B BRAUN
SHARING EXPERTISE

TRUSTED
EXPERIENCE

DEGENERATIVE
SPINAL DISORDERS

AESCULAP® S4®

MODULAR MIS PEDICLE SCREW SYSTEM

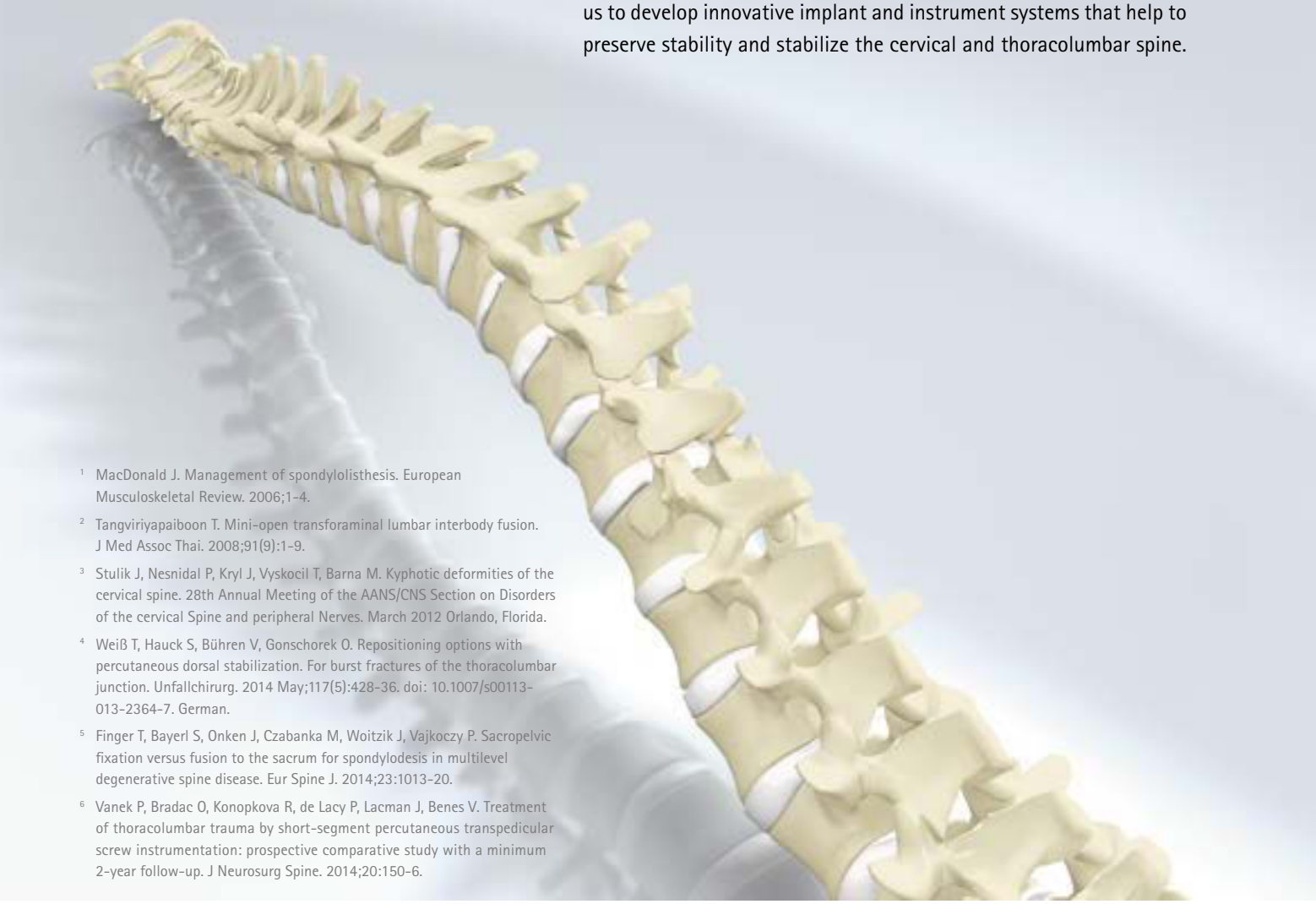
SURGICAL TECHNIQUE

DEGENERATIVE SPINAL DISORDERS

PROTECTING AND PRESERVING SPINAL STABILITY

Modern life style has resulted in increasing physical inactivity among people all over the world. Of the many medical problems associated with this, spinal disorders are among the most critical. This is even more significant as the spinal column is one of the most important structures in the human body. It supports and stabilizes the upper body and is the center of our musculoskeletal system, which gives the body movement.

Our work in the field of degenerative spinal disorders is dedicated to protecting the spinal column and preserving its stability. We support spine surgeons with durable, reliable products and partner services for safe procedures and outstanding clinical outcomes.[1-6] Our philosophy of sharing expertise with healthcare professionals and patients allows us to develop innovative implant and instrument systems that help to preserve stability and stabilize the cervical and thoracolumbar spine.



[1] MacDonald J. Management of spondylolisthesis. European Musculoskeletal Review. 2006;1-4.

[2] Tangviriyapaiboon T. Mini-open transforaminal lumbar interbody fusion. J Med Assoc Thai. 2008;91(9):1-9.

[3] Stulik J, Nesnidal P, Kryl J, Vyskocil T, Barna M. Kyphotic deformities of the cervical spine. 28th Annual Meeting of the AANS/CNS Section on Disorders of the cervical Spine and peripheral Nerves. March 2012 Orlando, Florida.

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[5] Finger T, Bayerl S, Onken J, Czabanka M, Woitzik J, Vajkoczy P. Sacropelvic fixation versus fusion to the sacrum for spondylodesis in multilevel degenerative spine disease. Eur Spine J. 2014;23:1013-20.

[6] Vanek P, Bradac O, Konopkova R, de Lacy P, Lacman J, Benes V. Treatment of thoracolumbar trauma by short-segment percutaneous transpedicular screw instrumentation: prospective comparative study with a minimum 2-year follow-up. J Neurosurg Spine. 2014;20:150-6.

AESCULAP THORACOLUMBAR SPINE

PORTFOLIO OVERVIEW

IMPLANT SYSTEMS

posterior


S4® Element MIS


S4® Element Open


Hydrolift®


S4® Element Augmentation


S4® Element Multilevel


S4® Long Tab

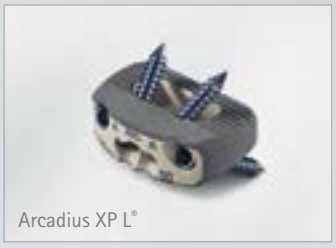

S4® Spinal System


PROSPACE® XP / PEEK / Titanium


TSPACE® XP / PEEK / Titanium

anterior


Macs II


Arcadius XP L®

INSTRUMENT SYSTEMS

posterior


Spine Classics MLD System


Mini-Open Retractor System

anterior


CLR


activ O

AESCULAP® S4®

CONTENT

CHAPTERS

AESCULAP® S4®

SYSTEM OVERVIEW

TRUSTED EXPERIENCE

The unique slim profile technology of S4 blends the experience of more than ten years of clinical application and continuously updated technologies, making it a reliable posterior spinal fixation system for a vast range of indications.

MODULAR VERSATILITY

The S4 is based on Aesculap's proven and versatile platform technologies that are especially designed for the requirements and needs in spinal surgery. As a result, the system is individually configurable and adaptable to a comprehensive range of pathologies and approach techniques, giving you the benefit to work with one system.

CUTTING-EDGE DIMENSIONS

The outstanding slim profile technology allows for a implant diameter of only 10.5 mm and a lean instrument design for true MIS skin incisions and effective instrument manipulation in tight anatomical spaces.

LEAN SURGICAL WORKFLOW

The contents of the individual implant and instrument modules are defined in a way that an intuitive and streamlined instrumentation can be supported throughout the whole hospital workflow.


6
5
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2

AESCULAP® S4®

A | SURGICAL TECHNIQUE – DEGENERATIVE SPINE

TRUSTED EXPERIENCE

DEGENERATIVE SPINE

AESCULAP® S4®

A | SURGICAL TECHNIQUE – DEGENERATIVE SPINE

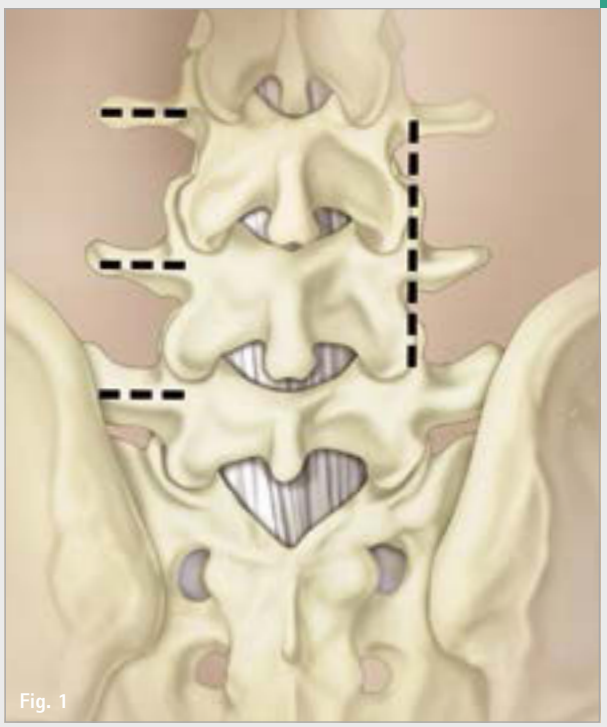

Fig. 1

A.1. PATIENT POSITIONING, MONITORING AND INCISION

- Position the patient on a radiolucent OR table in prone position. The OR table should have enough clearance for a fluoroscopic C-arm to rotate freely.
- Locate the pedicles of interest through A/P and lateral X-ray and mark appropriate incision areas on skin.
- On the ipsilateral side, make an incision of at least 10 mm at the location where each pedicle screw will be placed.
- Ensure the incision is located to allow proper trajectory for minimally invasive pedicle screw insertion. Ensure the fascia is cut to the same length.
- Perform the same procedure for the contralateral side.
- On the contralateral side, the mini-open TLIF technique can be used to adequately decompress and insert TLIF interbody to augment the percutaneous side.

Fig. 2

A.2. PEDICLE PREPARATION

- Once the entry point of the screw has been determined the guiding instrument consisting of Trocar (FW271M) and K-Wire Aiming Device (FW258M) is introduced at the junction of the facet and the transverse process. Ensure that the K-Wire Aiming Device is placed through the pedicle-vertebral body junction to facilitate the placement of the K-Wire.
- Use fluoroscopy to monitor position of the Trocar during insertion. Avoid inserting the needle too deep into the vertebral body as there is danger of perforating large vessels.
- The Trocar (FW271M) is removed while the K-Wire Aiming Device (FW258M) remains in position.

Fig. 3

A.3. K-WIRE INSERTION

- The K-Wire (FW247S) is introduced through the K-Wire Aiming Device (FW258M).
- The laser etchings on the K-Wire need to be placed away from the patient. The K-Wire should be introduced in a way that its distal tip represents the end position of the pedicle screw tip.
- Monitor the K-Wire tip to ensure it does not penetrate the anterior wall of the vertebral body. The depth of the K-Wire is essential for the determination of the screw length.
- Repeat the steps for each K-Wire to be placed.
- In order to avoid oscillating or bending the K-Wire the K-Wire Protection Sleeve (FW352R) may be used.

Fig. 4

A.4. SOFT TISSUE DILATION

- Fascia and muscle should be dilated to allow for screw placement.
- Dilate the fascia and spinal muscles by inserting the Tissue Dilation Sleeve (FW354R) over the K-Wire Aiming Device (FW258M). The Dilator should be docked on bony anatomy to minimize tissue creepage.

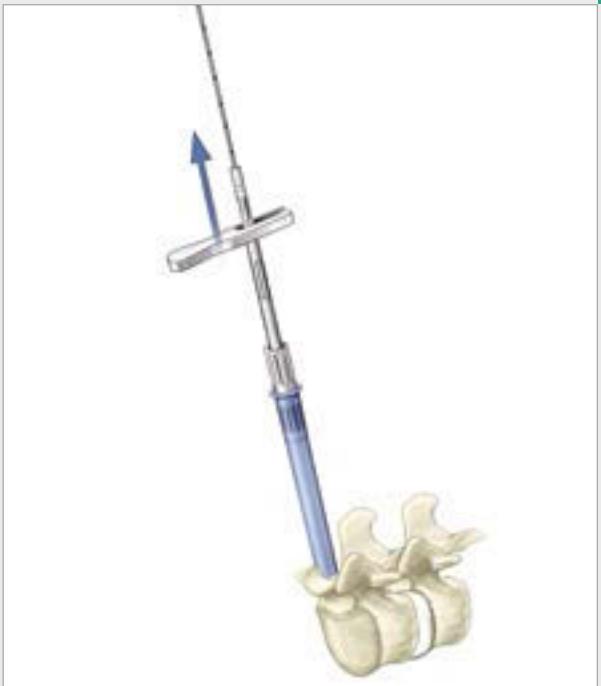

Fig. 5

- Remove the K-Wire Aiming Device (FW258M) by using the Handle (FW274M) and holding the K-Wire firmly in place.
- Slide the Tissue Protection Sleeve (FW355P) over the Tissue Dilation Sleeve until it touches the pedicle entry point.
- Remove the Tissue Dilation Sleeve (FW354R) while holding the Protection Sleeve firmly in place.

Fig. 6

A.5. BONE PROBING

- If additional bone probing is preferred, the straight cannulated Bone Probe (FW263R) can be used.
- Hold the K-Wire firmly and slide the cannulated Bone Probe (FW263R) over the K-Wire and probe to the desired depth.

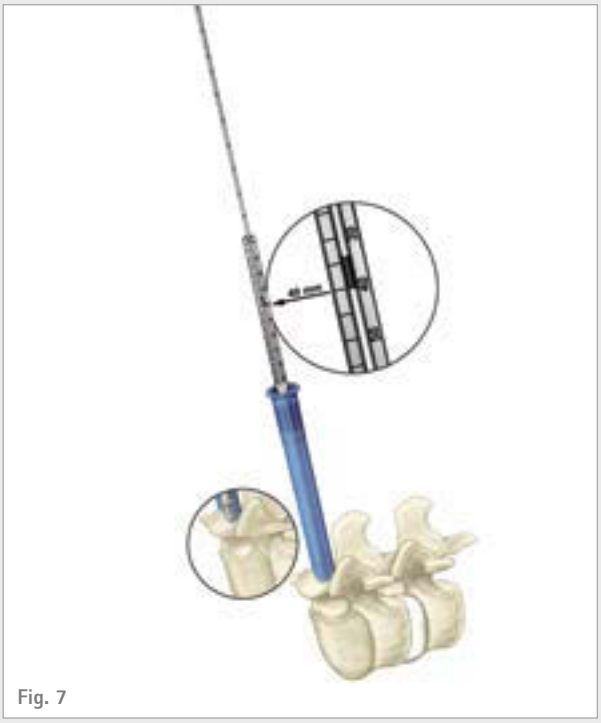

Fig. 7

A.6. SCREW LENGTH MEASURING

- Under fluoroscopic guidance, ensure the K-Wire is at an adequate depth, approximating the final screw location in the bone. Avoid inserting the K-Wire too deep into the vertebral body as there is danger of perforating large vessels.
- Hold the K-Wire firmly and slide the Screw Length Measuring Device (FW351R) over the K-Wire.
- Read the screw length at the bottom of the widest laser marking on the K-Wire. The reading is an approximation, depending on the depth of the K-Wire in the bone.

Fig. 8

A.7. PEDICLE TAPPING

- If additional bone tapping is preferred, the screw taps can be used.
- To tap, attach either the straight Ratchet Handle (FW165R) or t-shaped Ratchet Handle (FW167R) to the appropriate screw tap based on the corresponding screw diameter. The included screw taps range from 4.5 to 8.5 mm in 1 mm increments (FW264R – FW268R) and each is undersized by 0.5 mm.

Fig. 9

A.8. SLEEVE ASSEMBLY

- The placement of the poly- and monoaxial screws is performed with the Clamping Sleeve (FW693R), Monoaxial Screw Driver (FW696R) or Polyaxial Screw Driver (FW695R) and the Handle (FW165R or FW167R).
- Slide the blue clamping ring (1) onto the inner clamping sleeve (2) and screw it to the bottom of the thread.
- The inner clamping sleeve (2) is then inserted into the outer sleeve (3). Ensure the sliding groove and the groove stone are aligned.

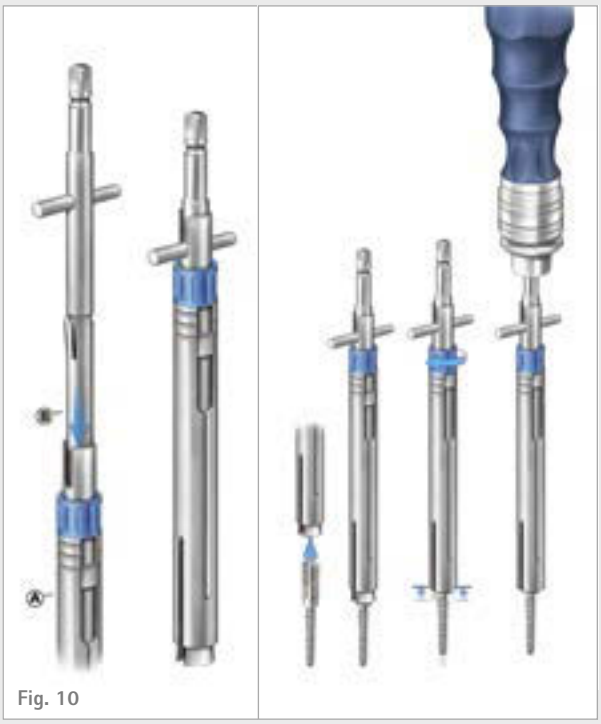

Fig. 10

A.8.1. ASSEMBLY OF MONOAXIAL SCREW

- The Monoaxial Screw Driver (FW696R) (B) is inserted into the Clamping Sleeve (FW693R) (A), the pins of the Screw Driver have to be fully inserted into the groove of the Clamping Sleeve.
- The monoaxial screw is inserted from the bottom. By turning the blue clamping ring down to the limit stop, the pedicle screw is firmly connected with the Clamping Sleeve.

Fig. 11

A.8.2. ASSEMBLY OF POLYAXIAL SCREW

- The Polyaxial Screw Driver (FW695R) (B) is inserted into the Clamping Sleeve (FW693R) (A), the pins of the Screw Driver have to be fully inserted into the groove of the Clamping Sleeve.
- The polyaxial screw is inserted from the bottom. By turning the blue clamping ring down to the limit stop, the pedicle screw is firmly connected with the Clamping Sleeve.
- If the polyaxicity of the screw remains, the Screw Driver is not fully engaged.

Fig. 12

A.9. SCREW PLACEMENT

- Slide the assembled Clamping Sleeve over the K-Wire.
- Insert the screw to the appropriate depth. If needed, fluoroscopic guidance can be used.
- Remove the K-Wire, using the Grasping Forceps (LX182R), after an appropriate amount of bone purchase is established to avoid driving the K-Wire into a vertebral artery.
- Once the screw is fully inserted, remove the Screw Driver from the screw, by pulling the handle.
- Repeat the steps for all subsequent screws.

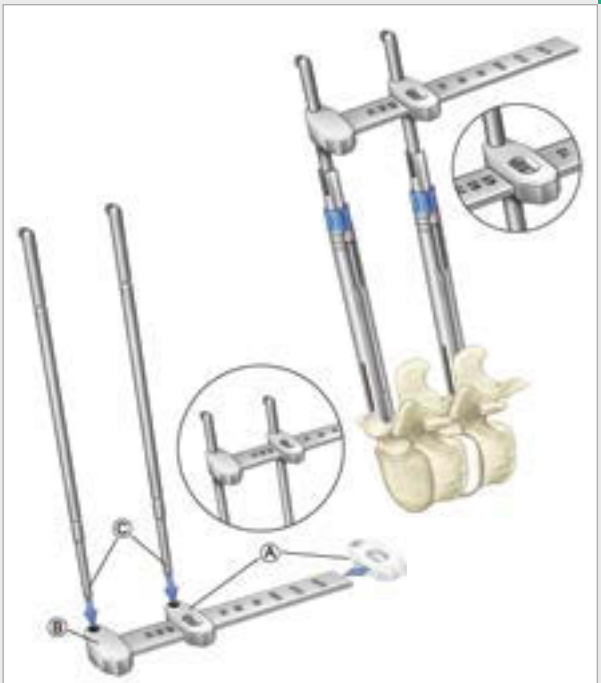

Fig. 13

A.10. ROD LENGTH MEASURING

- Place the sliding gauge (A) over the scale. The measuring pins (C) are slided through the holders (A and B) with the tip downwards.
- Determine the length of the rod using the Rod Measuring Instrument (FW242R) by inserting it through the Clamping Sleeve (FW693R) into the screw heads.
- The etched scale on top of the length measuring instrument indicates the minimum recommended rod length.

Note:

- When using a pre-bent rod, 10 mm has to be added to the indicated length.


Fig. 14

A.11. SLEEVE ALIGNMENT

- Once the rod measurements are taken, align the notches of the Clamping Sleeves to each other.
- If needed, the orientation of the notches can be changed by rotating the Clamping Sleeves (FW693R) to the desired position.

Fig. 15

A.12. ROD PLACEMENT

- Assemble the inner shaft of the Rod Inserter (FW240R) to the main body by fully engaging the shaft. The inner shaft of the Rod Inserter must be firmly tightened to prevent premature in-situ release of the rod.
- The minimally invasive rod has a bullet tip to ease passage through soft tissue and a hex end geometry to engage with the Rod Inserter.
- Unscrew the knob of the inner shaft of the Rod Inserter and slide in the hex end into the distal opening of the instrument.
- Firmly tighten the inner shaft clockwise to secure the rod in place.
- Guide the rod down through the longitudinal slots of the Clamping Sleeves.

Fig. 16

A.13. SET SCREW PLACEMENT

- Slide the Percutaneous Outer Sleeve (FW735R) over the Clamping Sleeve.
- The self-retaining Set Screw Starter (FW697R) may be used to obtain a set screw from the storage disc.
- The hex of the instrument is aligned with the hex on the set screw, and the instrument is then pushed into the set screw to secure the connection.
- Thread the set screw into the screw body until it touches the rod. In order to facilitate the insertion of the set screw, the rod can be pushed down using the Percutaneous Outer Sleeve (FW735R).

Fig. 17

A.14. FINAL TIGHTENING

Final tightening of each set screw is completed using the Torque Indicating Screw Driver (FW170R) along with the Counter Torque (FW736R).

- Insert the Torque Indicating Screw Driver (FW170R) through the Percutaneous Outer Sleeve (FW735R), so the tip is exposed.
- Fully seat the tip of the torque wrench into the socket of the set screw.
- Engage the Counter Torque Handle (FW736R) to the hexagonal bolt of the Percutaneous Outer Sleeve.
- Turn the Torque Wrench in a clockwise direction while firmly holding the Counter Torque. Ensure, the arrows on the Torque Wrench line up with each other.

Caution:

Do not use the Torque Wrench without the Counter Torque Handle. Over tightening the set screw more than the specified setting of 10 Nm (90 in/lbs) could lead to implant failure.
Damaged set screws must be replaced.

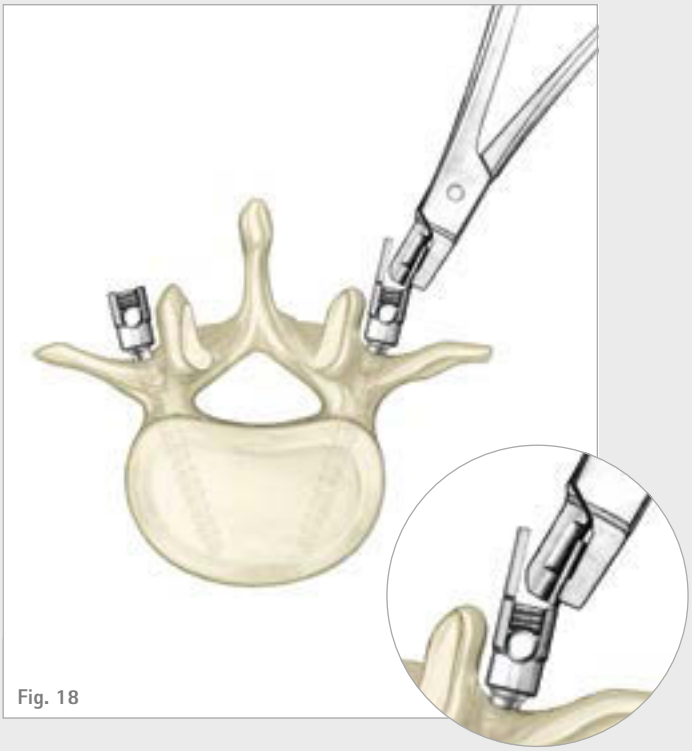

Fig. 18

A.15. TAB REMOVAL

- The locking mechanism of the Rod Inserter (FW240R) is opened and the rod released. Dismantle the whole instrumentation from the screws.
- After verifying that all screws are placed and tightened, remove the tabs with the Tab Breaker (FW179R).

AESCULAP® S4®

B | SURGICAL TECHNIQUE – OSTEOPOROTIC SPINE

TRUSTED EXPERIENCE

OSTEOPOROTIC SPINE

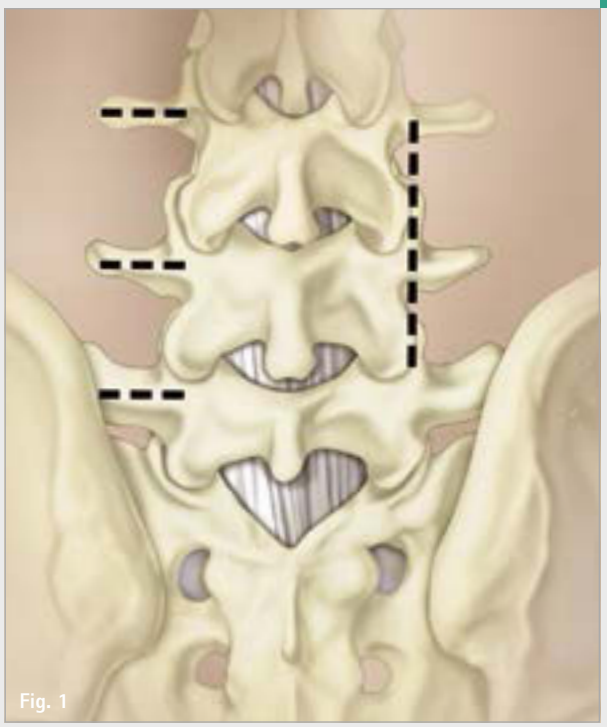
Fig. 1

B.1. PATIENT POSITIONING, MONITORING AND INCISION

- Position the patient on a radiolucent OR table in prone position. The OR table should have enough clearance for a fluoroscopic C-arm to rotate freely.
- Locate the pedicles of interest through A/P and lateral X-ray and mark appropriate incision areas on skin.
- On the ipsilateral side, make an incision of at least 10 mm at the location where each pedicle screw will be placed.
- Ensure the incision is located to allow proper trajectory for minimally invasive pedicle screw insertion. Ensure the fascia is cut to the same length.
- Perform the same procedure for the contralateral side.
- On the contralateral side, the mini-open TLIF technique can be used to adequately decompress and insert TLIF interbody to augment the percutaneous side.


Fig. 2

B.2. PEDICLE PREPARATION

- Once the entry point of the screw has been determined the guiding instrument consisting of Trocar (FW271M) and K-Wire Aiming Device (FW258M) is introduced at the junction of the facet and the transverse process. Ensure that the K-Wire Aiming Device is placed through the pedicle-vertebral body junction to facilitate the placement of the K-Wire.
- Use fluoroscopy to monitor position of the Trocar during insertion. Avoid inserting the needle too deep into the vertebral body as there is danger of perforating large vessels.
- The Trocar (FW271M) is removed while the K-Wire Aiming Device (FW258M) remains in position.

Fig. 3

B.3. K-WIRE INSERTION

- The K-Wire (FW247S) is introduced through the K-Wire Aiming Device (FW258M).
- The laser etchings on the K-Wire need to be placed away from the patient. The K-Wire should be introduced in a way that its distal tip represents the end position of the pedicle screw tip.
- Monitor the K-Wire tip to ensure it does not penetrate the anterior wall of the vertebral body. The depth of the K-Wire is essential for the determination of the screw length.
- Repeat the steps for each K-Wire to be placed.
- In order to avoid oscillating or bending the K-Wire the K-Wire Protection Sleeve (FW352R) may be used.

Fig. 4

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- Fascia and muscle should be dilated to allow for screw placement.
- Dilate the fascia and spinal muscles by inserting the Tissue Dilation Sleeve (FW354R) over the K-Wire Aiming Device (FW258M). The Dilator should be docked on bony anatomy to minimize tissue creepage.

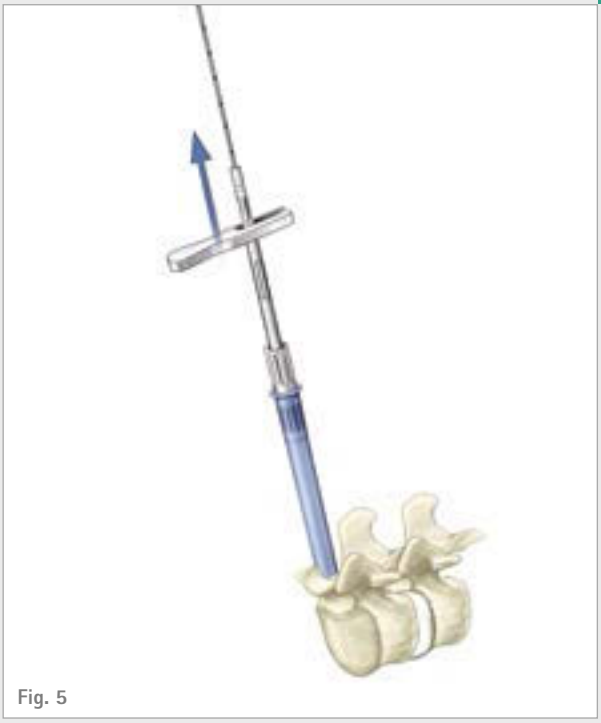


Fig. 5

- Remove the K-Wire Aiming Device (FW258M) by using the Handle (FW274M) and holding the K-Wire firmly in place.
- Slide the Tissue Protection Sleeve (FW355P) over the Dilation Sleeve (FW354R) until it touches the pedicle entry point.
- Remove the Dilation Sleeve (FW354R) while holding the Protection Sleeve (FW355P) firmly in place.

Fig. 6

B.5. BONE PROBING

- If additional bone probing is preferred, the straight cannulated Bone Probe (FW263R) can be used.
- Hold the K-Wire firmly and slide the cannulated Bone Probe (FW263R) over the K-Wire and probe to the desired depth.

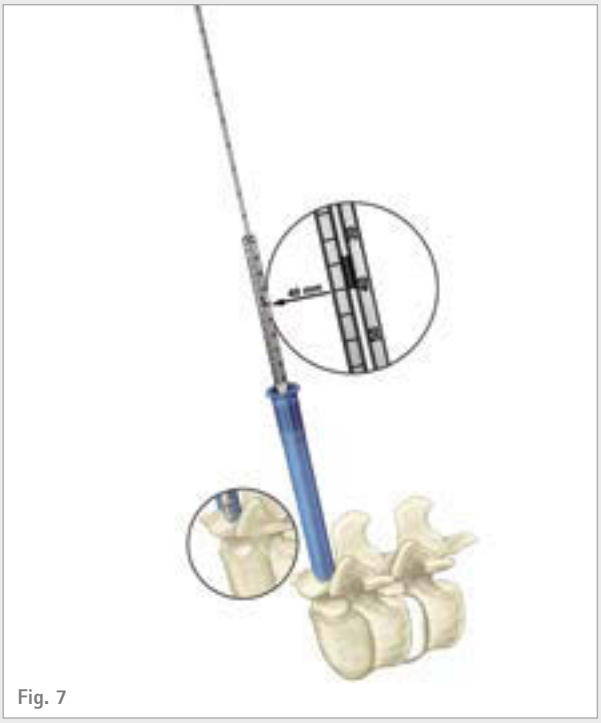


Fig. 7

B.6. SCREW LENGTH MEASURING

- Under fluoroscopic guidance, ensure the K-Wire is at an adequate depth, approximating the final screw location in the bone. Avoid inserting the K-Wire too deep into the vertebral body as there is danger of perforating large vessels.
- Hold the K-Wire firmly and slide the Screw Length Measuring Device (FW351R) over the K-Wire.
- Read the screw length at the bottom of the widest laser marking on the K-Wire. The reading is an approximation, depending on the depth of the K-Wire in bone.

Fig. 8

B.7. PEDICLE TAPPING

- If additional bone tapping is preferred, the screw taps can be used.
- To tap, attach either the straight Ratchet Handle (FW165R) or t-shaped Ratchet Handle (FW167R) to the appropriate screw tap based on the corresponding screw diameter. The included screw taps range from 4.5 to 8.5 mm in 1 mm increments (FW264R – FW268R) and each are undersized by 0.5 mm.

Fig. 9

B.8. SLEEVE ASSEMBLY

- The placement of the poly- and monoaxial screws is performed with the Clamping Sleeve (FW693R), Monoaxial Screw Driver (FW696R) or Polyaxial Screw Driver (FW695R) and the Handle (FW165R or FW167R).
- Slide the blue clamping ring (1) onto the inner clamping sleeve (2) and screw it to the bottom of the thread.
- The inner clamping sleeve (2) is then inserted into the outer sleeve (3). Ensure the sliding groove and the groove stone are aligned.

Fig. 10

B.8.1. ASSEMBLY OF MONOAXIAL AUGMENTATION SCREW

- Ensure that for the cement application only augmentation screws are used.
- The Monoaxial Screw Driver (FW696R) (B) is inserted into the Clamping Sleeve (FW693R) (A), the pins of the Screw Driver have to be fully inserted into the groove of the Clamping Sleeve.
- The monoaxial augmentation screw is inserted from the bottom. By turning the blue clamping ring down to the limit stop, the pedicle screw is firmly connected with the Clamping Sleeve.

Fig. 11

B.8.2. ASSEMBLY OF POLYAXIAL AUGMENTATION SCREW

- Ensure that for the cement application only augmentation screws are used.
- The Polyaxial Screw Driver (FW695R) (B) is inserted into the Clamping Sleeve (FW693R) (A), the pins of the Screw Driver have to be fully inserted into the groove of the Clamping Sleeve.
- The polyaxial augmentation screw is inserted from the bottom. By turning the blue clamping ring down to the limit stop, the pedicle screw is firmly connected with the Clamping Sleeve (FW693R).
- If the polyaxicity of the screw remains, the Screw Driver is not fully engaged.

Fig. 12

B.9. SCREW PLACEMENT

- Slide the assembled Clamping Sleeve over the K-Wire.
- Insert the augmentation screw to the appropriate depth. If needed, fluoroscopic guidance can be used.
- Remove the K-Wire, using the Grasping Forceps (LX182R), after an appropriate amount of bone purchase is established to avoid driving the K-Wire into a vertebral artery.
- Once the screw is fully inserted, slide the K-Wire (FW247S) into the cannulation of the Screw Driver and check its patency, in order to avoid unwanted penetration of bone into the augmentation area of the screw.
- Remove the Screw Driver from the augmentation screw, by pulling the handle.
- Repeat the steps for all subsequent augmentation screws.

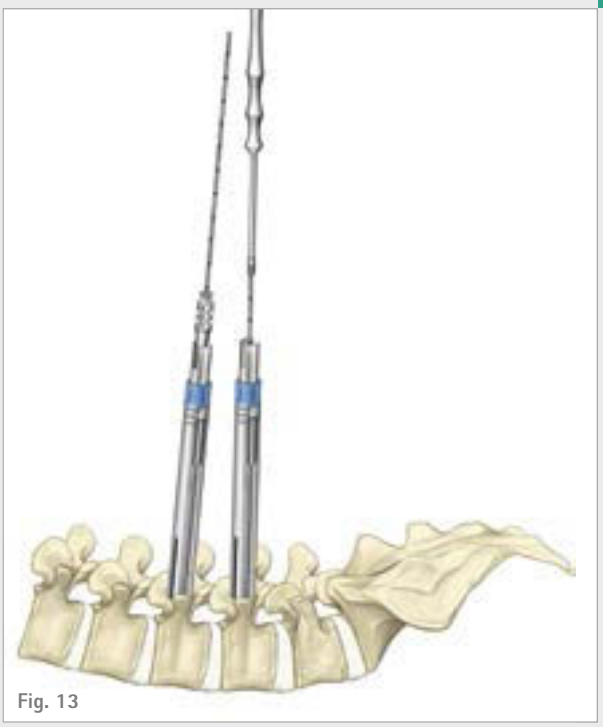


Fig. 13

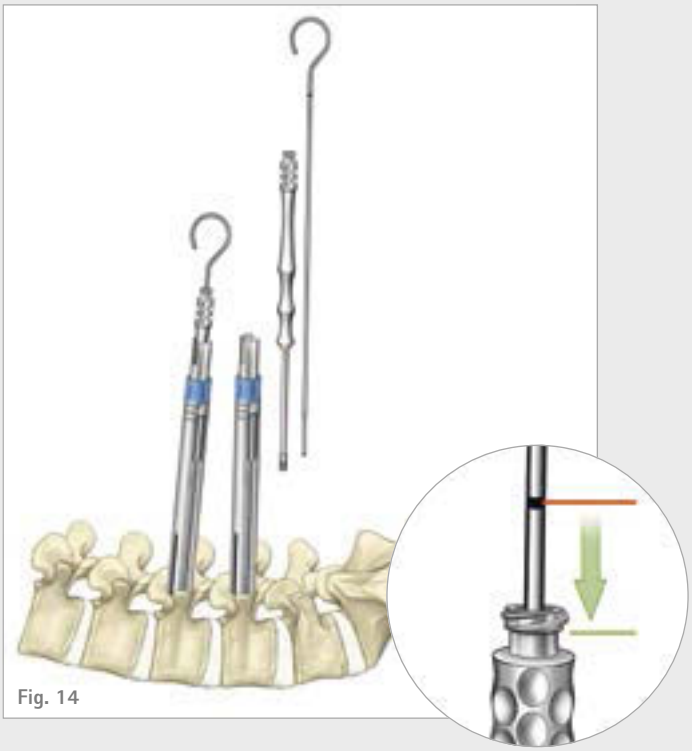


Fig. 14

B.10. CANNULA ATTACHMENT

The Augmentation Cannula (SR148SU) is placed over the K-Wire, connected with the augmentation screw and hand tightened. The K-Wire is removed afterwards. In case of having already removed the K-Wire the placement of the Cannula can be done by means of the Insertion Aid (included in the kit).

- Slide the Insertion Aid into the cannulation of the Augmentation Cannula. Slide the construct through the Clamping Sleeve (FW693R) and hand tighten the Augmentation Cannula to the augmentation screw. In order to avoid unwanted cement leakage make sure that there is a tight connection between Augmentation Cannula and Cement Applier.
- For each augmentation screw one Augmentation Cannula is required. When introducing the Augmentation Cannula ensure the polyaxial screw is aligned vertically in order to avoid cross threading. The marking on the Insertion Aid must not be visible.

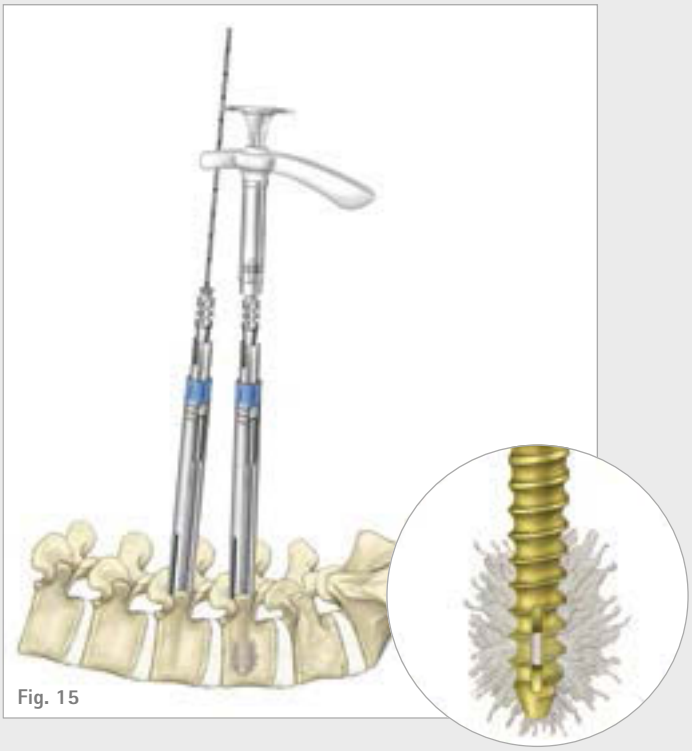


Fig. 15

B.11. CEMENT APPLICATION

- Ensure, that there is no cement at the connection between the Cement Applier and Augmentation Cannula.
- Attach the Cement Applier to the Augmentation Cannula. For cement application make sure that the consistency of the cement is pasty (see manufacturers specifications).
- Inject cement until it extrudes from the slots. Check that no cement leakage occurs. Cement injection should be effected under real time image intensifier control.
- Continue the injection until the adequate quantity of cement is introduced and shows in a cloud pattern.
- The manufacturers specifications for the cement hardening times have to be observed.
- The Augmentation Cannula remains in the pedicle screw until the cement has hardened. Otherwise there is a risk of contamination of the screw body.

Fig. 16

B.12. ROD LENGTH MEASURING

- Place the sliding gauge (A) over the scale. The measuring pins (C) are slided through the holders (A and B) with the tip downwards.
- Determine the length of the rod using the Rod Measuring Instrument (FW242R) by inserting it through the Clamping Sleeve into the screw heads.
- The etched scale on top of the length measuring instrument indicates the minimum recommended rod length.

Note:

- When using a pre-bent rod, 10 mm has to be added to the indicated length.


Fig. 17

B.13. SLEEVE ALIGNMENT

- Once the rod measurements are taken, align the notches of the Clamping Sleeves to each other.
- If needed, the orientation of the notches can be changed by rotating the Clamping Sleeves (FW693R) to the desired position.

Fig. 18

B.14. ROD INSERTION

- Assemble the inner shaft of the Rod Inserter (FW240R) to the main body by fully engaging the shaft. The inner shaft of the Rod Inserter must be firmly tightened to prevent premature in-situ release of the rod.
- The minimally invasive rod has a bullet tip to ease passage through soft tissue and a hex end geometry to engage with the Rod Inserter.
- Unscrew the knob of the inner shaft of the Rod Inserter and slide in the hex end into the distal opening of the instrument.
- Firmly tighten the inner shaft clockwise to secure the rod in place.
- Guide the rod down through the longitudinal slots of the Clamping Sleeves.

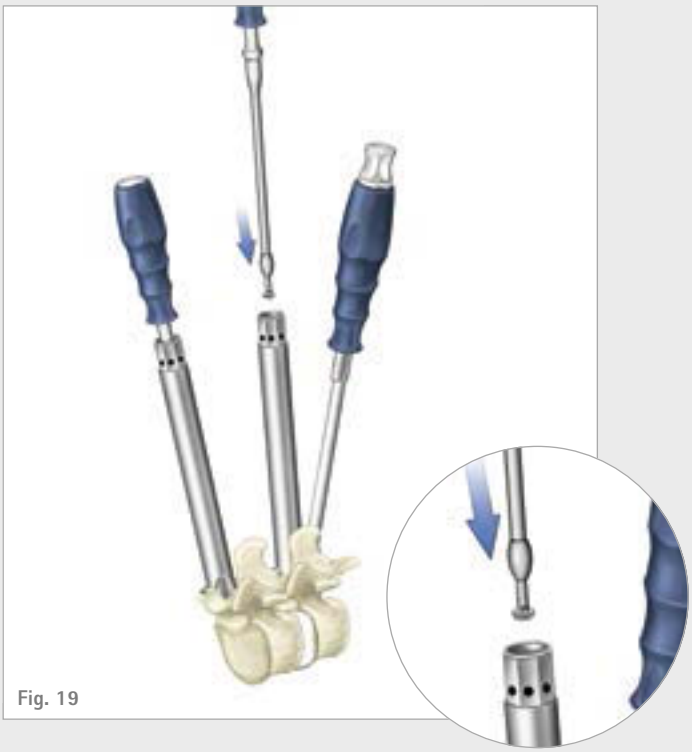


Fig. 19

B.15. SET SCREW PLACEMENT

- Slide the Percutaneous Outer Sleeve (FW735R) over the Clamping Sleeve.
- The self-retaining Set Screw Starter (FW697R) may be used to obtain a set screw from the storage disc.
- The hex of the instrument is aligned with the hex on the set screw, and the instrument is then pushed into the set screw to secure the connection.
- Thread the set screw into the screw body until it touches the rod. In order to facilitate the insertion of the set screw, the rod can be pushed down using the Percutaneous Outer Sleeve.

Fig. 20

B.16. FINAL TIGHTENING

Final tightening of each set screw is completed using the Torque Indicating Screw Driver (FW170R) along with the Counter Torque Handle (FW736R).

- Insert the Torque Indicating Screw Driver (FW170R) through the Percutaneous Outer Sleeve (FW735R), so the tip is exposed.
- Fully seat the tip of the torque wrench into the socket of the set screw.
- Engage the Counter Torque Handle (FW736R) to the hexagonal bolt of the Percutaneous Outer Sleeve.
- Turn the Torque Wrench in a clockwise direction while firmly holding the Counter Torque. Ensure, the arrows on the Torque Wrench line up with each other.

Caution:

Do not use the Torque Indicating Screw Driver without the Counter Torque Handle. Over tightening the set screw more than the specified setting of 10 Nm (90 in/lbs) could lead to implant failure. Damaged set screws must be replaced.

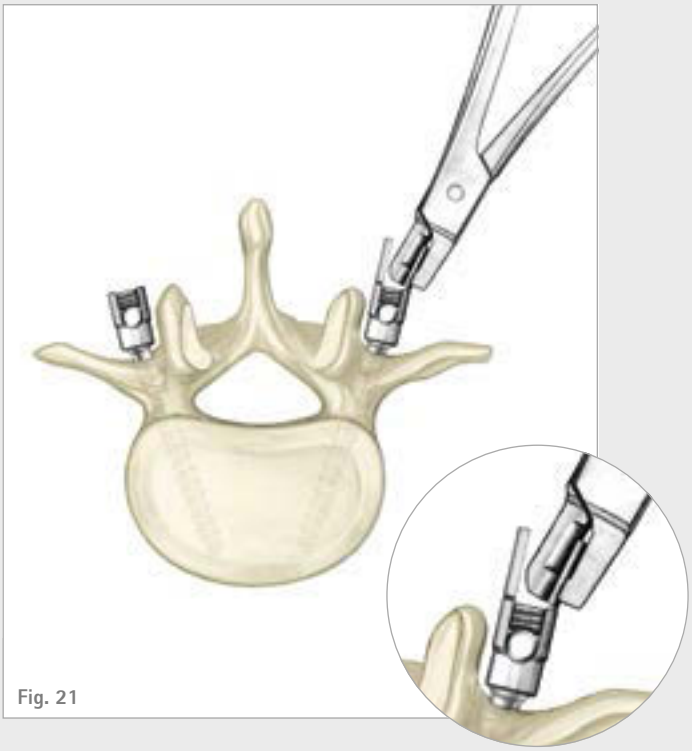


Fig. 21

B.17. TAB REMOVAL

- The locking mechanism of the Rod Inserter (FW240R) is opened and the rod released. Dismantle the whole instrumentation from the screws.
- After verifying that all screws are placed and tightened, remove the tabs with the Tab Breaker (FW179R).

TRUSTED EXPERIENCE

SPINAL FRACTURES AND TRAUMA

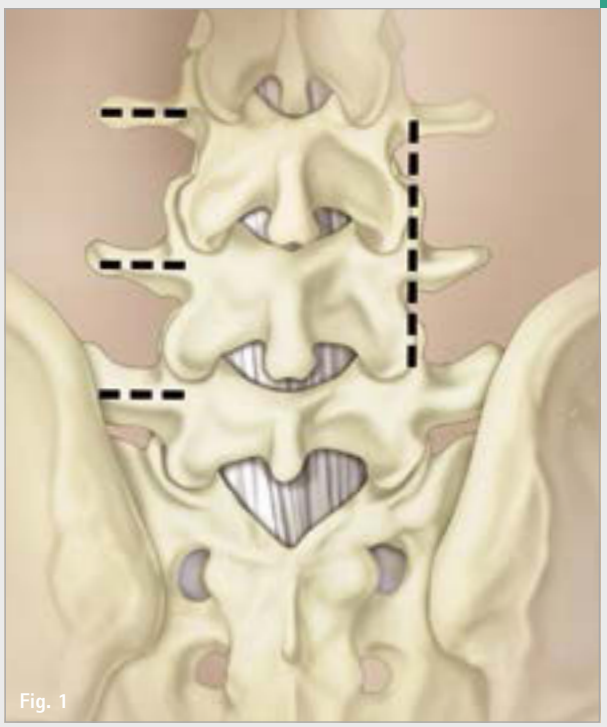


Fig. 1

C.1. PATIENT POSITIONING, MONITORING AND INCISION

- Position the patient on a radiolucent OR table in prone position. The OR table should have enough clearance for a fluoroscopic C-arm to rotate freely.
- Locate the pedicles of interest through A/P and lateral X-ray and mark appropriate incision areas on skin.
- On the ipsilateral side, make an incision of at least 10 mm at the location where each pedicle screw will be placed.
- Ensure the incision is located to allow proper trajectory for minimally invasive pedicle screw insertion. Ensure the fascia is cut to the same length.
- Perform the same procedure for the contralateral side.
- On the contralateral side, the mini-open TLIF technique can be used to adequately decompress and insert TLIF interbody to augment the percutaneous side.


Fig. 2

C.2. PEDICLE PREPARATION

- Once the entry point of the screw has been determined the guiding instrument consisting of Trocar (FW271M) and K-Wire Aiming Device (FW258M) is introduced at the junction of the facet and the transverse process. Ensure that the K-Wire Aiming Device is placed through the pedicle-vertebral body junction to facilitate the placement of the K-Wire.
- Use fluoroscopy to monitor the position of the Trocar during insertion. Avoid inserting the needle too deep into the vertebral body as there is danger of perforating large vessels.
- The Trocar (FW271M) is removed while the K-Wire Aiming Device (FW258M) remains in position.

Fig. 3

C.3. K-WIRE INSERTION

- The K-Wire (FW247S) is introduced through the K-Wire Aiming Device (FW258M).
- The laser etchings on the K-Wire need to be placed away from the patient. The K-Wire should be introduced in a way that its distal tip represents the end position of the pedicle screw tip.
- Monitor the K-Wire tip to ensure it does not penetrate the anterior wall of the vertebral body. The depth of the K-Wire is essential for the determination of the screw length.
- Repeat the steps for each K-Wire to be placed.
- In order to avoid oscillating or bending the K-Wire the K-Wire Protection Sleeve (FW352R) may be used.

Fig. 4

C.4. SOFT TISSUE DILATION

- Fascia and muscles should be dilated to allow for screw placement.
- Dilate the fascia and spinal muscles by inserting the Dilation Sleeve (FW354R) over the K-Wire Aiming Device (FW258M). The Dilator should be docked on bony anatomy to minimize tissue creepage.

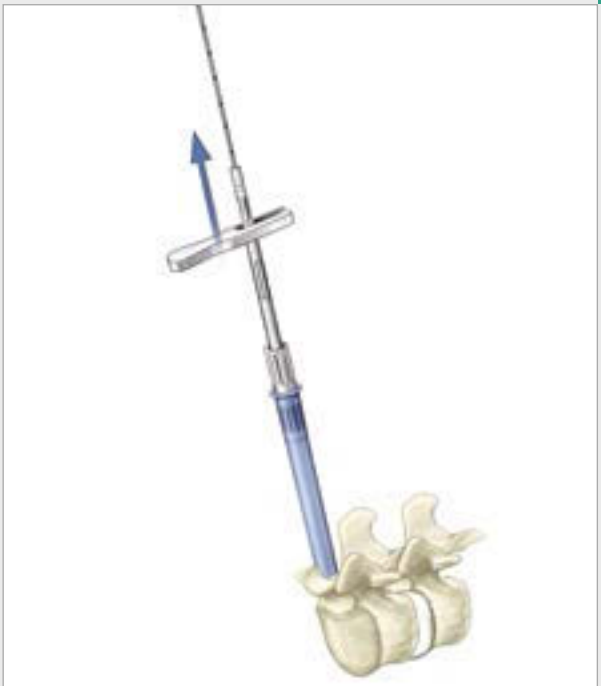


Fig. 5

- Remove the K-Wire Aiming Device (FW258M) by using the Handle (FW274M) and holding the K-Wire firmly in place.
- Slide the Tissue Protection Sleeve (FW355P) over the Dilation Sleeve (FW354R) until it touches the pedicle entry point.
- Remove the Dilation Sleeve (FW354R) while holding the Protection Sleeve firmly in place.

Fig. 6

C.5. BONE PROBING

- If additional bone probing is preferred, the straight cannulated Bone Probe (FW263R) can be used.
- Hold the K-Wire firmly and slide the cannulated Bone Probe (FW263R) over the K-Wire and probe to the desired depth.

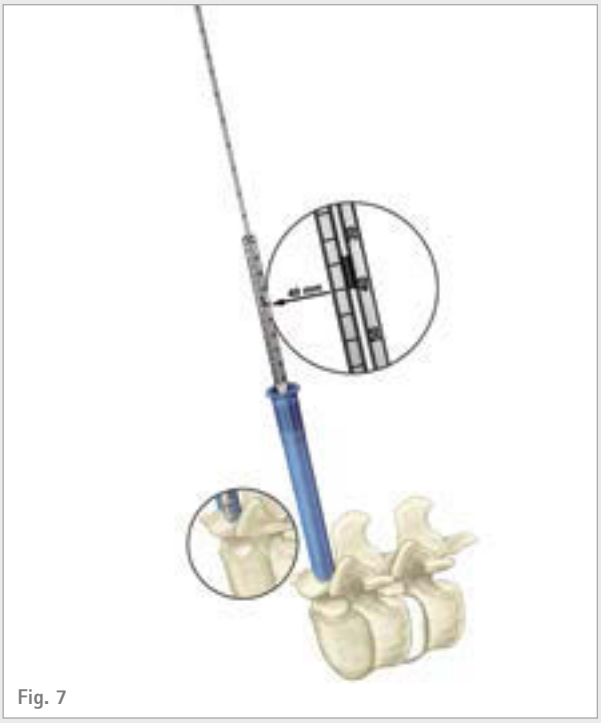


Fig. 7

C.6. SCREW LENGTH MEASURING

- Under fluoroscopic guidance, ensure the K-Wire is at an adequate depth, approximating the final screw location in the bone. Avoid inserting the K-Wire too deep into the vertebral body as there is danger of perforating large vessels.
- Hold the K-Wire firmly and slide the Screw Length Measuring Device (FW351R) over the K-Wire.
- Read the screw length at the bottom of the widest laser marking on the K-Wire. The reading is an approximation, depending on the depth of the K-Wire in bone.

Fig. 8

C.7. PEDICLE TAPPING

- If additional bone tapping is preferred, the screw taps can be used.
- To tap, attach either the straight Ratchet Handle (FW165R) or t-shaped Ratchet Handle (FW167R) to the appropriate screw tap based on the corresponding screw diameter. The included screw taps range from 4.5 to 8.5 mm in 1 mm increments (FW264R – FW268R) and each are undersized by 0.5 mm.

Fig. 9

C.8. SLEEVE ASSEMBLY

- The placement of the poly- and monoaxial screws is performed with the Clamping Sleeve (FW693R), Monoaxial Screw Driver (FW696R) or Polyaxial Screw Driver (FW695R) and the Handle (FW165R or FW167R).
- Slide the blue clamping ring (1) onto the inner clamping sleeve (2) and screw it to the bottom of the thread.
- The inner clamping sleeve (2) is then inserted into the outer sleeve (3). Ensure the sliding groove and the groove stone are aligned.

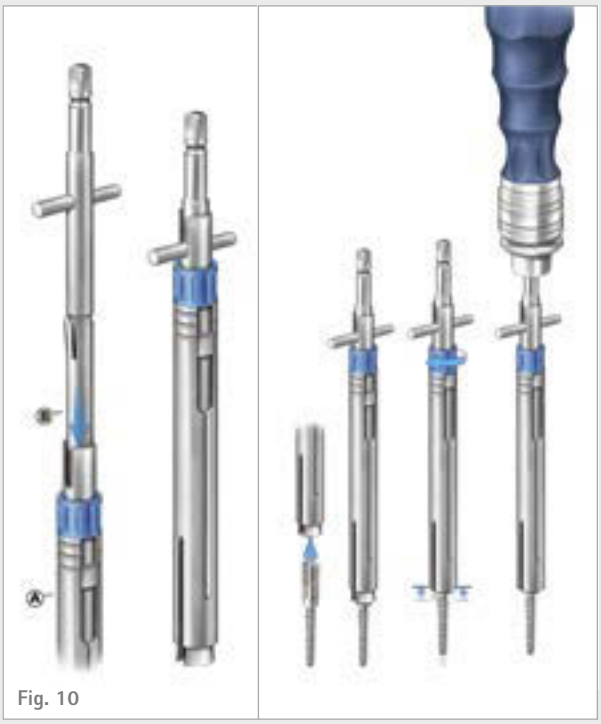


Fig. 10

C.8.1. ASSEMBLY OF MONOAXIAL SCREW

- The Monoaxial Screw Driver (FW696R) (B) is inserted into the Clamping Sleeve (FW693R) (A), the pins of the Screw Driver have to be fully inserted into the groove of the Clamping Sleeve.
- The monoaxial screw is inserted from the bottom. By turning the blue clamping ring down to the limit stop, the pedicle screw is firmly connected with the Clamping Sleeve (FW693R).

Fig. 11

C.8.2. ASSEMBLY OF POLYAXIAL SCREW

- The Polyaxial Screw Driver (FW695R) (B) is inserted into the Clamping Sleeve (FW693R) (A), the pins of the Screw Driver have to be fully inserted into the groove of the Clamping Sleeve.
- The polyaxial screw is inserted from the bottom. By turning the blue clamping ring down to the limit stop, the pedicle screw is firmly connected with the Clamping Sleeve (FW693R).
- If the polyaxicity of the screw remains, the Screw Driver is not fully engaged.

Fig. 12

C.9. SCREW PLACEMENT

- Slide the assembled Clamping Sleeve over the K-Wire.
- Insert the screw to the appropriate depth. If needed, fluoroscopic guidance can be used.
- Remove the K-Wire, using the Grasping Forceps (LX182R), after an appropriate amount of bone purchase is established to avoid driving the K-Wire into a vertebral artery.
- Once the screw is fully inserted, remove the Screw Driver from the screw, by pulling the handle.
- Repeat the steps for all subsequent screws.

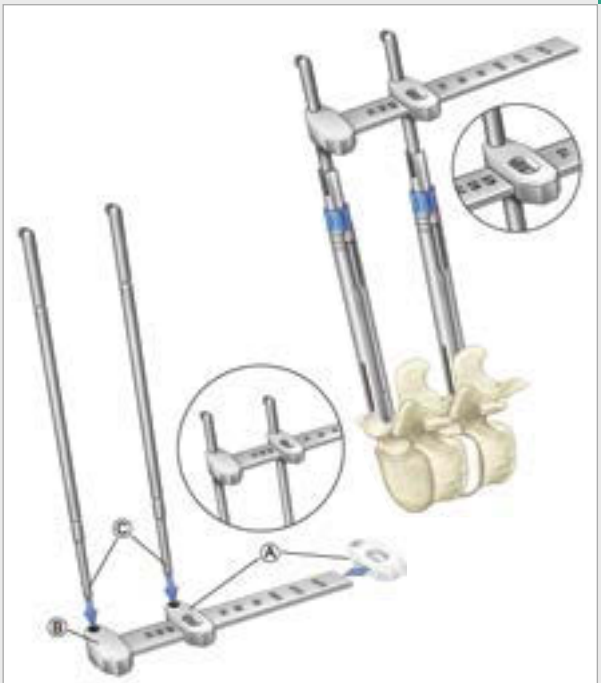


Fig. 13

C.10. ROD LENGTH MEASURING

- Place the sliding gauge (A) over the scale. The measuring pins (C) are slided through the holders (A and B) with the tip downwards.
- Determine the length of the rod using the Rod Measuring Instrument (FW242R) by inserting it through the Clamping Sleeve into the screw heads.
- The etched scale on top of the length measuring instrument indicates the minimum recommended rod length.

Note:

- When using a pre-bent rod, 10 mm has to be added to the indicated length.


Fig. 14

C.11. SLEEVE ALIGNMENT

- Once the rod measurements are taken, align the notches of the Clamping Sleeves to each other.
- If needed, the orientation of the notches can be changed by rotating the Clamping Sleeves to the desired position.

Fig. 15

C.12. ROD PLACEMENT

- Assemble the inner shaft of the Rod Inserter (FW240R) to the main body by fully engaging the shaft. The inner shaft of the Rod Inserter must be firmly tightened to prevent premature in-situ release of the rod.
- The minimally invasive rod has a bullet tip to ease passage through soft tissue and a hex end geometry to engage with the Rod Inserter.
- Unscrew the knob of the inner shaft of the Rod Inserter and slide in the hex end into the distal opening of the instrument.
- Firmly tighten the inner shaft clockwise to secure the rod in place.
- Guide the rod down through the longitudinal slots of the Clamping Sleeves (FW693R).

Fig. 16

C.13. SET SCREW PLACEMENT

- Slide the Percutaneous Outer Sleeve (FW735R) over the Clamping Sleeve.
- The self-retaining Set Screw Starter (FW697R) may be used to obtain a set screw from the storage disc.
- The hex of the instrument is aligned with the hex on the set screw, and the instrument is then pushed into the set screw to secure the connection.
- Thread the set screw into the screw body until it touches the rod. In order to facilitate the insertion of the set screw, the rod can be pushed down using the Percutaneous Outer Sleeve.

Fig. 17

C.14. LEVER PLACEMENT

- Insert the Lever Threadpipe (FW734R) through the Clamping Sleeve (FW693R) until it touches the screw body. Then screw the construct down until it blocks.

Fig. 18

C.15. DISTRACTOR ASSEMBLY

- Place the first distraction nut on the rear parallel guide of the frame (A).
- Position the free distraction portion (B) on the parallel guide.
- Place the second distraction nut on the rear parallel guide.
- Attach the Distraction Arms (FW239R) (C) on the connection parts of the Distractor (FW238R).

Fig. 19

Fig. 20

C.16. DISTRACTOR PLACEMENT

- The Distractor (consisting of FW238R and FW239R) is now fixed to the cranial and caudal Percutaneous Outer Sleeves by sliding the pivots down the guiding groove. Ensure that the distraction arms are inserted parallel to the Percutaneous Outer Sleeve.
- Repeat this process on the contra-lateral side.
- Distraction can be effected using the distraction nut. The distraction nut can be manipulated by hand or with the Fixation Nut Wrench (FW237R).
- If preferred, distraction may take place under fluoroscopic control.

Fig. 21

C.17. SPINDLE DISTRACTOR ASSEMBLY

- If necessary, the natural lordosis can be restored with the Distraction Spindle (FW241R).
- The attachment jig (A) is placed on the spindle (B) with the pivot inward and fixed with the distraction nut (C).

Fig. 22

Fig. 23

C.18. SPINDLE DISTRACTOR PLACEMENT

- The pivots of the spindle are inserted into the groove on the upper part of the Outer Sleeves. Ensure that the Distraction Spindle is placed parallel to the Outer Sleeve to avoid tilting.
- Repeat this process on the contra-lateral side.
- Lordosis can be corrected using the distraction nut. The distraction nut can be manipulated by hand or with the Fixation Nut Wrench (FW237R).

Fig. 24

Fig. 25

C.19. FINAL TIGHTENING

- With the regulating screw of the Lever Threadpipe (FW734R) the Percutaneous Outer Sleeve (FW735R) is threaded down until it blocks.
- The regulating screw of the Lever Threadpipe (FW734R) has to be threaded back by a quarter turn in order not to block the Screw Driver (FW228R).
- Attach the Ratchet Handle to the Screw Driver (FW228R). Finger tighten the set screw by turning the Ratchet Handle.
- Ensure the proper position of the rod within the screw body: the marking on the thread of the Lever Threadpipe (FW735R) must be visible above the regulating screw – "P" stands for polyaxial screws and "M" for monoaxial screws.
- Remove the instruments by pulling the Screw Driver (FW228R) out and unscrewing the Lever Threadpipe (FW734R).

Final tightening of each set screw is completed using the Torque Indicating Screw Driver (FW170R) along with the Counter Torque (FW736R).

- Insert the Torque Indicating Screw Driver (FW170R) through the Percutaneous Outer Sleeve (FW735R), so the tip is exposed.
- Fully seat the tip of the torque into the socket of the set screw.
- Engage the Counter Torque Indicating Screw Driver (FW170R) (FW736R) to the hexagonal bolt of the Percutaneous Outer Sleeve (FW735R).
- Turn the Torque Indicating Screw Driver in a clockwise direction while firmly holding the Counter Torque. Ensure that the arrows on the Torque Wrench are lined up with each other.

Caution:

- Do not use the Torque indictaing Screw Driver without the Counter Torque. Over tightening the set screw more than the specified setting of 10 Nm (90 in/lbs) could lead to implant failure. Damaged set screws must be replaced.

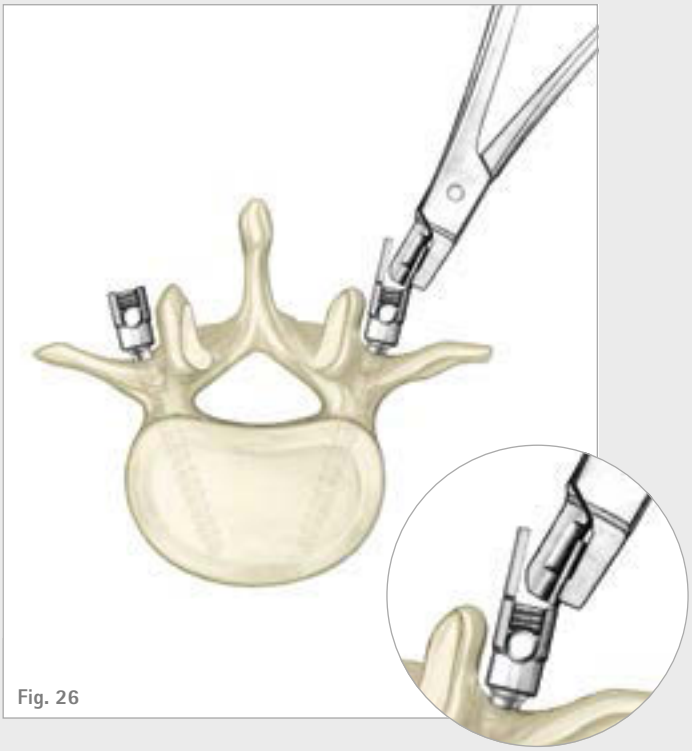


Fig. 26

C.20. TAB REMOVAL

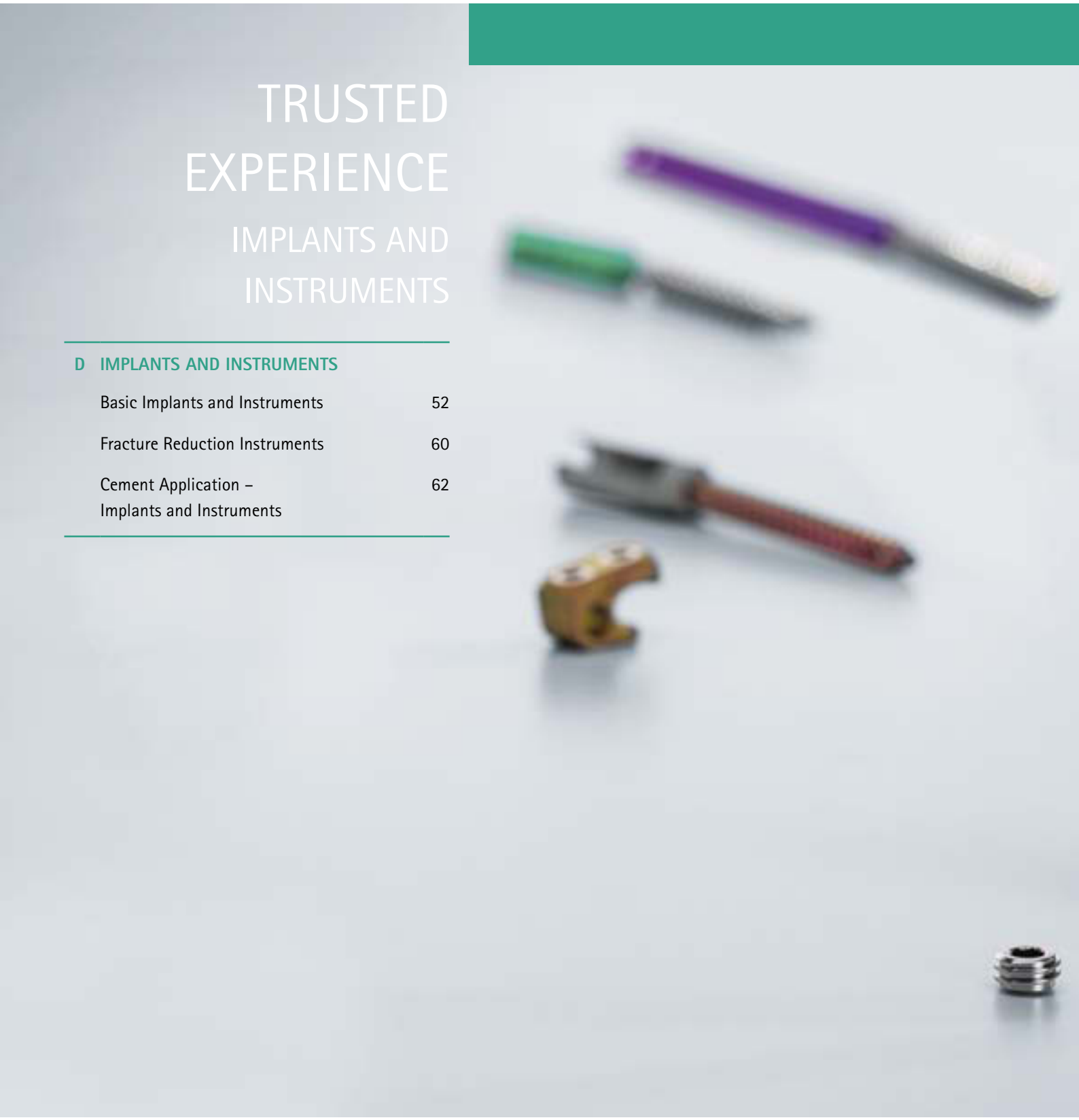
- The locking mechanism of the Rod Inserter (FW240R) is opened and the rod released. Dismantle the whole instrumentation from the screws.
- After verifying that all screws are placed and tightened, remove the tabs with the Tab Breaker (FW179R).

AESCULAP® S4®

D | IMPLANTS AND INSTRUMENTS OVERVIEW

TRUSTED EXPERIENCE

IMPLANTS AND INSTRUMENTS

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2

S4® Implant Tray for Percutaneous Approach

PINS FOR POLYAXIAL SCREWS (FOR IMPLANT TRAY)	Article No.	Description	Quantity
	TE854P	Pin for Polyaxial Screw, Ø 4.5 mm, Blue	1 Pack contains 10 pieces
	TE855P	Pin for Polyaxial Screw, Ø 5 mm, Yellow	
	TE856P	Pin for Polyaxial Screw, Ø 6 mm, Grey	
	TE857P	Pin for Polyaxial Screw, Ø 7 mm, Light Blue	
	TE858P	Pin for Polyaxial Screw, Ø 8 mm, Purple	

PINS FOR MONOAXIAL SCREWS (FOR IMPLANT TRAY)	Article No.	Description	Quantity
	TE864P	Pin for Monoaxial Screw, Ø 4.5 mm, Blue	1 Pack contains 10 pieces
	TE865P	Pin for Monoaxial Screw, Ø 5 mm, Yellow	
	TE866P	Pin for Monoaxial Screw, Ø 6 mm, Grey	
	TE867P	Pin for Monoaxial Screw, Ø 7 mm, Light Blue	
	TE868P	Pin for Monoaxial Screw, Ø 8 mm, Purple	

SET SCREWS	Article No.	Description
	SW790T	S4 Set Screw for Monoaxial / Polyaxial Screws
	SW375T	S4 Set Screw for Monoaxial / Polyaxial Screws cannulated

FW259P
Set

MONOAXIAL PEDICLE SCREWS	Article No.	Size	Description
	**SW421T**	4.5 x 25 mm	S⁴ Monoaxial Screw, Ø 4.5 mm, cannulated
	SW422T	4.5 x 30 mm	
	SW423T	4.5 x 35 mm	
	SW424T	4.5 x 40 mm	
	SW426T	4.5 x 45 mm	
	SW427T	4.5 x 50 mm	
	**SW431T**	5.5 x 25 mm	S⁴ Monoaxial Screw, Ø 5.5 mm, cannulated
	SW432T	5.5 x 30 mm	
	SW433T	5.5 x 35 mm	
	SW434T	5.5 x 40 mm	
	SW436T	5.5 x 45 mm	
	SW437T	5.5 x 50 mm	
	**SW441T**	6.5 x 25 mm	S⁴ Monoaxial Screw, Ø 6.5 mm, cannulated
	SW442T	6.5 x 30 mm	
	SW443T	6.5 x 35 mm	
	SW444T	6.5 x 40 mm	
	SW446T	6.5 x 45 mm	
	SW447T	6.5 x 50 mm	
	SW448T	6.5 x 55 mm	
	SW449T	6.5 x 60 mm	
	**SW461T**	7.5 x 25 mm	S⁴ Monoaxial Screw, Ø 7.5 mm, cannulated
	SW462T	7.5 x 30 mm	
	SW463T	7.5 x 35 mm	
	SW464T	7.5 x 40 mm	
	SW466T	7.5 x 45 mm	
	SW467T	7.5 x 50 mm	
	SW468T	7.5 x 55 mm	
	SW469T	7.5 x 60 mm	
	**SW472T**	8.5 x 30 mm	S⁴ Monoaxial Screw, Ø 8.5 mm, cannulated
	SW473T	8.5 x 35 mm	
	SW474T	8.5 x 40 mm	
	SW476T	8.5 x 45 mm	
	SW477T	8.5 x 50 mm	
	SW478T	8.5 x 55 mm	
	SW479T	8.5 x 60 mm	

FW259P – S4® Implant Tray for Percutaneous Approach

POLYAXIAL PEDICLE SCREWS	Article No.	Size	Description
	SW321T	4.5 x 25 mm	S4 Polyaxial Screw, Ø 4.5 mm, cannulated
	SW322T	4.5 x 30 mm	
	SW323T	4.5 x 35 mm	
	SW324T	4.5 x 40 mm	
	SW326T	4.5 x 45 mm	
	SW327T	4.5 x 50 mm	
	SW331T	5.5 x 25 mm	S4 Polyaxial Screw, Ø 5.5 mm, cannulated
	SW332T	5.5 x 30 mm	
	SW333T	5.5 x 35 mm	
	SW334T	5.5 x 40 mm	
	SW336T	5.5 x 45 mm	
	SW337T	5.5 x 50 mm	
	SW341T	6.5 x 25 mm	S4 Polyaxial Screw, Ø 6.5 mm, cannulated
	SW342T	6.5 x 30 mm	
	SW343T	6.5 x 35 mm	
	SW344T	6.5 x 40 mm	
	SW346T	6.5 x 45 mm	
	SW347T	6.5 x 50 mm	
	SW348T	6.5 x 55 mm	
	SW349T	6.5 x 60 mm	
	SW361T	7.5 x 25 mm	S4 Polyaxial Screw, Ø 7.5 mm, cannulated
	SW362T	7.5 x 30 mm	
	SW363T	7.5 x 35 mm	
	SW364T	7.5 x 40 mm	
	SW366T	7.5 x 45 mm	
	SW367T	7.5 x 50 mm	
	SW368T	7.5 x 55 mm	
	SW369T	7.5 x 60 mm	
	SW372T	8.5 x 30 mm	S4 Polyaxial Screw, Ø 8.5 mm, cannulated
	SW373T	8.5 x 35 mm	
	SW374T	8.5 x 40 mm	
	SW376T	8.5 x 45 mm	
	SW377T	8.5 x 50 mm	
	SW378T	8.5 x 55 mm	
	SW379T	8.5 x 60 mm	

FW259P
Set

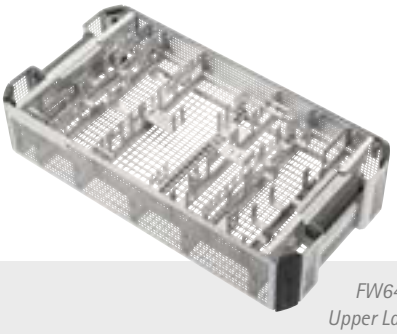
RODS

Article No.	Size	Description
SW554T	5.5 x 35 mm	Rod with tip and hexagonal connection, pre-bent, Ø 5.5 mm
SW555T	5.5 x 40 mm	
SW556T	5.5 x 45 mm	
SW557T	5.5 x 50 mm	
SW558T	5.5 x 55 mm	
SW559T	5.5 x 60 mm	
SW561T	5.5 x 70 mm	
SW562T	5.5 x 80 mm	
SW563T	5.5 x 90 mm	
SW564T	5.5 x 100 mm	
SW566T	5.5 x 110 mm	
SW567T	5.5 x 120 mm	

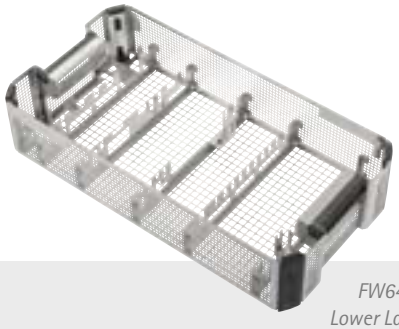
SW573T	5.5 x 35 mm	Rod with tip and hexagonal connection, straight, Ø 5.5 mm
SW574T	5.5 x 40 mm	
SW576T	5.5 x 45 mm	
SW577T	5.5 x 50 mm	
SW578T	5.5 x 55 mm	
SW579T	5.5 x 60 mm	
SW581T	5.5 x 70 mm	
SW582T	5.5 x 80 mm	
SW583T	5.5 x 90 mm	
SW584T	5.5 x 100 mm	
SW585T	5.5 x 110 mm	
SW586T	5.5 x 120 mm	
SW587T	5.5 x 150 mm	
SW588T	5.5 x 180 mm	
SW589T	5.5 x 200 mm	Rod with hexagonal connection, straight, Ø 5.5 mm
SW590T	5.5 x 300 mm	
SW591T	5.5 x 400 mm	
SW592T	5.5 x 500 mm	

FW640 – S4® Basic Instruments

UPPER LAYER	Article No.	Description	Quantity
	**FW692R**	Percutaneous Cleaning Device	1
	**FW170R**	Torque Indicating Screw Driver	1
	**FW179R**	Tab Breaker	1
	**FW263R**	Bone Probe, straight	1
	**FW165R**	Ratchet Handle, straight	2
	**FW258M**	K-Wire Aiming Device	2
	**FW271M**	Trocar	1
	**FW352R**	K-Wire Protection Sleeve	1
	FW351R	Screw Length Measuring Device	1



FW649R
Upper Layer



FW649R
Lower Layer

LOWER LAYER	Article No.	Description	Quantity
	**FW264R**	Screw Tap, Ø 4.5 mm	1
	FW265R	Screw Tap, Ø 5.5 mm	1
	FW266R	Screw Tap, Ø 6.5 mm	1
	FW267R	Screw Tap, Ø 7.5 mm	1
	FW268R	Screw Tap, Ø 8.5 mm	1
	**FW240R**	Rod Insertion Instrument	2
	**FW242R**	Rod Length Measuring Instrument	1
	**FW024R**	French Rod Bender	1
	**FW174R**	Screw Driver with 3.5 mm hex tip	1
	**FW193R**	Set Screw Revision Screw Driver 4 mm hex tip	1
	**FW247S**	K-Wire, blunt	8
	**FW274M**	Handle for removal of FW258R	1

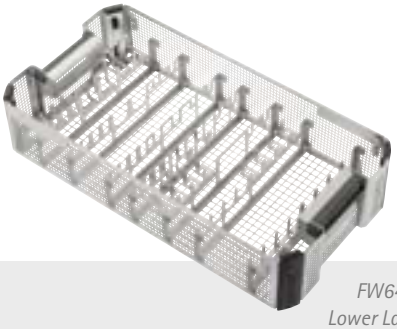
TRAY AND OTHERS	Article No.	Description	Quantity
	FW649R	Tray Basic Instruments	1
	JA455R	Lid for Aesculap OrthoTray DIN w/o handle	1
	TF130	Packing Stencil f/FW649R	1
	TF140	Graphic Template f/FW649R	1*

** This article is optional.*

FW640 – S4® Percutaneous Instruments

UPPER LAYER	Article No.	Description	Quantity
	**FW354R**	Dilatation Sleeve	2
	**FW693R**	Clamping Tube	8
LOWER LAYER	**Article No.**	**Description**	**Quantity**
	**FW355P**	Tissue Protection Sleeve	4
	**FW695R**	Polyaxial Driver	2
	**FW696R**	Monoaxial Driver	2
	**FW697R**	Set Screw Starter	2
	**FW735R**	Percutaneous Outer Sleeve	4
	**FW736R**	Counter Torque	1

FW641R
Upper Layer



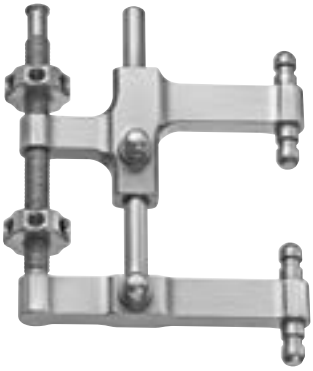
FW641R
Lower Layer

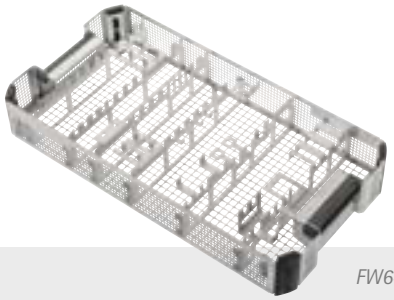
TRAY AND OTHERS

Article No.	Description	Quantity
FW641R	Tray Percutaneous Preparation Instruments	1
JA455R	Lid for Aesculap OrthoTray DIN w/o handle	1
TF131	Packing Stencil f/FW641R	1
TF141	Graphic Template f/FW641R	1*

** This article is optional.*

FW640 – S4® Percutaneous FRI Instruments

INSTRUMENTS	Article No.	Description	Quantity
	**FW237R**	Fixation Nut Wrench	2
	**FW238R**	Distractor	2
	**FW239R**	Distraction Arm	4
	**FW241R**	Distraction Spindle	2
	**FW734R**	Rep. Lever Threadpipe Percutaneous	4
	**FW228R**	Screw Driver	2



FW642R

TRAY AND OTHERS	Article No.	Description	Quantity
	FW642R	Tray Percutaneous Reduction Instruments	1
	JA455R	Lid for Aesculap OrthoTray DIN w/o handle	1
	TF132	Packing Stencil f/FW642R	1
	TF142	Graphic Template f/FW642R	1*

** This article is optional.*

AESCULAP® S4®

D | CEMENT APPLICATION – IMPLANTS AND INSTRUMENTS

Additional to FW259P – Implants

MONOAXIAL PEDICLE SCREWS
(STERILE PACKED)

Article No.	Size	Description
SW510TS	5.5 x 35 mm	S4 Monoaxial Pedicle Screw, Ø 5.5 mm, cannulated
SW515TS	5.5 x 40 mm	
SW518TS	5.5 x 45 mm	
SW519TS	5.5 x 50 mm	
SW531TS	6.5 x 35 mm	S4 Monoaxial Pedicle Screw, Ø 6.5 mm, cannulated
SW532TS	6.5 x 40 mm	
SW533TS	6.5 x 45 mm	
SW534TS	6.5 x 50 mm	
SW536TS	6.5 x 55 mm	
SW537TS	6.5 x 60 mm	
SW538TS	6.5 x 70 mm	
SW539TS	6.5 x 80 mm	
SW541TS	7.5 x 35 mm	S4 Monoaxial Pedicle Screw, Ø 7.5 mm, cannulated
SW542TS	7.5 x 40 mm	
SW543TS	7.5 x 45 mm	
SW544TS	7.5 x 50 mm	
SW546TS	7.5 x 55 mm	
SW547TS	7.5 x 60 mm	
SW548TS	7.5 x 70 mm	
SW549TS	7.5 x 80 mm	

POLYAXIAL PEDICLE SCREWS
(STERILE PACKED)

Article No.	Size	Description
SW621TS	5.5 x 35 mm	S4 Polyaxial Pedicle Screw, Ø 5.5 mm, cannulated
SW622TS	5.5 x 40 mm	
SW623TS	5.5 x 45 mm	
SW624TS	5.5 x 50 mm	
SW631TS	6.5 x 35 mm	S4 Polyaxial Pedicle Screw, Ø 6.5 mm, cannulated
SW632TS	6.5 x 40 mm	
SW633TS	6.5 x 45 mm	
SW634TS	6.5 x 50 mm	
SW636TS	6.5 x 55 mm	
SW637TS	6.5 x 60 mm	
SW638TS	6.5 x 70 mm	
SW639TS	6.5 x 80 mm	
SW641TS	7.5 x 35 mm	S4 Polyaxial Pedicle Screw, Ø 7.5 mm, cannulated
SW642TS	7.5 x 40 mm	
SW643TS	7.5 x 45 mm	
SW644TS	7.5 x 50 mm	
SW646TS	7.5 x 55 mm	
SW647TS	7.5 x 60 mm	
SW648TS	7.5 x 70 mm	
SW649TS	7.5 x 80 mm	

Additional to FW641R and FW649R

INSTRUMENT
(STERILE PACKED)

Article No.	Description	Quantity
SR148SU	S4 Injection Cannula, short, 200 mm	1

NOTES

AESCULAP® – a B. Braun brand

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