

DePuy Synthes CONDUIT™ SYNFIX™ Evolution Secured Spacer System Instruments Instructions

PART LIST

| Part Number | Description | GTIN |
|-------------|-------------------------|----------------|
| 440125135 | Trial AH 13.5mm 25DEG S | 00190776386672 |
| 440125150 | Trial AH 15mm 25DEG S | 00190776386689 |
| 440125170 | Trial AH 17mm 25DEG S | 00190776386696 |
| 440125190 | Trial AH 19mm 25DEG S | 00190776386702 |
| 440130150 | Trial AH 15mm 30DEG S | 00190776386719 |
| 440130170 | Trial AH 17mm 30DEG S | 00190776386726 |
| 440130190 | Trial AH 19mm 30DEG S | 00190776386733 |
| 440225150 | Trial AH 15mm 25DEG M | 00190776386740 |
| 440225170 | Trial AH 17mm 25DEG M | 00190776386757 |
| 440225190 | Trial AH 19mm 25DEG M | 00190776386764 |
| 440230170 | Trial AH 17mm 30DEG M | 00190776386771 |
| 440230190 | Trial AH 19mm 30DEG M | 00190776386788 |
| 440325170 | Trial AH 17mm 25DEG L | 00190776386795 |
| 440325190 | Trial AH 19mm 25DEG L | 00190776386801 |
| 440330190 | Trial AH 19mm 30DEG L | 00190776386818 |
| 440300002 | Trial Caddy | 00190776386832 |

DePuy Synthes CONDUIT™ SYNFIX™ Evolution Secured Spacer System Instruments Instructions

INTENDED USE

- Manual surgical instruments intended for use in confirming adequate disc space preparation for interbody spinal fusion.

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

- Interbody fusion trial instruments composed of medical grade titanium alloy.
- 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.
- Wash the instrument case and trays with an aluminum safe, neutral pH detergent to avoid faded surface colors and deterioration of anodized surfaces.
- All cleaning agent solutions should be replaced frequently before becoming heavily soiled.
- Prior to cleaning, sterilization and use, all instruments should be inspected to ensure proper function and condition. Do not use instruments if they do not perform satisfactorily.
- The sterilization methods described have been validated with the devices in predetermined placement locations per the case and tray designs. Areas intended for specific devices shall contain only those devices.
- 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



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, and is left to the user to determine the acceptable condition of the device.

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 | Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, Enzol - Validated with Enzol enzymatic detergent at 1 oz per gallon of tap water Neutral Detergent pH 6.0-8.0 i.e. Liqui-nox, Valsure - Validated with Valsure neutral detergent at 1oz per gallon of tap water (manual) and 1/4oz per gallon of tap water (automated) |
| 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 lumens, surfaces, crevices, threads, and all other hard-to-clean design features.
- 2) Suction or flush lumens with a cleaning solution immediately after use.
- 3) Follow universal precautions and contain devices in closed or covered containers for transport to central supply.

MANUAL CLEANING

- 4) Rinse devices under cold running tap water for a minimum of 3 minutes while wiping off residual soil or debris. Flush all lumens, cracks and/or crevices while rinsing.
- 5) 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 threads, crevices, seams, and any hard to reach areas.
 - a. If the device contains a lumen, use a tight-fitting nylon brush or pipe cleaner while pushing in and out with a twisting motion to facilitate removal of debris; ensure the full diameter and depth of the lumen is accessed. Flush the lumen, three times minimum, with a syringe containing a minimum solution of 60mL.
- 6) Remove devices and rinse/agitate in cold tap water for a minimum of 3 minutes. Flush all lumens, cracks and/or crevices while rinsing.
- 7) 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 contains a lumen, use a tight-fitting nylon brush or pipe cleaner while pushing in and out with a twisting motion to facilitate removal of debris; ensure the full diameter and depth of the lumen is accessed. Flush the lumen, three times minimum, with a syringe containing a minimum solution of 60mL.
- 8) Remove devices and rinse/agitate in cold tap water for a minimum of 3 minutes. Flush all lumens, cracks and/or crevices while rinsing.
- 9) 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. Devices with lumens should be flushed with cleaning solution under the surface of the solution to ensure adequate perfusion of channels.
- 10) Remove devices and rinse/agitate in ambient DI/RO water for a minimum of 4 minutes. Flush all lumens, cracks and/or crevices while rinsing. Flush internal lumens a minimum of 3 times with RO/DI water (minimum of 15mL) using an appropriately sized syringe. If available, use flush ports for flushing.
- 11) Dry the device using an absorbent cloth. Dry any internal areas with filtered, compressed air.

- 12) Visually inspect the device for soil under magnification including all, cracks, crevices, and lumens. If not visibly clean, repeat steps 4-12.

AUTOMATED CLEANING

Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-8. Steps 9-12 are optional but advised.

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

| Phase | Time (minutes) | Temperature | Detergent Type |
|----------------------|----------------|----------------|-------------------|
| 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 |

- 14) Dry excess moisture using an absorbent cloth. Dry any internal areas with filtered, compressed air.
 15) Visually inspect the device for soil under magnification including all actuating mechanisms, cracks, crevices and lumens. If not visibly clean, repeat steps 4-8, 13-15.

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) | RI/DO Water |
| Thermal Disinfection | 5 | >90°C (194°F) | RI/DO 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 and threads) continue to function as intended without complications.

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**
 - Cases may be wrapped in a standard, medical grade sterilization wrap using an approved double wrap method
- **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.

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. Repackage and re-sterilize the packages with visible signs of moisture.

STORAGE

- Prior to first use, keep devices in their original packaging and store in a clean, dry, and dust-free environment.
- 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 wrap barrier.

MAINTENANCE

- Discard damaged, worn or non-functional devices. No special measures are necessary with regard to disposal. Dispose of device per healthcare facility biohazardous waste protocols.

WARRANTY

- All products are guaranteed to be free from defects in material and workmanship at the time of shipping.
- Aalign instruments are reusable and meet AAMI standards for sterilization. All our products are designed and manufactured to meet the highest quality standards. We 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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Label Glossary

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