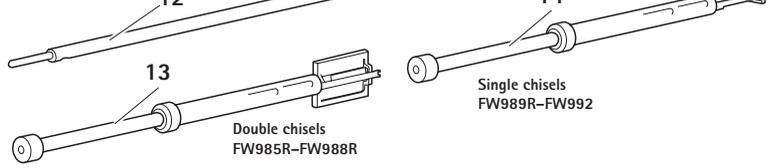
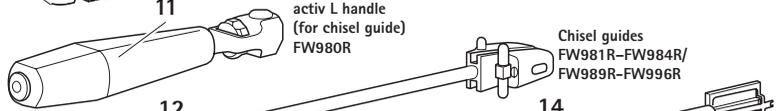
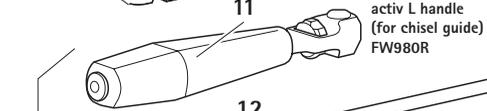
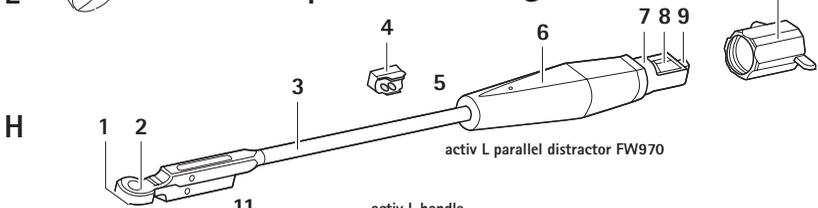
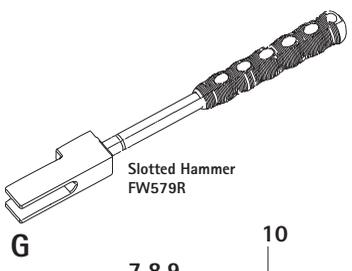
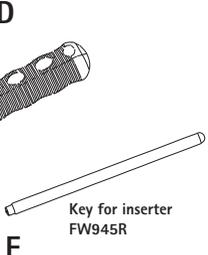
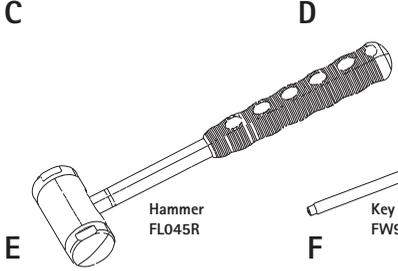
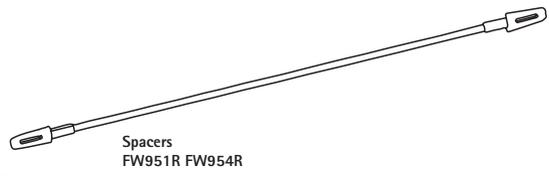
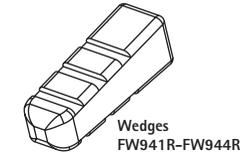
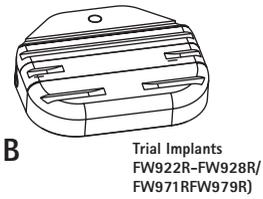
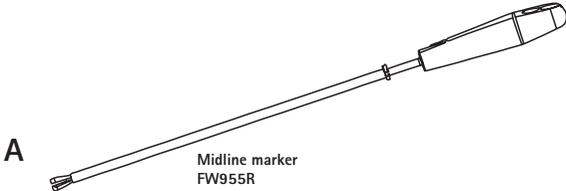
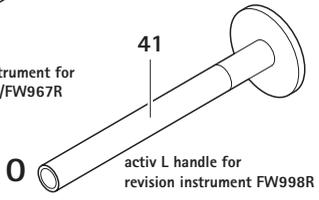
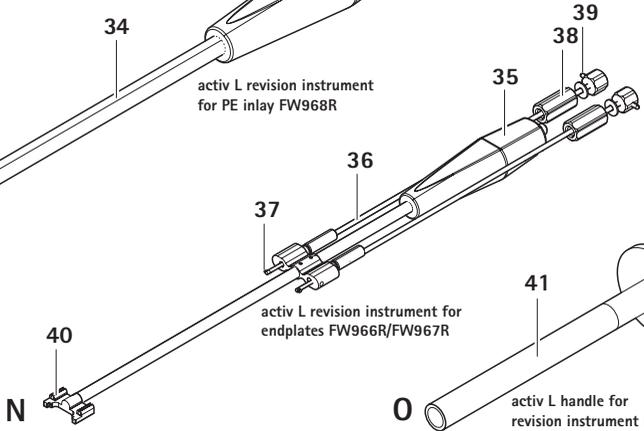
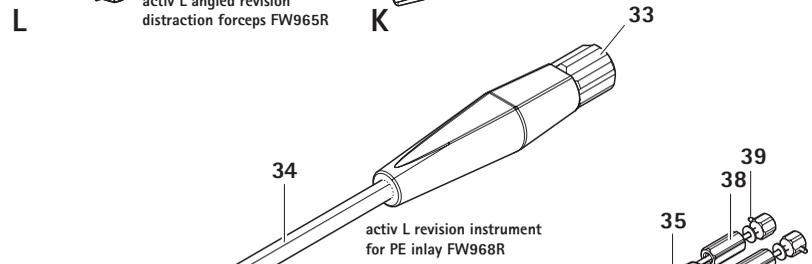
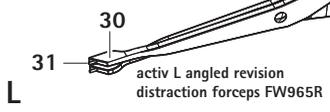
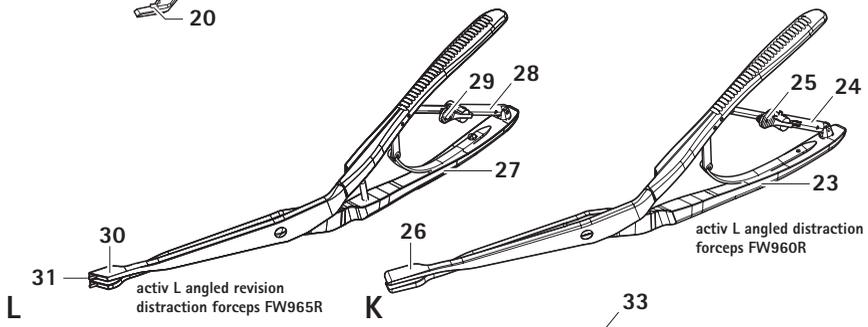
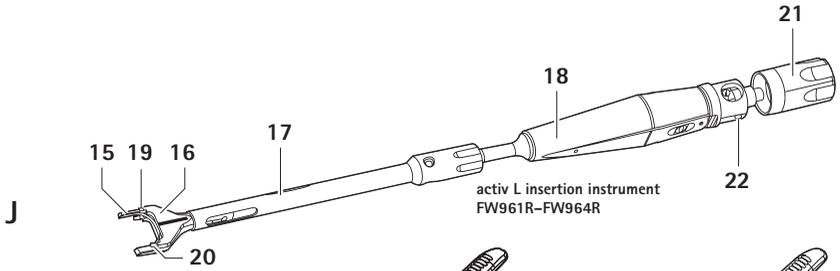


Aesculap Spine

 **Instructions for use/Technical description**
activ L instruments





Aesculap®

activ L instruments

Legend

- A** Midline marker FW955R
- B** Trial Implants FW922R-FW928R/FW971R-FW979R)
- C** Wedges FW941R-FW944R and shaft for wedge FW940R
- D** Spacers FW951R-FW954R
- E** Hammer FL045R
- F** Key for inserter FW945R
- G** Slotted Hammer FW579R
- H** **activ L parallel distractor FW970**
- 1 Cranial jaw piece
- 2 Caudal jaw piece
- 3 Sheath
- 4 Scale
- 5 Indicator pin
- 6 Handle
- 7 Nut cage
- 8 Nut
- 9 Pushing rod
- 10 Twist cap
- I** **activ L handle (for chisel guide) FW980R, double chisels FW985R-FW988R, single chisels FW989R-FW992 & chisel guides FW981R-FW984R/FW989R-FW996R**
- 11 Handle (for chisel guide)
- 12 Chisel guide
- 13 Double chisel
- 14 Single chisel
- J** **activ L insertion instrument FW961R-FW964R**
- 15 Spacer
- 16 Clamp
- 17 Clamping sleeve
- 18 Insertion instrument handle
- 19 Slotted-hole pin
- 20 Coupling pin
- 21 Twist cap
- 22 Unlocking button
- K** **activ L angled distraction forceps FW960R**
- 23 Handle parts
- 24 Lock
- 25 Locking lever
- 26 Working tip
- L** **activ L angled revision distraction forceps FW965R**
- 27 Handle parts
- 28 Lock
- 29 Locking lever
- 30 Working tip
- 31 Pins
- M** **activ L revision instrument for PE inlay FW968R**
- 32 Jaw piece
- 33 Adjustment knob
- 34 Tubular shaft
- N** **activ L revision instrument for endplates FW966R/FW967R**
- 35 Handpiece
- 36 Anchoring rods
- 37 Hooks
- 38 Lock nuts
- 39 Pins
- 40 Slots
- O** **activ L handle for revision instrument FW998R**
- 41 Handle

Symbols on product and packages



Caution, general warning symbol
Caution, see documentation supplied with the product

Applicable to

- For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at <https://extranet.bbraun.com>

Intended use

The intended use of the activ L instruments are to allow successful implantation of the Aesculap activ L device. These instruments aid in selecting, placing, and revising the activ L device. The activ L device comprises of superior and inferior endplates that are offered in four footprint sizes (S, M, L, and XL), two footprint shapes (Normal and S1), and two fixation options (spiked and keeled) as well as a polyethylene core that results in 4 possible implant heights, (8,5 mm, 10 mm, 12 mm, and 14 mm). This instructions for use document refers to these variables, and the instruments themselves are clearly labelled, but additional information regarding use can be found in the surgical technique guide.

activ L parallel distractor FW970

The activ L parallel distractor is used for distraction and determining the correct size and height of the intervertebral disk prosthesis.

activ L handle (for chisel guide) FW980R, double chisels FW985R–FW988R, single chisels FW989R–FW992 & chisel guides FW981R–FW984R/FW989R–FW996R

activ L chisels and chisel guides are used to prepare the keel bed in one or two vertebral bodies for anchoring the activ L disk prosthesis with keel.

A double or single chisel is required depending on whether the keel or combined version is being used.

activ L insertion instrument FW961R–FW964R

The activ L insertion instrument is used for implanting the intervertebral disc prosthesis through anterior (0°) approach. The appropriate color-coded and labeled insertion instrument is used according to the implant height.

activ L revision instruments and distraction forceps

The activ L revision instruments and distraction forceps are used for the distraction/mobilization of two adjacent lumbar vertebral bodies or prostheses plates, as well as for the repositioning and revision of activ L intervertebral disk prostheses.

activ L angled distraction forceps FW960R

The activ L angled distraction forceps is used for the distraction/mobilization of two adjacent vertebral bodies.

activ L angled revision distraction forceps FW965R

The activ L angled revision distraction forceps is used for distracting the two activ L metal plates of an implanted activ L prosthesis in order to remove the PE inlay in corrective surgery.

activ L revision instrument for PE inlay FW968R

The activ L revision instrument for PE inlay is used for the revision of the activ-L PE inlay.

activ L revision instrument for endplates FW966R/FW967R

The activ L revision instrument for endplates and the corresponding handle are used for the repositioning and revision of activ L intervertebral disk prostheses.

Aesculap®

activ L instruments

Available sizes

Trial implants

Art. no.	Designation	Size
FW922R	Trial implant caudal S1	S 5°
FW923R	Trial implant caudal S1	M 5°
FW924R	Trial implant caudal S1	L 5°
FW925R	Trial implant caudal S1	XL 5°
FW926R	Trial implant caudal	XL 0°
FW927R	Trial implant cranial	XL 6°
FW928R	Trial implant cranial	XL 11°
FW971R	Trial implant caudal	S 0°
FW972R	Trial implant caudal	M 0°
FW973R	Trial implant caudal	L 0°
FW974R	Trial implant cranial	S 6°
FW975R	Trial implant cranial	S 11°
FW976R	Trial implant cranial	M 6°
FW977R	Trial implant cranial	M 11°
FW978R	Trial implant cranial	L 6°
FW979R	Trial implant cranial	L 11°

Note

The trial implants are used with the activ L parallel dis-tractor FW970R.

activ L wedges, spacers, chisels and chisel guides

Art. no.	Designation	Size
FW941R	Wedge	6 mm
FW942R		8 mm
FW943R		10 mm
FW944R		12 mm
FW951R	Spacer	8,5 mm
FW952R		10 mm
FW953R		12 mm
FW954R		14 mm
FW981R	activ L chisel guide	8.5 mm, 6°
FW982R		10 mm, 6°
FW983R		12 mm, 6°
FW984R		14 mm, 6°
FW985R	activ L double chisel	8,5 mm
FW986R		10 mm
FW987R		12 mm
FW988R		14 mm
FW989R	activ L single chisel	8,5 mm
FW990R		10 mm
FW991R		12 mm
FW992R		14 mm
FW993R	activ L chisel guide	8.5 mm, 11°
FW994R		10 mm, 11°
FW995R		12 mm, 11°
FW996R		14 mm, 11°

Note

The chisels and chisel guides are used with activ L handle for chisel guide FW980R.

The wedges are used with activ L shaft for wedge FW940R.

activ L insertion instrument

Art. no.	Size
FW961R	8.5 mm
FW962R	10 mm
FW963R	12 mm
FW964R	14 mm

activ L revision instruments and distraction forceps

Art. no.	Designation
FW960R	activ L angled distraction forceps
FW965R	activ L angled revision distraction forceps
FW966R	activ L revision instrument for endplates; size S/M
FW967R	activ L revision instrument for endplates; size L/XL
FW968R	activ L revision instrument for PE inlay
FW998R	activ L handle for revision instrument

Safe handling and preparation

CAUTION

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

Use of the activ L instruments requires precise knowledge about spine surgery and the stabilization and bio-mechanical situation at the spine.

Operative use of the activ L instruments is described in detail in the relevant surgical technique guide.

- ▶ Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- ▶ Read, follow, and keep the instructions for use.
- ▶ Use the product only in accordance with its intended use, see Intended use.
- ▶ Remove the transport packaging and thoroughly clean the new product manually, prior to its initial sterilization, see Validated 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.

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activ L instruments

Disassembling for reprocessing

activ L parallel distractor FW970R

- ▶ Turn twist cap **10** counterclockwise until scale **4** reads "R" (Release), see Fig. 1.
- ▶ Laterally pull out indicator pin **5** from the parallel distractor.
- ▶ Detach twist cap **10**.

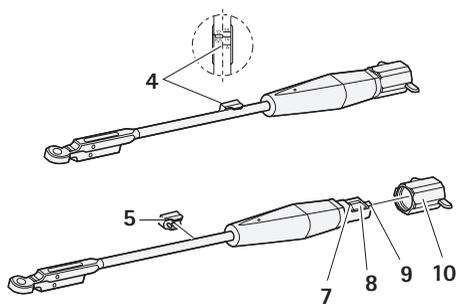


Fig. 1 Dismounting the indicator pin

- ▶ Turn nut **8** counterclockwise until the pushing rod **9** protrudes from the end of the handle **6** by approximately 3 mm, see Fig. 2.
- ▶ Pull out complete pushing rod **9** from the parallel distractor.
- ▶ Remove nut **8**, which now lies unscrewed in nut cage **7**, either upward or downward.

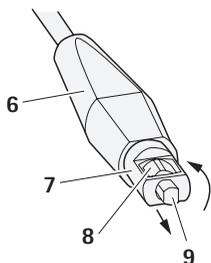


Fig. 2 Dismounting the pushing rod

activ L double chisels FW985R–FW988R & single chisels FW989R–FW992R

- ▶ Slide cage **l** back and rotate counterclockwise by 90°, see Fig. 3.
- ▶ Position guideway **m** on cage **l** in the chisel bridge.

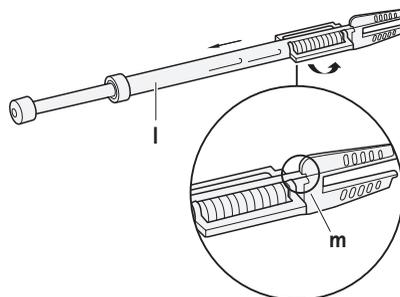


Fig. 3 Preparing the double and single chisels

Legend

l Cage

m Guideway

activ L chisel guides FW981R–FW984R/ FW989R–FW996R

- ▶ Push irrigation tube (outer diameter 7 mm/inner diameter 4 mm) at least 20 mm onto the end of the guide. In doing so, ensure that guideway **n** is covered by the tube.
- ▶ Adjust the safety stop to the central position **o**, see Fig. 4.

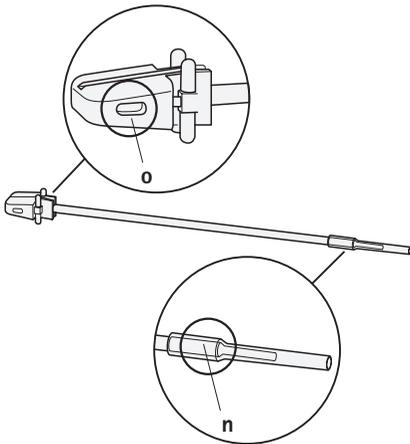


Fig. 4 Preparing the chisel guide

Legend

n Guideway

o Central position of safety stop

activ L insertion instruments FW961R– FW964R

- ▶ Turn twist cap **21** clockwise until it can be removed, see Fig. 5.
- ▶ Hold unlocking button **22** pressed down.
- ▶ Pull out spacer **15** to the front.

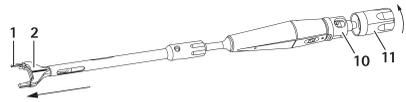


Fig. 5 Disassembling insertion instruments

activ L revision instrument for PE inlay FW968R

- ▶ Turn the adjustment knob **33** counterclockwise and gently pull on the jaw piece **32** until the jaw part comes out, see Fig. 6.

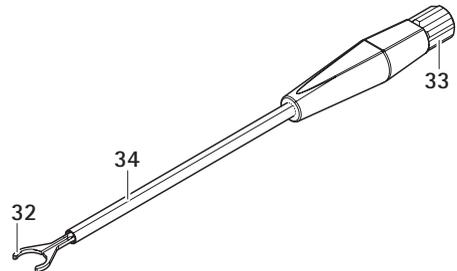


Fig. 6 Disassembling revision instrument for PE inlay

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activ L instruments

activ L revision instruments for endplates FW966R & FW967R

- ▶ Unscrew handle **39** of revision instrument, see Fig. 7.
- ▶ Turn the anchoring rods **36** so that the hooks **37** are positioned in the direction of the slots **40**.
- ▶ Slide the anchoring rods **36** behind the handpiece until the hooks **37** are positioned on the middle section of the revision instrument. When doing so, slide the hooks **37** through the slots **40**.
- ▶ Turn the lock nuts **38** counterclockwise until they are fully undone.
- ▶ Slide the lock nuts **38** along the anchoring rods behind the handpiece.

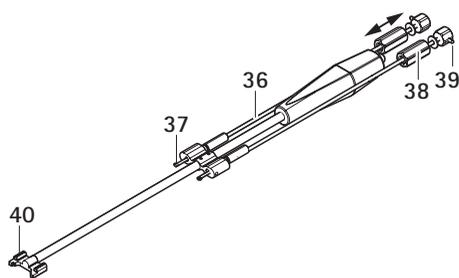


Fig. 7 Disassembling revision instruments for endplates

Validated 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 reprocessing 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

If there is no final sterilization, then a virucidal disinfectant must be used.

Note

For the latest information on reprocessing and material compatibility see also the Aesculap extranet at www.extranet.bb Braun.com

The validated steam sterilization procedure was carried out in the Aesculap sterile container system.

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; also, neither fixating pre-cleaning temperatures >45 °C 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.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VAH or FDA approval or CE mark) 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.
- ▶ Further detailed advice on hygienically safe and material-/value-preserving reprocessing can be found at www.a-k-i.org, link to Publications, Red Brochure – Proper maintenance of instruments.

Preparations at the place of use

- ▶ Clean instruments as quickly as possible after usage.
- ▶ Prevent contamination from drying on the instruments prior to cleaning.

Preparation before cleaning

- ▶ Clean container system components under water with a soft sponge and mild detergent until all visible debris has been removed from the surfaces.
- ▶ Inspect tray to insure all debris has been removed.
- ▶ Repeat as many times as necessary until no visible debris remains.
- ▶ If not already done, dismantle the individual instruments prior to cleaning, see Disassembling for reprocessing.
- ▶ Open all products with hinges.

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 attack softeners (e.g. in silicone).
- ▶ Observe specifications regarding concentration, temperature and exposure time.
- ▶ Do not exceed the maximum allowable washing temperature of 60 °C.



Aesculap®

activ L instruments

Manual cleaning/disinfection

Manual cleaning with ultrasound and immersion disinfection

Phase	Step	T [°C/°F]	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 ~ 9 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 ~ 9 ²
IV	Final rinse	RT (cold)	1	-	Distilled water	-
V	Drying	RT	-	-	-	-

D-W: Drinking water

RT: Room temperature

¹Recommended: Steris Prolystica enzymatic presoak and cleaner - manual cleaning

²Recommended: Steris Prolystica neutral detergent - manual cleaning

³Prepare according to manufactures instructions

Suitable cleaning brushes

Instrument	Recommended lumen brush dimensions	
	Diameter	Min. length, overall
FW985R- FW992R	4.8 mm (3/16 in.)	450 mm (18 in.)
FW980R, FW981R- FW996R	6.35 mm (1/4 in.)	450 mm (18 in.)
FW961R- FW964R	5 mm	450 mm (18 in.)
FW966R- FW968R	7 mm	450 mm (18 in.)
FW970R	10 mm	450 mm (18 in.)
All other	4.5 mm	450 mm (18 in.)

Phase I

- ▶ Fully immerse the product in a prepared room temperature enzymatic detergent solution (Recommended "Prolystica enzymatic presoak and cleaner - manual cleaning" prepared according to the manufacturers recommendations).
- ▶ Rinse lumens at least five times with a disposable syringe (20 ml). 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 (see reference table above) for at least 1 min.
- ▶ Mobilize non-rigid components, such as set screws, links, etc. during cleaning.

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 "Prolystica neutral detergent - manual cleaning" prepared according to the manufacturers recommendations) in an ultrasonic cleaning bath.
- ▶ Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
- ▶ Visually inspect all lumens and gaps to ensure there is no remaining contamination.
- ▶ Thoroughly rinse through these components with the cleaning solution (at least five times), using a disposable syringe (20 ml).

Phase IV

- ▶ Rinse/flush the product thoroughly (all accessible surfaces) under running distilled 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).

Inspection, maintenance and checks

- ▶ 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 corroded, loose, bent, broken, cracked, worn, or fractured components).
- ▶ Dry the product if it is wet or damp.
- ▶ Repeat cleaning and disinfection of products that still show impurities or contamination.
- ▶ Check that the product functions correctly.
- ▶ Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical Service.
- ▶ Assemble disassembled products, see Assembling prior to sterilization and see Assembling after sterilization.
- ▶ Check for compatibility with associated products.

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activ L instruments

Packaging

- ▶ Appropriately protect products to prevent damage of fine working tips.
- ▶ 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.

Storage

- ▶ Store sterile products in sterile barrier packaging, protected from dust, in a dry, dark, temperature-controlled area.

Assembling prior to sterilization

activ L double chisels (FW985R–FW988R) & single chisels FW989R–FW992R

- ▶ Slide cage I back.
- ▶ Rotate cage I clockwise by 90°, see Fig. 8.

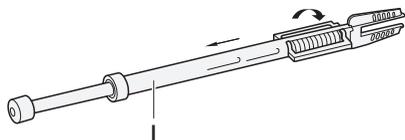


Fig. 8 Assembling double and single chisels

Legend

I Cage

- ▶ Assemble double and single chisels in reverse order, see activ L double chisels FW985R–FW988R & single chisels FW989R–FW992R.

activ L chisel guides FW981R–FW984R/ FW989R–FW996R

- ▶ Remove the irrigation tube $A\varnothing 7/1\varnothing 4$ from the end of the guide.

activ L revision instrument for PE inlay FW968R

- ▶ Insert the jaw piece **32** into the tubular shaft **34** of the revision instrument until it engages, see Fig. 9. When doing so, ensure that the "caudal" marking on the tubular shaft is aligned with the edge of the jaw piece **31**.
- ▶ Push the jaw piece **31** in the direction of the adjustment knob **33** and turn the adjustment knob clockwise until the jaw part is positioned just in front of the tubular shaft. When doing so, ensure that the jaw part is not compressed by the tubular shaft.

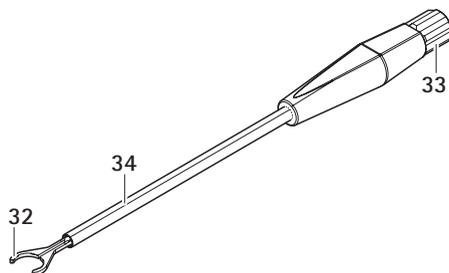


Fig. 9 Assembling revision instrument for PE inlay

activ L revision instruments for endplates FW966R & FW967R

- ▶ Slide the lock nuts **38** along the anchoring rods **36** as far as the threaded rods, see Fig. 10.
- ▶ Turn the lock nuts **38** clockwise onto the threaded rods.
- ▶ Turn the anchoring rods **36** so that the hooks **37** are positioned in the direction of the slots **40**.
- ▶ Slide the hooks **36** through the slots **40**.

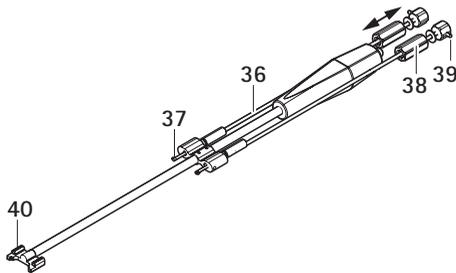


Fig. 10 Assembling revision instruments for endplates

Sterilization

- Aesculap advises against sterilizing the device by immediate use steam sterilization (IUSS) or chemical sterilization.
- Sterilization may be accomplished by a standard prevacuum 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.	Time	Minimum drying time
Prevacuum	270 °F	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 products. 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.

WARNING for the US market

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 crosscontamination.

Aesculap®

activ L instruments

Assembling after sterilization

activ L parallel distractor FW970R

- ▶ Put nuts **8** into nut cage **7**.
- ▶ Slide pushing rod **9**, with the two flat sides at right angles to the parallel distractor, through nut **8** into sheath **3** as far as it will go, see Fig. 11.
- ▶ Apply mild pressure on the protruding end of pushing rod **9** and, at the same time, turn nut **8** clockwise until both of the drill holes in pushing rod **9** can be seen through the slotted hole of the sheath.

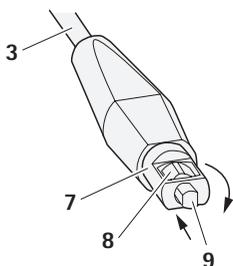


Fig. 11 Inserting the pushing rod

- ▶ Push indicator pin **5** from one side through the drill holes of pushing rod **9**, see Fig. 12.
- ▶ Press the plastic body of indicator pin **5** onto sheath **3** and make certain that it clicks into position.
- ▶ Install twist cap **10** until it engages and turn it clockwise until scale **4** reads "8.5 mm".

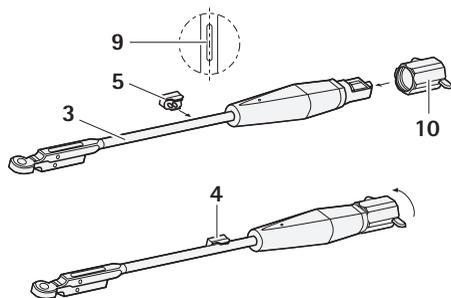


Fig. 12 Assembly

activ L insertion instruments FW961R-FW964R

- ▶ Insert spacer **15** from the front through clamp **16** and, with unlocking button **22** pressed down, push in the clamp as far as it will go, see Fig. 13.
- ▶ Release unlocking button **22**.
- ▶ Attach twist cap **21** and screw it on counterclockwise for at least half a turn.
- ▶ To position spacer **15** as required: Turn twist cap **21** accordingly.

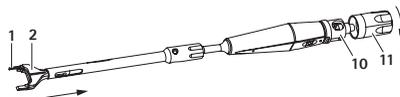


Fig. 13 Assembling insertion instruments

Safe operation



Risk of injury and/or malfunction!

- ▶ Always carry out a function check prior to using the product.

activ L parallel distractor FW970R

Coupling the trial implants for anterior access (0°)

- ▶ Turn twist cap **10** counterclockwise until jaw pieces **1** and **2** are in contact with each other and the scale **4** reads less than 8.5 mm, see Fig. 14.
- ▶ Put cranial trial implant **a** onto cranial jaw piece **1** in such a way that the small guide pin on the cranial trial implant engages in central guide hole **b** of the cranial jaw piece and audibly clicks into position.
- ▶ Put caudal trial implant **d** onto caudal jaw piece **2** in such a way that the small guide pin **c** on the caudal trial implant engages in central guide hole of the caudal jaw piece and audibly clicks into position.

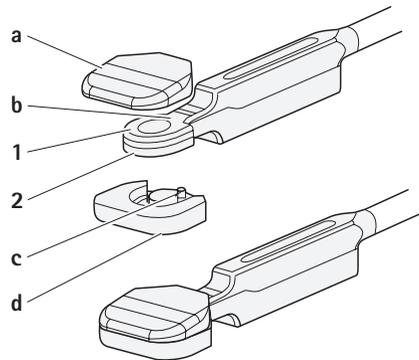


Fig. 14 Coupling the trial implants

Legend

- a** Cranial trial implant
- b** Central guide hole
- c** Small guide pin
- d** Caudal trial implant

- ▶ To distract, turn twist cap **10** clockwise.
- ▶ Read the distraction height from scale **4**.

Decoupling the trial implants

The trial implants can be decoupled with jaw pieces **1** and **2** opened to any width.

- ▶ Pull at the right and left sides of trial implant **a** or **d**, respectively while simultaneously applying counterforce on sheath **3** of the parallel distractor, see Fig. 14.

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activ L instruments

activ L handle (for chisel guide) FW980R, double chisels FW985R–FW988R, single chisels FW989R–FW992 & chisel guides FW981R–FW984R/FW989R–FW996R



WARNING

Risk of injury when using the product beyond the field of view!

- ▶ Apply the product only under visual control.
- ▶ Handle the chisel with utmost care in order to prevent injuries to the vessels and nerve structures, as well as to surgical staff.



WARNING

Damage to the implant from bone residues!

- ▶ Prior to inserting the implant, ensure that no residual bone can be found in the intervertebral space and slits.

- ▶ Mount chisel guide 12 with the desired implant height and angle onto the handle 11, see Fig. 15.
- ▶ Turn wheel e clockwise and adjust safety stop f to the shortest chisel length.

- ▶ Insert chisel guide 12 centrally into the disk space and adjust safety stop f to the desired chisel depth while monitoring radiographically.

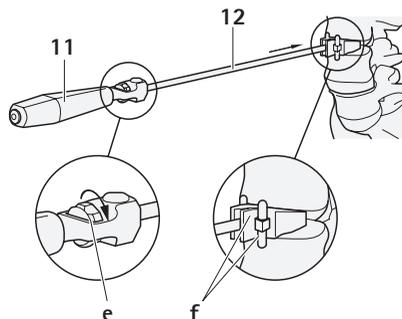


Fig. 15

Legend

e Wheel

f Safety stop

- ▶ Press button g and remove handle 11, see Fig. 16.

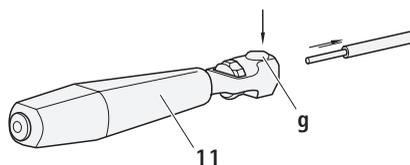


Fig. 16

Legend

g Button

- ▶ Introduce double chisel 13 or single chisel 14 via chisel guide 12.
- ▶ Under radiographic control, insert the chisel into the vertebral body as far as safety stop f. In doing so, the protective sleeve will push back automatically.
- ▶ Once safety stop f is reached, carefully withdraw the chisel using a slotted hammer.

activ L insertion instruments FW961R–FW964R

Coupling the implant

- ▶ Select the appropriate insertion instrument according to the height of the intervertebral disc prosthesis.
- ▶ Completely assemble the intervertebral disc prosthesis.
- ▶ Extend spacer **15** as far as possible. If necessary, change the position of the spacer by turning twist cap **21**.
- ▶ Put the intervertebral disc prosthesis **h** onto clamp **16** of the insertion instrument, observing the marking on the insertion instrument, see Fig. 17. The inferior prosthesis plate must abut the part of the insertion instrument clamp **16** marked "CAUDAL"; the superior prosthesis plate must abut the part marked "CRANIAL".

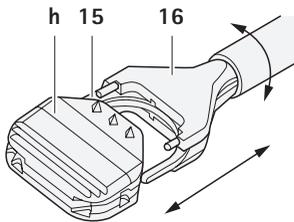


Fig. 17 Coupling for anterior access (0°)

Legend

h Intervertebral disc prosthesis

- ▶ Guide the prosthesis plates on the spacer **15** onto coupling pins **19** and **20** of the clamp **16**.
- ▶ Make certain that the coupling pins of the clamp fully engage in the coupling holes of the prosthesis plates.
- ▶ Turn clamping sleeve **17** clockwise until the intervertebral disc prosthesis is securely coupled.

Decoupling the implant

- ▶ Release clamping sleeve **17**.
- ▶ Carefully detach the insertion instrument from the implant.
- ▶ If the insertion instrument cannot be detached without applying force: Turn twist cap **21** anti-clockwise to move back spacer **15**.

activ L revision instruments and distraction forceps

Distracting/mobilizing vertebral bodies with the activ L angled distraction forceps FW960R



DANGER

Risk of fracture of the vertebral body endplates and/or injury to surrounding structures due to overdistraction!

- ▶ Apply proper care when distracting.
- ▶ Avoid excessive distraction.



CAUTION

Damage to the product caused by actuation of the locking lever!

- ▶ To release lock, gently press the handle parts together and actuate locking lever.

Note

Mobilization of the intervertebral disk space is a critical process and should be performed under X-ray control.

Note

The intervertebral space distraction is often wedge-shaped. Sufficient load relief in the posterior intervertebral disk space is required so that parallel distraction can be performed over the entire intervertebral space.

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activ L instruments

- ▶ Insert the working tip **26** into the intervertebral space, see Fig. 18. When doing so, ensure that the instrument is pushed as dorsally as possible into the intervertebral disk space.

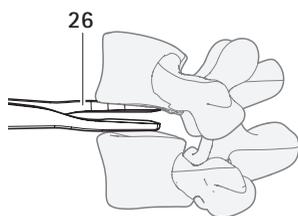


Fig. 18 Inserting working tip into intervertebral space

- ▶ Distract/mobilize the distraction forceps by pressing the handle parts **23** together as required.

Note

Lock **24** engages automatically when handle parts **23** are released.

Removing the activ L angled distraction forceps FW960R

- ▶ Gently press the handle parts **23** together and actuate locking lever **29**. This releases the lock **28** of the distraction forceps.

Applying the activ L angled revision distraction forceps FW965R



**Injury to surrounding blood vessels and soft tissue!
Damage to the product or to the activ L disk prosthesis!**

- ▶ To protect the blood vessels, always use a retractor in conjunction with this product.
- ▶ Always insert the product into the two holes at the right-hand side of the prosthesis.



Damage to the product caused by actuation of the locking lever!

- ▶ To release the lock, gently press the handle parts together and actuate locking lever.

- ▶ Insert pins **31** of the distraction forceps into the holes on the right-hand side of the implant, see Fig. 19.

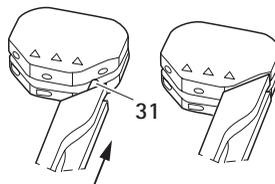


Fig. 19 Applying the activ L angled revision distraction forceps

- ▶ Open the distraction forceps by pressing the handle parts **27** together as required.

Note

Lock **28** engages automatically when handle parts **27** are released.

Removing the activ L angled revision distraction forceps FW965R

- ▶ Gently press the handle parts **27** together and actuate locking lever **29**.
This releases the lock **28** of the distraction forceps.

Removing the PE inlay with activ L revision instrument for PE inlay FW968R from the intervertebral disk prosthesis

- ▶ Insert the jaw piece **32** of the revision instrument between the two endplates **i** of the intervertebral disk prosthesis, see Fig. 20. Ensure the following:
 - The orientation of the revision instrument in the caudal direction corresponds with the "caudal" marking on the revision instrument.
 - The edges of the jaw piece **32** are pointing in the direction of the inferior endplates.

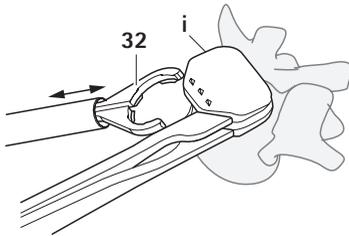


Fig. 20 Inserting the jaw piece between the two endplates

Legend

i Endplates

- ▶ Push the revision instrument along the lower endplate, until the jaw piece **32** engages on the PE inlay.
- ▶ Turn the adjustment knob **33** clockwise to fix the PE inlay in place on jaw piece **32**.
- ▶ Lift the revision instrument with fixated PE inlay over the edge of the inferior endplate and remove from the endplate by pulling in the anterior direction.

- ▶ To remove the PE inlay from the revision instrument:
 - Rotate the adjustment knob **33** in a counter-clockwise direction.
 - Pull the PE inlay from the jaw piece **32**.

Reposition/remove endplates with activ L revision instrument for endplates FW966R/ FW967R



Risk of injury to nerves and surrounding structures due to uncontrolled posterior pressure of the hooks of the anchoring rods!

- ▶ Apply proper care when manipulating the anchoring rods.
- ▶ Do not apply excessive pressure.

- ▶ Screw handle **41** onto handpiece **35** of the revision instrument, see Fig. 21.

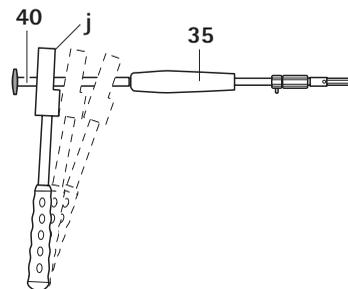


Fig. 21 Revision instrument for endplates with handle and slotted hammer

Legend

j Slotted hammer

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activ L instruments

Note

The pins **39** on the screw connection of the anchoring rods of the revision instrument will point in the same direction as the corresponding hooks on the front part.

Note

In case of an incomplete revision of the implant, the endplates are removed one after another. The slotted hammer **j** is also used for the revision procedure.

Note

The endplates can grow into and adhere strongly to the vertebral bodies. This can considerably complicate the revision procedure. If the revision is of a prosthesis implanted a number of years ago, the endplates may need to be removed from the intervertebral body with a chisel or elevator prior to using the revision instrument.

- ▶ Turn the anchoring rods **36** so that both hooks **37** are pointing outwards, see Fig. 22.

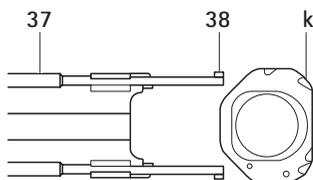


Fig. 22 Hooks of anchoring rods facing outwards

Legend

k Recesses

- ▶ Push the revision instrument between the endplates. When doing so, ensure that the hooks **37** reach over the posterior edges of the plates.
- ▶ Turn the anchoring rods **36** in the direction of the plate to be removed.
- ▶ Pull back the anchoring rods **36**. When doing so, ensure that the anchoring rods engage securely in the recesses **k** on the posterior side of the plate, see Fig. 23.

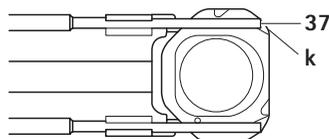


Fig. 23 Anchoring rods engage securely in recesses

Legend

k Recesses

- ▶ Fix the anchoring rods **36** in place by turning the lock nut **38** counterclockwise. When doing so, hold the anchoring rods so that they cannot turn anymore.
- ▶ Carefully reposition or withdraw the plate.
- ▶ To remove the endplate completely, hit it out with the slotted hammer.
- ▶ Undo the lock nut **38** by turning it clockwise.
- ▶ Turn the anchoring rods **36** 90° in the anterior direction and remove the endplate.
- ▶ If applicable, remove other endplates in the same way.

Technical Service



WARNING

Risk of injury and/or malfunction!

▶ **Do not modify the product.**

- ▶ For service and repairs, please contact your national B. Braun/Aesculap agency.

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service addresses

Aesculap Technischer Service

Am Aesculap-Platz

78532 Tuttlingen / Germany

Phone: +49 (7461) 95-1602

Fax: +49 (7461) 16-5621

E-Mail: ats@aesculap.de

Or in the US:

Aesculap Implant Systems LLC

Attn. Aesculap Technical Services

615 Lambert Pointe Drive

Hazelwood

MO, 63042

Aesculap Repair Hotline

Phone: +1 (800) 214-3392

Fax: +1 (314) 895-4420

Other service addresses can be obtained from the address indicated above.

Disposal

- ▶ Adhere to national regulations when disposing of or recycling the product, its components and its packaging!

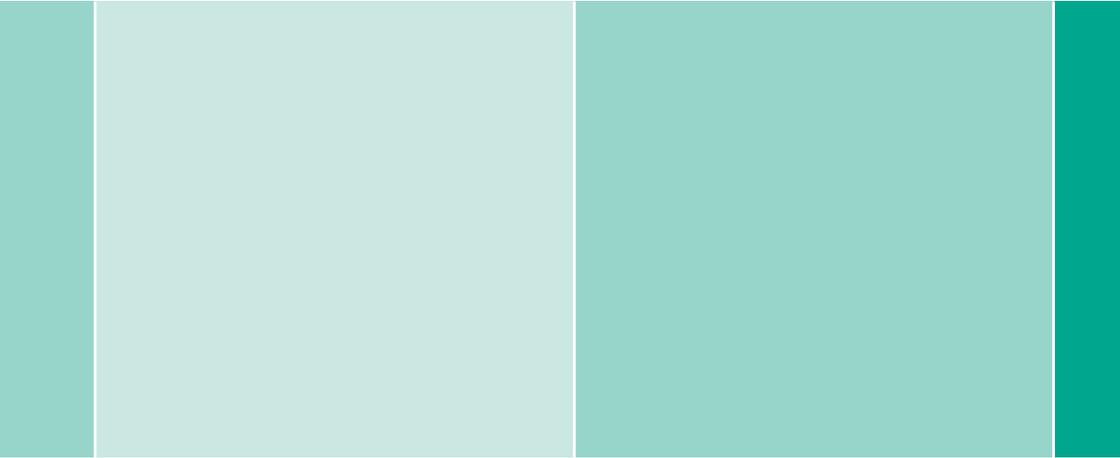
Distributor in the US/Contact in Canada for product information and complaints

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