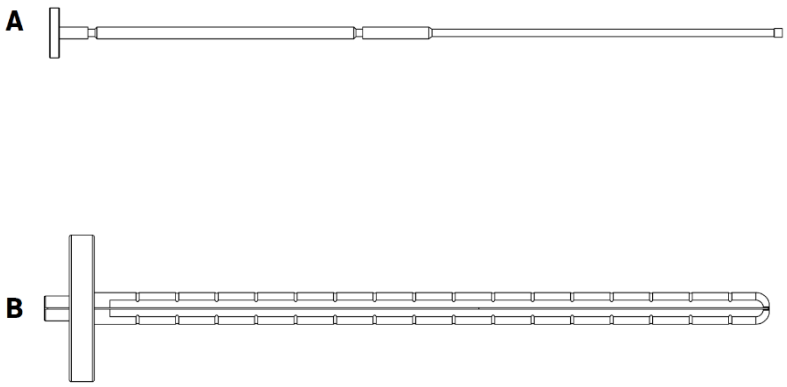

Figure 1 Rigicon Furlow Insertion Tool components: a) Obturator b) Cylinder handle

LIMITATIONS ON REPOROCESSING

The useful life of the surgical instruments depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life for the medical device. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear, and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices

should not be used. If surgical instruments are to be returned to Rigicon, they must be clean, packaged, and sterilized.

CLEANING, INSPECTION, PACKAGING STEPS	
STEP -1- Pre-treatment at the point-of-use	• As soon as after use, remove excessive soiling with a disposable wipe, rinse, and flush the device with sterile or deionized water to prevent the drying of soil and/or debris to the inside.
STEP -2- Containment and transportation	• Process instruments as soon as is reasonably possible after use. It is recommended not to delay cleaning for more than 2 hours. • If transfer to the reprocessing area likely to be delayed, consider covering the medical devices with a damp cloth or store the medical devices in closed boxes to avoid drying of soil.
STEP -3- Disassembly	• Instruments designed to come apart must be disassembled prior to cleaning. Disassembly, where necessary, is generally self-evident however for more complicated instruments instructions are provided and should be followed. Note: All recommended disassembly will be possible by hand. Never use tools to disassemble instruments beyond what is recommended.
STEP -4- Preparation for Cleaning	• All cleaning solutions should be prepared at the dilution and temperature recommended by the manufacturer. • Softened tap water may be used to prepare cleaning solutions.

	Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (turbid). • Soft-bristled brushes, lint-free cloths, syringes, pipettes in various sizes and/or water jet, ultrasonic cleaner, cleaning bath or vessel large enough to allow complete immersion of the instruments.
STEP -5- Manual cleaning	• Soak soiled instruments and prevent air bubbles to ensure that all surfaces have contact in an enzyme solution for a minimum recommended time specified by the enzymatic cleaning solution manufacturer or 20 minutes, whichever is longer. • Brush the instruments with cleaned soft-bristled, nylon brush to clean to remove all traces of blood and debris. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipecleaner brush). For flexible shafts and springs, flex and relax the instrument under the cleaning solution while brushing. Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution. • Flush each difficult brush area thoroughly and aggressively in cold tap water for a minimum of 30 seconds. Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated

	surfaces. Repeat Step 2 and 3 until no visual soil has been removed. • Rinse the instruments in cold top water for a minimum of 3 minutes. • Dry the instruments after final rinse with a clean towel or compressed air until visibly dry.
STEP -6- INSPECTION AND FUNCTIONAL CHECK	• After cleaning, all devices should be thoroughly inspected for residue biologic soil or detergent. If contamination is still present repeat the cleaning process. • Visually inspect each device for completeness, damage and excessive wear. If damage or wear is observed that might compromise the function of the device, do not process them further and contact your Rigicon representative for a replacement. • When inspecting devices look for the following: ▪ Cutting edges should be free of nicks and have a continuous edge. ▪ Jaws and teeth should align properly. ▪ Movable parts should operate smoothly throughout the intended range of motion. ▪ Locking mechanisms should fasten securely and close easily. ▪ Long thin instruments should be free of bending or distortion
STEP -7- PACKAGING FOR STERILIZATION	• Single devices may be packaged in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization pouch or wrap. Care should be used when packaging so that the pouch or wrap is not torn.

	Devices should be wrapped using the double wrap or equivalent method (ref: AAMI ST79, AORN Guidelines). To double pouch: a) Place the tool in a smaller pouch and seal the pouch. b) Place the smaller sealed pouch in a larger pouch and seal it. • Reusable wraps are not recommended.

STEAM STERILIZATION

Use of ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care is recommended. A verified, properly maintained, and calibrated steam sterilizer is recommended. The process parameters of sterilization should be followed explicitly. It is the responsibility of the medical facility to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained.

Load trays per the sterilization equipment manufacturer's instructions.

In the United States

Sterilization Method	Exposure Temperature	Minimum Exposure Time	Minimum Drying Times
Pre-vacuum	270°F (132°C)	4 minutes	20 minutes

Outside the United States

Sterilization Method	Exposure Temperature	Minimum Exposure Time	Minimum Drying Times
Pre-vacuum	134°C	3 minutes	30 minutes

STORAGE CONDITIONS

Sterile packaged instruments should be stored is a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

Note: Inspect every package before use to ensure that the sterile barrier (e.g. wrap, pouch, or filter) is not torn, perforated, shows signs of moisture, or appears to be tampered with. If any of those conditions are present, then the contents are considered non-sterile and should be re-processed through cleaning, packaging and sterilization.

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