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DePuy Synthes Obstetric Fistula Instrumentation Instructions

INTENDED USE

- The Obstetric Fistula Surgical Instruments are intended to be used during fistula repair surgery.

INTENDED USER PROFILE

- Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques.
- Consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure. Before using the product, all instructions regarding its safety features must be read carefully.

DEVICE DESCRIPTION

- Surgical instruments of simple components composed of medical grade stainless steels and medical grade plastics.
- Trays and organizers may consist of different materials including stainless steels and medical grade silicone.
- Devices are supplied NON-STERILE and must be inspected, cleaned and sterilized before each use.
- Devices are critical and require terminal sterilization.
- Devices are not implantable.

WARNINGS

- Avalign recommends thorough manual and automated cleaning of medical devices prior to sterilization. Automated methods alone may not adequately clean devices.
- Devices should be reprocessed as soon as possible following use. Instruments must be cleaned separately from cases and trays.
- All cleaning agent solutions should be replaced frequently before becoming heavily soiled.
- Prior to cleaning, sterilization and use, remove all protective caps carefully. All instruments should be inspected to ensure proper function and condition. Do not use instruments if they do not perform satisfactorily.
- Risk of damage – The surgical instruments are precision devices. Careful handling is important for the accurate functioning of the devices. Improper external handling can cause the devices to malfunction.
- Use caution when handling sharp instruments to avoid injury.
- If a device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.

CAUTION

℞ ONLY

Federal U.S. Law restricts this device to sale, distribution, and use, by, or on order of a physician.

LIMITATIONS ON REPROCESSING

Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

DISCLAIMER

It is the responsibility of the reprocessor to ensure reprocessing 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. Any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

Reprocessing Instructions

TOOLS AND ACCESSORIES

Water	Cold Tap Water (< 20°C / 68°F) Warm Water (38°- 49°C / 100°- 120°F) Hot Tap Water (> 40°C / 104°F) Deionized (DI) or Reverse Osmosis (RO) Water (ambient)
Cleaning Agents	Neutral Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, Enzol
Accessories	Assorted Sizes of Brushes and/or Pipe Cleaners with Nylon Bristles Sterile Syringes or equivalent Absorbent, Low Lint Disposable Cloths or equivalent Soaking Pans
Equipment	Medical Compressed Air Ultrasonic Cleaner (Sonicator) Automated Washer

POINT-OF-USE AND CONTAINMENT

1) Follow health care facility point of use practices. Keep devices moist after use to prevent soil from drying and remove excess soil and debris from all, surfaces, crevices, hinged joints, and all other hard-to-clean design features.
2) Follow universal precautions and contain devices in closed or covered containers for transport to central supply.

MANUAL CLEANING

3) Rinse devices under cold running tap water for a minimum of 3 minutes while wiping off residual soil or debris. Actuate moveable mechanisms and flush cracks and/or crevices while rinsing.
4) Prepare an enzymatic cleaning solution per manufacturer's instructions including dilution/concentration, water quality and temperature. Immerse devices and soak for a minimum of 10 minutes. While in the solution, use a soft, bristle brush to remove all traces of blood and debris from the device, paying close attention to crevices, seams, and any hard to reach areas.
   a. If the device has sliding mechanisms or hinged joints, actuate the device while scrubbing to remove trapped soil.
5) Remove devices and rinse/agitate in warm tap water for a minimum of 3 minutes. Actuate moveable mechanisms and flush all cracks and/or crevices while rinsing.
6) Prepare a neutral detergent cleaning solution per manufacturer's instructions including dilution/concentration, water quality and temperature. Immerse devices and soak for a minimum of 5 minutes. While in the solution, use a soft, bristle brush to remove all traces of blood and debris from the device, paying close attention to threads, crevices, seams, and any hard to reach areas.
   a. If the device has sliding mechanisms or hinged joints, actuate the device while scrubbing to remove trapped soil.
7) Remove devices and rinse/agitate in cold tap water for a minimum of 3 minutes. Actuate moveable mechanisms and flush all cracks and/or crevices while rinsing.
8) Prepare an enzymatic cleaning solution using hot water per manufacturer's recommendations in an ultrasonic unit. Sonicate the devices for a minimum of 15 minutes using a minimum frequency of 40 kHz. It is recommended to use an ultrasonic unit with flushing attachments.
9) Remove devices and rinse/agitate in ambient DI/RO water for a minimum of 4 minutes. Actuate moveable mechanisms and flush all cracks and/or crevices while rinsing.
10) Dry the device using an absorbent cloth. Dry any internal areas with filtered, compressed air.
11) Visually inspect the device for soil including all actuating mechanisms, cracks, and crevices. If not visibly clean, repeat steps 3-11.

AUTOMATED CLEANING

Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-7. Steps 8-11 are optional but advised.

12) Transfer the devices to an automatic washer/disinfector for processing per the below minimum parameters.

Phase	Time (minutes)	Temperature	Detergent Type & Concentration
Pre-wash 1	02:00	Cold Tap Water	N/A
Enzyme Wash	02:00	Hot Tap Water	Enzyme Detergent

Wash 1	02:00	63°C / 146°F	Neutral Detergent
Rinse 1	02:00	Hot Tap Water	N/A
Purified Water Rinse	02:00	146°F / 63°C	N/A
Drying	15:00	194°F / 90°C	N/A

13) Dry excess moisture using an absorbent cloth. Dry any internal areas with filtered, compressed air.
14) Visually inspect the device for soil including all actuating mechanisms, cracks, crevices and lumens. If not visibly clean, repeat steps 3-7, 12-14.

DISINFECTION

- Devices must be terminally sterilized (See § Sterilization).
- Avalign instruments are compatible with washer/disinfector time-temperature profiles for thermal disinfection per ISO 15883.
- Load the devices in the washer-disinfector according to the manufacturer's instructions, ensuring that the devices and lumens can drain freely.
- The following automated cycles are examples of validated cycles:

Phase	Recirculation Time (min.)	Water Temperature	Water Type
Thermal Disinfection	1	>90°C (194°F)	RO/DI Water
Thermal Disinfection	5	>90°C (194°F)	RO/DI Water

INSPECTION AND FUNCTIONAL TESTING

- Visually inspect devices for damage or wear, including sharp edges. Instruments with broken, cracked, chipped or worn features, should not be used, but should be replaced immediately.
- Verify device interfaces (junctions) continue to function as intended without complications.
- Check for smooth movement of hinges.
- Lubricate hinged joints before autoclaving with Instra-Lube, or a steam permeable instrument lubricant.

PACKAGING

- Only FDA cleared sterilization packaging materials should be used by the end user when packaging the devices.
- The end user should consult ANSI/AAMI ST79 or ISO 17665-1 for additional information on steam sterilization.
- **Sterilization Wrap**
  - Instruments and organizers may be wrapped in a standard, medical grade sterilization wrap using the AAMI double wrap method or equivalent.
- **Rigid Sterilization Container**
  - For information regarding rigid sterilization containers, please refer to appropriate instructions for use provided by the container manufacturer or contact the manufacturer directly for guidance.

STERILIZATION

Sterilize with steam. The following are minimum cycles required for steam sterilization of Avalign devices:

1. Sterilization Wraps:

Cycle Type	Temperature	Exposure Time	Pulses	Drying Time
Prevacuum	132°C (270°F)	4 minutes	4	30 minutes
Prevacuum	134°C (273°F)	3 minutes	4	30 minutes

- The operating instructions and guidelines for maximum load configuration of the sterilizer manufacturer should be followed explicitly. The sterilizer must be properly installed, maintained, and calibrated.
- Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material. It is critical that process parameters be validated for each facility's individual type of sterilization equipment and product load configuration.
- A facility may choose to use different steam sterilization cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate steam penetration and contact with the devices for sterilization. Note: rigid sterilization containers cannot be used in gravity steam cycles.
- Water droplets and visible signs of moisture on sterile packaging/wrap or the tape used to secure it may compromise the sterility of the processed loads or be indicative of a sterilization process failure. Visually check outside wrap for dryness. If

there are water droplets or visible moisture observed, the pack or instrument tray is considered unacceptable. Repackaging and re-sterilize the packages with visible signs of moisture.

STORAGE

- After sterilization, instruments should remain in sterilization packaging and be stored in a clean, dry cabinet or storage case.
- Care should be taken when handling devices to avoid damaging the sterile barrier.

MAINTENANCE

- Attention: Apply lubricant only on the hinged parts.
- Discard damaged, worn or non-functional devices.

WARRANTY

- All products are guaranteed to be free from defects in material and workmanship at the time of shipping.
- Avalign instruments are reusable and meet AAMI standards for sterilization. All Avalign products are designed and manufactured to meet the highest quality standards. Avalign cannot accept liability for failure of products which have been modified in any way from their original design.

CONTACT

- **Notice to Patient and User**: Any serious incident that has occurred in relation to the medical devices should be reported to the manufacturer

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Symbol	Title	Symbol	Title and Translations
	Manufacturer & Date of Manufacture		Caution
	Lot Number / Batch Code		Non-Sterile
	Catalogue Number		Federal Law (USA) restricts this device to sale by or on the order of a physician
	Consult Instructions for Use		

Part Number	Description	UDI
03.012.101	Bladder Sound	00190776160340
03.012.102	Fistula Scissors	00190776160357
03.012.103	Suture/Catheter Organizer	00190776160364