Instrument Reprocessing Instructions for Reusable Instruments: Automated Cleaning Method

1. Introduction

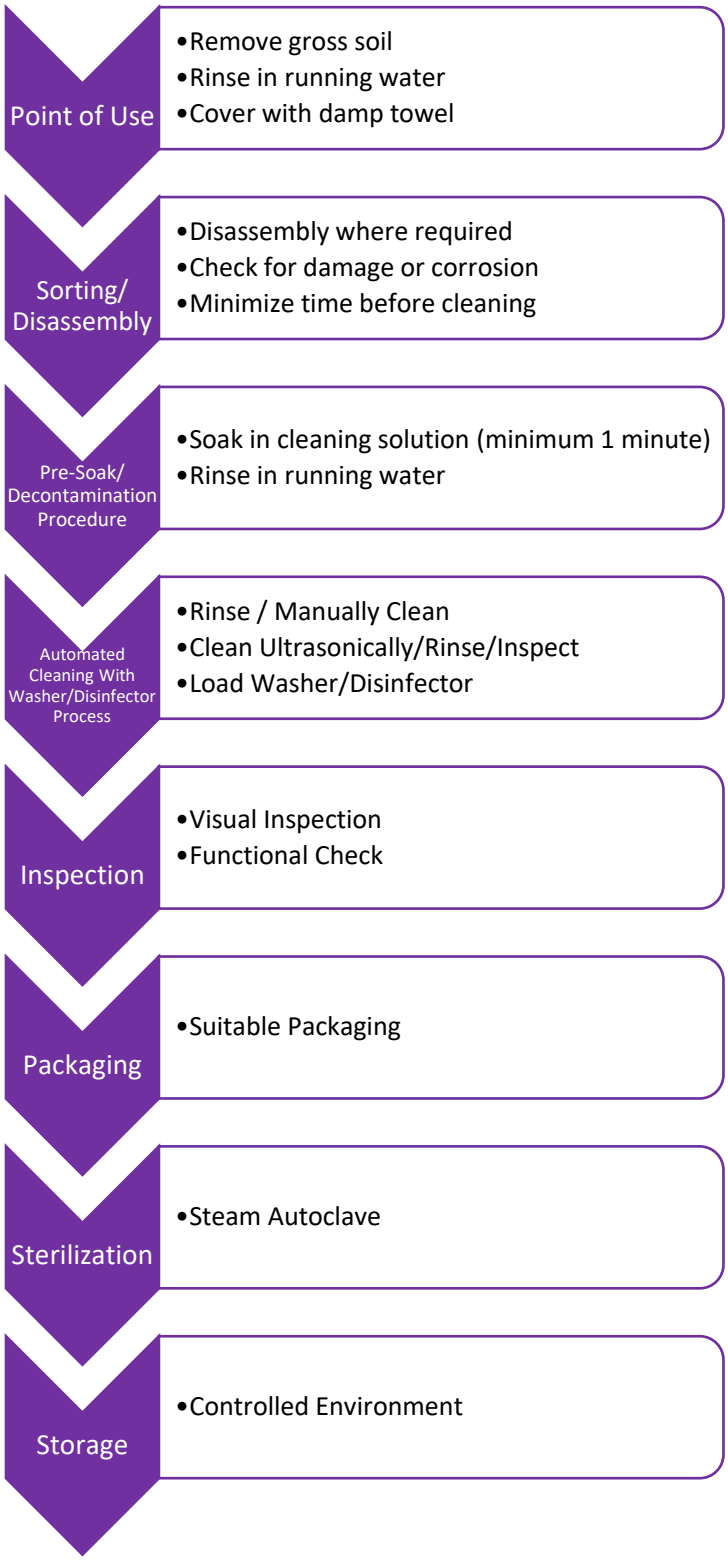
This document is intended to give general guidance on how reusable medical devices supplied by Paragon 28, Inc., may be automatically processed to prepare them for use. Paragon 28 reusable devices include certain surgical instruments, instrument trays and cases. The information provided does not apply to Paragon 28 implants, tissue products, or disposable instruments. These recommendations are to be followed unless otherwise noted on specific product inserts.

2. Warnings and Precautions

- Single use devices must not be re-used or re-processed (e.g. cleaning and re-sterilization). This may compromise the structural integrity of the device and/or lead to diminished safety, performance and/or compliance with relevant specifications and may create a risk of contamination that could result in patient injury, illness or death.
- Do not reprocess soiled implants. Any Paragon 28 implant that has been soiled by blood, tissue, and/or bodily fluids/matter should be discarded according to hospital protocol. Implants may have small defects and internal stress patterns that may cause material fatigue.
- The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665.
- Do not allow contaminated devices to dry prior to cleaning and reprocessing. Residual organic matter and/or a large number of micro-organisms may reduce the effectiveness of the sterilization process.
- Do not use steel wool or abrasive cleaners.
- Avoid prolonged exposure to saline to minimize the potential for corrosion.
- Avoid highly alkaline conditions and hypochlorite solutions as they can damage and corrode surgical instruments.
- Cleaning agents with a pH between 7–9.5 are recommended. Cleaning agents with a pH-value up to 11 and higher than 11 respectively should only be used considering the data regarding material compatibility according to its data sheet. Refer to Material Compatibility of Paragon 28 Instruments and Implants in Clinical Reprocessing, see below.
- Products supplied in a sterile condition are labeled “STERILE”. Remove products from the package in an aseptic manner. The manufacturer cannot guarantee sterility if the package seal is broken or if the package is improperly opened, and assumes no liability in such instances.
- Paragon 28® surgical instruments and implants are provided non-sterile, unless it is explicitly labeled “STERILE”, and are intended to contact normally sterile tissue or body space during use, therefore, the instruments are considered critical devices and must be cleaned and sterilized prior to and after each use.
- Sterilization requirements for implants are contained in the Instructions for Use (IFU) (www.paragon28.com/ifus) and should be strictly adhered to.
- The sterilization parameters are only valid for devices that are adequately cleaned.
- Treat instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) according to the health care facility’s standard operating procedure. Sterilization parameters recommended in this document, or the device IFU (refer to www.paragon28.com/ifus for the complete and most current IFU) are not intended and not suitable for inactivation of prions.
- Consult national regulations and guidelines for additional information. Compliance is additionally required with internal hospital policies and procedures and recommendations of manufacturers of detergents, disinfectants, and any clinical processing equipment.

3. Reprocessing Steps

The sequence of steps required to prepare medical devices for re-use or to prepare new devices for initial use are summarized in the chart below. More detailed instructions for each step are provided in the following table.



4. Recommended Reprocessing Instructions for Reusable Devices

Point of Use	– Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface. – Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside. – Soiled instruments should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. They should not be loaded into a case or tray for cleaning. The devices must be processed separate from trays and cases. – Devices should be covered with a towel dampened with sterile or purified water to prevent blood and/or debris from drying.
Sorting/ Disassembly	– It is recommended that devices should be reprocessed as soon as is reasonably practical following use. – Disassemble device, if device is able to be disassembled, prior to cleaning and disinfection. Non-interchangeable components of assemblies shall be kept together to ensure correct reassembly. – Instruments that are complex and/or designed to be disassembled prior to cleaning are provided in Appendix A of this procedure. – Inspect the instruments for damage and corrosion. If a component is lost, damaged, or corroded then contact Paragon 28 directly or your local representative.
Pre-Soak/ Decontamination Preparation	– Complex surgical instrumentation (multiple components, moving parts, textured surfaces, cannulations) are to be manually processed prior to cleaning through an ultrasonic cleaner or automated washer/disinfector. The instruments should first be cleared of gross soil and debris and then brushed thoroughly, using a soft bristled brush. Manual Reprocessing Instructions can be found at www.paragon28.com/resources. – Soak and/or rinse heavily soiled devices or cannulated devices prior to cleaning to loosen any dried soil or debris. Use an enzymatic cleaner or detergent solution, such as Enzol® by Advanced Sterilization Products®, for a minimum of 1 minute, using a soft-bristled brush to assist in the removal of gross soil and debris. – Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct dilution, temperature, and soak time. Use cold tap water to rinse devices. – Paragon 28 devices must be cleaned separately from Paragon 28 instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable.
Automated Cleaning With Washer/Disinfector Process	Equipment: Ultrasonic cleaner, washer/disinfector, various sized soft-bristled non-metallic brushes, lint-free cloths, syringes, pipettes and/or water jet, Enzymatic cleaner or detergent solution **Pre-Cleaning Process:** Pre-soak/Decontamination process above must be performed prior to the Automated Cleaning with Washer-Disinfector Process listed below. 1. Rinse soiled device under running cold tap water for a minimum of 1 minute. Remove gross soil using a soft-bristled brush or soft, lint-free cloth.

2. Manually clean device for a minimum of 2 minutes in a freshly prepared enzymatic cleaner or detergent solution, following the manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Use a soft-bristled brush to remove soil and debris. Fully immerse and clean articulating instruments, actuating joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Note: fresh solution is a newly made, clean solution.
3. Rinse device using cold to lukewarm running tap water for a minimum of 1 minute. Use a syringe, pipette or water jet to flush hard to reach areas and cannulations. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
4. Prepare a fresh detergent solution using enzymatic cleaner or detergent, following the manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. *Note: fresh solution is a newly made, clean solution.*
5. Clean Paragon 28 devices ultrasonically for a minimum of 10 minutes, using a minimum frequency of 40 KHz.
6. Rinse device using DI or PURW water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush hard to reach areas. DI or PURW water must be used for final rinse.
7. Visually inspect device. Repeat steps 2–7 until no visible soil remains on device.

Washer/Disinfector Process: Pre-Cleaning steps 1–7 above should occur prior to this step. *Note: The washer/disinfector should fulfill requirements specified in ISO 15883. Use MIS injector unit to process lumens and cannulations.*

Process device using the following cycle parameters:

Cycle	Minimum Time (minutes)	Minimum Temperature / Water	Type of Detergent
Pre-soak/ Disinfect	2	Cold tap water	N/A
Pre Clean Wash I	4	Cold tap water (>43 °C)	Cleaning agent*
Auto/Disinfect Washer II	4	Warm tap water (>65 °C)	Cleaning agent*
Rinse 1	2	Warm Tap (>43 °C)	N/A
Thermal Disinfection Rinse 2	2	Warm RO/DI (>82 °C)	N/A
Dry	20	>90 °C	N/A

*see Additional Information

Thermal Disinfection

For automated cleaning with washer-disinfector, thermally disinfect at a minimum of 90 °C for a minimum of 1 minute. For devices with cannulations or lumens, orient the part such that the lumen or cannulation is in a vertical position. If this is not possible due to space limitations within the

	automated/washer-disinfector, use an irrigating rack/load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if necessary.
Drying	If a dry cycle is not included in the automated washer: Dry each device thoroughly inside and out to prevent rusting and malfunction. Use a clean, soft, lint-free single-use cloth to avoid damage to the surface. Pay special attention to areas where fluid can accumulate. Open and close devices so that all areas are reached. Dry hollow parts (lumens, cannulations) using the air jet with compressed air.
Inspection	Paragon 28 instruments should be inspected after processing, and prior to sterilization for the following: 1. Cleanliness: Ensure complete removal of all soil from surfaces, tubes, holes, and moveable parts. The ANSI/AAMI ST79 acceptance standard for cleanliness is visibly clean. Some surfaces of an instrument can be visually obstructed which prevents this verification. If a borescope is not available for inspection, check for blood by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present, and cleaning must be repeated. Rinse instruments thoroughly after using hydrogen peroxide solution. 2. Damaged instruments: Do not use severely damaged instruments, instruments with corrosion (rust, pitting), discoloration, unrecognizable markings, missing or removed (buffed off) part numbers, lot numbers, excessive scratches, flaking, cracks and wear. 3. Proper function: Including but not limited to, sharpness of cutting tools, bending of flexible devices, and moveable features such as handles and ratcheting. Check for smooth movement of assemblies without excessive play. Locking mechanisms should attach and detach easily. Cutting edges should be free of nicks and have a continuous edge. Long slender instruments should be straight and free of distortion. 4. Disassembled devices should be reassembled prior to sterilization unless otherwise noted.
Packaging	Instruments should be loaded in the instruments trays that are provided with the sets. When possible, instruments should be placed in the holders in an open position. If packaged individually, a standard packaging material may be used and packed in accordance with local packaging procedures or ANSI/AAMI ST46-1993.
Sterilization	The recommended autoclave cycle is stated on the product insert, which is supplied with the set in the individual packaging of the product or can also be found in the Indications for Use (IFU) statement at www.paragon28.com/ifus.
Storage	Store sterile packaged instruments in a clean environment that provides protection from dust, moisture, insects, vermin, and extreme temperature or humidity.

5. Additional Information*

Paragon 28 used the following supplied during validation of these reprocessing recommendations. These supplies are not listed in preference to other available supplies which may perform satisfactorily. Cleaning Agent Information: ProCleanse Plus 8mL/L (Alkaline), ProWash 8mL/L (Neutralizer)

The cleaning and sterilization information is provided in accordance with ANSI/AAMIST81, ISO 17664, AAMI TIR 12, ISO 17665-1 and AAMI ST77.

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 to ensure that the processing is performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

6. Manufacturer Contact

For further information, contact your local Paragon 28, Inc. sales representative.

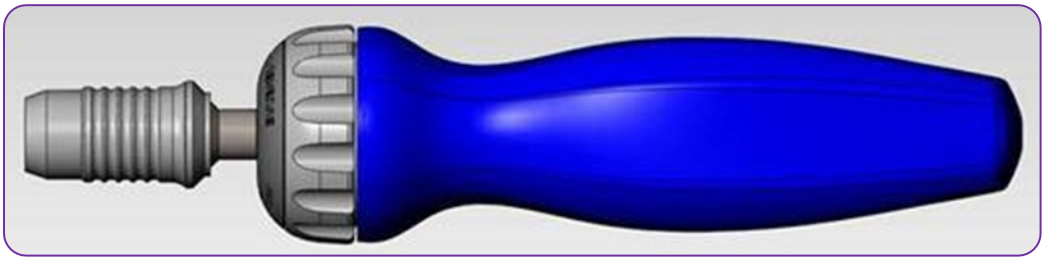
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO
80112 USA
(855) 786-2828

Paragon 28 Medical Devices Trading Limited
First Floor Block 7 Beckett Way
Park West Business Park
Dublin 12, D12 X884,
Ireland
+353 (0) 1588 0350

CE 2797

Appendix A

Cleaning of Ratchet Handles*



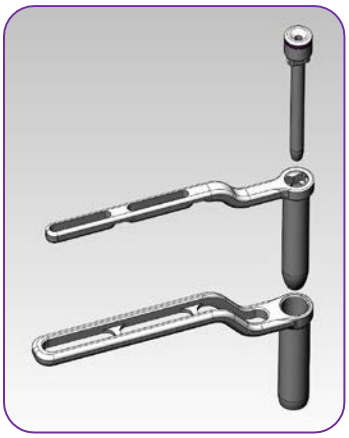
Detailed Instructions:

1. Submerge the instrument in an enzymatic detergent that is safe for surgical instruments. To avoid damage, avoid highly aggressive agents, (NaOH, NaOCL), and salt solutions. Soak the instrument for a minimum of five (5) minutes in the detergent.
2. Scrub the submerged instrument with a soft bristled brush. (Note: Using a wire brush or scouring pads will damage the surface finish of the handle causing corrosion.)

3. The inside diameter should be thoroughly cleaned with a nylon brush and a syringe.
4. The locking sleeve should be actuated in alternating positions while scrubbing with a nylon brush.
5. Rinse the instrument with warm (38-49° C) distilled or deionized water.
6. Place the instrument into a bath containing warm (38-49° C) water and agitate by hand for at least three (3) minutes.
7. Dry the exterior of the instruments with a clean, lint-free cloth. When medical grade compressed air is available, the inclusion of a compressed air-drying step is recommended. Special attention should be given to internal moving mechanisms (the ratchet, sliding collet, direction knob, etc.).
8. Repeat this cleaning procedure if the instruments appear to be soiled after cleaning.

* Tested at Nelson Labs and documented in Study number 1222079 and 1252436, this was considered "worst case" instrument to clean.

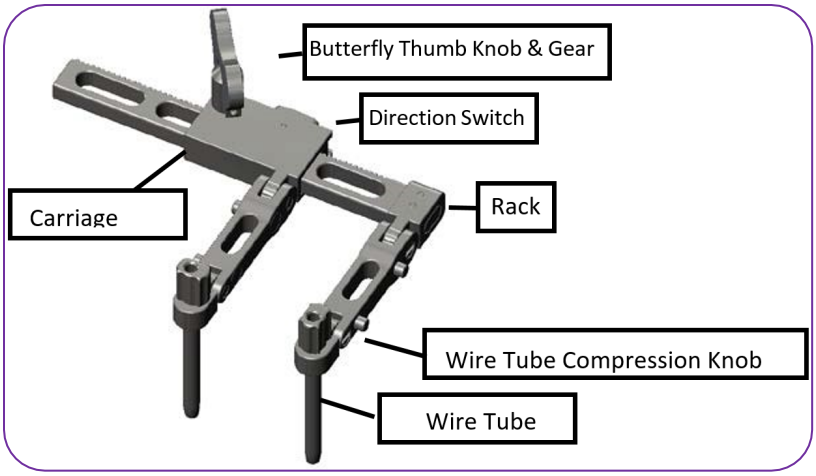
Cleaning of K-Wire Guide, Drill Guide and Tissue Protector



Detailed Instructions:

1. Cleaning of this instrument should be performed while immersed in the cleaning solution.
2. Completely disassemble the k-wire guide from the drill guide and the drill guide, from the tissue
3. protector.
4. The slotted holes of each component of the instrument should be cleaned with a soft bristled brush.
5. Cannulations should be cleaned with appropriately sized soft bristled lumen brushes.

Cleaning of Caspar Distraction/Compression Device



Detailed Instructions

1. Cleaning of this instrument should be performed while immersed in the cleaning solution.
2. Move the Direction Switch to the middle position to slide the Carriage back and forth on the Rack.
3. Slide the Carriage to the fully open position and clean the exposed section of the Rack.
4. Slide the Carriage to the fully closed position and clean the exposed section of the Rack.
5. Use a small brush to clean inside the Carriage along the Rack.
6. Move the Direction Switch to the far-left position and use a brush to clean inside the Carriage.
7. Move the Direction Switch to the far-right position and use a brush to clean inside the Carriage.
8. Loosen the Wire Tube Compression Knobs and clean the threads with a soft bristle brush.
9. Actuate the hinges while cleaning with a soft bristled brush.
10. Clean the slotted holes of each component of the instrument with a soft bristled brush.
11. Clean cannulations and holes with appropriately sized soft bristled lumen brushes.