



***Instrument Reprocessing Instructions for Reusable  
APEX 3D™ Total Ankle Replacement System  
Instruments***

## Introduction

This document is intended to establish safe and effective reprocessing procedures in health care facilities for surgical instruments supplied by Paragon 28® Inc. This procedure details the requirements to 1) minimize the organic soil transfer from one patient to another 2) prevent accumulation of residual soil through the product's use life, and 3) allow for successful, subsequent sterilization steps.

## Warning and Precautions

This instruction is not intended for implants, tissue products, or disposable instruments. Sterilization requirements for implants are contained in the IFU and should be strictly adhered to. Paragon 28®, Inc. surgical instruments are provided non-sterile unless it is explicitly labeled sterile. Instruments provided non-sterile must be sterilized prior to use.

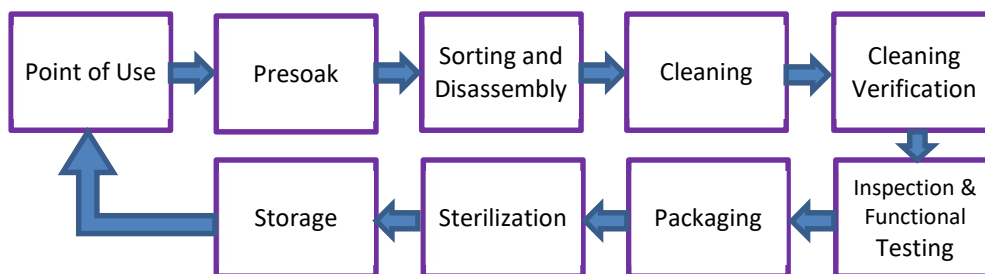
Paragon 28®, Inc. surgical instruments are intended to contact normally sterile tissue or body space during use. Due to this intended use it is considered a critical device and must be thoroughly cleaned and sterilized after each use. Do not allow contaminated devices to dry prior to cleaning and reprocessing as subsequent reprocessing steps are facilitated by not allowing blood, bodily fluid, bone and tissue debris, saline, or disinfectants to dry on used instruments.

Surgical instrumentation of complexity (multiple components, moving components, textured surfaces, cannulations) requires special attention and must be manually cleaned prior to processing through an ultrasonic cleaner. Avoid highly alkaline conditions and hypochlorite solutions as they can damage and corrode surgical instruments.

Please 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 are not intended and not suitable for inactivation of prions. Contact World Health Organization (WHO) or local regulatory authorities for further information on special CJD inactivation processing procedures.

## Cleaning and Decontamination

To assist health care personnel in the decontamination processes and procedures for various types of reusable surgical instruments, this section provides guidelines for the selection and use of available cleaning and microbicidal processes. The cleaning process must be thorough as residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. An outline of the reprocessing procedures is shown below in *Figure 1*.



**Figure 1**

**Point of Use**

Reprocessing begins at the point of use, which includes initial cleaning measures to prevent drying of the soil and contaminants in and on the device. Prolonged exposure to saline should be avoided to minimize the potential for corrosion.

**Presoaking**

Presoaking the instruments with an enzymatic solution, such as Enzol® by Advanced Sterilization Products®, for a minimum of 1 minute will moisten and loosen the soil, thus making the cleaning step more efficient. Rinsing thoroughly ensures the removal of any potentially harmful residue from the soaking solution. When presoaking the instruments, personnel should refer to the solution manufacturer's written instructions for the correct dilution, temperature, and soak time.

**Sorting and Disassembling**

Upon arrival in the decontamination area, contaminated items should be removed from their transport containers, and prepared for cleaning. All instruments and sterilization trays should be checked for damage and corrosion prior to cleaning. If a component is lost, damaged, or corroded then contact Paragon 28 directly or your local representative.

If the device consists of more than one component, and designed to be disassembled, the instrument should be disassembled prior to cleaning. Non-interchangeable components of assemblies shall be kept together to ensure correct reassembly. An example of an instrument that is complex and/or designed to be disassembled prior to cleaning is provided in Appendix A of this document.

**Cleaning**

For reusable medical devices, the most important step in decontamination is thorough cleaning and rinsing. Cleaning primarily removes rather than kills microorganisms. The factors that contribute to cleanliness are: quality of water; the quality, concentration, and type of cleaner; washing method; rinsing and drying; preparation of the contaminated devices; the time, temperature, load capacity of the equipment being used; and operator performance.

Many types of soil could be present on a device, but dried blood is especially difficult to remove. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to clean. It must be rehydrated and then washed.

Instruments and sterilization trays are optimally cleaned in water and detergent solutions at temperatures between 80°F and 110°F (27° to 44°C), but not to exceed 140°F. They should be cleaned with a brush, cloth, or sponge, and a low foaming, pH neutral detergent solution, such as Renu-Klenz™ by Steris Corporation®, or equivalent. Use a soft bristle brush to remove all traces of blood and debris; pay close attention to textured areas, crevices, blind holes, hinges, joints, and cannulated parts.

When cleaning an articulating instrument, fully immerse the instrument in the detergent and remove traces of blood and debris with a soft bristle brush. If the instrument can be articulated, retract and open the instrument in the detergent repeatedly.

Heavy instruments should not be placed on top of delicate instruments and small components should be placed in baskets.

Surgical instrumentation of complexity (multiple components, moving components, textured surfaces, cannulations) requires special attention and must be manually cleaned and then can be subsequently cleaned by sonication. Ultrasonic cleaning should not exceed temperatures of 140°F (60°C) to prevent coagulation and should be conducted for a period of 10 minutes. Sole use of an ultrasonic cleaner is not validated.

Rinse components under warm purified water (RO/DI water recommended). Every surface should be thoroughly rinsed to ensure removal of all detergent and soil.

Dry the instruments and sterilization trays with lint-free cloths. When drying internal areas of instruments, use compressed air. When drying instruments with concave features, place the concave surface down to facilitate draining.

### **Cleaning Verification**

Inspect all instruments and sterilization trays before sterilizing to ensure the 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, checking for blood can be accomplished by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, then blood is present and cleaning must be repeated. Rinse instruments thoroughly after using hydrogen peroxide solution.

### **Inspection and Functional Testing**

Instruments and sterilization trays should be inspected for damage and wear. 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. Instruments should be removed of any excessive moisture with a clean, absorbent, and non-shedding wipe.

### **Packaging**

Instruments should be loaded in the instrument 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 Instructions for Use (IFU) document at <http://www.paragon28.com/index.php/ifu/index>.

The instrument trays can be stacked in the cases as they are provided, but stacking of the cases is not permitted. Weight of the case should not exceed 25lbs. The instrument trays provided in the APEX 3D™ Total Ankle Replacement System are intended to be used with the instrumentation of the APEX 3D™ Total Ankle Replacement System.

### **Storage**

Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extreme temperature or humidity.

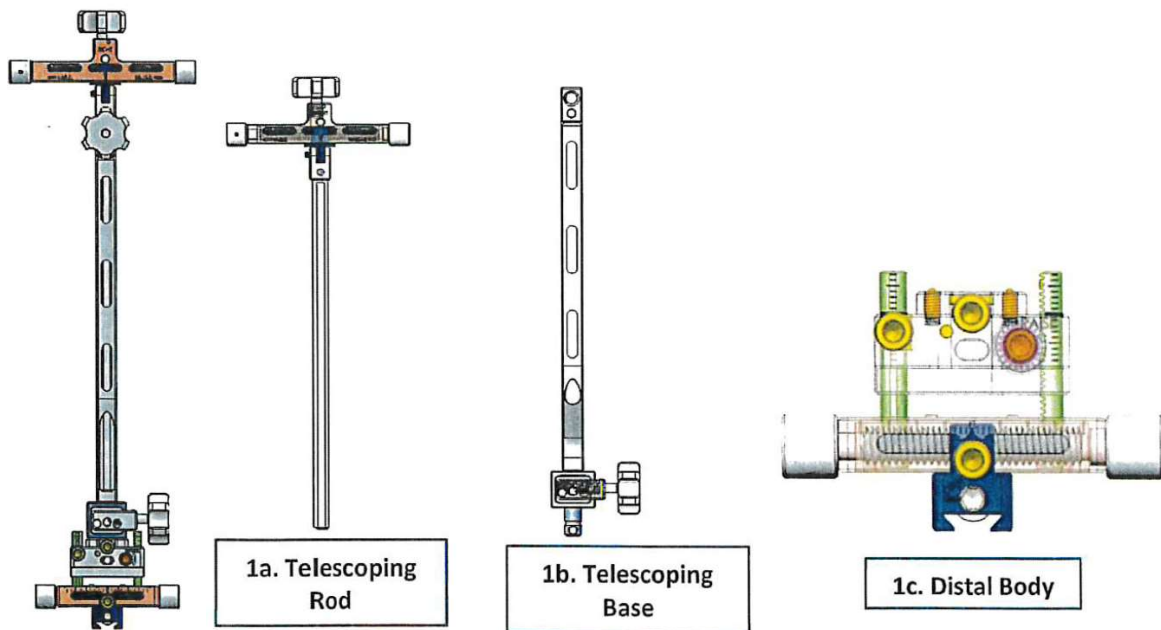
### **Contact Information**

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## Appendix A

### Cleaning of Tibial Alignment Guide



#### Detailed Instructions:

1. Remove the telescoping rod from the telescoping base by turning the knob and sliding the rod out from the base.
2. Remove the distal body from the telescoping base by loosening the middle bolt, turning the telescoping base counter clockwise and pulling apart the devices.
3. Rinse the disassembled alignment guide under running tap water to remove gross soil.
  - a. While rinsing, use a soft bristled brush to remove soil. Pay special attention to cracks, crevices and hard to reach areas.
  - b. Actuate, articulate and retract movable parts.
4. Prepare a detergent solution following the manufacturer's instructions.
  - a. Paragon 28 recommends using Enzol, 1 oz. per gallon using warm tap water.
5. Immerse the disassembled alignment guide in the prepared detergent solution for 1 minute.
  - a. While immersed, brush the articles using a soft bristled brush. Pay attention to cracks, crevices and hard to reach areas.
  - b. Actuate, articulate and retract movable parts.
6. Prepare detergent solution in an ultrasonic unit. Follow the manufacturer's instructions.
  - a. Paragon 28 recommends using Enzol, 1 oz. per gallon using warm tap water.
7. Immerse the disassembled alignment guide in the prepared detergent solution and allow the pieces to sonicate for 10 minutes.
8. Rinse the disassembled alignment guide under running reverse osmosis deionized (RO/DI) water.
9. Dry the article using a clean soft lint-free cloth.
10. Repeat this cleaning procedure if the instruments appear to be soiled after cleaning.