Applicable Devices	Devices supplied by Signature Orthopaedics non-sterile and intended for end-user cleaning and sterilisation prior to use. These devices are typically in contact with tissues, blood and body fluids or subject to splatter or splash of body fluids or blood because of proximity to the patient. The devices be subject to reprocessing with disinfectants or other chemicals that might leave harmful residues, or adversely affect device materials or performance, if inadequately rinsed;	**Identification** Signature Orthopaedics devices are identified by this logo	
Warnings	Long narrow cannulations and blind holes require particular attention during cleaning. Enzymatic or other cleaning agents with neutral pH are recommended. Chlorinated water should not be used to clean devices. Devices that are showing signs of corrosion and rust should not be used. Personnel must thoroughly clean the devices to ensure all visual contamination is removed. All processes detailed herein should be carried out by trained personnel.		
Limitations on Reprocessing	Devices should be thoroughly inspected to ensure that they are in good condition and operating order following reprocessing. Conditions that may necessitate repair include but are not limited to: • Surface gouges, dents, scratches, rust, tears, chips, cracks, bent, wear • Discoloration • Poor fit or function • Blunt cutting tips and edges If inspection identified damage and/or broken mechanisms, do not use the instrument and contact Signature Orthopaedics for further instructions and instrument disposition.		
INSTRUCTIONS			
Cleaning at point of use	Remove excess soil with disposable non shedding wipes.		
Containment and transportation	It is recommended that devices are reprocessed as soon as is reasonably practical following use. Signature Orthopaedics recommends cleaning within 30 minutes of completion of use		
Preparation for cleaning	Devices should be disassembled in reverse of the assembly instructions provided in the surgical technique and placed in the allocated position within the instrument tray as initially supplied prior to cleaning. Devices are to be reassembled per the surgical technique at the point of clinical use.		

Cleaning	**Equipment:** Sonication unit, Enzymatic Cleaner (e.g. Enzol), brush, running water, deionized water NOTE: Cleaning of devices in chlorinated water is not recommended. Deionized water should be used for the final rinse. 1. Immerse the device in an enzymatic cleaner (e.g. Enzol) prepared per the manufacturer's recommendations. Allow the devices to soak for a minimum of 5 minutes. 2. Using a soft bristled brush, brush the device and internal components. Ensure that hinged devices are cleaned in both open and closed positions. Clean cannulations and holes using an appropriate brush ensuring that full depth of the feature is reached. A sterile syringe and pipe cleaner may be used to brush and flush hard to reach areas. NOTE: If the solution becomes bloody or turbid, prepare a new solution. 3. Rinse the devices under running cool tap water until all evidence of visible detergent is removed. 4. Prepare a fresh enzymatic solution (e.g. Enzol) in a sonication unit per manufacturer's recommendations. Fully immerse the devices in the solution and allow the devices to sonicate for a minimum of 9 minutes. 5. Rinse the devices in warm critical water for a minimum of 1 minute until all evidence of visible detergent is removed, whichever is longer. Ensure that the water passes through cannulations, and that blind holes are repeatedly filled and emptied. Rinsing should remove all evidence of detergent. A syringe may be used to flush hard to reach areas. NOTE: Check the device for visual soil, if found repeat steps 1-5. 6. Dry the devices with a clean soft cloth and filtered pressurized air (no greater than 40psi). Visually inspect the devices with an unaided eye for any signs of visible soil or debris. NOTE: The use of lubricating agents is not recommend. If devices are not in good condition or operating order, then please refer to 'Limitations on Reprocessing" section stated above.
Visual Inspection	Following cleaning, the devices must be visually inspected to ensure they are visually clean and have no visual contamination. If necessary, repeat the above cleaning instructions until all visual contamination is removed.
Cleanliness Test	Following visual inspection, it is recommended that the devices are tested for cleanliness. Testing for Hemoglobin using Peroxidase reaction is recommended. Activate 1 ml TetraMethyl Benzidine (TMB) with 4 drops of 3% hydrogen peroxide solution. Using peroxidase free cotton swab, swab the worst case surfaces and lumens (where possible). If surfaces are dry, the swab should be moistened with a drop of RO/DI water. Immerse the swab into the activated TMB solution and watch for color change in the swab. If the color of the cotton swab turns to clear blue, it indicates that haemoglobin residual were detected on the device, therefore, that particular batch of devices has to be re-cleaned until no color change is detected on the swab.
Disinfection	The preceding reprocessing guideline has been validated for Signature Orthopaedics' product without the need for an additional disinfection step. The effectiveness and compatibility of disinfection with Signature Orthopaedics devices has therefore not been evaluated. It is the responsibility of the processing facility to consider the effectiveness and compatibility of any additional disinfection process.
Drying	Manual drying should be done with clean soft dry cloth and filtered pressurized air (no greater than 40psi). The devices must be dry prior to packaging for sterilisation.
Maintenance	Return blunt or damaged devices to Signature Orthopaedics for repair.
Inspection and function Testing	**Hinged instruments:** Check for smooth movement of hinge without excessive "play". Locking (ratchet) mechanisms should be checked for action. **All devices:** Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check devices with long slender features (particularly rotating instruments) for distortion. Where devices form part of a larger assembly, check assembly with mating components.

Packaging	In sets: Devices may be loaded into dedicated trays. Devices supplied in a Signature Orthopaedics tray are to be sterilised in the tray, with devices placed at the locations as indicated by the tray's marking. Loaded and packaged trays must weigh less than 25 pounds (11.3kgs) including the devices, tray and wrap, in accordance with AAMI ST77. Ensure that cutting edges are protected. Wrap the trays using Disposable Surgical Instrument Wrap following AANSI/AAMI ST79 sequential envelope folding technique. **USA only:** only FDA-Cleared sterilzation packaging material may be used **Warning:** Do not stack trays during sterilization
Sterilization	Pre-vacuum Sterilization, temperature 132°C, 4 minutes exposure with 70 minute drying time. (NOTE: Drying time is subject to variation depending on machine load. The sterilised packages should be thoroughly inspected for moisture following sterilisation. If visible signs of moisture are present, the packages should be reprocessed and re-sterilised.) Any type of sterilizer is appropriate if the above stated parameters are used.
Storage	In accordance with AS4187:2014 **(Australia and EU)** In accordance with ANSI/AAMI ST79-2017 **(USA)**
Additional Information	Devices supplied sterile should have packaging examined for damage prior to use.

For further information please contact:

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