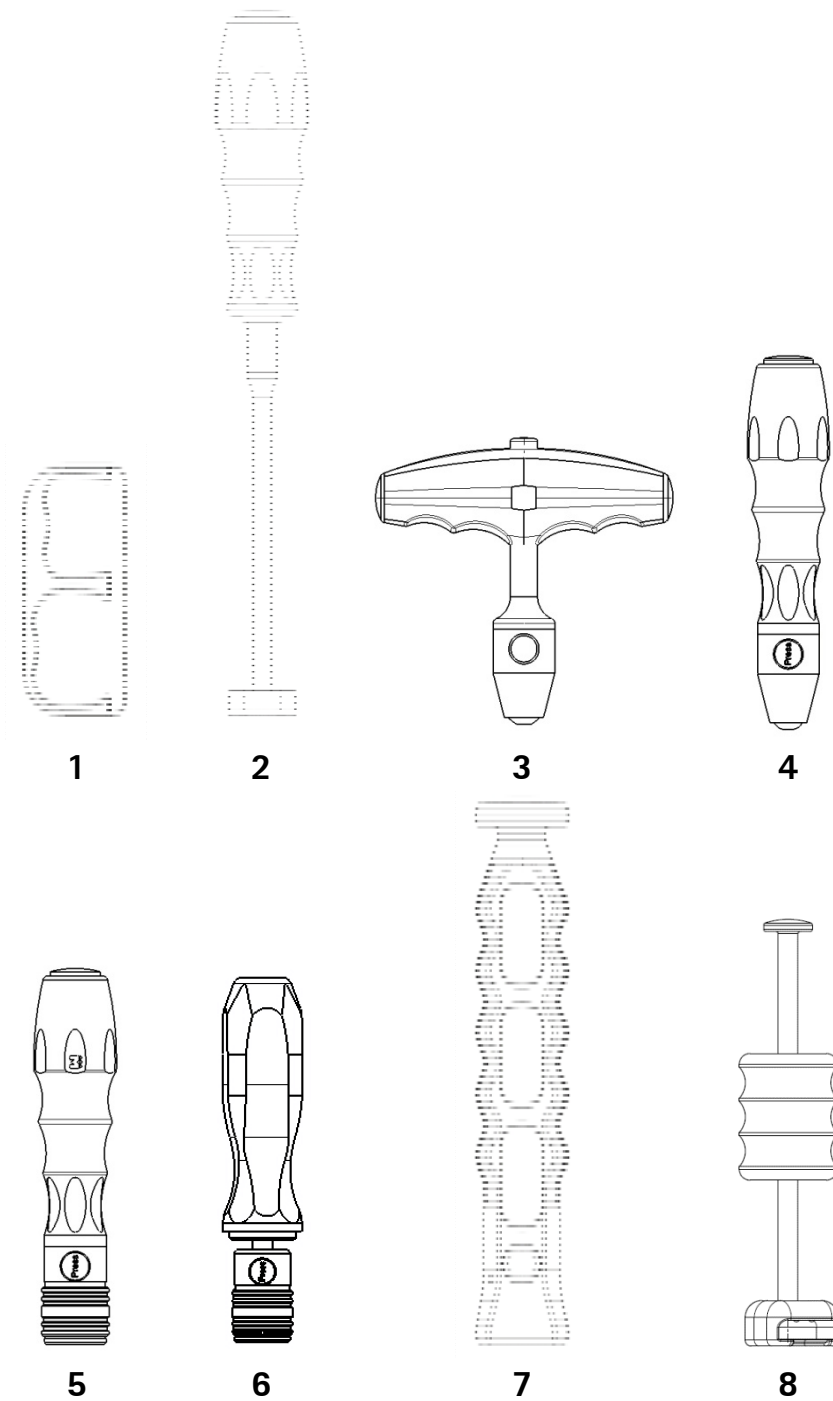
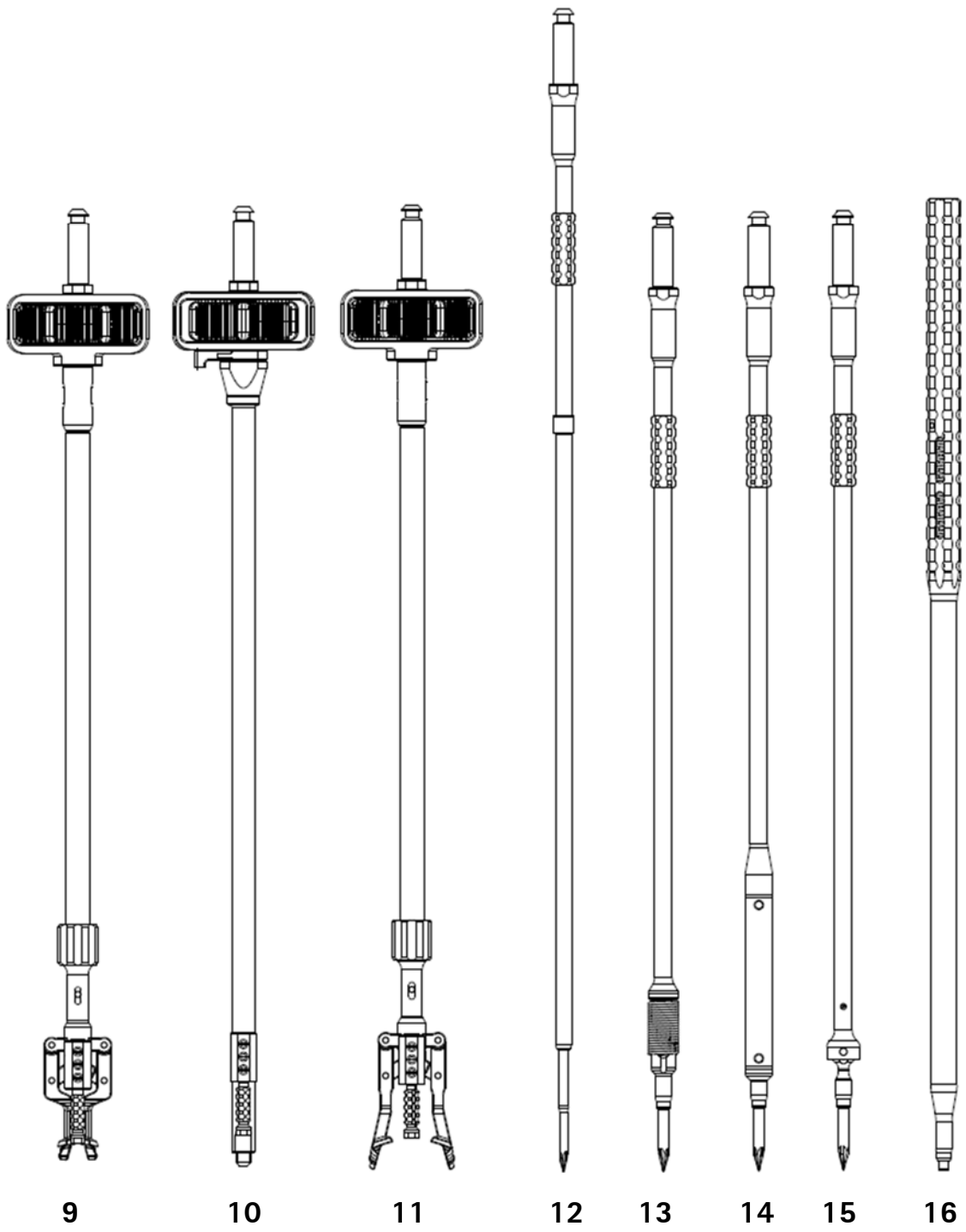


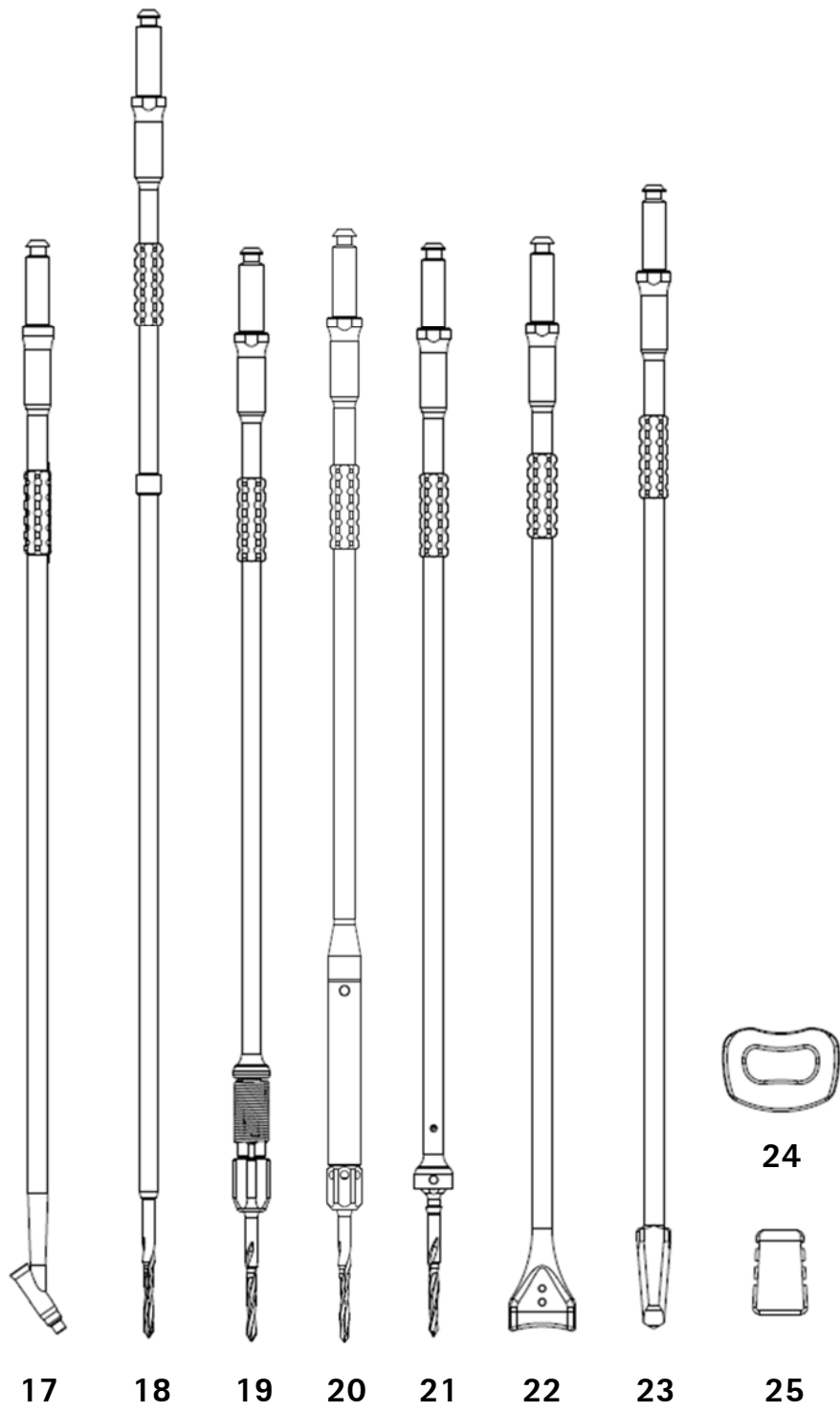
Aesculap® Implant Systems

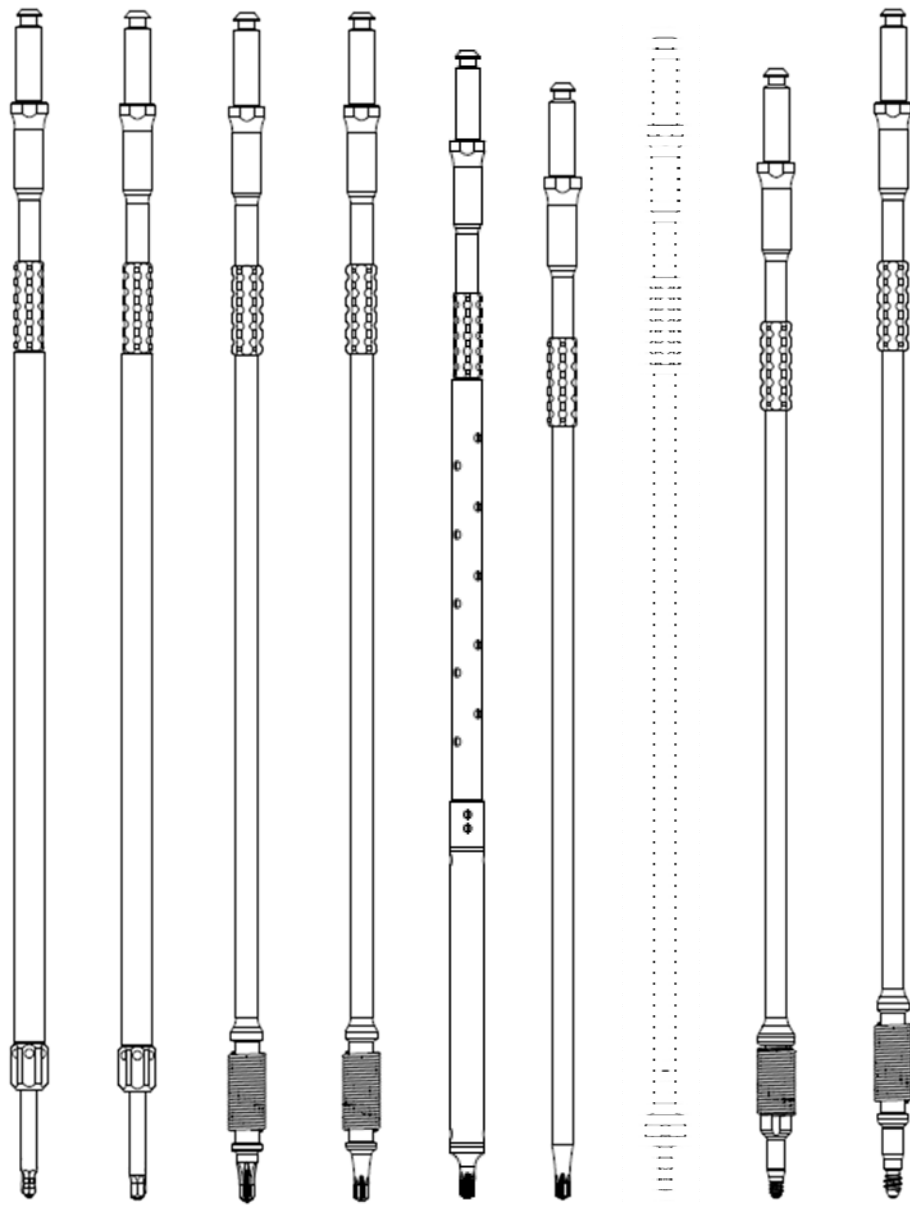
Aesculap® Implant Systems Spine

USA Instructions for Use / Technical Description
A-Space and SIBD Arcadius®^{XP} L Instruments









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Legend

- 1 Packing Block (SJ604R)
- 2 Tamp (SJ608R)
- 3 T-Handle (SJ033R)
- 4 Handle (FW440R)
- 5 Ratchet Handle (SJ705R)
- 6 Torque Limit Handle (ME012R) (***refer to SOP-AIS-5001204**)
- 7 Slap Hammer Handle (SJ708R)
- 8 Slap Hammer Extension (SJ709R)
- 9 Implant Introducer (SJ605R)*
- 10 Trial Insertion Instrument (ME020R)
- 11 Implant Inserter Manipulator (ME015R)
- 12 Straight Bone Awl (ME017R)
- 13 ALIF U-Joint Bone Awl (ME190R)
- 14 Flexible Bone Awl (SJ607R)
- 15 Ball Joint Bone Awl (ME172R)
- 16 Straight Drill Guide (SJ724R)
- 17 Angled Drill Guide (SJ722R)
- 18 Straight Drill (SJ725R)
- 19 U-Joint Drill (ME189R)
- 20 Flexible Drill (SJ723R)
- 21 Ball Joint Drill (ME173R)
- 22 Impactor (SJ606R)
- 23 Distractor 10mm – 20mm (SJ020R, SJ022R, SJ024R, SJ026R, SJ028R, SJ030R)
- 24 Trial Implant (SJ664T – SJ798T: 36 sizes)
- 25 Detachable Wedge 18mm -24mm (ME628R-ME633R: 6 sizes)
- 26 Straight Ball Hex Screwdriver (ME013R)
- 27 Straight Hex Screwdriver (ME016R)
- 28 U-Joint Screwdriver (ME014R)
- 29 U-Joint Hexalobe Screwdriver (ME052R)
- 30 Snake Driver (Hex) (ME176R)
- 31 Straight Hexalobe Screwdriver (ME054R)
- 32 Ball Joint Hexalobe Screwdriver (ME174R)
- 33 Revision Instrument (ME078R)
- 34 Implant Extraction Instrument (ME018R)

** Instrument offered upon customer request only, not included in the instrument set.*

Symbols on product packages



Caution, general warning symbol.
See documentation supplied with the product.

Indications for Use

The A-Space SIBD and Arcadius^{XP} L Instruments are used for the implantation of A-Space SIBD and Arcadius^{XP} L devices into the lumbar spine.

Note For the full list of indications and contraindications for the A-Space SIBD and Arcadius^{XP} L implants systems, please see SOP-AIS-5000942 and SOP-AIS-5000643.

Safe Handling and Preparation



Risk of injury caused by incorrect operation of the product.

- Attend appropriate product training before using the product.
- For information about product training, please contact your national B. Braun/Aesculap agency

Federal law restricts this device to sale by, or on order of a physician!

- Always follow the Instructions for Use of the A-Space SIBD and Arcadius^{XP} L Implants (SOP-AIS-5000942 and SOP-AIS-5000643) and the respective surgical techniques.
- Ensure that the products and accessories are operated and used only by persons with the requisite training, knowledge, and experience.
- Read, follow, and keep the Instructions for Use.
- Remove the transport packaging and thoroughly clean the new product manually, prior to its initial sterilization, see reprocessing procedure.
- Store any new or unused products in a dry, clean, and safe place.
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Replace any damaged components immediately with original spare parts if available.

Safe Operation



Risk of injury and/or product malfunction!

- Always carry out a function check before using the product.

Distraction

- The desired distraction of the vertebral bodies can be achieved by using the A-Space SIBD Distractors (SJ020R – SJ030R).

The desired working height can be gradually achieved by coupling a Distractor to a T-Handle (SJ033R), inserting horizontally into the disc space and rotating by 90°.

Safe Operation



Risk of damage to the spinal cord, spinal nerve roots, adjacent intervertebral bodies or soft tissue when inserting and using the Distractor!

- Do not over insert the Distractor into the disc space.
- Do not over distract the disc space.

Selection of Implant Size Using Trial Implants

- Attach selected Trial Implant to the Trial Insertion Instrument (ME020R) by inserting the Instrument into the anterior face of the Trial Implant. Turn the wheel clockwise to engage the Trial Implant onto the Trial Insertion Instrument.
- To advance the Trial Implant into the disc space use either a mallet or a Slap Hammer Extension (SJ709R) assembled onto a Slap Hammer Handle (SJ708T).



Risk of over distracting, damaging the endplates, or adjacent vertebral bodies in the course of incorrectly applying the Trial Insertion Instrument.

- During the Trial Implant insertion, do not apply an excessive bending/ tilting/ levering force to the Trial Insertion Instrument (ME020R).
- Keep the instrument directly in the plane of the disc.

- Under lateral and anterior-posterior fluoroscopy confirm the:
 - o Implant depth, height, and lordosis.
 - o Endplate coverage (anterior-posterior / medial-lateral).
 - o Midline placement.
 - o Implant rotation.



If the Trial implant is inserted too deep there is a risk of damage to the spinal cord, spinal nerve roots, and posterior structures!

- Always use the Trial Insertion Instrument (ME020R) with a depth stop.
- Don't apply excessive hammering force.

- Select the implant size that corresponds with the final Trial Implant size chosen.



Risk of selecting incorrect implant size!

- Fluoroscopy is mandatory to confirm the final Trial Implant size.
- Trial Implant must provide good contact with the inferior and superior endplates. Therefore the proper footprint, height, and lordotic angle should be chosen for the disc space.

Filling the Implant

- The implant can be filled with bone or bone replacement material by using the Packing Block (SJ604R) and Tamp (SJ608R)

Implant Placement and Positioning

- Securely attach the implant (corresponding to the final Trial Implant size) to the distal end of the insertion instrument by turning the wheel clockwise.
- The laser markings (CRANIAL/CAUDAL) on the implant insertion instrument indicate the correct orientation for implant engagement.
 - The Implant Inserter/Manipulator (ME015R) will grip the implant utilizing the two lateral implant screw holes.
 - The Implant Introducer (SJ605R) will grip the implant utilizing the two medial implant screw holes.
- Use appropriate care when inserting the implant.
 - Drive the Implant into the disc space using either a mallet or the Slap Hammer Extension (SJ709R) assembled onto the Slap Hammer Handle (SJ708T).



Inaccurate marking of the midline may result in incorrect positioning of the implant.

- Always mark the midline under X-ray visualization.
- Determine the center of the vertebral disc using the midline marker, under X-Ray visualization.



If the implant is inserted too deep, the spinal canal and other posterior elements may be compressed!

- Always use the Implant Inserter/Manipulator (ME015R) with a depth stop.
- Excessive hammering may over-insert implant.

- Confirm an anatomically suitable position and orientation of the implant. It is recommended to confirm implant position prior to removing the implant inserter.
 - Obtain an AP fluoroscopic image to confirm midline placement of the device.
 - Obtain a lateral fluoroscopic image to confirm that the anterior edge of the implant is seated flush with the anterior border of the vertebral body.
 - Observe the X-Ray markers in both the AP and lateral views to ensure that the implant is not rotated within the disc space.
- Impactor (SJ606R) can be used to adjust the position (in AP direction) of the implant as necessary.

Bone Screw Placement

- The bone awl (Straight Bone Awl (ME017R) or U-Joint Bone Awl (ME190R) or Ball Joint Bone Awl (ME172R)) and the drills (Straight Drill (SJ725R) or U-Joint Drill (ME189R) or Ball Joint Drill (ME173R)) should be used to prepare a pilot hole for the bone screws at the intended screw placement site.
- Always use the Drills and Straight Bone Awl with the drill guides (Straight Drill Guide (SJ724R) or Angled Drill Guide (SJ722R)).



Risk of damaging biological structures (spinal cord, spinal nerve roots, ligaments, vessels, soft tissues, etc.) with the drills and the bone awls, especially if the PEEK cage is placed off midline!

- The instruments are sharp, always use the bone awls/drills under X-Ray control.



Risk of damaging biological structures (spinal nerve roots, ligaments, vessels, soft tissues, etc.) upon disengaging the instruments!

- The working end of the U-Joint Bone Awl (ME190R) or Ball Joint Bone Awl (ME172R) may elastically spring back to the original shape upon disengagement from the Implant and the working end the U-Joint Drill (ME189R) or Ball Joint Drill (ME173R) may elastically spring back to the original shape upon disengagement from the Angled Drill Guide (SJ722R).
- Follow the surgical technique, or training by Aesculap.



Risk of damaging biological structures (spinal cord, spinal nerve roots, ligaments, vessels, soft tissues, etc.) due to Straight Bone Awl tip or Straight Drill tip breaking!

- Do not apply an excessive compressive/hammering/bending/tilting/levering force to the bone awls and the drills.
- The bone awls and drills must be pushed/advanced by hand only.



Risk of damaging PEEK cage with incorrectly applied Straight Drill Guide (SJ724R)!

- Do not apply an excessive bending/ tilting/ levering force to the instrument.

- Attach bone screw of appropriate length to the selected self-retaining screwdriver (Straight Hex Screwdriver (ME016R) or Straight Ball Hex Screwdriver (ME013R), or when using the self-tapping screws: U-Joint Hexalobe Screwdriver (ME052R), Snake Driver (Hex) (ME176R), Ball Joint Screwdriver (ME174R), or Straight Hexalobe Screwdriver (ME054R).



Engaging the screwdriver incorrectly when turning the bone screw into the PEEK cage may result in damage to the bone screws!

- Fully insert the tip of the screwdriver into the bone screw.

- Place a bone screw through selected screw hole on the anterior face of the implant.



Risk of damaging biological structures (spinal cord, spinal nerve roots, ligaments, vessels, soft tissues, etc.) while advancing incorrectly sized bone screws, especially if the PEEK cage is placed off midline!

- Always advance the bone screws, especially the diverging lateral screws, under X-Ray control.
- Follow surgical technique, or training by Aesculap.

- Turn the screwdriver in a clockwise motion to advance the bone screw into the vertebral body.



Applying too much torque may result in damage to the bone screws and the PEEK cages!

- Use of the Torque Limiting Handle (ME012R) is recommended.



Risk of damage to the PEEK cage, or the bone screw head in the course of incorrectly driving the bone screw!

- Do not apply an excessive bending/ tilting/ levering force to the Straight Hex Screwdriver (ME016R), Straight Ball Hex Screwdriver (ME013R), U-Joint Hexalobe Screwdriver (ME052R), Snake Driver (Hex) (ME176R), Ball Joint Screwdriver (ME174R), or Straight Hexalobe Screwdriver (ME054R) engaged in the bone screw.
- Keep the screwdrivers directly aligned with the axis of the bone screws.

- Insert the bone screws until they reach the final seated position, ensuring full engagement of the two locking mechanisms.



The screws could back out or loosen if they are not fully inserted into the cage!

- Insert the bone screw until it is fully engaged.
- Follow surgical technique, or training by Aesculap.

- Repeat the bone screw placement steps outlined above to insert the remaining bone screws through the implant.



Risk of insufficient stability or implant failure if fewer than four screws are used!

- Apply all four screws or use an additional supplemental spinal fixation system such as the Aesculap Ennovate Spinal System.

Revision



Risk of compression screw removal failure if revision instrument is not used.

- Locate compression screw, which is to be revised, and engage revision instrument (ME078R). Ensure thread is engaged properly to avoid cross threading
 - Retract the bone screw from the vertebral body by applying an axial distraction force while turning the screw in a counterclockwise motion.
 - When removing the screw from the revision instrument, use FW076R to hold the screw.
 - Repeat the compression bone screw removal process with the remaining compression bone screws in the PEEK cage.
-
- Locate implant, which is to be revised, and engage selected self-retaining screwdriver Straight Hex Screwdriver (ME016R), Straight Ball Hex Screwdriver (ME013R), U-Joint Screwdriver (ME014R), U-Joint Hexalobe Screwdriver (ME052R), Ball Joint Hexalobe Screwdriver (ME174R), Snake Driver (Hex) (ME176R), or Straight Hexalobe Screwdrivers (ME054R). Remove the bone screw from the vertebral body by turning the screw in a counterclockwise motion.
 - For self-tapping screw engage the Revision Instrument (ME078R) and retract the bone screw from the vertebral body by turning the screw in a counterclockwise motion.
 - Repeat the bone screw removal process with the remaining bone screws in the PEEK cage.
 - Engage Implant Extraction Instrument (ME018R) or the Implant Insertor/Manipulator (ME015R) to the implant and remove it from the disc space.



Risk of injury to the patient!

- Remove implant in the direction it was inserted.
- Excessive force during extraction may cause implant to dislodge suddenly and impact the surrounding tissues.

Note: If a fully seated bone screw is removed from the implant, a small piece of PEEK debris from the locking rim in the locking mechanism may be present.

General

- Caution should be taken while operating the instruments with quick connect modular handles: T-Handle (SJ033R), Handle (FW440R), Ratchet Handle (SJ705R), Slap Hammer Handle (SJ708T) and Torque Limiting Handle (ME012R).



Activating the “PRESS” button on the handle while actively using the instruments can result in the instrument shaft detaching from the handle!

- Do not cover the “PRESS” button with hand when utilizing fully assembled instruments.

- Caution should be taken for assembling the following modular instruments: Implant Inserter/Manipulator (ME1015R), Implant Introducer (SJ605R), U-Joint Drill (ME189R), ALIF U-Joint Bone Awl (ME190R), U-Joint Drill (ME189R), Flexible Drill (SJ723R), Straight Ball Hex Screwdriver (ME013R), Straight Hex Screwdriver (ME016R), U-Joint Screwdriver (ME014R), U-Joint Hexalobe Screwdriver (ME052R), Revision Instrument (ME078R), Implant Extraction Instrument (ME018R).

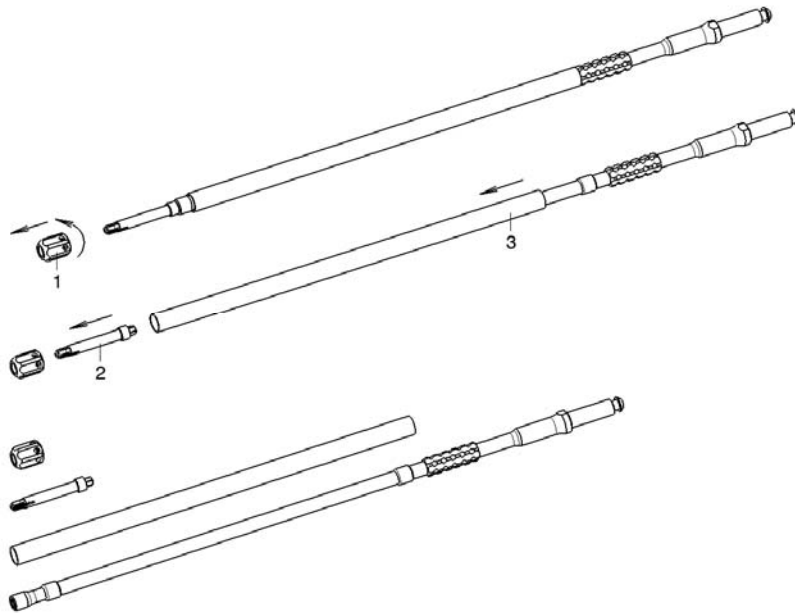


Risk of not being able to securely engage implant or damaging the instrument with incorrectly assembled Implant Inserter/Manipulator (ME015R) or Introducer (SJ605R)!

- Ensure that the instruments are correctly assembled prior to the surgery.

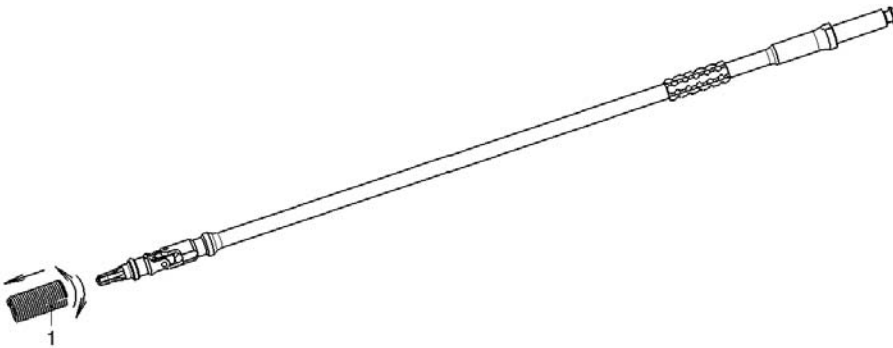
Disassembling

Straight Ball Hex Screwdriver (ME013R) and Straight Hex Screwdriver (ME016R):

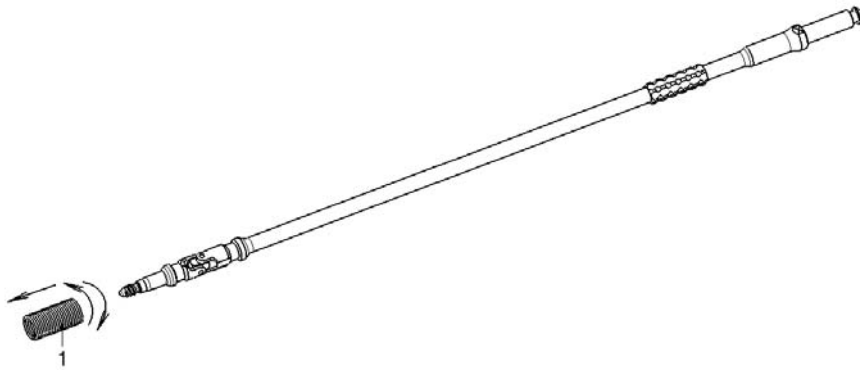


Unthread the nut [1] from the distal end of the shaft. Remove the screwdriver bit [2] from the shaft. Remove the soft tissue protection sleeve [3] from the shaft.

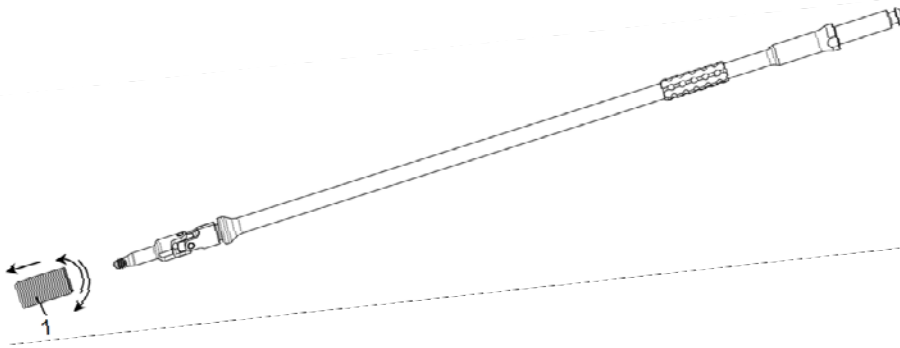
U-Joint screwdriver (ME014R), Implant Extraction Instrument (ME018R), Revision Instrument (ME078R) and ALIF U-Joint Bone Awl (ME190R):



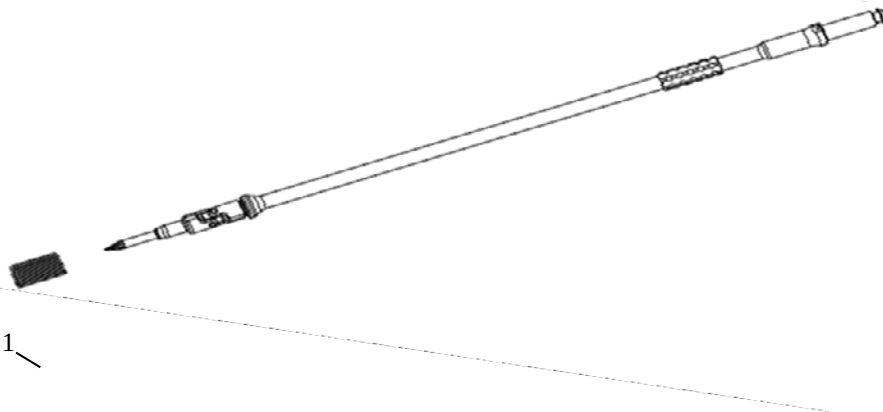
ME014R



ME018R



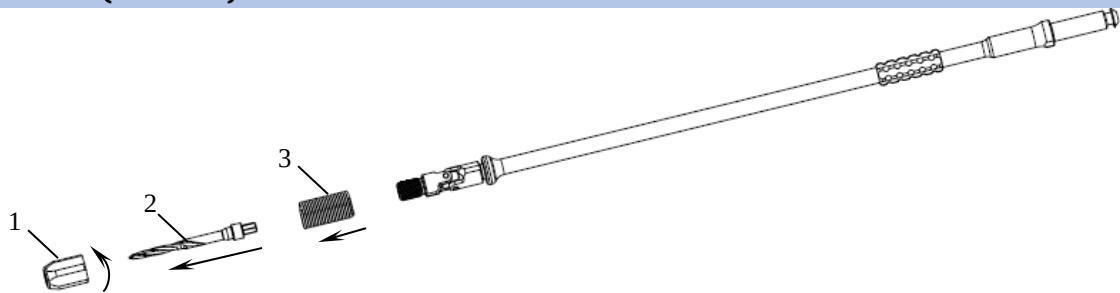
ME078R



ME190R

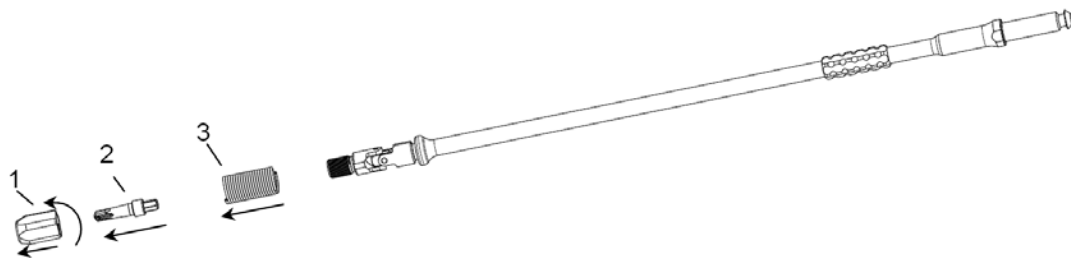
Remove the spring [1] covering the u-joint from the distal end of the shaft.

U-Joint Drill (ME189R):



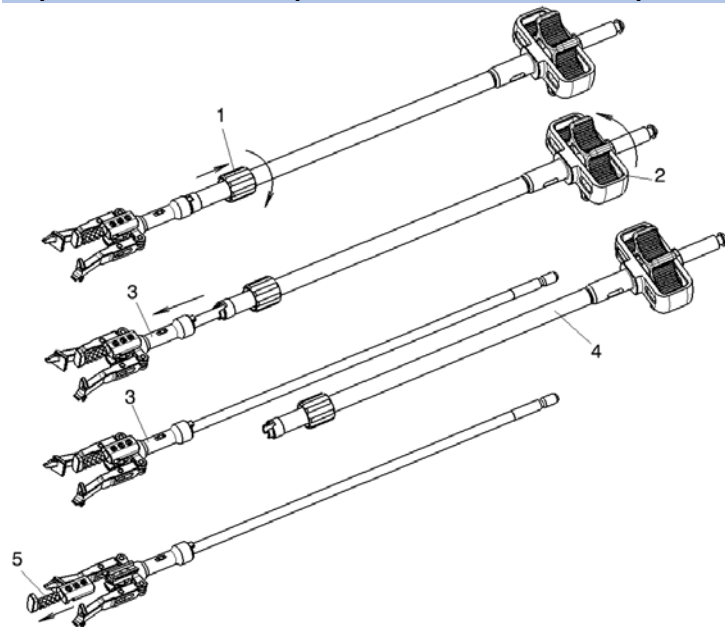
Unthread the nut [1] from the distal end of the shaft. Remove the drill bit [2] from the shaft end and slide the spring off the U-joint [3].

U-Joint Hexalobe Screwdriver (ME052R):

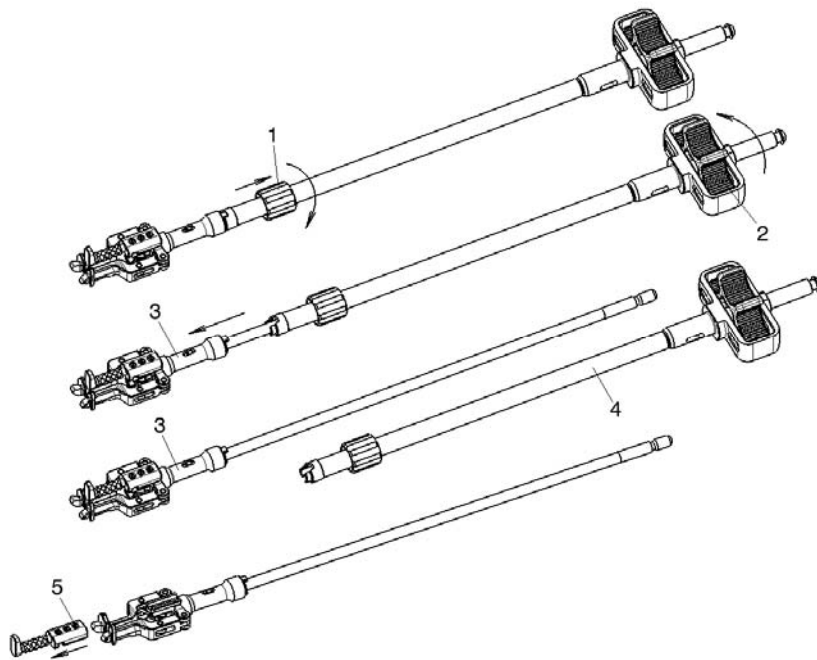


Unthread collar (1) and remove. Remove hexalobe bit (2) and spring (3).

Implant Inserter Manipulator (ME015R) and Implant Introducer (SJ605R):



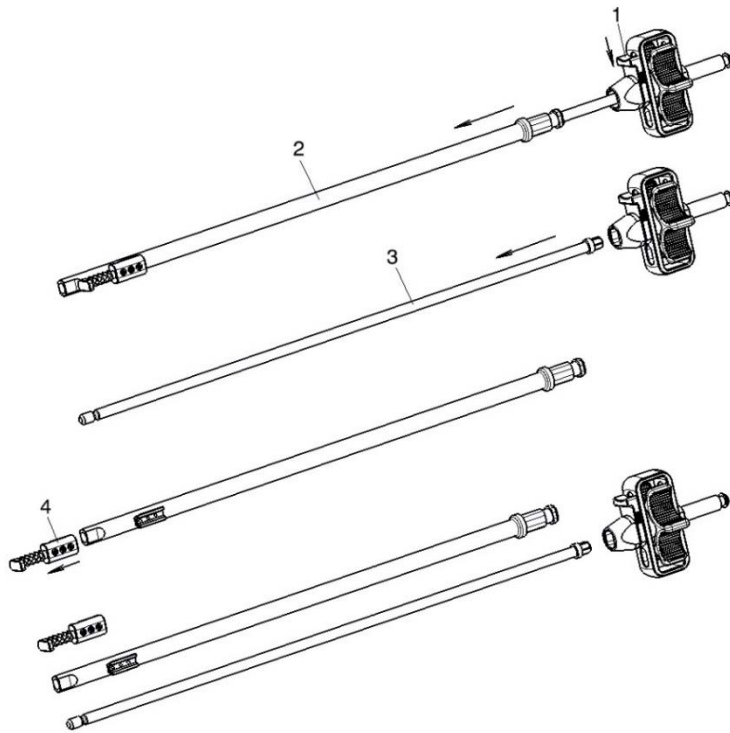
ME159R



SJ605R

While holding the proximal end (mechanism with thumb wheel) upright, unthread the nut [1] counterclockwise towards the proximal end. With the nut disengaged from its threading, turn the thumb wheel [2] clockwise ("LOCK" - direction) until the sub-assembly [3] disengages from the outer sheath [4]. Pull out the sub-assembly [3] from the outer sheath [4]. Remove the depth stopper [5] by pushing it distally parallel along the shaft until it disengages from its rail.

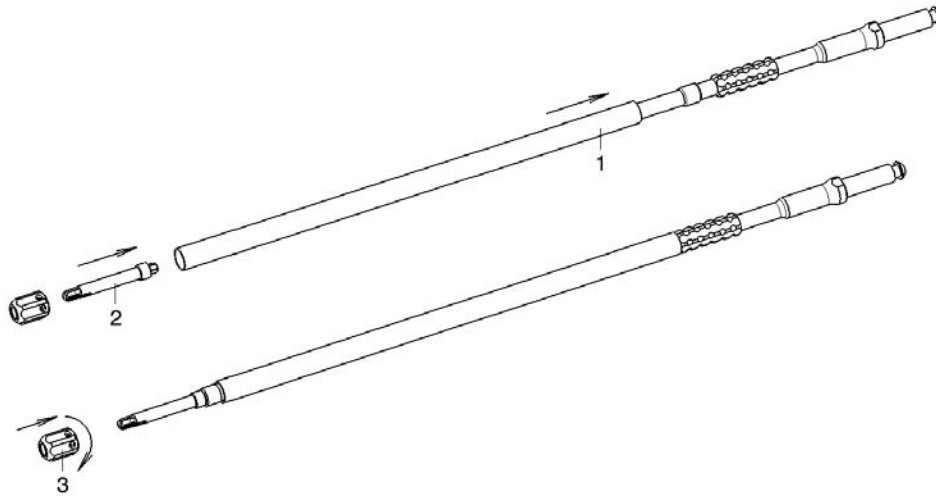
Trial Insertion Instrument (ME020R):



Press the locking mechanism button [1] near the thumb wheel and pull out the outer sheath [2]. Remove the inner shaft [3] from the thumb wheel. Remove the depth stopper [4] by pushing it distally parallel along the shaft until it disengages from its rail.

Assembling

Straight Ball Hex Screwdriver (ME013R) and Straight Hex Screwdriver (ME016R):



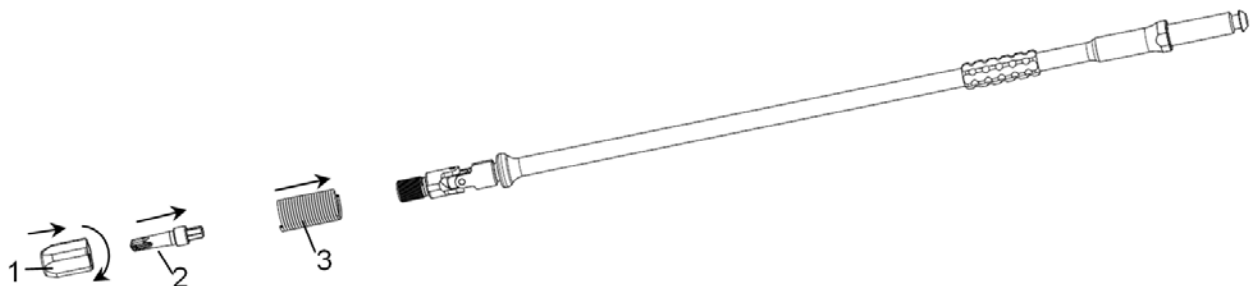
Place the soft tissue protection sleeve [1] over the inner shaft. Insert the screwdriver bit [2] into the internal hexagon of the distal end of the shaft. Firmly thread the nut [3] proximally over the screwdriver bit until it is fully threaded.



Danger from improperly assembled Straight Hex Screwdriver (ME016R) or Straight Ball Hex Screwdriver (ME013R): the screwdriver bit may disengage from the instrument shaft during shipment or operation!

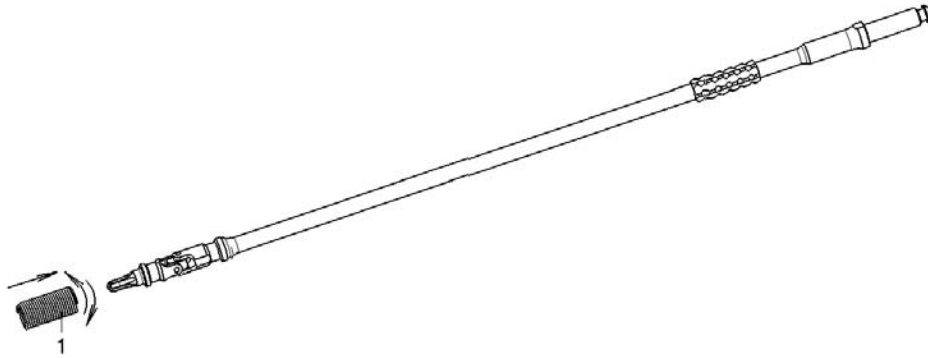
- Ensure the screwdriver bit [2] is secured to the shaft, by firmly tightening the nut [3] until it is fully threaded.

U-Joint Hexalobe Screwdriver (ME052R):

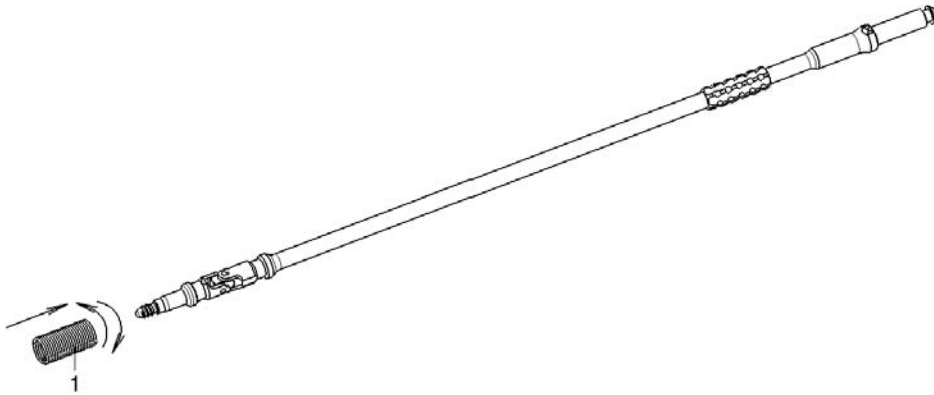


Slide the spring over the u-joint (3). Insert the screwdriver bit (2) into the internal hexagon of the distal end of the shaft. Firmly thread the nut (1) proximally over the screwdriver bit until it is fully threaded.

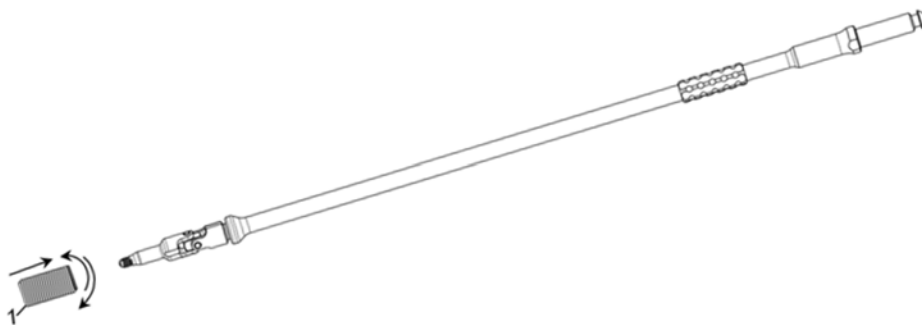
U-Joint screwdriver (ME014R), U-Joint Revision instrument (ME078R), Implant Extraction Instrument (ME018R), and ALIF U-Joint Bone Awl (ME190R):



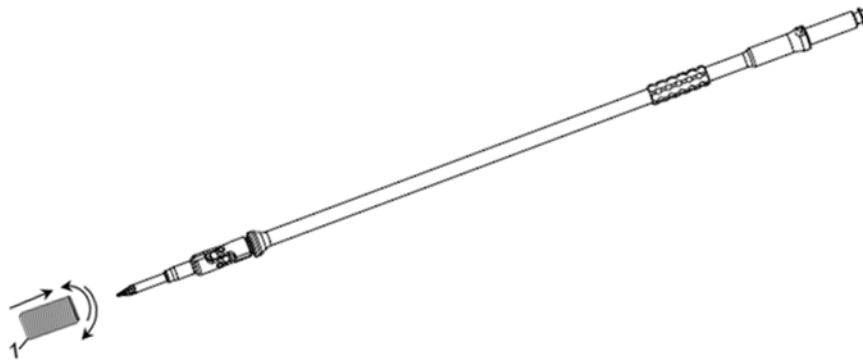
ME014R



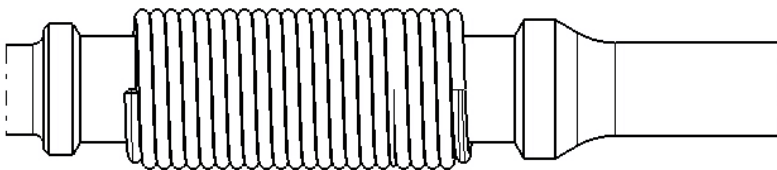
ME018R



ME078R

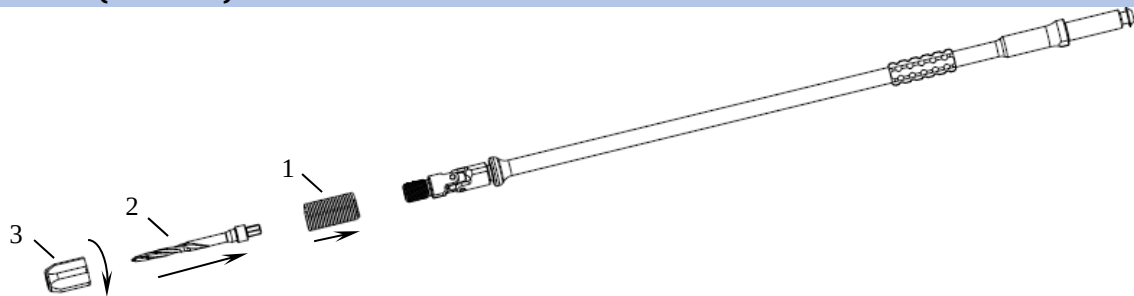


ME190R



Slide the spring [1] over the distal end until it is completely covering the u-joint. The ends of the spring should sit within the flange on the shaft and the flange on the distal head.

U-Joint Drill (ME189R):



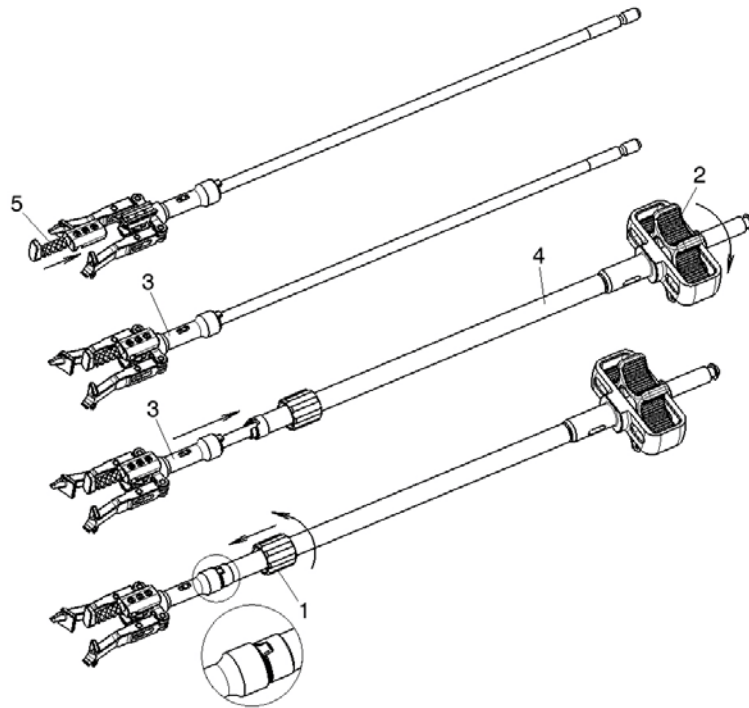
Slide spring [1] over u-joint. Insert the drill bit [2] into the internal hexagon of the distal end of the shaft. Firmly thread the nut [3] over the drill bit towards the proximal end until it is fully threaded.



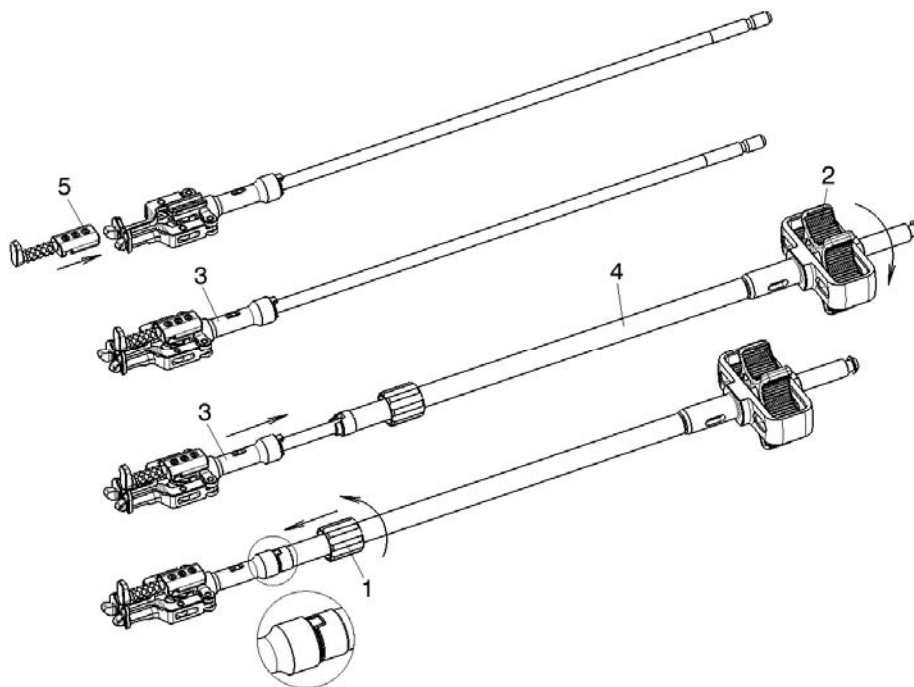
Danger from improperly assembled U-Joint Drill (ME189R): the drill bit may disengage from the instrument shaft during shipment or operation!

- Ensure that the drill bit [2] is secured to instrument shaft, by firmly tightening the nut [3] until it is fully threaded.

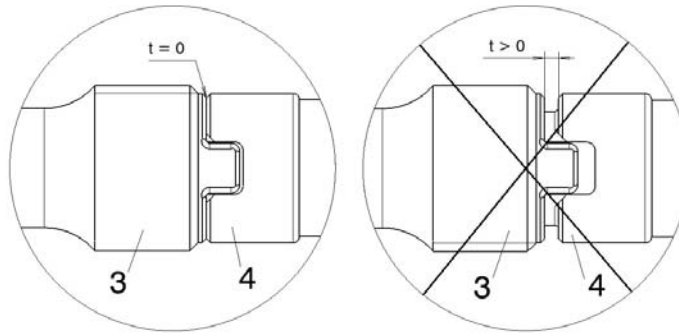
Implant Inserter Manipulator (ME015R) and Implant Introducer (SJ605R):



ME015R



SJ605R



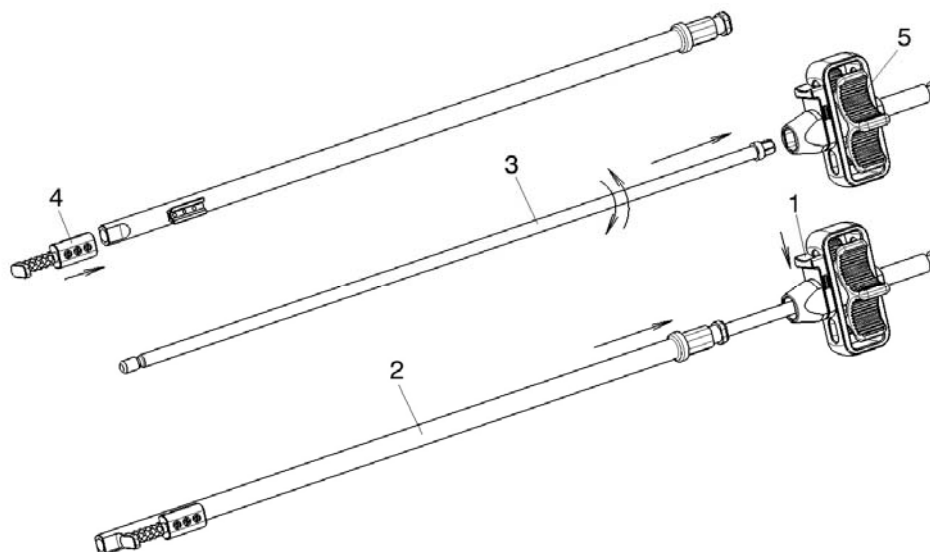
Place the depth stopper [5] on its rail and press it proximally along the shaft until it is fully engaged. Insert the sub-assembly [3] all the way into the outer sheath [4]. Start turning the thumb wheel [2] counterclockwise (“RELEASE” - direction) while pressing the sub-assembly towards the thumb wheel. The threads between the end of the sub-assembly shaft and the inner thread in the thumb wheel will start to engage. Continue turning the thumb wheel until the protrusions of the sub-assembly are flush with the slots in the outer sheath. Visually verify that both components ([3] and [4]) are fully engaged (see picture above for correct and incorrect engagement). Firmly thread the nut [1] towards the distal end until it is fully threaded.



Risk of not being able to securely engage the implant or damaging the instrument with incorrectly assembled Implant Inserter/Manipulator (ME015R) or Introducer (SJ605R)!

- Ensure that there is no gap between components [3] and [4].
- Firmly tighten the nut [1] until it is fully threaded.

Trial Insertion Instrument (ME020R):



Place the depth stop [4] on its rail and press it proximally along the shaft until it is fully engaged. Insert the hexagonal end of the inner shaft [3] into the inner hexagon of the thumb wheel [5]. Place the outer sheath [2] over the inner shaft [3]. Press the locking mechanism button [1] and fully insert the outer sheath into the locking mechanism (until it reaches the hard stop). Release the button [1].

Reprocessing Procedure

General Safety Instructions

- Note** Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.
- Note** For patients with Creutzfeldt-Jakob-Disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of products.
- Note** Mechanical processing should be favored over manual cleaning as it gives better and more reliable results.
- Note** Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this. The recommended chemistry was used for validation
- Note** For the latest information on reprocessing and material compatibility, see reprocessing brochure at Aesculap® US website www.aesculapimplantsystems.com.

General Information

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore the time interval between application and processing should not exceed 6 h. Neither pre-cleaning fixation temperatures >45 °C/113°F nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) should be used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or to fading and the laser marking becoming unreadable visually or by machine for stainless steel.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfection and sterilization will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Only process chemicals that have been tested and approved (e.g. FDA clearance) and which are compatible with the product's materials according to the chemical manufacturers' recommendations may be used for processing the product. All the chemical manufacturer's application specifications must be strictly observed. Failure to do so can result in the following problems:

- Optical changes of materials, e.g., fading or discoloration of titanium or aluminum. For aluminum, the application/process solution only needs to be of pH >8 to cause visible surface changes.
- Material damage such as corrosion, cracks, fracturing, premature aging or swelling.
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

Disassembling the product before reprocessing

- Disassemble the product (if applicable) immediately after use, as described in the respective Disassembly section of the Instructions for Use.

Preparations at the place of use

- Clean instruments as quickly as possible after usage.
- Prevent any significant contaminants from drying onto the instrument surface prior to cleaning.
- If applicable, rinse non-visible surfaces preferably with deionized water, e.g. with a disposable syringe.
- Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.
- Transport the dry product in a sealed waste container, for cleaning and disinfection within 6 h.

Preparation before cleaning

- Inspect tray to insure all debris have been removed.
- Repeat as many times as necessary until no visible debris remains in the tray.
- Disassemble each product (if applicable) prior to cleaning, see Disassembly section.

Cleaning & Disinfection

Product-specific safety notes on the reprocessing procedure



Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- Use cleaning and disinfecting agents, according to the manufacturer's instructions, which
 - are approved for plastics and high-grade steel.
 - do not degrade softeners (e.g. silicone).
- Observe specifications regarding concentration, temperature and exposure time.
- Do not exceed the maximum allowable washing temperature.



Risk to patients!

- The Ratchet Handle (SJ705R), Slap Hammer Handle (SJ708T), Slap Hammer Extension (SJ709R), Torque Limiting Handle (ME012R), Implant Inserter Manipulator (ME015R), Implant Introducer (SJ605R), Straight Drill Guide (SJ724R), and Trial Insertion Instrument (ME020R) must only be cleaned mechanically.

- Use suitable cleaning/disinfecting agents if the product is put away in a wet condition. Rinse the product thoroughly with water prior to mechanical cleaning and disinfecting in order to prevent foam formation and reduced effectiveness of the process chemicals.
- Carry out ultrasound cleaning:
 - as an effective mechanical supplement to manual cleaning/disinfecting.
 - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfecting.
 - as an integrated mechanical support measure for mechanical cleaning/disinfecting.
 - for additional cleaning of products with residues left after mechanical cleaning/disinfecting.

Validated Cleaning & Disinfection Procedures

Note Reprocessing may only take place with the following listed procedures in Version V6. These are documented in Validated Reprocessing Procedures brochure (AVA-V6). See Aesculap site www.aesculapimplantsystems.com (US website) for reprocessing brochure.

Validated Procedure	Devices	Specific Requirements	Reference
Manual Cleaning with Immersion Disinfection	ME189R, ME190R, ME172R, ME173R, ME174R, ME078R, ME052R, SJ604R, SJ608R, SJ606R, SJ664T-SJ798T, SJ020R-SJ030R, SJ724R, SJ722R, ME628R-ME633R	• Disposable syringe 20ml • Cleaning brush: TA011944, TTE654202, or GK469200 • When cleaning products with movable hinges, ensure these are in an open position; move joint while cleaning • Drying phase: Use lint-free cloth or medical compressed air	<i>Chapter:</i> Validated Cleaning/Disinfection Procedures <i>Sub-Chapter:</i> Manual Cleaning with Immersion Disinfection
Manual Cleaning with Immersion Disinfection with Pre-Soak	SJ725R, ME017R, ME054R, ME020R, SJ708R, SJ709R	• Disposable syringe 20ml • Cleaning brush: TA011944, TTE654202, or GK469200 • When cleaning products with movable hinges, ensure these are in an open position; move joint while cleaning • Drying phase: Use lint-free cloth or medical compressed air	<i>Chapter:</i> Validated Cleaning/Disinfection Procedures <i>Sub-Chapter:</i> Manual Cleaning with Immersion Disinfection with Pre-Soak
Manual Cleaning with Ultrasound & Immersion Disinfection	ME015R, ME013R, ME014R, ME016R, ME018R, ME176R, SJ723R, SJ607R, FW440R, SJ033R, SJ705R, ME012R, SJ605R	• Disposable syringe 20ml • Cleaning brush: TA011944, TTE654202, or GK469200 • When cleaning products with movable hinges, ensure these are in an open position; move joint while cleaning • Drying phase: Use lint-free cloth or medical compressed air	<i>Chapter:</i> Validated Cleaning/Disinfection Procedures <i>Sub-Chapter:</i> Manual Cleaning with Ultrasound & Immersion Disinfection
Manual Pre-Cleaning with Immersion & subsequent Mechanical Cleaning	ME189R, ME190R, ME172R, ME173R, ME174R, ME078R, ME052R, SJ725R, ME017R, ME054R, SJ604R, SJ608R, SJ606R, SJ664T-SJ798T, SJ020R-SJ030R, SJ724R, SJ722R, ME628R-ME633R	• Disposable syringe 20ml • Cleaning brush: TA011944, TTE654202, or GK469200 • When cleaning products with movable hinges, ensure these are in an open position; move joint while cleaning • Place products in tray suitable for cleaning (avoid rinsing blind spots) with any hinges open.	<i>Chapter:</i> Validated Cleaning/Disinfection Procedures <i>Sub-Chapter:</i> Manual Pre-Cleaning with Immersion & Subsequent Mechanical Cleaning
Manual Pre-Cleaning with Immersion & subsequent Mechanical Cleaning with Pre-Soak	ME020R, SJ708R, SJ709R	• Disposable syringe 20ml • Cleaning brush: TA011944, TTE654202, or GK469200 • When cleaning products with movable hinges, ensure these are in an open position; move joint while cleaning • Place products in tray suitable for cleaning (avoid rinsing blind spots) with any hinges open.	<i>Chapter:</i> Validated Cleaning/Disinfection Procedures <i>Sub-Chapter:</i> Manual Pre-Cleaning with Immersion & Subsequent Mechanical Cleaning with Pre-Soak
Manual Pre-Cleaning with Ultrasound &	ME015R, ME013R, ME014R, ME016R, ME018R, ME176R, SJ723R, SJ607R,	• Disposable syringe 20ml • Cleaning brush: TA011944, TTE654202, or GK469200	<i>Chapter:</i> Validated Cleaning/Disinfection Procedures

subsequent Mechanical Cleaning	FW440R, SJ033R, SJ705R, ME012R, SJ605R	Place products in a tray suitable for cleaning (avoid rinsing blind spots) with any hinges open.	<i>Sub-Chapter:</i> Manual Pre-Cleaning with Ultrasound & Subsequent Mechanical Cleaning
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- Prior to manual disinfection, allow water to drip off for a sufficient length of time to prevent dilution of the disinfecting solution.
- After manual cleaning/disinfection, check visible surface for residues.
- Repeat the cleaning/disinfection process if necessary.

Manual Cleaning with Immersion Disinfection

ME189R, ME190R, ME172R, ME173R, ME174R, ME078R, ME052R, SJ604R, SJ608R, SJ606R, SJ664T-SJ798T, SJ020R-SJ030R, SJ724R, SJ722R, ME628R-ME633R, SJ725R*, ME017R*, ME054R*, ME020R*, SJ708R*, SJ709R*

Phase	Step	T [°F/°C]	t [min]	Conc. [%]	Water Quality	Chemical
I	Pre-Cleaning	RT (cold)	>15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ¹
II	Intermediate rinse	RT (cold)	1	-	D-W	-
III	Disinfection	RT (cold)	15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ²
IV	Final rinse	RT (cold)	1	-	Distilled Water	-
V	Drying	RT	-	-	-	-

D-W: Drinking water

RT: Room temperature

¹Recommended: Steris Polystica 2x concentrate enzymatic presoak and cleaner

²Recommended: Steris Polystica 2x concentrate neutral detergent

³Prepare according to manufacturer's instructions

- Note information on appropriate cleaning brushes and disposable syringes. See Cleaning & Disinfection Procedures section.

*Pre-Soak

- If an instrument is denoted with a *, follow the pre-soak step.
- Prior to manual cleaning with immersion, completely immerse parts in an appropriate enzymatic manual cleaning solution and allow to soak for 4 minutes.

Phase I

- Fully immerse the product in a prepared room temperature enzymatic detergent solution (Recommended: Steris Polystica) for at least 15 min. Ensure all accessible surfaces are moistened.
- Rinse lumens at least five times with disposable syringe (20ml). Ensure that all accessible surfaces are moistened.
- Thoroughly clean the product with a suitable soft bristled brush in the solution until all discernible residues have been removed from the surface.
- Brush any non-visible surfaces with a suitable soft-bristled brush for ≥1 min.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- Thoroughly rinse these components with the cleaning disinfectant solution ≥ 5x with a disposable syringe.

Phase II

- Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Drain any remaining water fully.

Phase III

- Fully immerse the product in the disinfectant solution (Recommended: Steris Prolystica).
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Visually inspect all lumens and gaps to ensure there is no remaining contamination.
- Thoroughly rinse these components with the cleaning solution (≥ 5 times), using a disposable syringe (20 ml). Ensure all accessible surfaces are moistened.

Phase IV

- Rinse/flush the product thoroughly (all accessible surfaces) under running desalinated water.
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse lumens with a disposable syringe (20 ml) at least five times.
- Drain any remaining water fully.

Phase V

- Dry the product in the drying phase with suitable equipment (e.g. lint-free cloth, compressed filtered air), see Cleaning & Disinfection Procedures.

Manual Cleaning with Ultrasound & Immersion Disinfection

ME015R, ME013R, ME014R, ME016R, ME018R, ME176R, SJ723R, SJ607R, FW440R, SJ033R, SJ705R, ME012R, SJ605R

Phase	Step	T [°F/°C]	t [min]	Conc. [%]	Water Quality	Chemical
I	Pre-Cleaning	RT (cold)	>15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ¹
II	Intermediate rinse	RT (cold)	1	-	D-W	-
III	Ultrasonic Cleaning	RT (cold)	15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ²
IV	Final rinse	RT (cold)	1	-	Distilled Water	-
V	Drying	RT	-	-	-	-

D-W: Drinking water

RT: Room temperature

¹Recommended: Steris Prolystica 2x concentrate enzymatic presoak and cleaner

²Recommended: Steris Prolystica 2x concentrate neutral detergent

³Prepare according to manufacturer's instructions

- Note information on appropriate cleaning brushes and disposable syringes. See Validated Cleaning/Disinfection Procedures section.

Phase I

- Fully immerse the product in a prepared room temperature enzymatic detergent solution (Recommended: Steris Prolystica) for at least 15 min. Ensure all accessible surfaces are moistened.
- Rinse lumens at least five times with a disposable syringe (20ml). Ensure all accessible surfaces are moistened.
- Thoroughly clean the product with a suitable soft bristled brush in the solution until all discernible residues have been removed from the surface.
- Brush any non-visible surfaces with a suitable soft-bristled brush for ≥ 1 min.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- Thoroughly rinse these components with the cleaning disinfectant solution $\geq 5x$ with a disposable syringe.

Phase II

- Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Drain any remaining water fully.

Phase III

- Prepare neutral detergent (Recommended: Steris Prolystica) in an ultrasonic cleaning bath.
- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure all accessible surfaces are immersed and acoustic shadows are avoided.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Visually inspect all lumens and gaps to ensure there is no remaining contamination.
- Thoroughly rinse these components ≥ 5 times with the cleaning solution, using a disposable syringe (20 ml). Ensure all accessible surfaces are moistened.

Phase IV

- Rinse/flush the product thoroughly (all accessible surfaces) under running desalinated water.
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse lumens with a disposable syringe (20 ml) at least five times.
- Drain any remaining water fully.

Phase V

- Dry the product in the drying phase with suitable equipment (e.g. lint-free cloth, compressed filtered air), see Cleaning & Disinfection Procedures.

Manual Pre-Cleaning with Immersion & Subsequent Mechanical Cleaning

ME189R, ME190R, ME172R, ME173R, ME174R, ME078R, ME052R, SJ725R, ME017R, ME054R, SJ604R, SJ608R, SJ606R, SJ664T-SJ798T, SJ020R-SJ030R, SJ724R, SJ722R, ME628R-ME633R, ME020R*, SJ708R*, SJ709R*

Phase	Step	T [°F/°C]	t [min]	Conc. [%]	Water Quality	Chemical
I	Pre-Cleaning	RT (cold)	>15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ¹
II	Intermediate rinse	RT (cold)	1	-	D-W	-

III	Disinfection	RT (cold)	15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ²
IV	Rinse	RT (cold)	1	-	Distilled Water	-
V	Wash Phase I	131/55	5	See # ³	D-W	Aldehyde-free, phenol-free, QUAT-free enzymatic cleaner, pH 6-8.5 ^{1,4}
VI	Wash Phase II	131/55	3	-	T-W	Aldehyde-free, phenol-free, QUAT-free neutral detergent, pH 6-8.5 ^{2,4}
VII	Rinse	194/90	2	See # ³	Distilled Water	-
VIII	Drying	194/90	10	-	-	-

D-W: Drinking water

T-W: Tap water

RT: Room temperature

¹Recommended: Steris Prolystica 2x concentrate enzymatic presoak and cleaner

²Recommended: Steris Prolystica 2x concentrate neutral detergent

³Prepare according to manufacturer's instructions

⁴Always follow the manufacturer's specifications for automatic washer-sterilizers and use a free-rinsing, low sudsing detergent with a neutral pH (6.0-8.5). Due to variations in water quality, the type of detergent and its concentrations may require adjustment for optimal disinfection and cleaning.

*Pre-Soak

- If an instrument is denoted with a *, follow the pre-soak step.
- Prior to manual cleaning with immersion, completely immerse parts in an appropriate enzymatic manual cleaning solution and allow to soak for 4 minutes.

Phase I

- Fully immerse the product in a prepared room temperature enzymatic detergent solution (Recommended: Steris Prolystica) for at least 15 min. Ensure all accessible surfaces are moistened.
- Rinse lumens at least five times with disposable syringe (20ml). Ensure that all accessible surfaces are moistened.
- Thoroughly clean the product with a suitable soft bristled brush in the solution until all discernible residues have been removed from the surface.
- Brush any non-visible surfaces with a suitable soft-bristled brush for ≥1 min.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- Thoroughly rinse these components with the cleaning disinfectant solution ≥ 5x with a disposable syringe.

Phase II

- Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Drain any remaining water fully.

Phase III

- Fully immerse the product in the disinfectant solution (Recommended: Steris Prolystica).
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Visually inspect all lumens and gaps to ensure there is no remaining contamination.
- Thoroughly rinse these components with the cleaning solution (≥ 5 times), using a disposable syringe (20 ml). Ensure all accessible surfaces are moistened.

Phase IV

- Rinse/flush the product thoroughly (all accessible surfaces) under running desalinated water.
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse lumens with a disposable syringe (20 ml) at least five times.
- Drain any remaining water fully.

Phases V–VIII (Washer Disinfector)

- Place the products in a tray that is suitable for cleaning (avoiding rinsing blind spots).
- Place any hinged instruments in the tray with their hinges open.
- Check visible surfaces for residues after mechanical cleaning/disinfection.

Manual Pre-Cleaning with Ultrasound & Subsequent Mechanical Cleaning

ME015R, ME013R, ME014R, ME016R, ME018R, ME176R, SJ723R, SJ607R, FW440R, SJ033R, SJ705R, ME012R, SJ605R

Phase	Step	T [°F/°C]	t [min]	Conc. [%]	Water Quality	Chemical
I	Pre-Cleaning	RT (cold)	>15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ¹
II	Intermediate rinse	RT (cold)	1	-	D-W	-
III	Ultrasonic Cleaning	RT (cold)	15	See # ³	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH 6-8.5 ²
IV	Rinse	RT (cold)	1	-	Distilled Water	-
V	Wash Phase I	131/55	5	See # ³	D-W	Aldehyde-free, phenol-free, QUAT-free enzymatic cleaner, pH 6-8.5 ^{1,4}
VI	Wash Phase II	131/55	3	-	T-W	Aldehyde-free, phenol-free, QUAT-free neutral detergent, pH 6-8.5 ^{2,4}
VII	Rinse	194/90	2	See # ³	Distilled Water	-
VIII	Drying	194/90	10	-	-	-

D-W: Drinking water

T-W: Tap water

RT: Room temperature

¹Recommended: Steris Prolystica 2x concentrate enzymatic presoak and cleaner

²Recommended: Steris Prolystica 2x concentrate neutral detergent

³Prepare according to manufacturer's instructions

⁴Always follow the manufacturer's specifications for automatic washer-sterilizers and use a free-rinsing, low sudsing detergent with a neutral pH (6.0-8.5). Due to variations in water quality, the type of detergent and its concentrations may require adjustment for optimal disinfection and cleaning.

Phase I

- Fully immerse the product in a prepared room temperature enzymatic detergent solution (Recommended: Steris Prolystica) for at least 15 min. Ensure all accessible surfaces are moistened.
- Rinse lumens at least five times with a disposable syringe (20ml). Ensure all accessible surfaces are moistened.
- Thoroughly clean the product with a suitable soft bristled brush in the solution until all discernible residues have been removed from the surface.
- Brush any non-visible surfaces with a suitable soft-bristled brush for ≥ 1 min.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- Thoroughly rinse these components with the cleaning disinfectant solution ≥ 5 x with a disposable syringe.

Phase II

- Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Drain any remaining water fully.

Phase III

- Prepare neutral detergent (Recommended: Steris Prolystica) in an ultrasonic cleaning bath.
- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure all accessible surfaces are immersed and acoustic shadows are avoided.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Visually inspect all lumens and gaps to ensure there is no remaining contamination.
- Thoroughly rinse these components ≥ 5 times with the cleaning solution, using a disposable syringe (20 ml). Ensure all accessible surfaces are moistened.

Phase IV

- Rinse/flush the product thoroughly (all accessible surfaces) under running desalinated water.
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse lumens with a disposable syringe (20 ml) at least five times.
- Drain any remaining water fully.

Phases V–VIII (Washer Disinfector)

- Place the products in a tray that is suitable for cleaning (avoiding rinsing blind spots).
- Place any hinged instruments in the tray with their hinges open.
- Check visible surfaces for residues after mechanical cleaning/disinfection.

Inspection, Maintenance, and Functional Checks



Damage (metal seizure/friction corrosion) to the product caused by insufficient lubrication!

- Prior to function checks, lubricate moving parts (e.g., joints, pusher components and threaded rods) at the marked lubrication points, using maintenance oil suitable for the respective sterilization process

- Allow the product to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the product is: dry, clean, operational, and free of damage (e.g., broken insulation or loose, bent, broken, cracked, worn, or fractured components).
- Dry the product if it is wet or damp.
- Repeat cleaning and disinfecting of products that still show impurities or contamination.
- Check that the product functions correctly.
- Immediately put aside damaged or inoperative products and sent them to Aesculap Technical Service, see Technical Service.
- Assemble dismountable products, see Assembling.
- Check for compatibility with associated products.

Packaging

- Appropriately protect products with fine working tips for the following instruments: SJ607R, ME017R, SJ723R, SJ725R, SJ706R, ME013R, ME014R, ME016R, ME189R and ME190R.
- Place the product in its holder or on a suitable tray. Ensure that all cutting edges are protected.
- Pack trays appropriately for the intended sterilization process (e.g., in Aesculap sterile containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

Steam Sterilization

- Aesculap® advises against sterilizing the device by immediate use steam sterilization (e.g. “flash” sterilization) or chemical sterilization.
- Sterilization may be accomplished by a standard pre-vacuum cycle in a steam autoclave.
- Do not stack containers during sterilization.

To achieve a sterility assurance level of 10^{-6} , Aesculap recommends the following parameters:

Aesculap Orga™ Tray/Sterile container (perforated bottom)			
Minimum cycle parameters*			
Sterilization Method	Temp. °F/°C	Time	Minimum Drying Time
Pre-vacuum	270/132	4 min	30 min

*Aesculap® has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap® sterile container cleared by FDA for the sterilization and storage of these instruments. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. Use an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.

- When sterilizing several products at the same time in a steam sterilizer, ensure that the maximum load capacity of the steam sterilizer specified by the manufacturer is not exceeded.



If this 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.

Disposal

- Adhere to national regulations when disposing of or recycling the products, their components and all packaging!

Technical Service



Risk of injury and/or product malfunction!

- Do not modify the product.

If any Arcadius^{XP} L Spinal System instrument or its components require repair or maintenance, return the entire instrument set in a sturdy box with adequate foam, bubble wrap, or other packaging material to protect it.

Instruments returned to Aesculap Implant Systems, LLC for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Send the packaged instrument to:

Aesculap Implant Systems, LLC
Attn. Aesculap Technical Services
615 Lambert Point
Hazelwood, St. Louis, MO 63042

Aesculap® Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (314) 895-4420



FEDERAL LAW RESTRICTS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Product Information and Complaints

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