B BRAUN
SHARING EXPERTISE

AESCULAP® Ennovate®
SOLUTIONS BEYOND FUSION

SPINE SURGERY

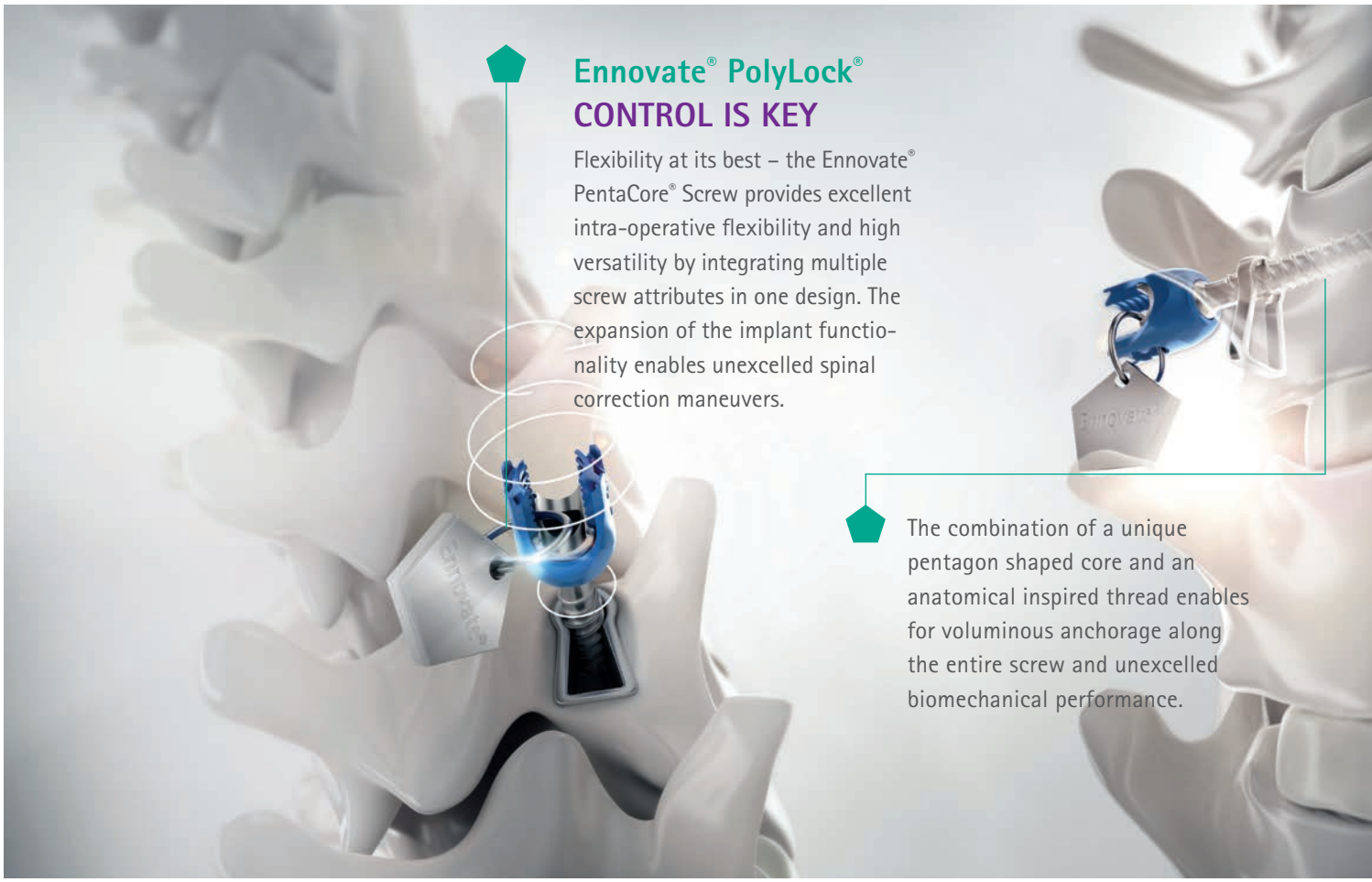
AESCULAP® Ennovate®

DEGENERATIVE SPINE

MINIMALLY INVASIVE WORKFLOW

AESCULAP® Ennovate®

DEGENERATIVE SPINE



Ennovate® PolyLock®
CONTROL IS KEY

Flexibility at its best – the Ennovate® PentaCore® Screw provides excellent intra-operative flexibility and high versatility by integrating multiple screw attributes in one design. The expansion of the implant functionality enables unexcelled spinal correction maneuvers.

The combination of a unique pentagon shaped core and an anatomical inspired thread enables for voluminous anchorage along the entire screw and unexcelled biomechanical performance.

Ennovate® PentaCore® Screw TURNS DESIGN INTO STABILITY

The unique design allows for immediate grip and traction from the first turn, providing you with immediate bone purchase, tactile feedback and sense of control.

TABLE OF CONTENT

ENGINEERED FOR SURGEONS, DESIGNED FOR HOSPITALS

Ennovate® is the epitome of the most advanced spinal platform provided by AESCULAP®. This solution platform leverages spinal fusion on a whole new level by placing the patient in the center of the treatment and allowing the surgeon to perform uncompromising spinal corrections across all surgeries.

The surgical manual is intended to be used as a guideline for correction techniques with Ennovate® in presence of a degenerated spine. Instrumented levels and the combination of implants and instruments are based on surgeon preference and patient pathology.

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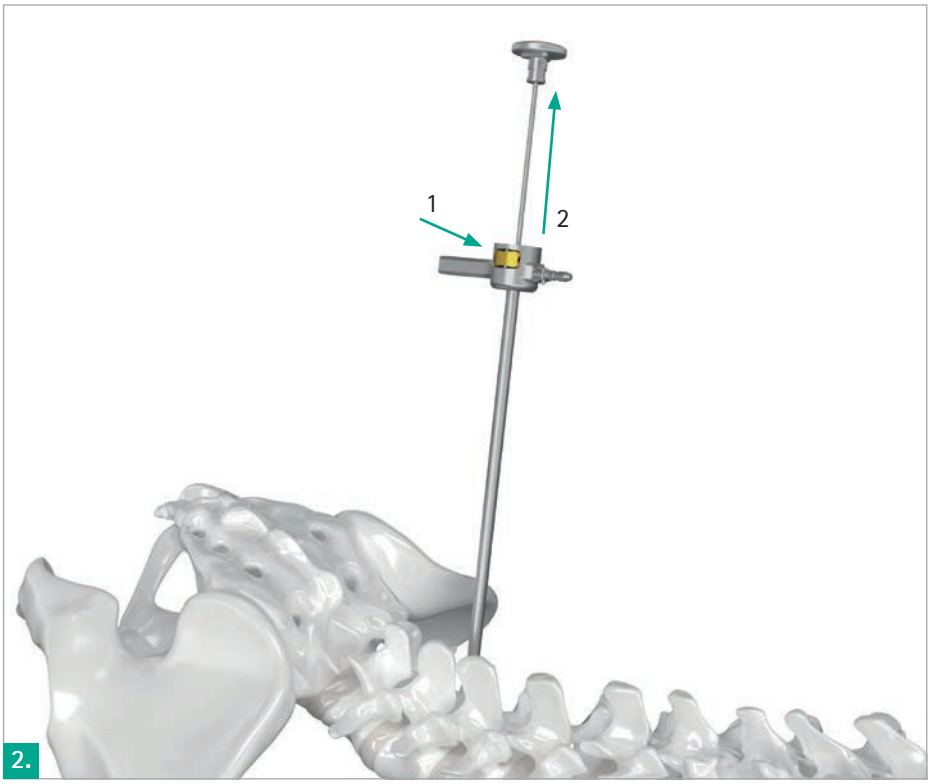
DEGENERATIVE SPINE
A. PEDICLE PREPARATION

PEDICLE PREPARATION

- After determining the entry point of the screw and the surgical trajectory, an incision in the skin and the fascia can be performed.
- The perforation of the cortex is created with either the single-use or re-usable Bone Access Needle.
- The Bone Access Needle consists of two parts, a Bone Access Needle Handle and a Bone Access Needle Trocar which is located inside of the sleeve of the Bone Access Needle Handle.

1.

- After cortex perforation, push the golden button (1) and remove the Bone Access Needle Trocar (2). Ensure that the Bone Access Needle Handle remains in position.
- The placement of the Bone Access Needle tip shall be confirmed using intra-operative imaging prior to screw placement.



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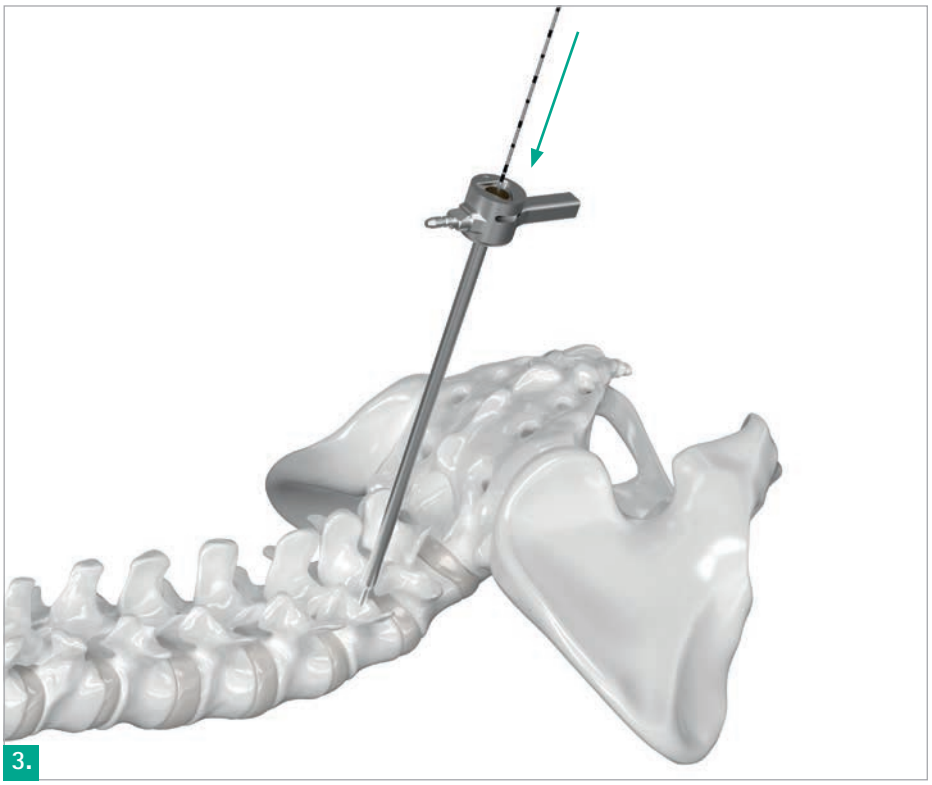

- The Guide Wire is introduced through the canulation of the Bone Access Needle Handle, using the Guide Wire Forceps and Slotted Hammer.
- Ensure the roughened tip of the Guide Wire is placed inside the vertebra. The Guide Wire should be introduced so its distal tip represents the end position of the pedicle screw tip.
- While introducing the Guide Wire, ensure that the tip of the Guide Wire does not penetrate the anterior wall of the vertebral body.
- The placement of the Guide Wire tip shall be confirmed using intra-operative imaging prior to screw placement.

- Remove the Bone Access Needle Handle by pulling it off the patient. If needed, the Slotted Hammer can be used.
- Ensure that the Guide Wire is held firmly in place during the removal of the Bone Access Needle Handle.
- If desired, the Skin Incision Guide can be slid over the Guide Wire for skin and fascia incision. The depth of penetration conforms to the desired incision length.

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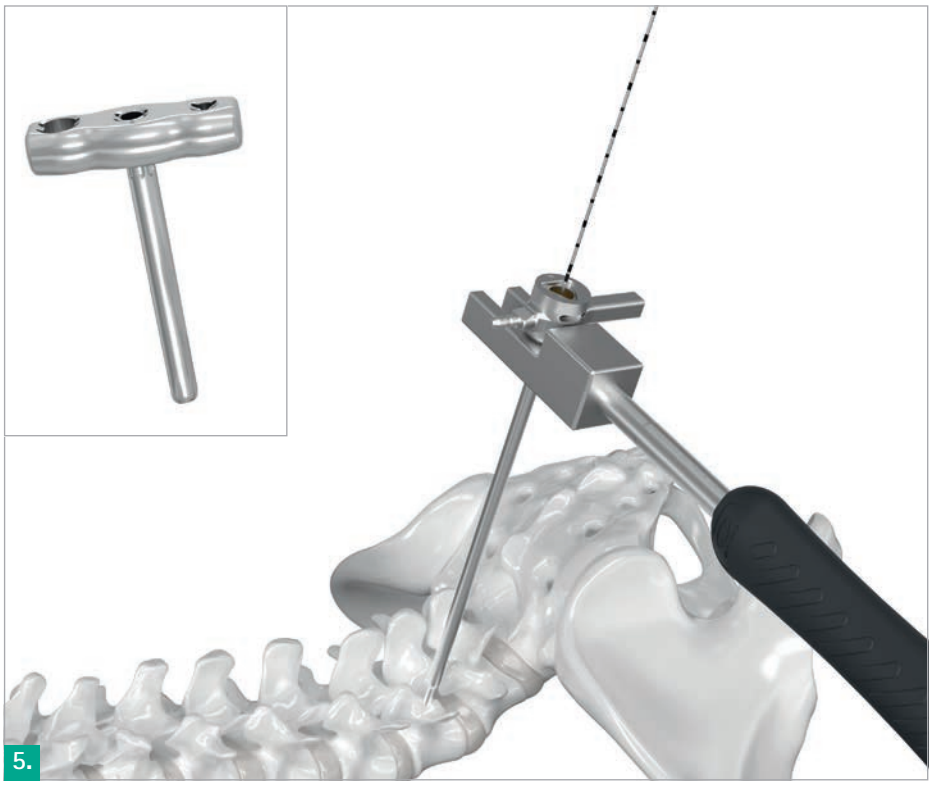
DEGENERATIVE SPINE

A. PEDICLE PREPARATION

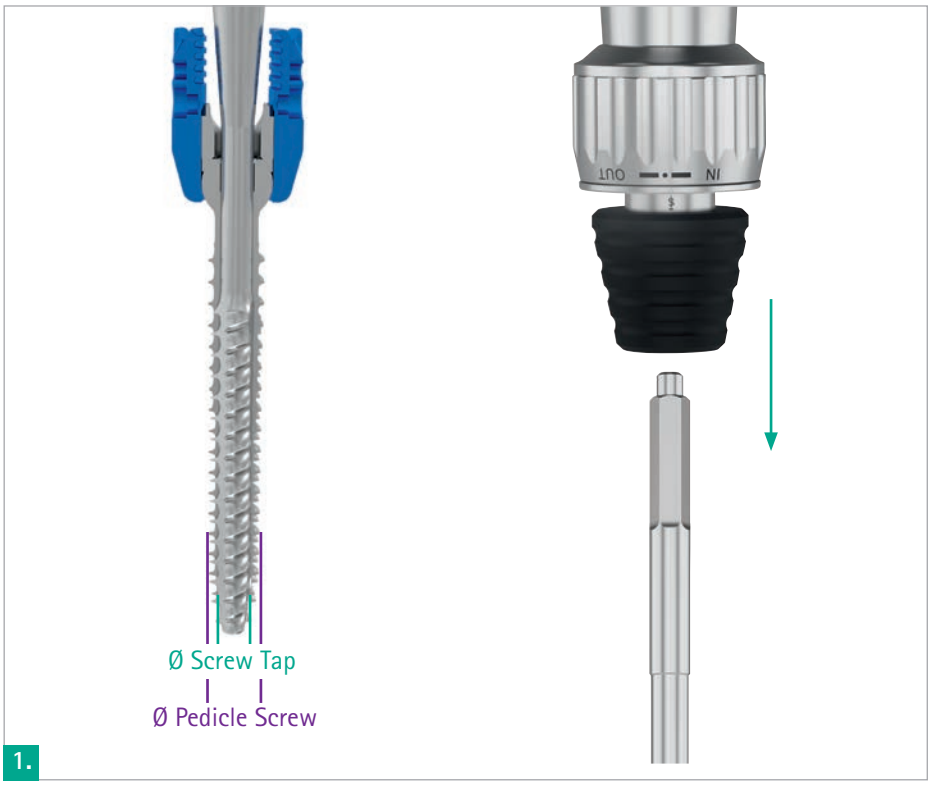
- The fascia and muscles should be dilated to allow for screw placement with the Downtube.
- Hold the Guide Wire firmly in place and slide the Dilators over the Guide Wire in sequence. The Dilators should be docked on bony anatomy to minimize tissue impingement.
- If needed, the Dilator Handle may be attached to the Dilator to facilitate introduction.



5.

- If preferred, the perforation is followed by a canulated Pedicle Probe to open the pedicle canal.
- The Medium Dilator can be used as a working port during pedicle canal preparation.
- The canulated Pedicle Probe is intended for use in combination with pedicle screws with a diameter starting from 5.5 mm.
- The canulated Pedicle Probe provides depth markings from 30 to 80 mm, in 10 mm increments, for additional visual confirmation of the advancement into the pedicle canal.

6.



1.

BONE TAPPING

- Screw Taps are undersized by 0.25 mm of the final screw diameter.
- For screw diameters 7.5 mm and larger it is recommended to apply a sequential tapping procedure, starting with a smaller tap and increasing the diameter stepwise until the desired diameter is reached.
- Attach the desired handle to the Screw Tap by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- The ratcheting handles can be moved between forward (IN), locked (·), and reverse (OUT) positions by rotating the collar of the handle.

2.

- Switch the ratchet to the forward (IN) position (1), apply the instrument to the prepared entry point and advance the tap to the desired depth by turning the handle clockwise.
- Once the pedicle has been tapped to the desired depth, switch the ratchet to the reverse (OUT) position (2) and turn the handle counter-clockwise.
- Remove the Screw Tap from the handle by pulling the black collar backwards and then removing the Screw Tap.

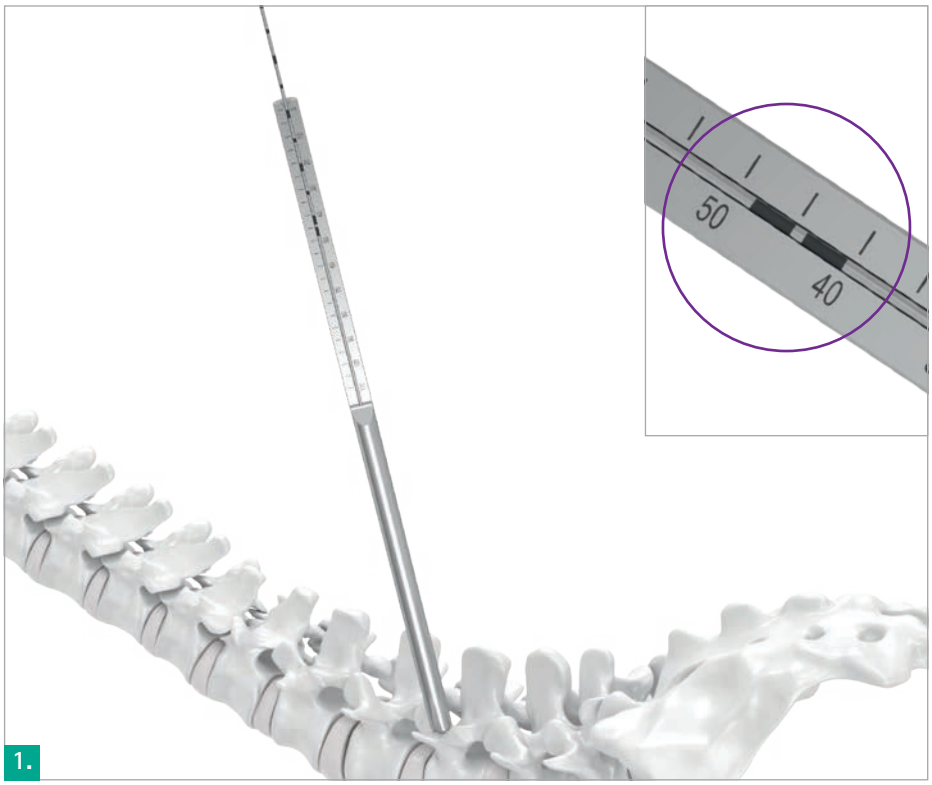
AESCULAP® Ennovate®

DEGENERATIVE SPINE

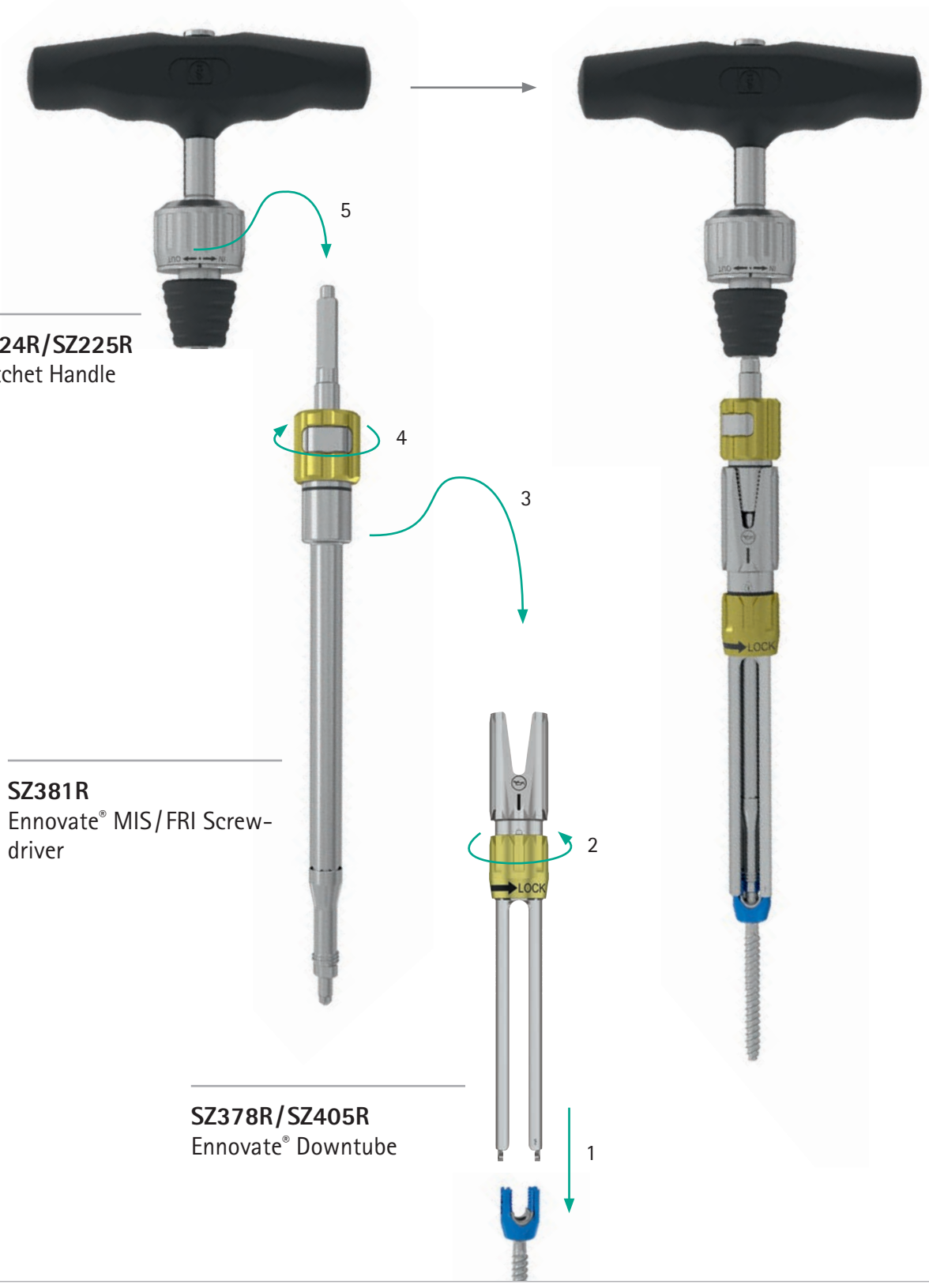
A. PEDICLE PREPARATION

SCREW LENGTH MEASUREMENT

- The screw length is approximated by sliding the Screw Length Gauge over the Guide Wire. Ensure that the distal Guide Wire tip represents the end position of the pedicle screw tip.
- Hold the Guide Wire firmly while sliding the blunt end of the Screw Length Gauge over it.
- Read the screw length between the two widest laser markings on the Guide Wire.



1.



SZ222R/SZ224R/SZ225R
Ennovate® Ratchet Handle

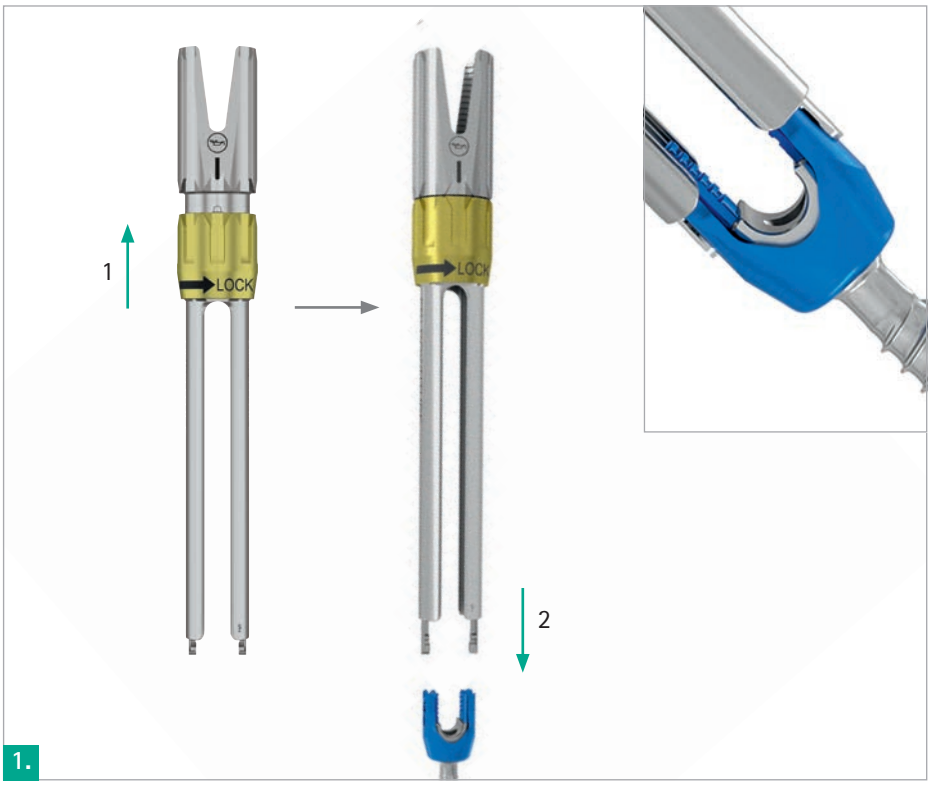
SZ381R
Ennovate® MIS/FRI Screw-driver

SZ378R/SZ405R
Ennovate® Downtube

AESCULAP® Ennovate®

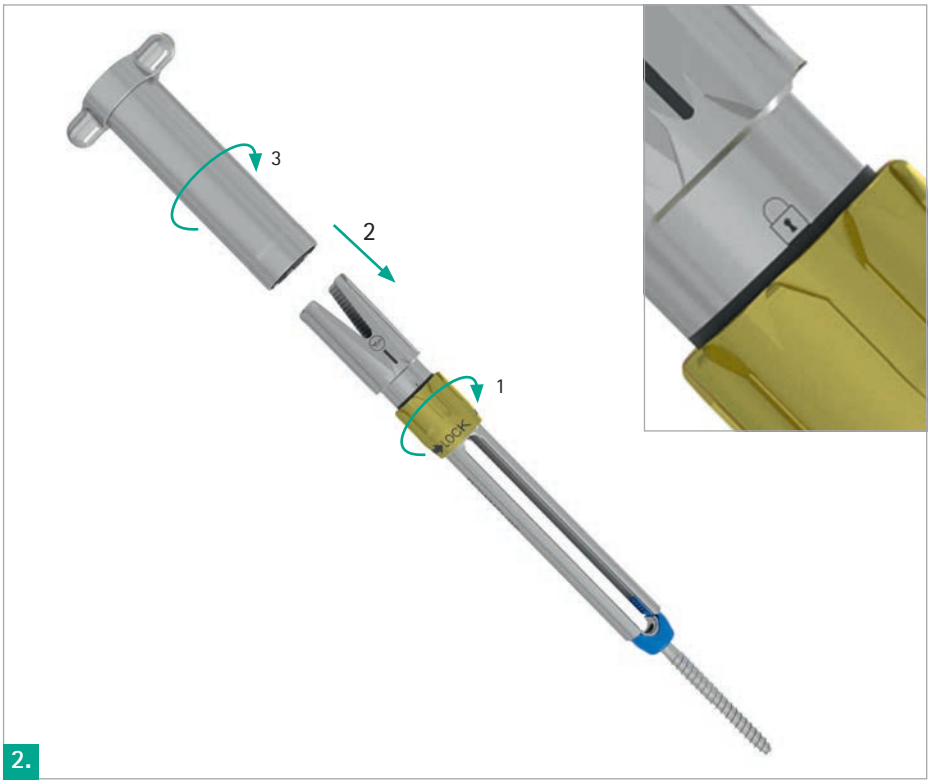
DEGENERATIVE SPINE
B. PEDICLE SCREW PLACEMENT

- Pull the outer sleeve of the Downtube backwards until the golden ring touches the silver crown (1).
- Lower the Downtube onto the pedicle screw head from above (2). The acoustic signal is an indicator that the Downtube connection arms have attached to the pedicle screw head.
- Proper coupling is achieved when the connection arms fully engage with the screw head. Visual and tactile confirmation of the connection is recommended.

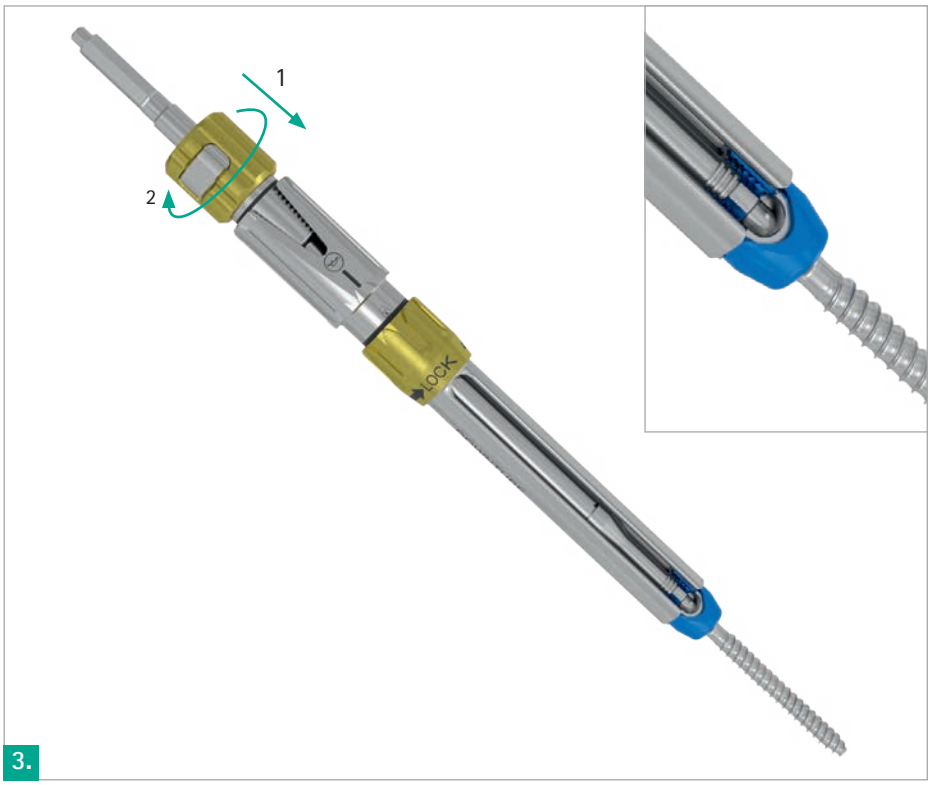


1.

- Release the outer sleeve of the Downtube and turn the golden ring counter-clockwise until (1) the upper portion of the golden ring is flush with the line marking.
- If needed, the Tightening Key may be used to enhance the tightening. Slide the Tightening Key over the Downtube (2) and turn it counter-clockwise (3) until a positive stop is perceived.

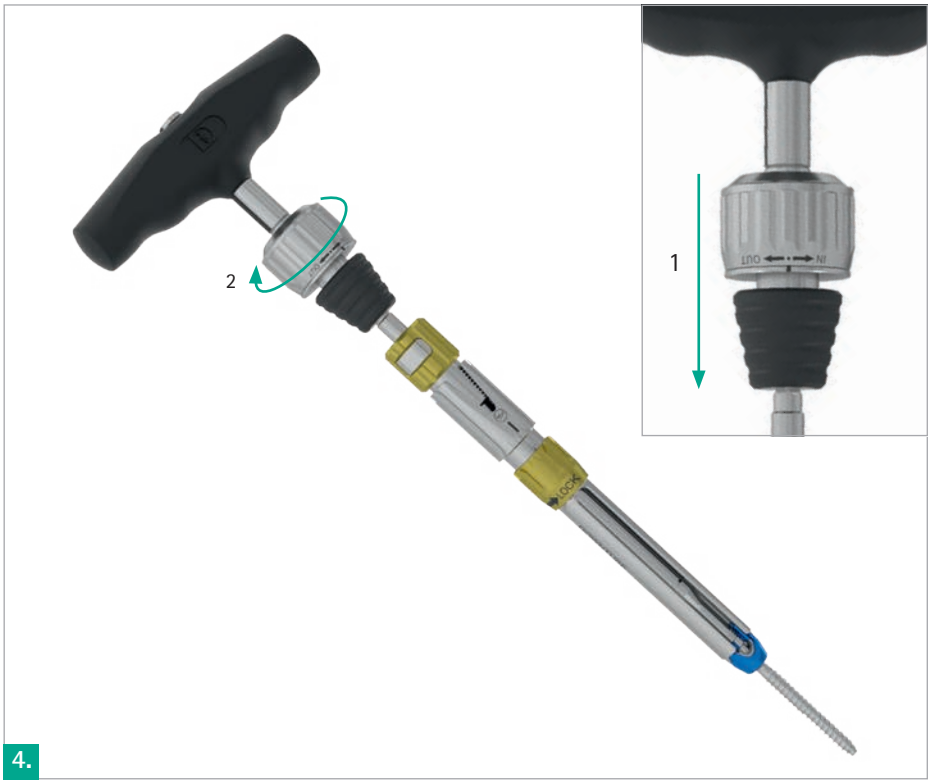


2.



3.

- Insert the Screwdriver into the Downtube (1) while ensuring the tip of the Screwdriver fully engages to the screw head.
- Rotate the golden knob of the Screwdriver clockwise (2) to lock the threaded end of the Screwdriver into the screw head.
- Proper fixation is reached when the screw is restricted polyaxially.



4.

- Attach the desired handle to the Screwdriver by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop (1).
- If desired, additional screw connection can be achieved by holding the handle while turning the golden knob of the Screwdriver clockwise.
- Switch the ratchet to the forward (IN) position (2) and slide the Downtube assembly over the Guide Wire.

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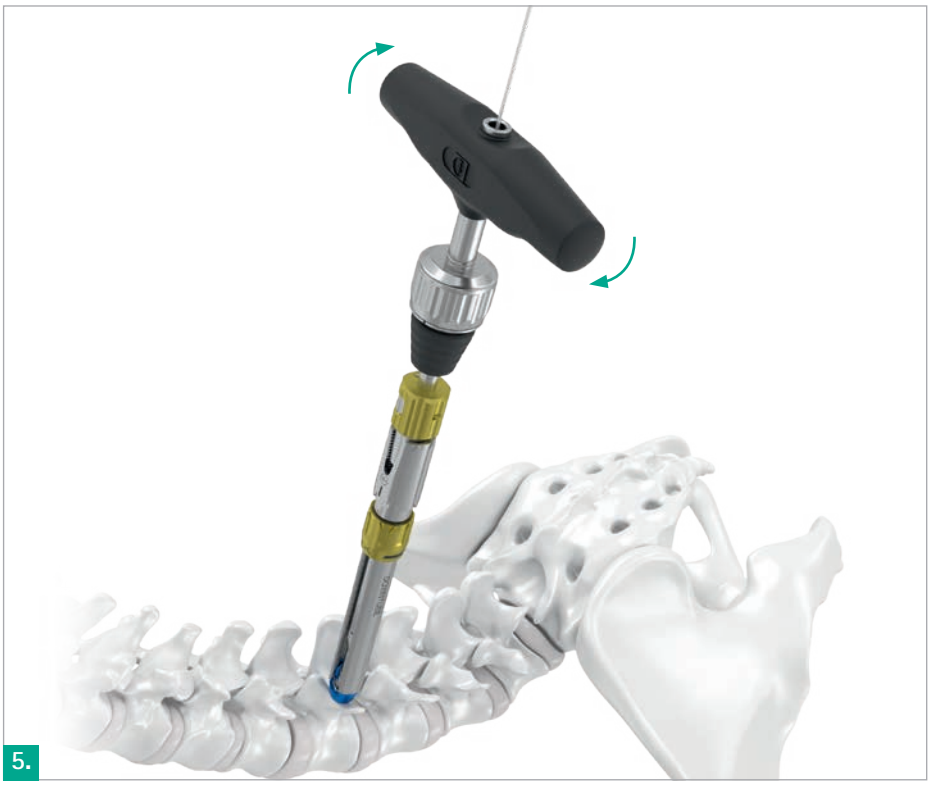
DEGENERATIVE SPINE
B. PEDICLE SCREW PLACEMENT

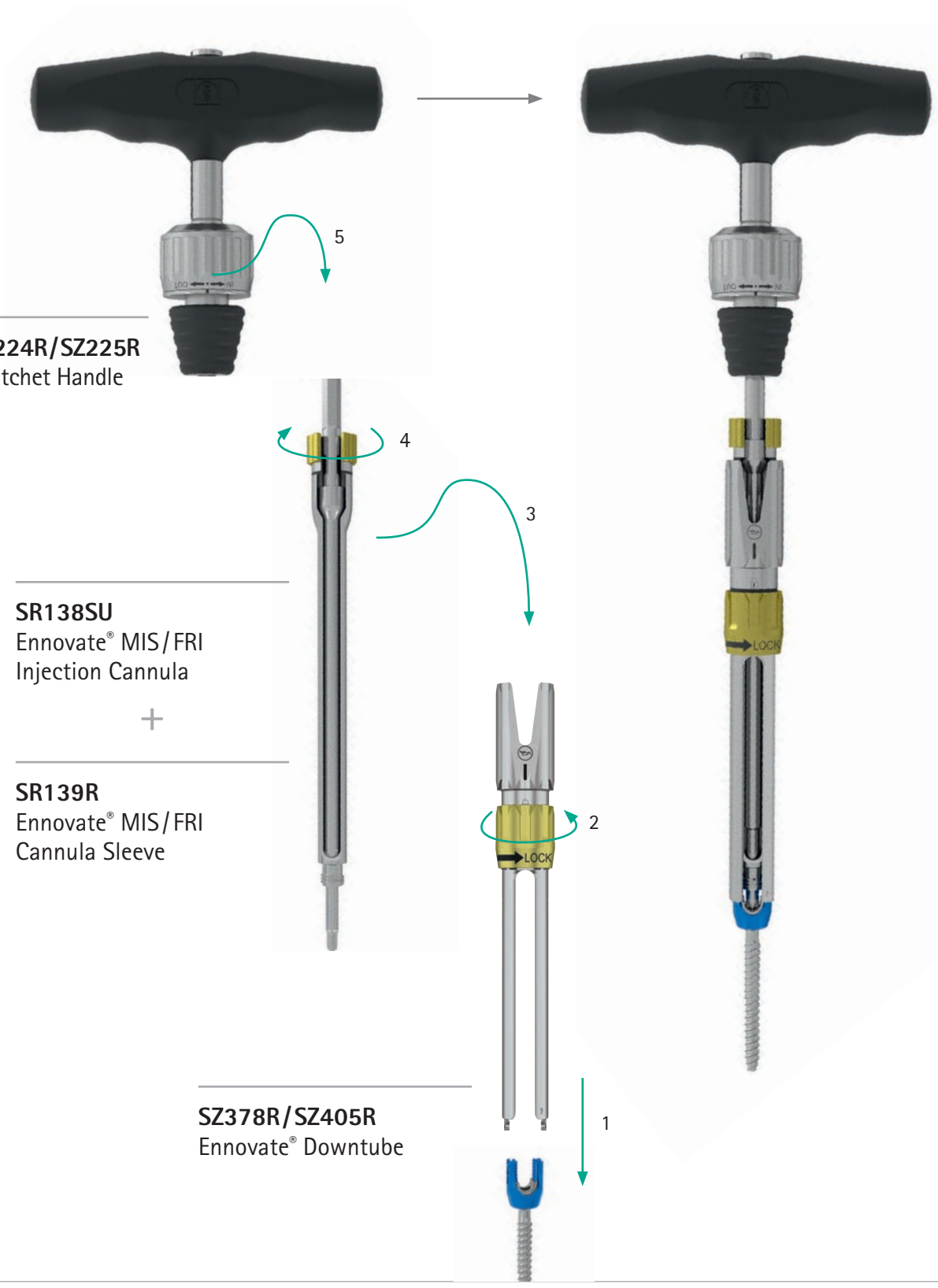
- Advance the pedicle screw to the desired depth by turning the handle clockwise.
- If using a Guide Wire, ensure that the Guide Wire is removed after an appropriate amount of bone purchase is established.
- Intra-operative imaging may be used to avoid cortical wall/vascular perforation.


5.

- Once the screw is fully inserted, turn the golden knob of the Screwdriver counter-clockwise to disengage the Screwdriver from the Downtube.
- Ensure that the polyaxiality of the screw head is intact and that it shows limited interference with anatomical structures.
- Ensure that the Downtubes are aligned parallel to each other.
- The placement and size of the screws may be confirmed using intra-operative imaging prior to rod insertion.

6.

C. CEMENT DELIVERY (OPTIONAL)



SZ222R/SZ224R/SZ225R
Ennovate® Ratchet Handle

SR138SU
Ennovate® MIS/FRI
Injection Cannula

+

SR139R
Ennovate® MIS/FRI
Cannula Sleeve

SZ378R/SZ405R
Ennovate® Downtube

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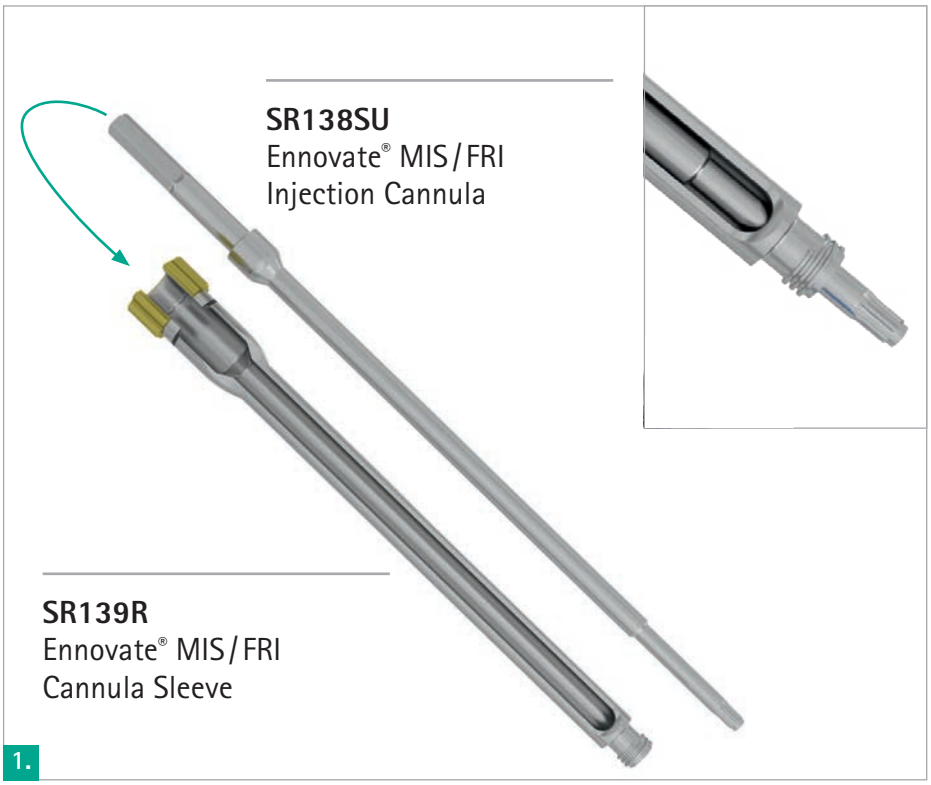
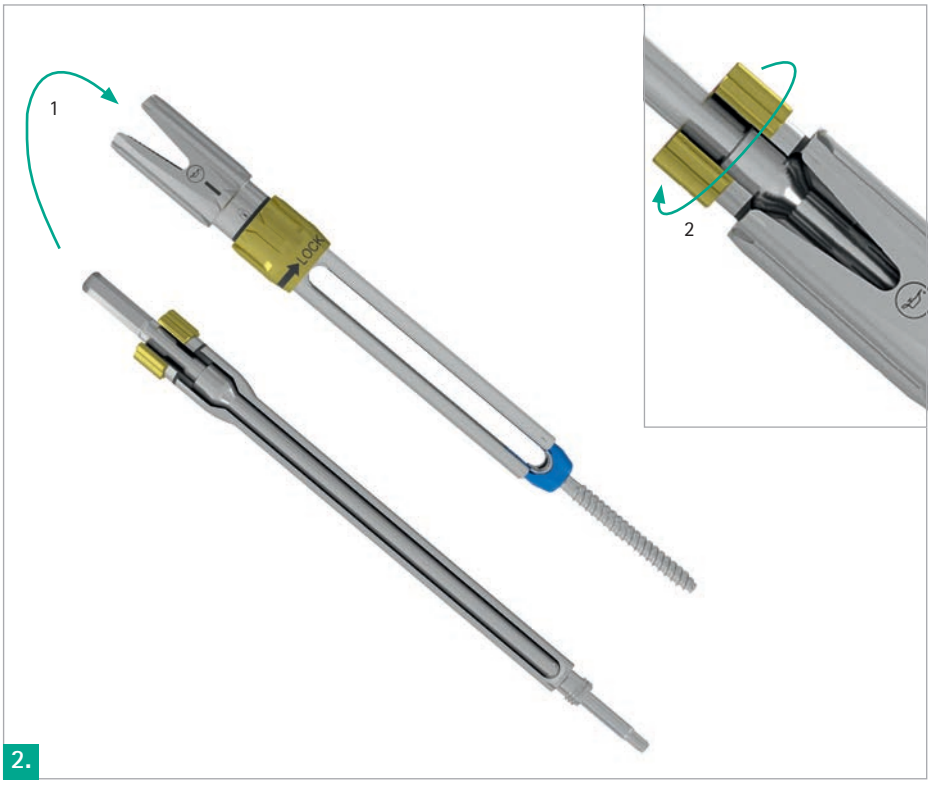
DEGENERATIVE SPINE

C. CEMENT DELIVERY (OPTIONAL)

- Please ensure that only Ennovate® Fenestrated PentaCore® Screws are used for the following steps.
- Please note that the Injector is intended to replace the Screwdriver.
- For the Injector assembly, insert the Injection Cannula into the Cannula Sleeve. Ensure that the tip of the Injection Cannula is aligned with the threaded portion of the Cannula Sleeve.

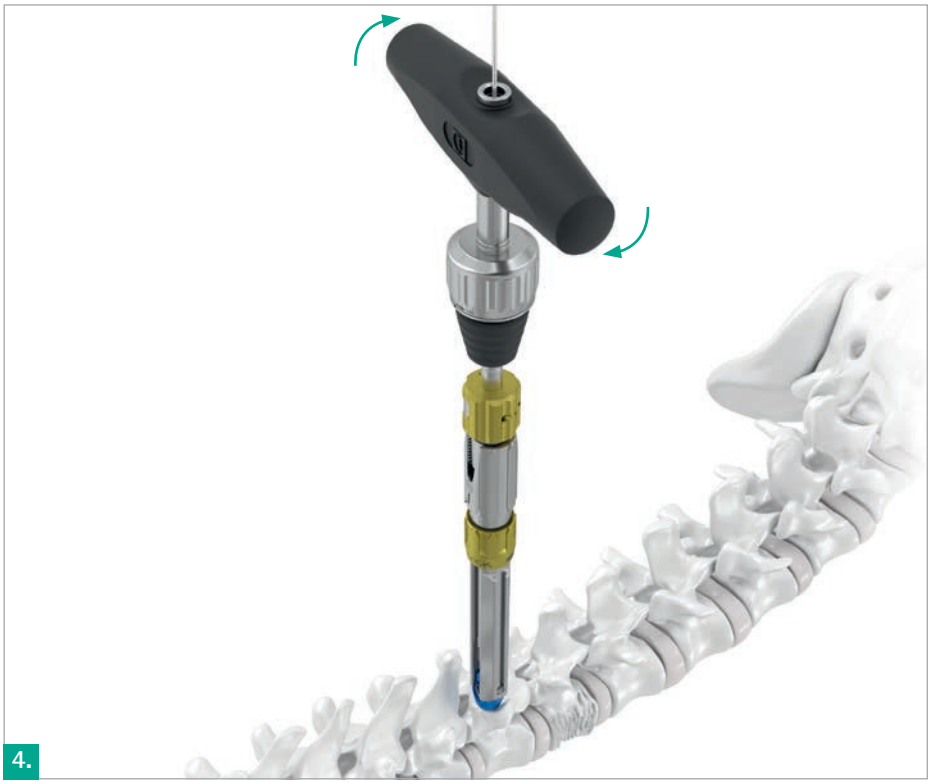


- Slide the Injector through the Downtube (1) and place the tip of the Injector into the head of the screw to be cemented.
- The Injector is engaged by turning the golden portion of the Cannula Sleeve clockwise (2) while firmly holding the silver crown of the Downtube.
- Proper fixation is reached when the screw is restricted polyaxially and the line marking on the Injector is flush with the silver crown of the Downtube. Visual and tactile confirmation of the connection is recommended.



3.

- Attach the desired handle to the Injector by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- If desired, additional connection can be achieved by holding the handle while turning the golden knob of the Injector clockwise.
- Switch the ratchet to the forward (IN) position and slide the Downtube assembly over the Guide Wire.



4.

- Advance the pedicle screw to the desired depth by turning the handle clockwise.
- Intra-operative imaging may be used to avoid cortical wall/vascular perforation.

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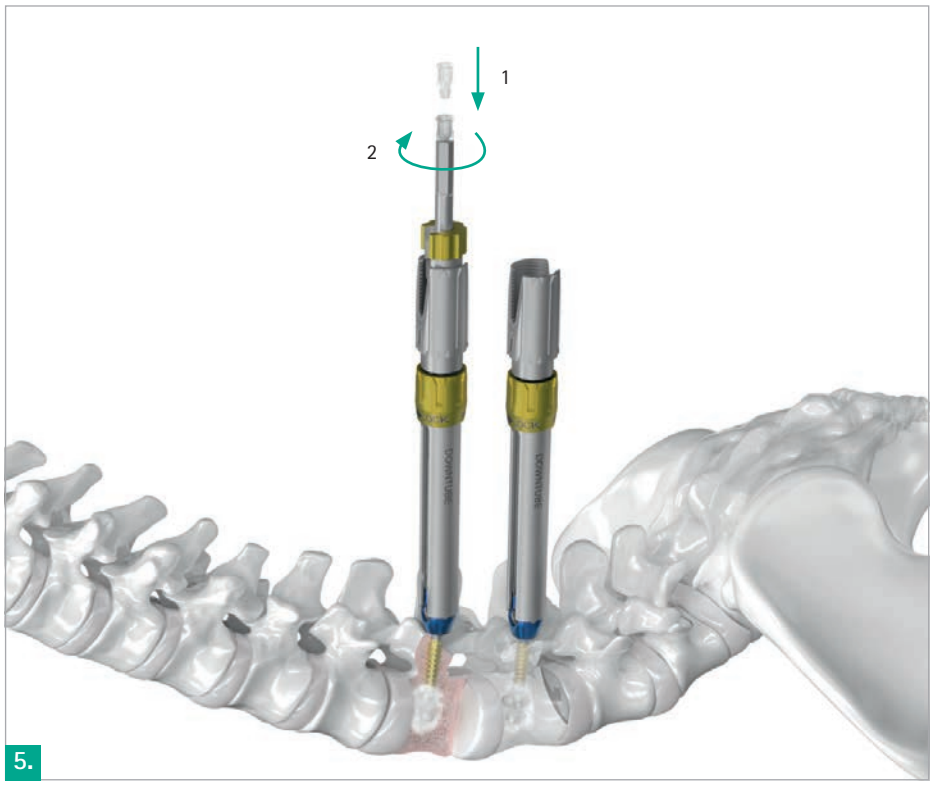
DEGENERATIVE SPINE

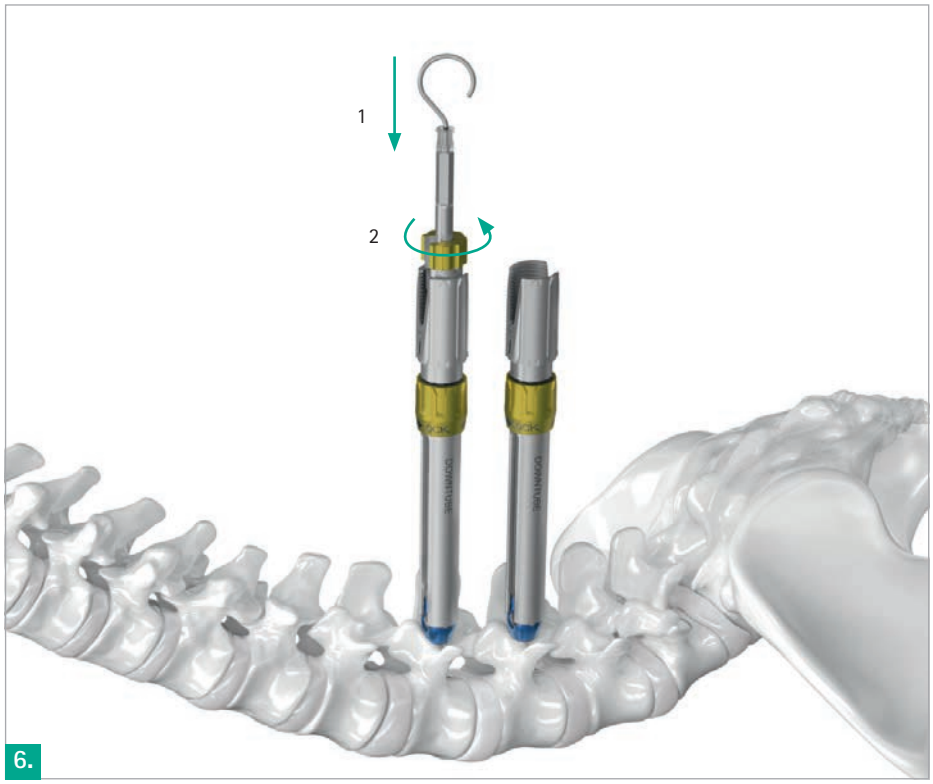
C. CEMENT DELIVERY (OPTIONAL)

- Before cement delivery, attach the Luer Lock adapter to the Injector by turning the adapter clockwise until the stop.
- Check if the cement has reached the desired viscosity for application and that the cement application system provides a Luer Lock connection part.
- Attach the cement application system firmly to the Luer Lock of the Injector.
- Inject the cement under slight pressure with the assistance of radiological imaging. The procedure may be monitored closely by the surgeon.
- Inject cement until it extrudes from the lateral slots of the Ennovate® Fenestrated PentaCore® Screw. Check continuously that no cement leakage occurs.
- Continue the injection until an adequate quantity of cement is introduced and shows in a cloud pattern.



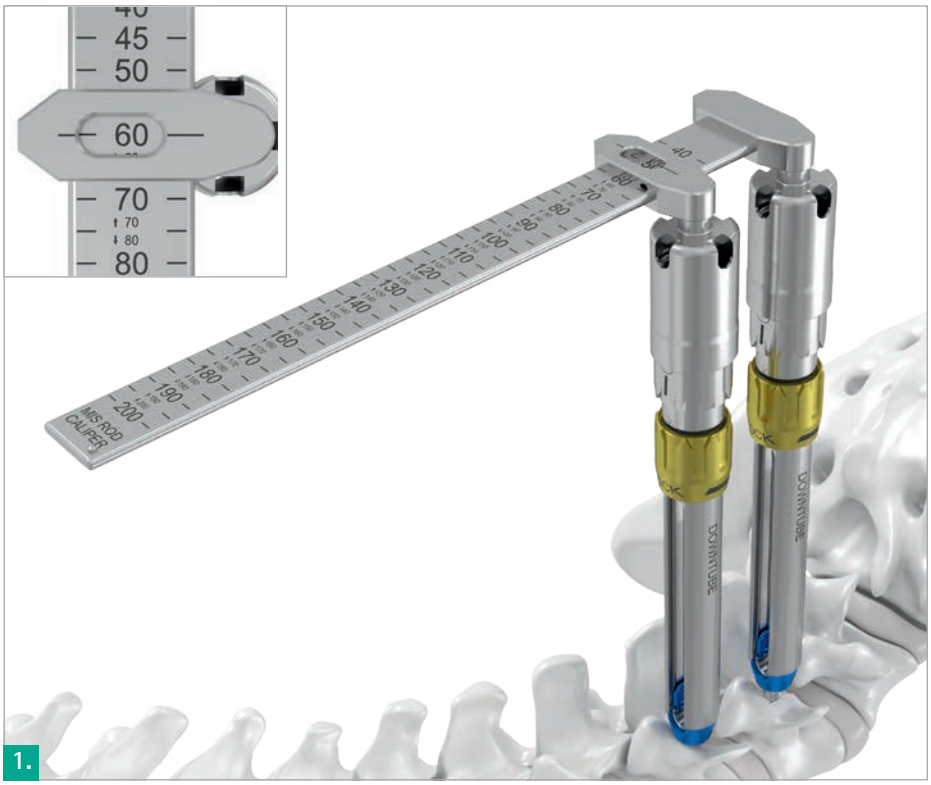
5.

- The handling time of the cement ends when its viscosity is so high that no further cement delivery is possible.
- After cement delivery, ensure the Injector remains in its position until the cement has hardened to its final stage.
- The Pestle may be used to push the remaining cement from the Injector into the screw (1).
- Once the cement has hardened, the Injector can be removed by turning the golden portion counter-clockwise (2) while firmly holding the Downtube in place.
- Visual confirmation of the screw head integrity is recommended.



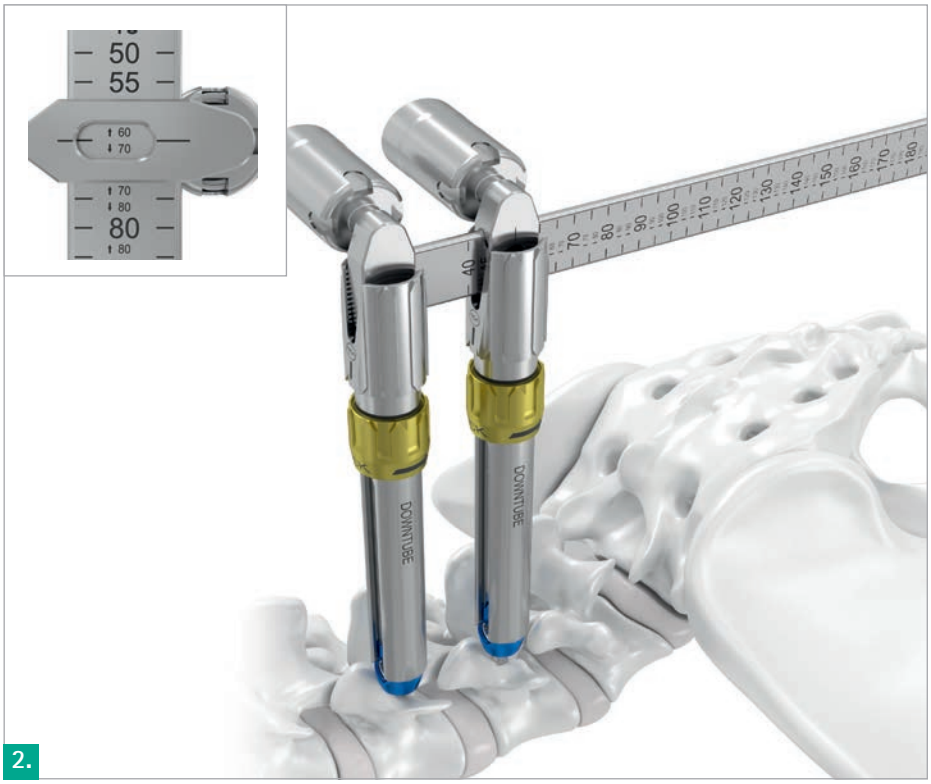
6.

D. ROD CONTOURING AND PLACEMENT



1.

- Align the Downtubes parallel to each other and fully seat the cylinders of the Rod Length Gauge onto the Downtubes of the most cranial and caudal screw.
- The scale on top of the Rod Length Gauge reflects the spectrum of the Ennovate® rods and indicates the minimum recommended rod length. In case two sizes are shown (see detail picture below), it is recommended to select a longer rod.
- Once the rod measurement is taken, align the Downtubes to each other to facilitate rod placement.



2.

- If desired, the Rod Length Gauge can be flipped by 90° and the slide bars can be placed into the Downtubes of the most cranial and caudal screw.
- The scale on top of the Rod Length Gauge reflects the spectrum of the Ennovate® rods and indicates the minimum recommended rod length. In case two sizes are shown (see detail picture left), it is recommended to select a longer rod.
- Once the rod measurement is taken, align the Downtubes to each other to facilitate rod placement.

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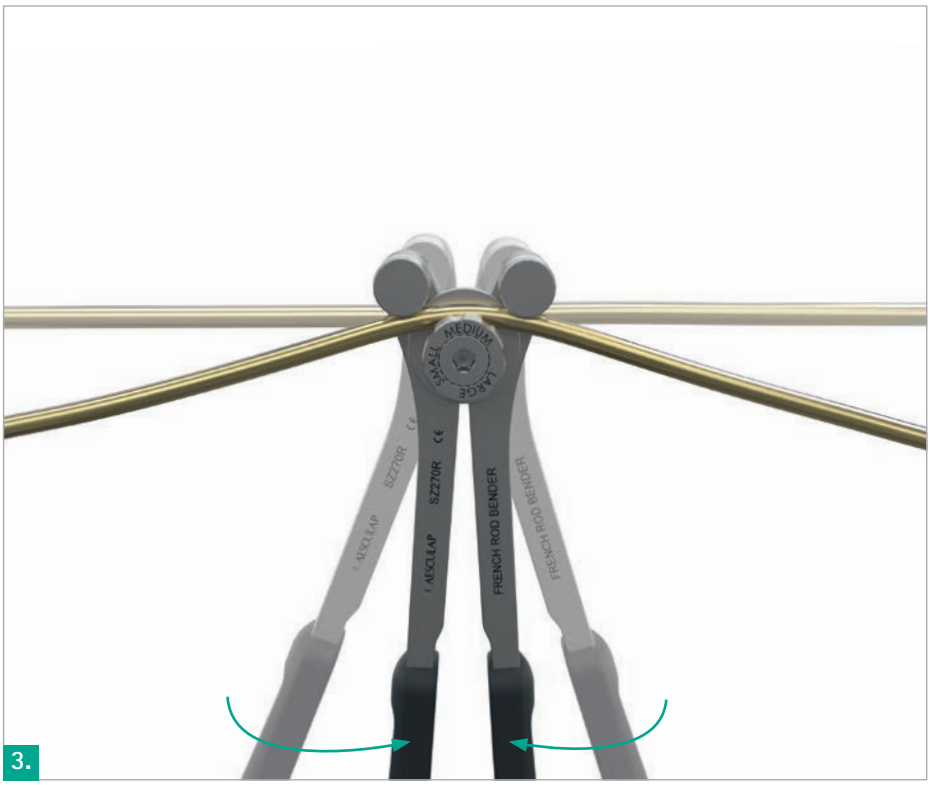
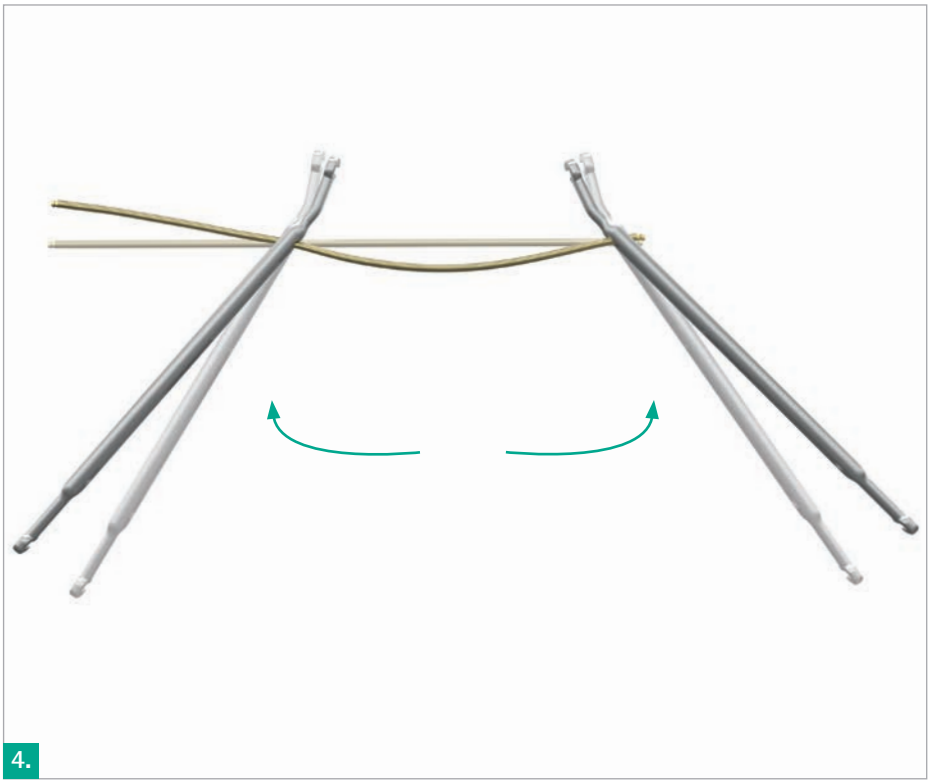
DEGENERATIVE SPINE
D. ROD CONTOURING AND PLACEMENT

- Rods may be contoured using the Rod Bender, which offers various bending radii.
- To contour the rod, set the bending radius by pulling the knob and turning it to the desired radius.
- Place the rod between the bending knob and both holding knobs. All rods show a line marking as a reference to assist bending in sagittal plane.
- For rod contouring, squeeze both handles, and repeat the contouring process along the rod, until the desired rod contour is achieved.



3.

- Rods may be contoured using the Sagittal Rod Benders, which allow high radius bending.
- The Sagittal Rod Benders show straight and angled holes for enhanced rod accomodation.
- To contour the rod, slide the rod into the desired hole of each Sagittal Rod Bender.
- Grip the most distal portions of the Sagittal Rod Benders for enhanced mechanical advantage during contouring.
- By levering the Sagittal Rod Benders the rod is bent according to the desired contour.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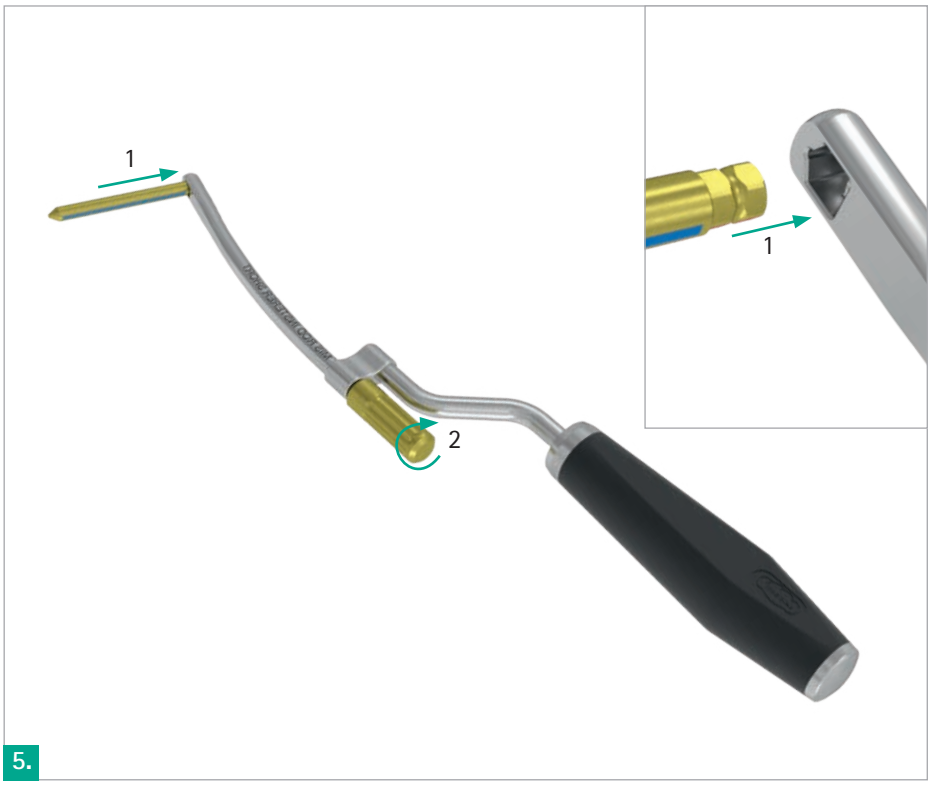
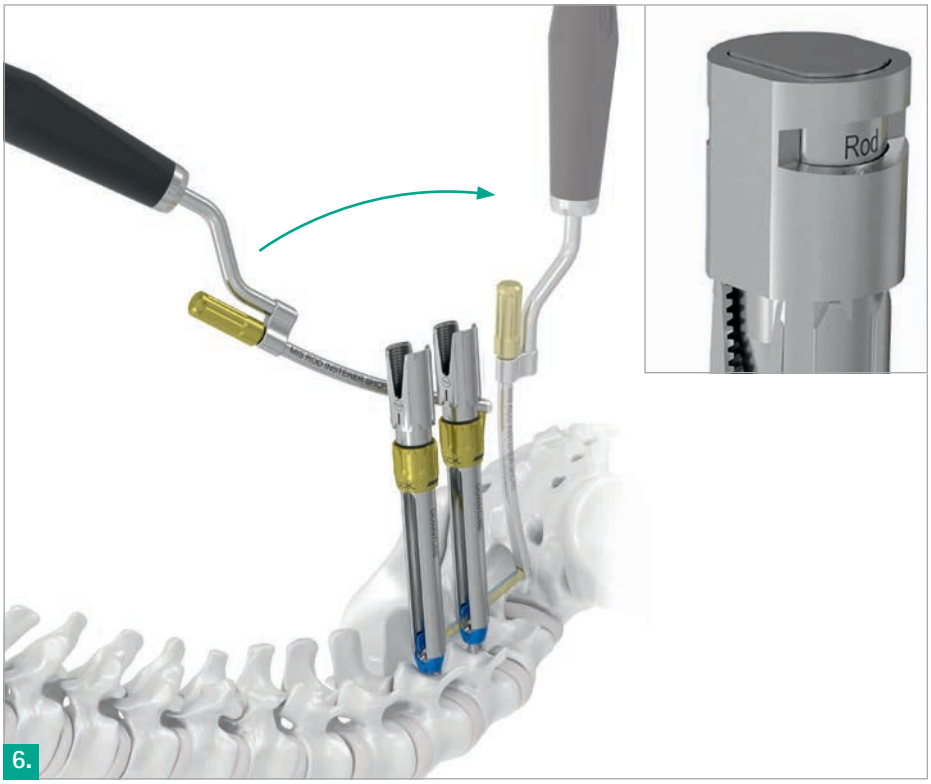


5.

- Prior to rod attachment, ensure the clamping unit of the Rod Inserter does not interfere with the coupling geometry at the distal portion.
- Engage the Ennovate® rod to the Rod Inserter by sliding the hexagon shaped portion of the rod into the distal opening until the stop (1).
- Turn the golden knob clockwise until the stop (2). Visual and tactile confirmation of the connection is recommended.
- The line marking on the Ennovate® rod may be aligned to the line marking on the Rod Inserter. If desired, the rod may be tilted according to surgeon preference.



6.

- Guide the Ennovate® rod through the longitudinal slots of the Downtubes.
- Ensure that the rod has been inserted through all Downtubes using the Rod Indicator.
- Slide the Rod Indicator into the desired Downtube until the stop. When the rod is properly inserted, "Rod" appears. In case "no Rod" appears, the rod is not placed in the Downtube.

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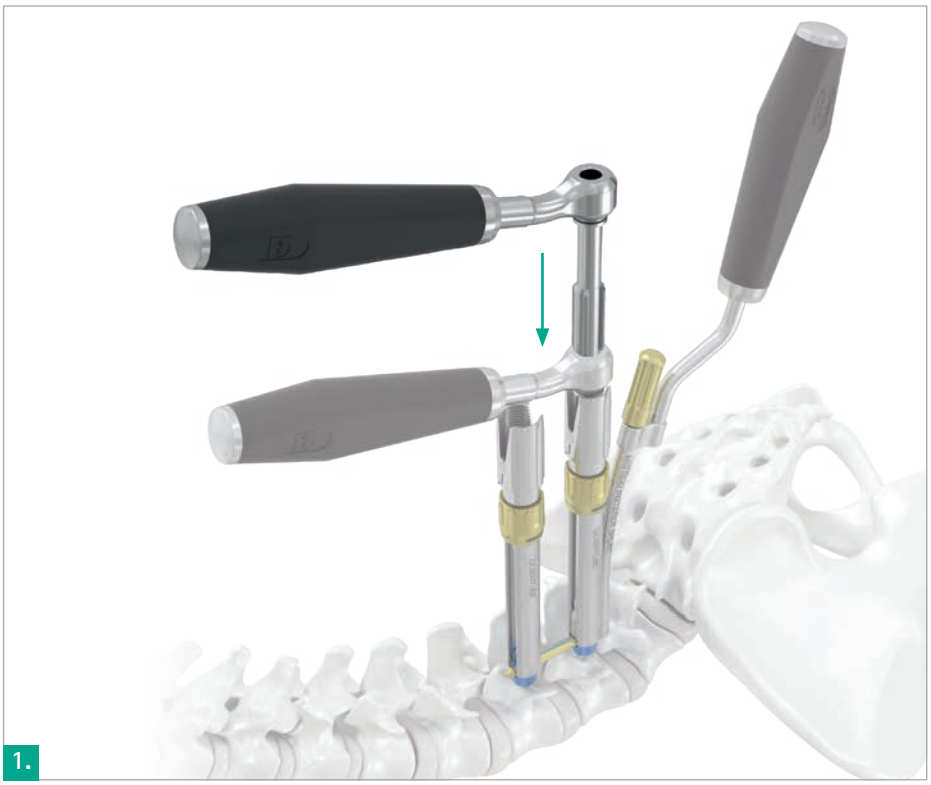
DEGENERATIVE SPINE
E. ROD REDUCTION

REDUCTION WITH QUICK ROD PUSHER

- Once the rod has been inserted through all Downtubes, slide the Quick Rod Pusher into the Downtube that requires reduction.
- Reduce the rod by pushing the Quick Rod Pusher down until the stop.
- Full rod reduction is achieved when the line marking on the Quick Rod Pusher is flush with the silver crown of the Downtube.



- Secure the rod reduction by placing a Set Screw into the screw head.
- Assemble the Torque Wrench by attaching the Torque Wrench Handle 10 Nm to the Set Screw Driver by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- Load a Set Screw on the Set Screw Driver and ensure proper fixation of the implant based on its alignment with the laser marking on the instrument.
- Insert the Torque Wrench through the canulation of the Quick Rod Pusher, hold the Quick Rod Pusher in place and turn the Torque Wrench until an acoustic signal sounds. The acoustic signal is an indicator that final tightening of 10 Nm has been achieved.

REDUCTION WITH ROD PUSHER

- Once the rod has been inserted through all Downtubes, slide the Rod Pusher into the Downtubes that require reduction.
- Reduce the rod by turning the golden part of the Rod Pusher clockwise until the Rod Pusher contacts the rod.
- Once all Rod Pushers contact the rod, it is recommended to reduce the rod sequentially in order to distribute the forces evenly.

- If needed, the Reduction/Tightening Handle may be used to facilitate rod pushing.

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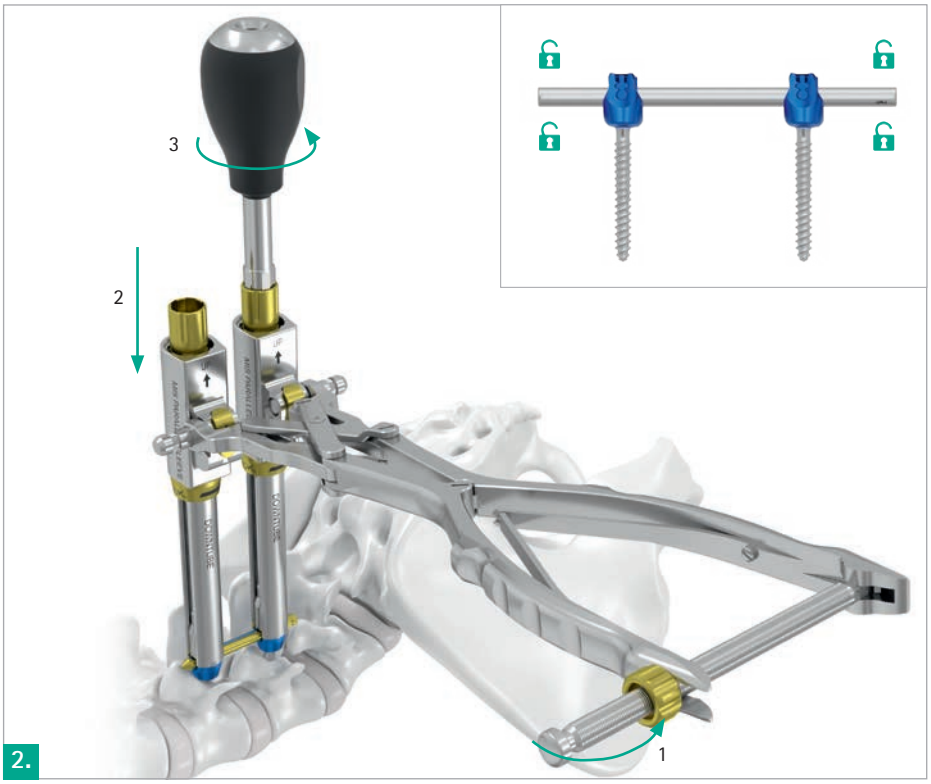
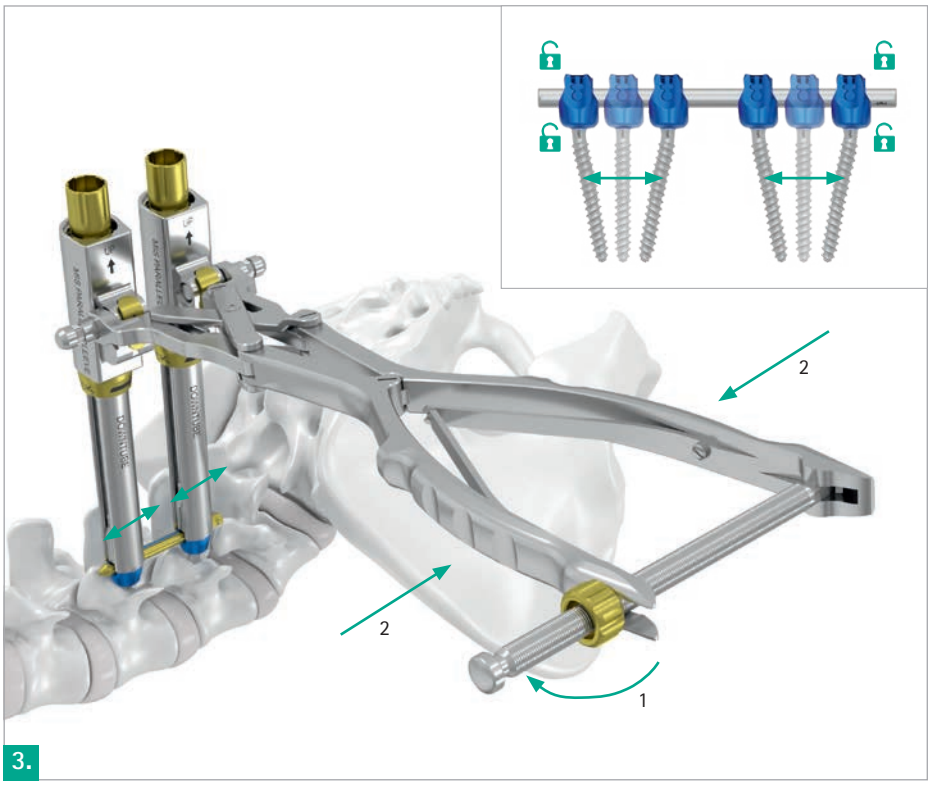
DEGENERATIVE SPINE
F. SPINAL CORRECTION

LORDOSIS AND KYPHOSIS CORRECTION

- Ensure the rod is fully reduced.
- Attach either the Parallel Sleeves or C-Rings onto the Compression/ Distraction Forceps by sliding the connection pins of the forceps into the coupling of the Parallel Sleeves/C-Rings.
- Ensure that the distance of the Downtubes is taken into account while attaching the Parallel Sleeves/C-Rings to the forceps.
- In the presence of high anatomical angulation, the Set Screws may be engaged to further pedicle screws prior to correction maneuvers.

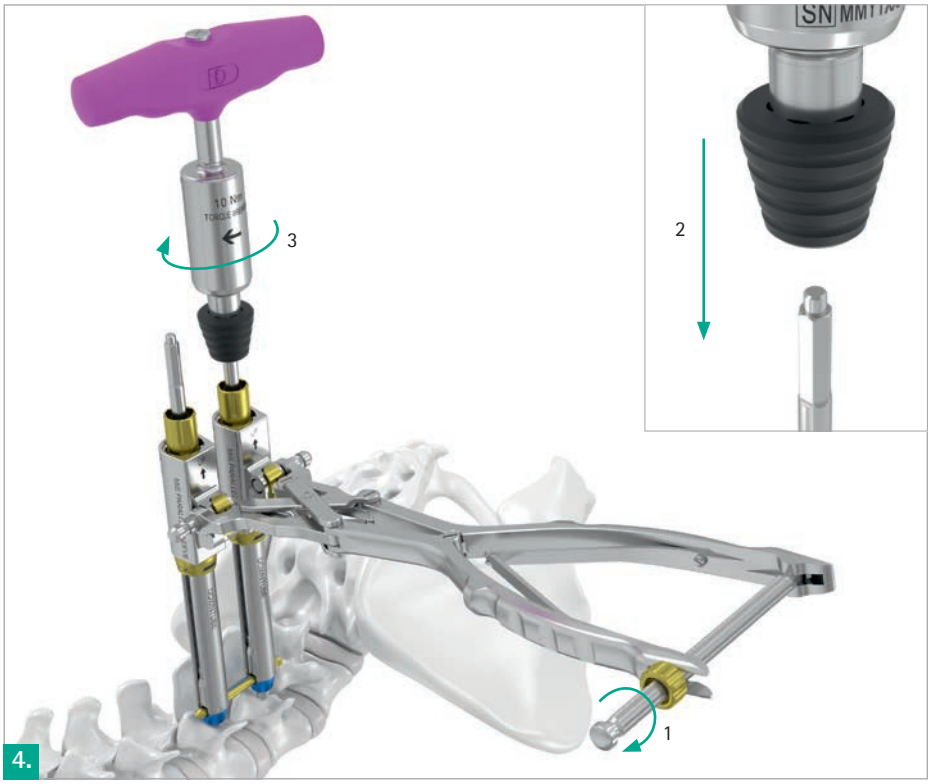
- Release the ratchet bar from the forceps handle (1) and slide the Parallel Sleeves/C-Rings onto the silver crown of the Downtubes until the stop (2).
- If desired, the Rod Pusher may be turned slightly counter-clockwise (3) to enhance the polyaxiality of the Downtubes.





3.

- Engage the ratchet bar to the forceps handles (1).
- For compression, squeeze (2) the handles of the Compression Forceps until the aimed correction is achieved. As a result, the distance between the posterior elements decreases, increasing lordosis and decreasing kyphosis.
- For distraction, squeeze (2) the handles of the Distraction Forceps until the aimed correction is achieved. As a result, the distance between the posterior elements increases, increasing kyphosis and decreasing lordosis.



4.

- Once the desired correction is achieved, secure the correction by turning the golden ratchet bar nut until it contacts the forceps handle (1).
- Assemble the Torque Wrench by attaching the Torque Wrench Handle 10 Nm to the Set Screw Driver by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop (2).
- Load a Set Screw on the Set Screw Driver and ensure proper fixation of the implant based on its alignment with the laser marking on the instrument.
- Slide the assembly through the canulation of the Rod Pusher and turn the Torque Wrench clockwise until the Set Screw engages with the screw head (3).
- If desired, final tightening can be performed.

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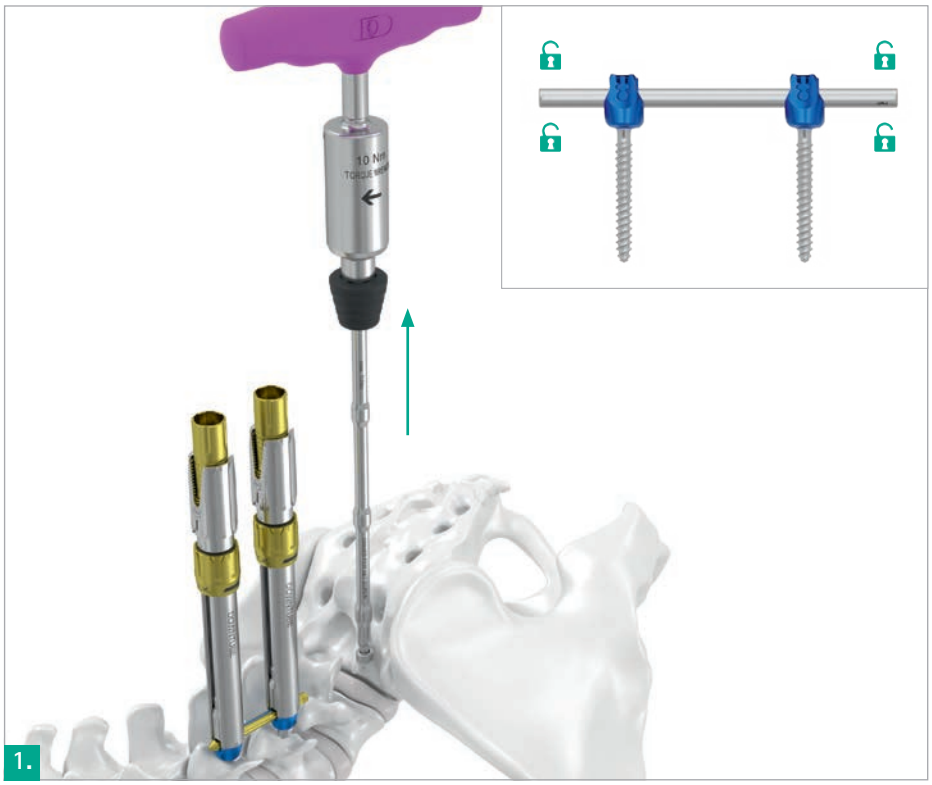
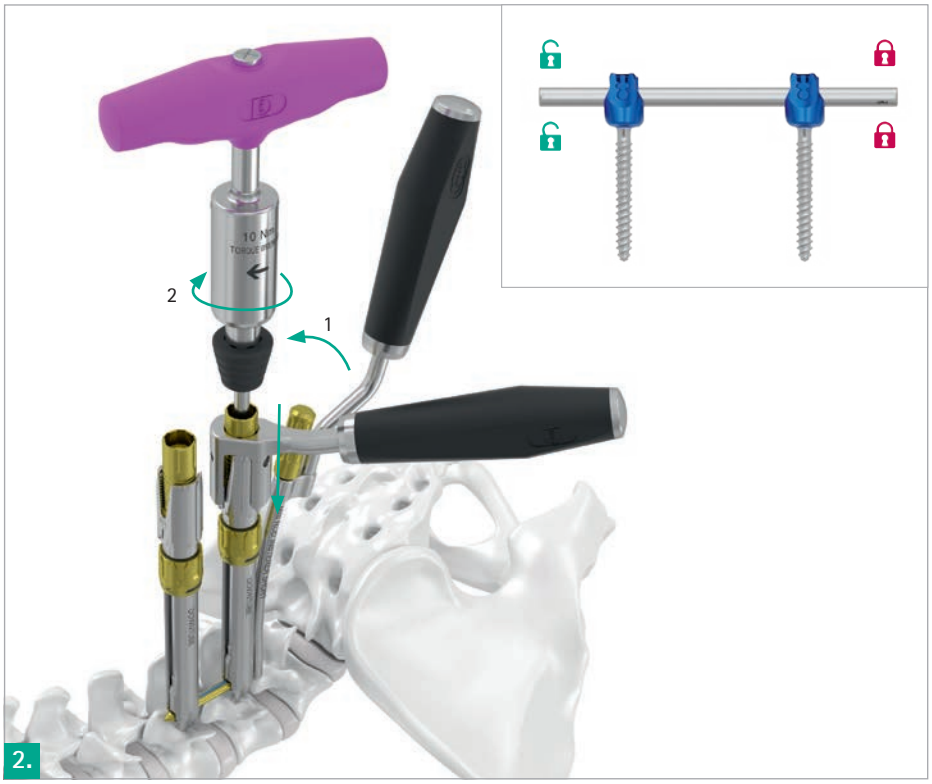
DEGENERATIVE SPINE
F. SPINAL CORRECTION

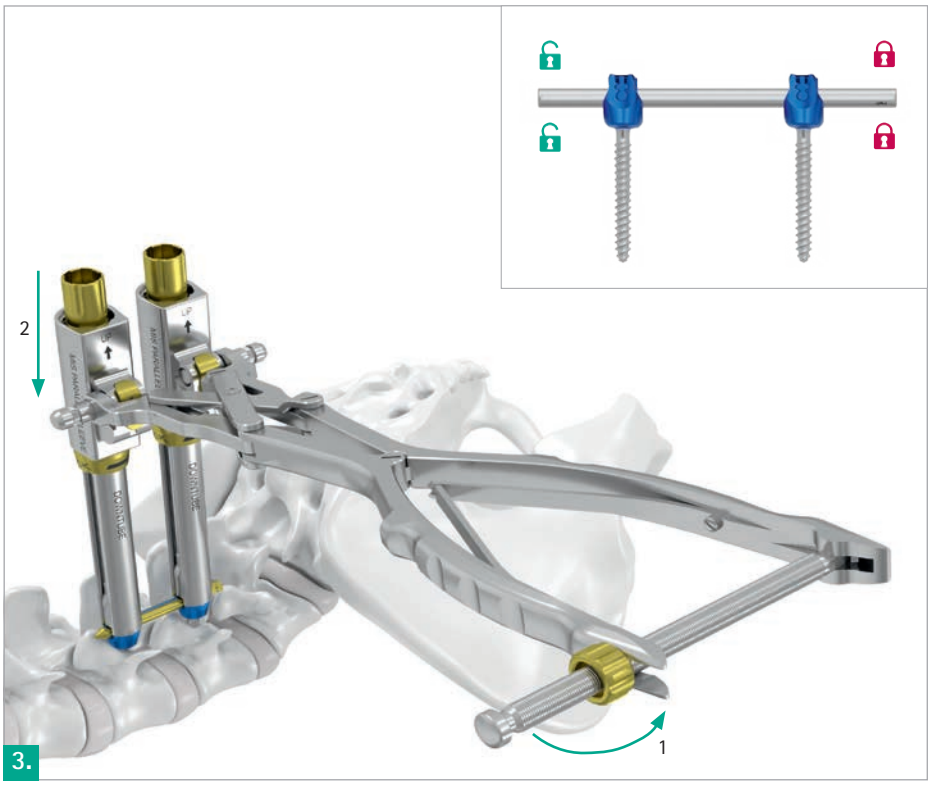
COMPRESSION AND DISTRACTION

- Ensure the rod is fully reduced.
- Select a starting point for the distraction or compression maneuver. Assemble the Torque Wrench by attaching the Torque Wrench Handle 10 Nm to the Set Screw Driver by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- Load a Set Screw on the Set Screw Driver and ensure proper fixation of the implant based on its alignment with the laser marking on the instrument.

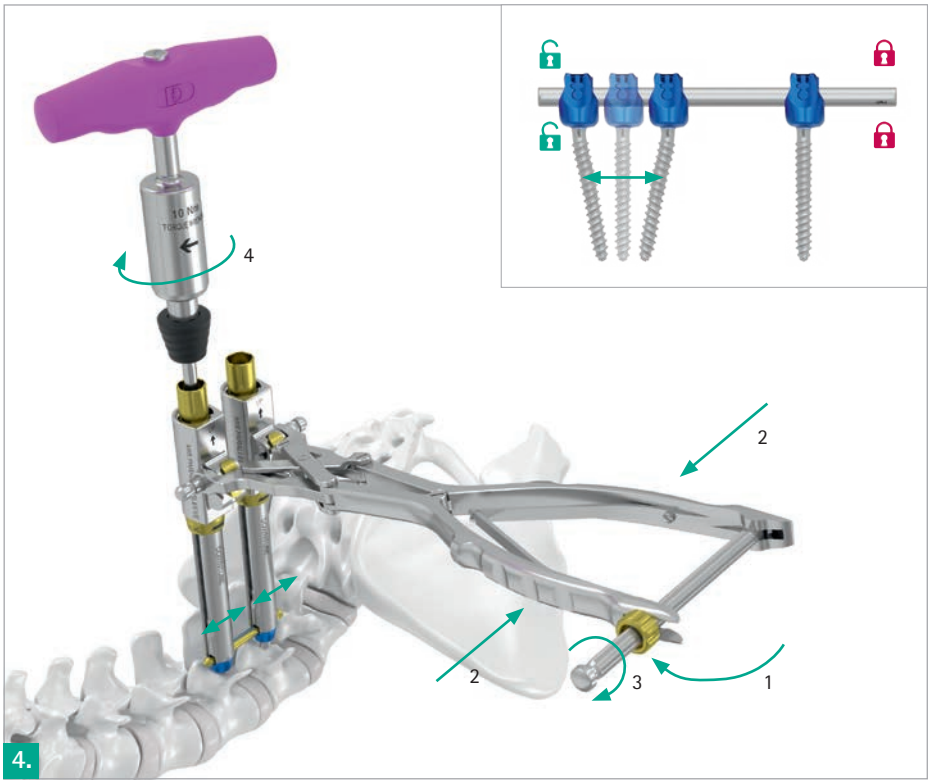


- Engage the Counter Torque Handle to the coupling geometry on the starting point Downtube (1).
- Insert the Torque Wrench through the canulation of the Rod Pusher, hold the Counter Torque Handle in place and turn the Torque Wrench clockwise (2) until an acoustic signal sounds. The acoustic signal is an indicator that final tightening of 10 Nm has been achieved.
- In the presence of high anatomical angulation, the Set Screw may be engaged to further pedicle screws prior to correction maneuvers.





- Attach either the Parallel Sleeves or C-Rings onto the Compression/Distraction Forceps by sliding the connection pins of the forceps into the coupling of the Parallel Sleeves/C-Rings.
- Ensure that the distance of the Downtubes is taken into account while attaching the Parallel Sleeves/C-Rings to the forceps.
- Release the ratchet bar from the forceps handle (1) and slide the Parallel Sleeves/C-Rings onto the silver crown of the Downtubes until the stop (2).
- If desired, the Rod Pusher may be turned slightly counter-clockwise to enhance the polyaxiality of the Downtubes.



- Engage the ratchet bar to the forceps handles (1) and squeeze (2) them until the aimed correction is achieved. As a result, the distance between the loaded elements decreases/increases evenly.
- Once the desired correction is achieved, turn the golden nut on the ratchet bar towards the forceps handle to secure the distance (3).
- Assemble the Torque Wrench by attaching the Torque Wrench Handle 10 Nm to the Set Screw Driver by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- Load a Set Screw on the Set Screw Driver and slide the assembly through the canulation of the Rod Pusher and turn the Torque Wrench clockwise until the Set Screw engages with the screw head (4).
- If desired, final tightening can be performed.

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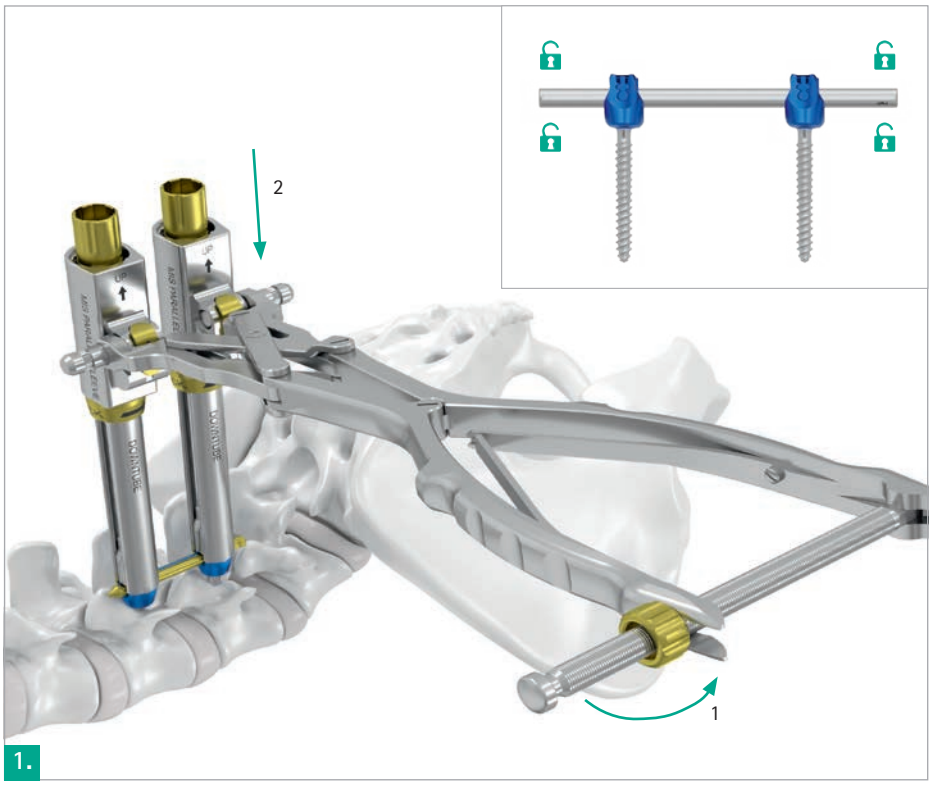
DEGENERATIVE SPINE
F. SPINAL CORRECTION

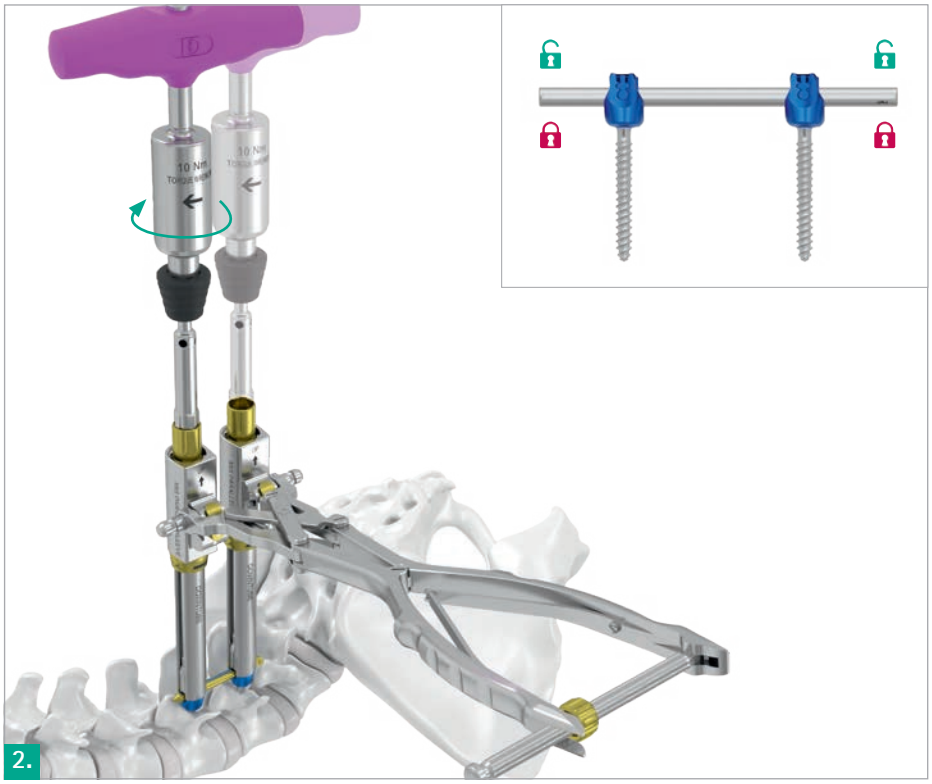
PARALLEL COMPRESSION AND DISTRACTION

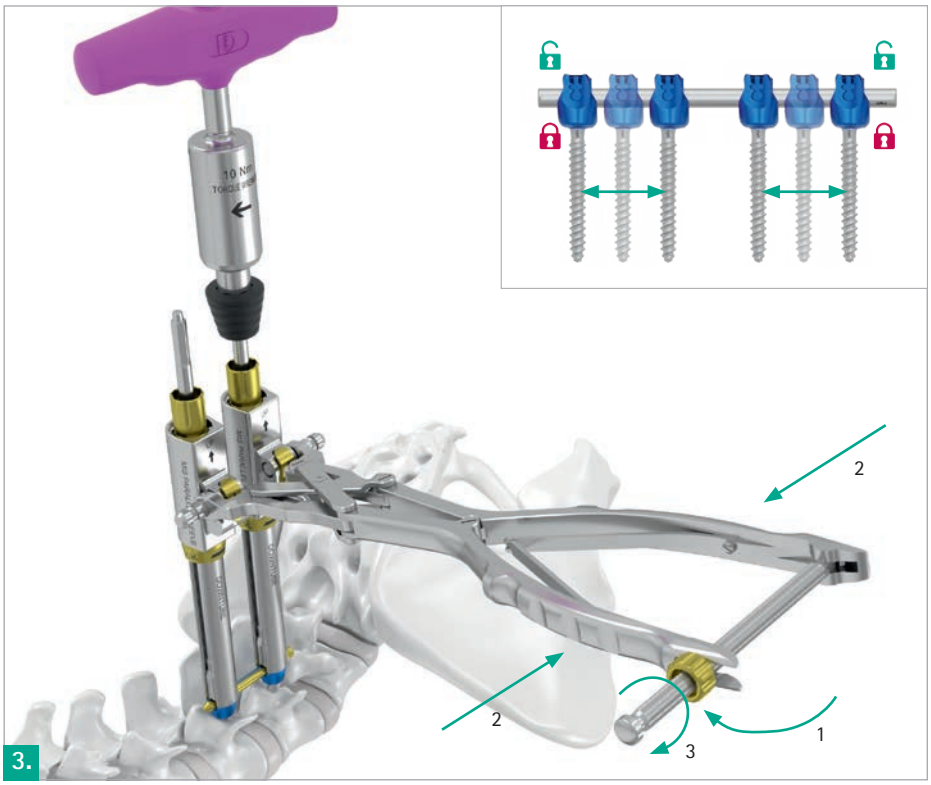
- Ensure the rod is fully reduced.
- Attach either the Parallel Sleeves or C-Rings onto the Compression/Distraction Forceps by sliding the connection pins of the forceps into the coupling of the Parallel Sleeves/C-Rings.
- Ensure that the distance of the Downtubes is taken into account while attaching the Parallel Sleeves/C-Rings to the forceps.
- Release the ratchet bar from the forceps handle (1) and slide the Parallel Sleeves/C-Rings onto the silver crown of the Downtubes until the stop (2).
- If desired, the Rod Pusher may be turned slightly counter-clockwise to enhance the polyaxiality of the Downtubes.



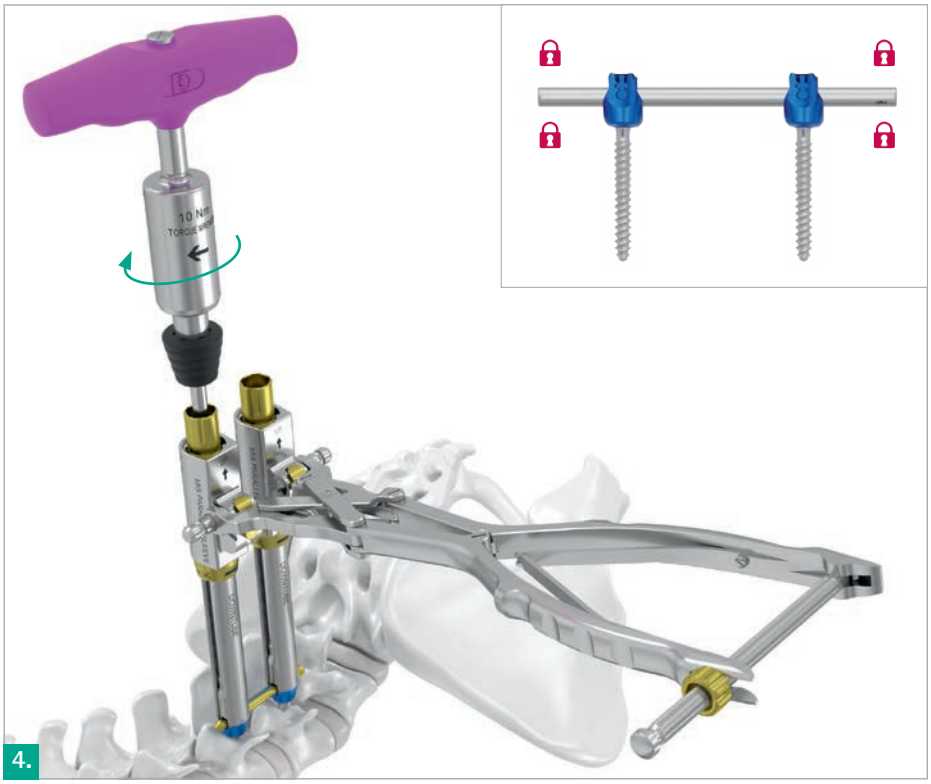
1.

- Connect the Torque Wrench Handle 10 Nm to the PolyLock® Key by sliding the hexagonal shaped portion of the shaft into the coupling until the stop.
- Place the PolyLock® assembly into the golden portion of the Rod Pusher.
- Ensure that the golden nut on the ratchet bar is located on the inner side of the forceps handle during PolyLock® activation.
- Turn the PolyLock® assembly clockwise while firmly holding the forceps handles until an acoustic signal sounds. The sound is an indicator that PolyLock® has been activated.
- In the presence of high anatomical angulation, the Set Screw may be engaged to further pedicle screws prior to correction maneuvers.


2.



- Engage the ratchet bar to the forceps handle (1) and squeeze (2) them until the aimed correction is achieved. As a result, the distance between the loaded elements decreases/increases evenly.
- Once the desired correction is achieved, secure the correction by turning the golden ratchet bar nut until it contacts the forceps handle (3).



- Assemble the Torque Wrench by attaching the Torque Wrench Handle 10 Nm to the Set Screw Driver by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- Load a Set Screw on the Set Screw Driver and ensure proper fixation of the implant based on its alignment with the laser marking on the instrument.
- Slide the assembly through the canulation of the Rod Pusher and turn the Torque Wrench clockwise until the Set Screw engages with the screw head.
- If desired, final tightening can be performed.

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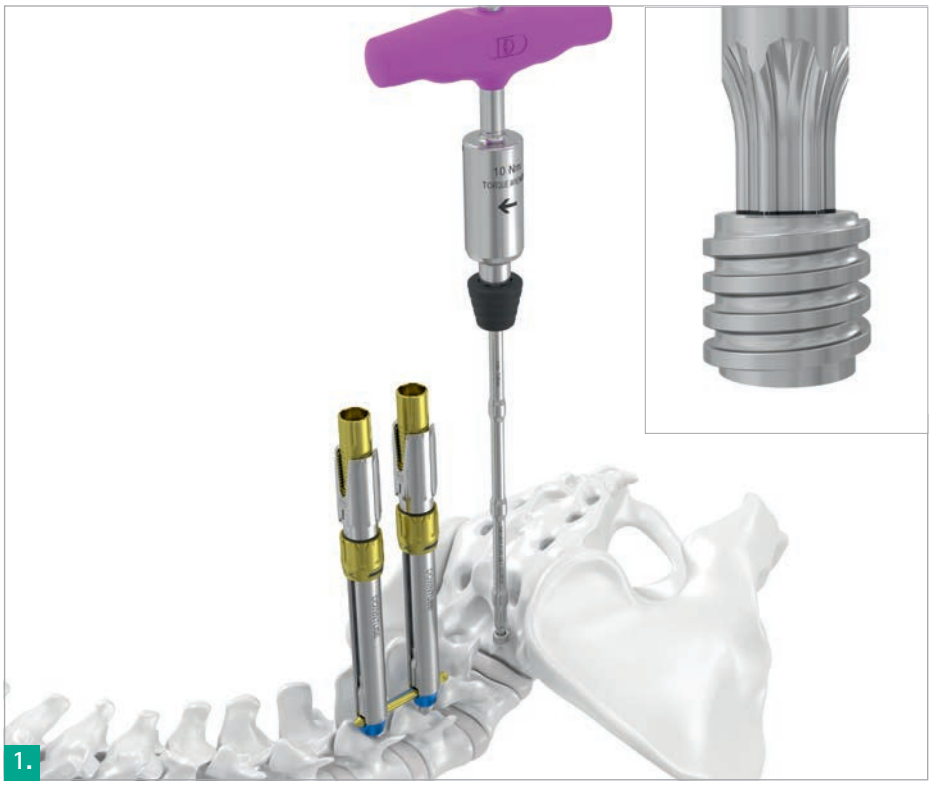
DEGENERATIVE SPINE

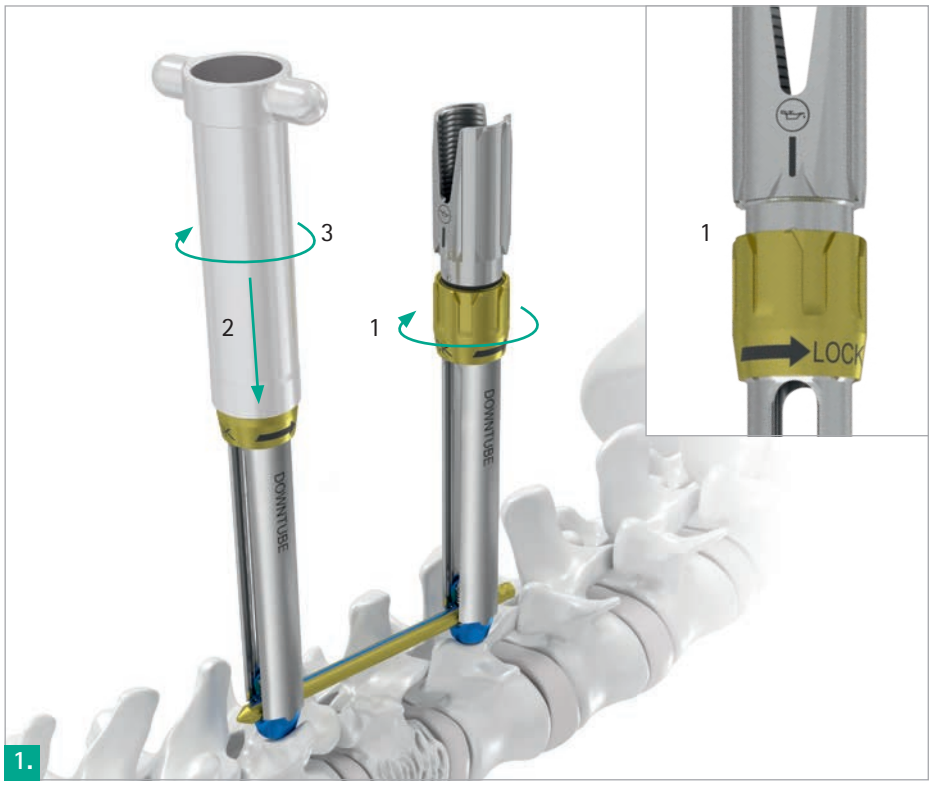
G. FINAL TIGHTENING AND DOWNTUBE REMOVAL

FINAL TIGHTENING

- Assemble the Torque Wrench by attaching the Torque Wrench Handle 10 Nm to the Set Screw Driver by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- Load a Set Screw on the Set Screw Driver and ensure proper fixation of the implant based on its alignment with the laser marking on the instrument.



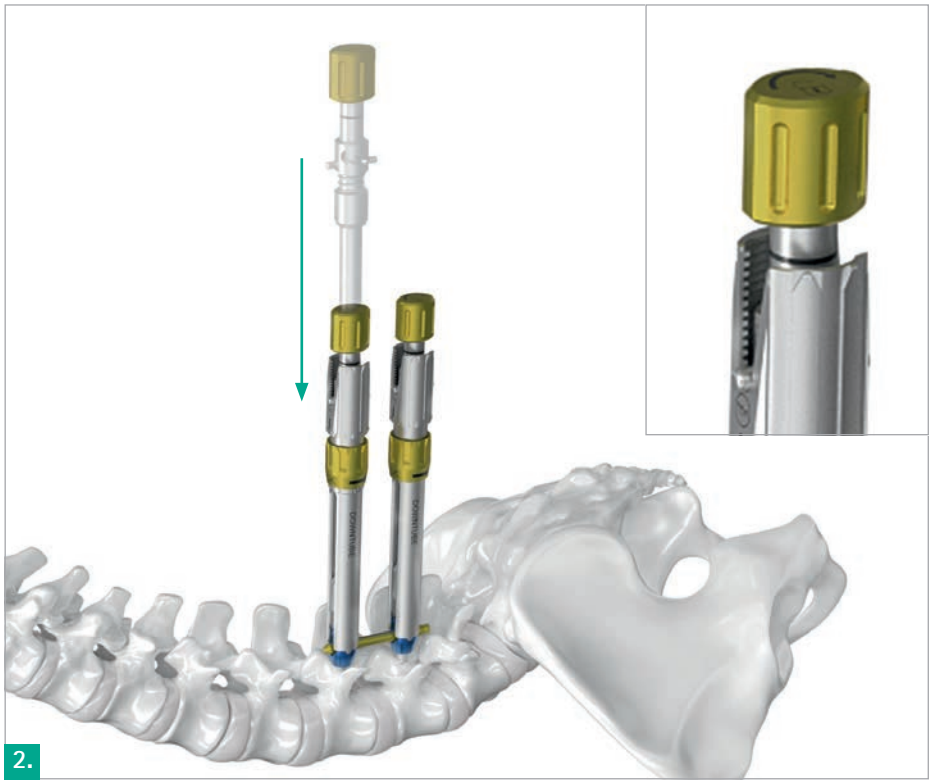
- Engage the Counter Torque Handle to the coupling geometry on the Downtube (1).
- Insert the Torque Wrench through the canulation of the Rod Pusher, hold the Counter Torque Handle in place and turn the Torque Wrench clockwise (2) until an acoustic signal sounds. The acoustic signal is an indicator that final tightening of 10 Nm has been achieved.



1.

DOWNTUBE REMOVAL

- Once all instruments have been removed from the Downtube, the golden ring is turned clockwise until the line marking disappears (1).
- If needed, the Tightening Key may be used to enhance this procedure. Slide the Tightening Key over the Downtube (2) and turn it clockwise (3) until a positive stop is perceived.



2.

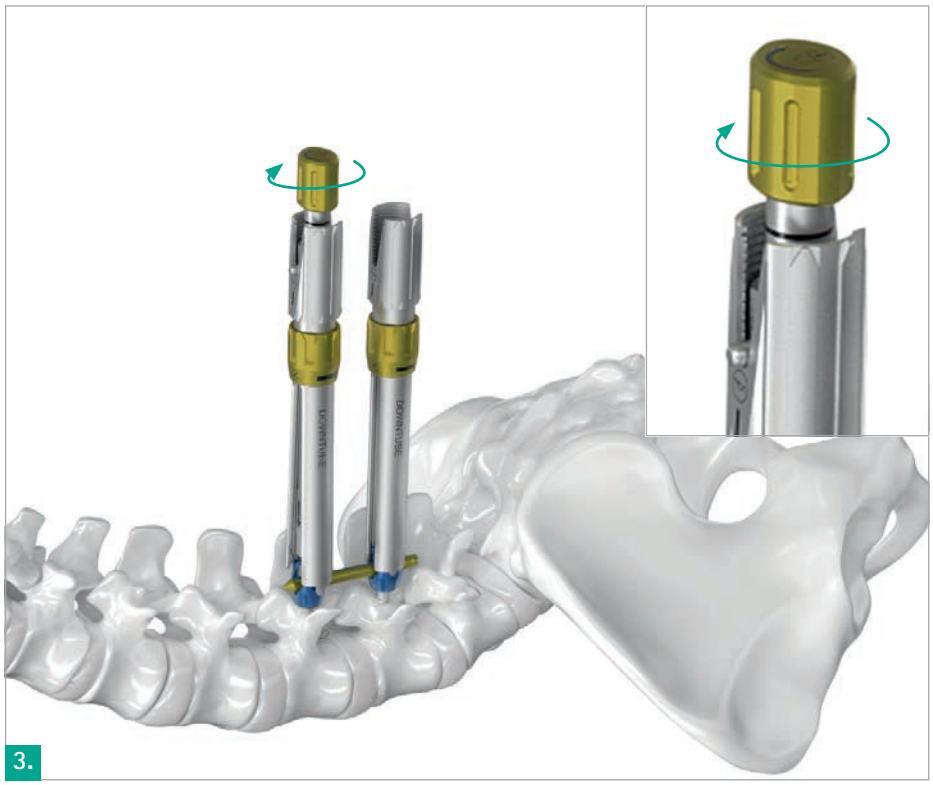
- Ensure that the pins of Removal Key are aligned with the oval shaped distal portion. If needed, hold both pins and turn them counter-clockwise until the stop.
- Slide the Removal Key into the Downtube until the stop.
- Ensure the line marking on the Removal Key is flush with the top of the silver crown of the Downtube.

AESCULAP® Ennovate®

DEGENERATIVE SPINE

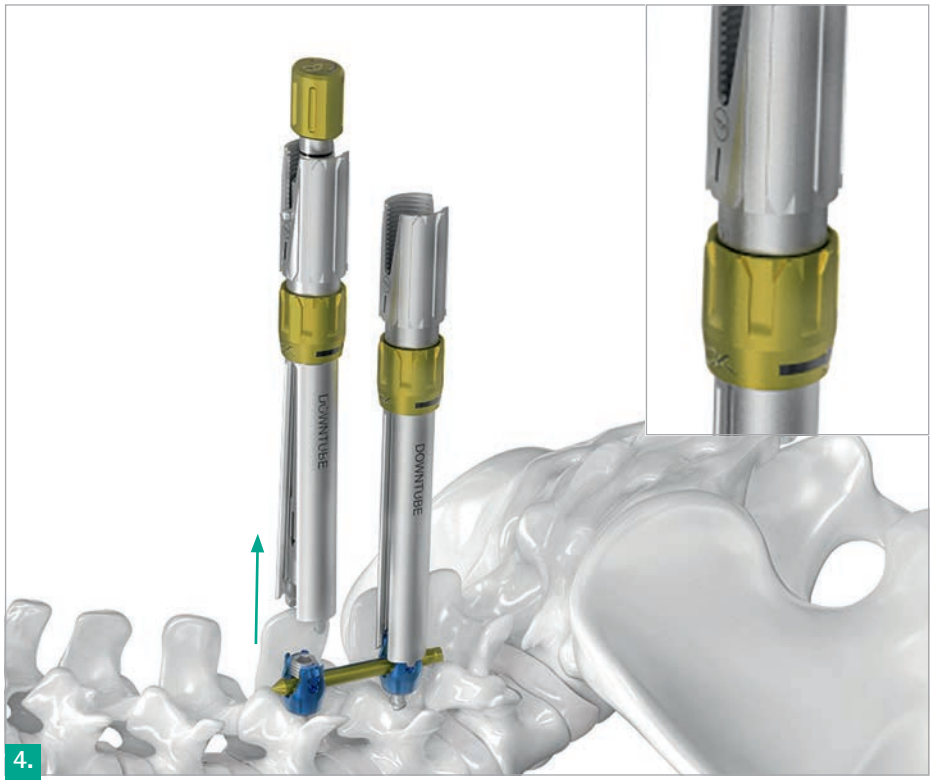
G. FINAL TIGHTENING AND DOWNTUBE REMOVAL

- Turn the golden knob of the Removal Key clockwise until the stop while firmly holding the silver crown of the Downtube.
- Ensure that the outer sleeve of the Downtube is released and not pulled backwards. Thus, the golden ring of the Downtube is not touching the silver crown.



3.

- Disengage the Downtube from the screw head by pulling the golden knob of the Removal Key off the patient.
- Turn the golden knob of the Removal Key counter-clockwise in order to bring the instrument into its initial position.



4.

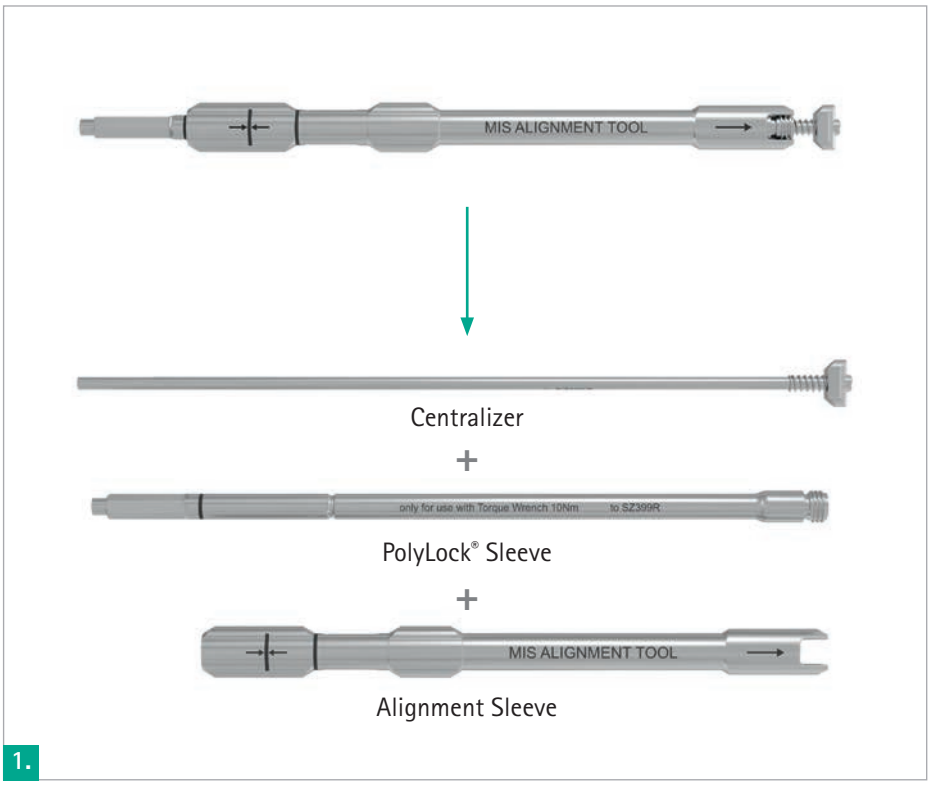
G

AESCULAP® Ennovate®

DEGENERATIVE SPINE
H. IN-SITU DOWNTUBE REMOVAL AND ATTACHMENT

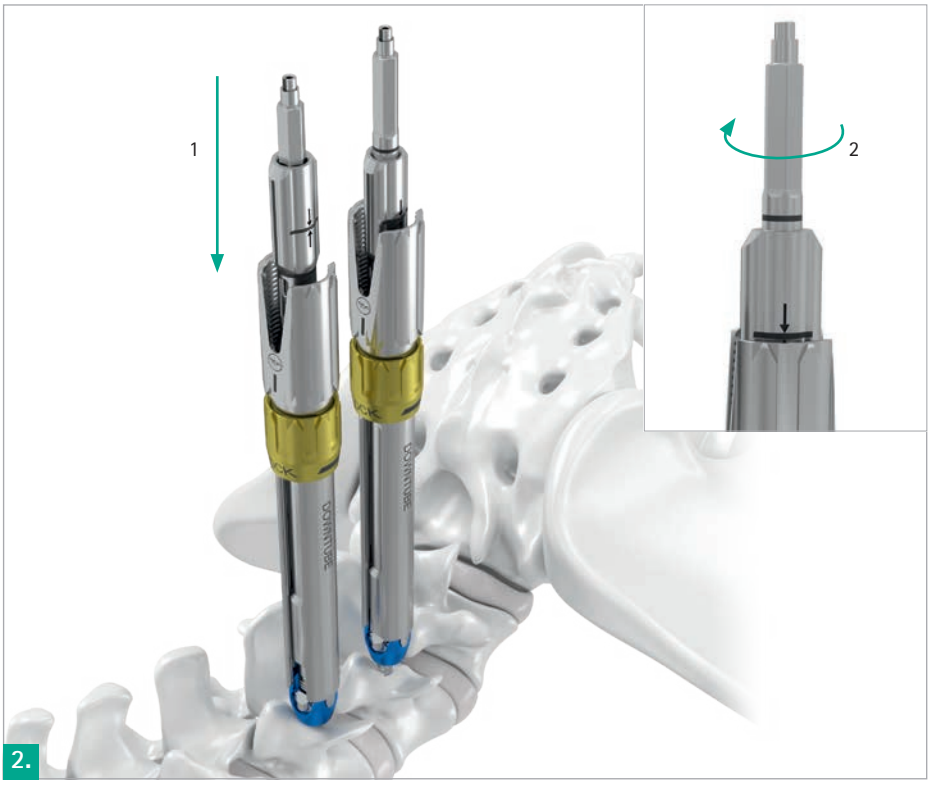
DOWNTUBE REMOVAL

- The Alignment Tool is an instrument that consists of three components:
- Centralizer: inner part that aligns to the screw head.
- PolyLock® Sleeve: middle part that can be slid over the Centralizer and be connected to the screw head with its set screw thread. The hexagon shaped portion is intended for the attachment to the Torque Wrench Handle 10 Nm and thus for PolyLock® activation/release.
- Alignment Sleeve: The outer contour reflects the inner geometry of the Downtube. This ensures proper alignment to the screw head interface.



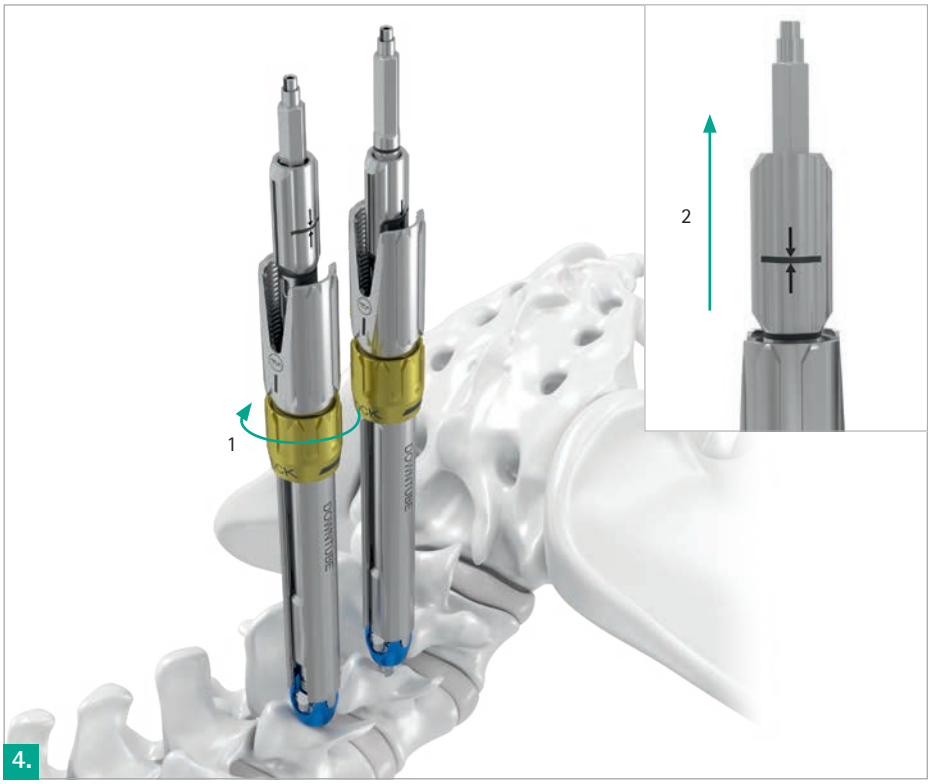
1.

- Assemble the Alignment Tool, with all three components, and attach a desired handle to it by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop.
- Insert the Alignment Tool into the Downtube (1) and turn the handle clockwise (2) until the set screw thread of the PolyLock® Sleeve engages with the screw head.
- Proper fixation is reached when the Downtube is restricted polyaxially and the line marking on the Alignment Sleeve is flush with the silver crown of the Downtube.



2.

- Engage the Counter Torque Handle to the coupling geometry on the Downtube (1).
- Attach the Torque Wrench Handle 10 Nm handle to the hexagon shaped portion of the PolyLock® Sleeve by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop (2).
- Ensure the Downtubes are aligned parallel to each other.
- Turn the Torque Wrench clockwise (3) while firmly holding the Counter Torque Handle until an acoustic signal sounds. The acoustic signal is an indicator that PolyLock® has been achieved.



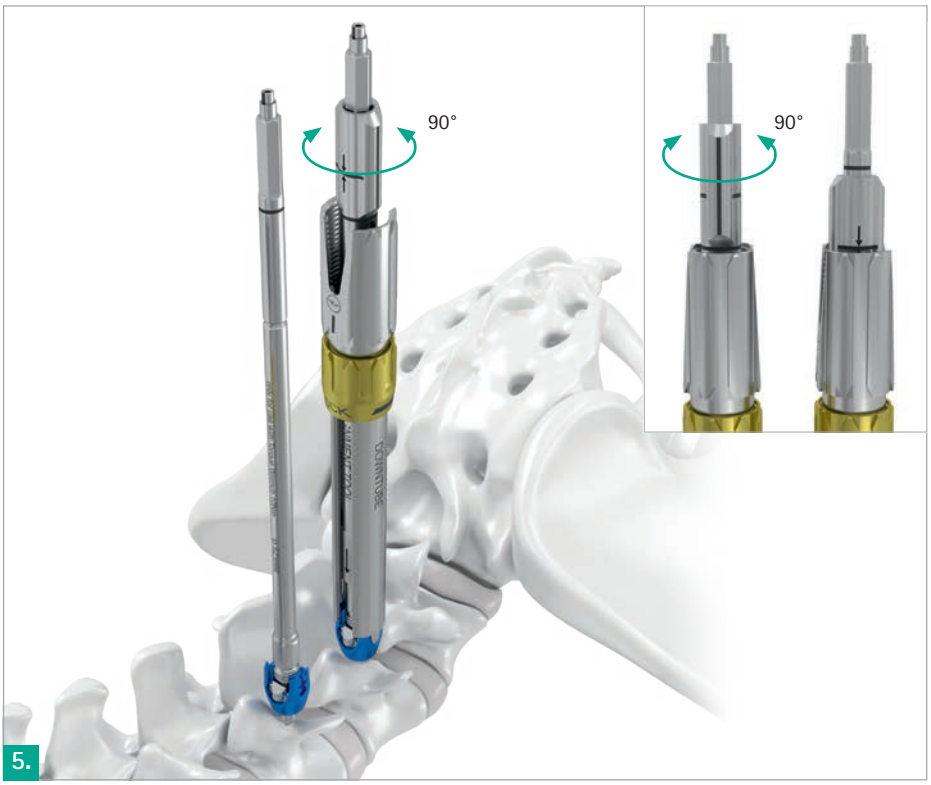
- Turn the golden ring of the Downtube clockwise until the line marking disappears (1).
- Pull back the Alignment Sleeve until the circumferential line marking is aligned with the silver crown of the Downtube (2).

AESCULAP® Ennovate®

DEGENERATIVE SPINE

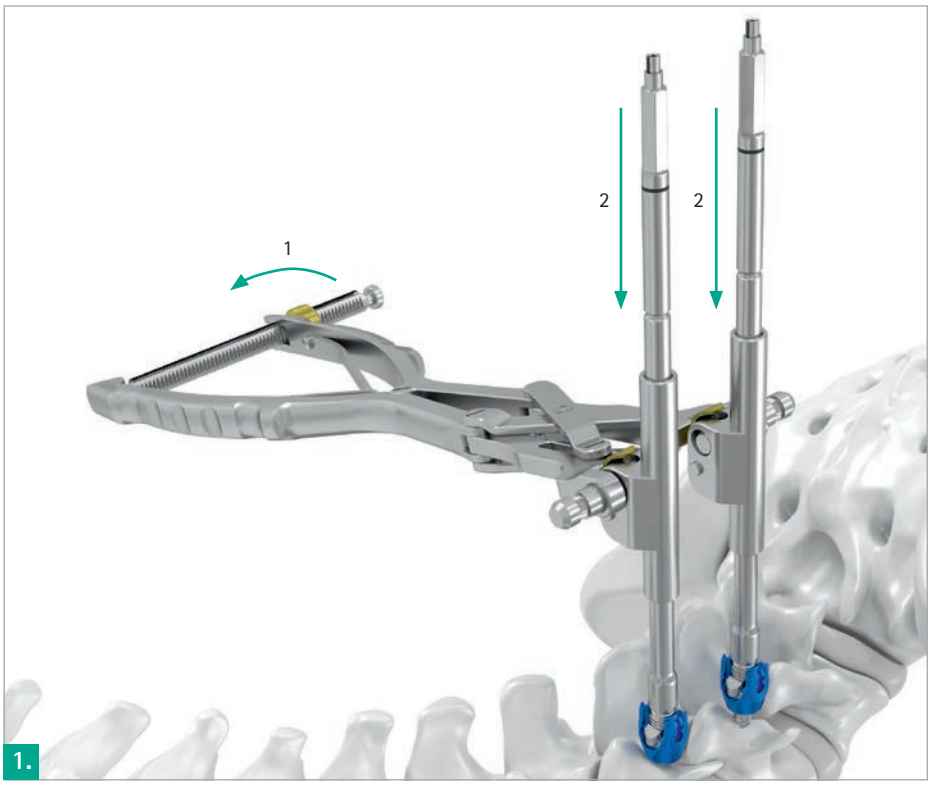
H. IN-SITU DOWNTUBE REMOVAL AND ATTACHMENT

- Turn the Alignment Sleeve either clockwise or counter-clockwise by 90°.
- Ensure that the outer sleeve of the Downtube is not pulled backwards. Thus, the golden ring of the Downtube is not touching the silver crown.



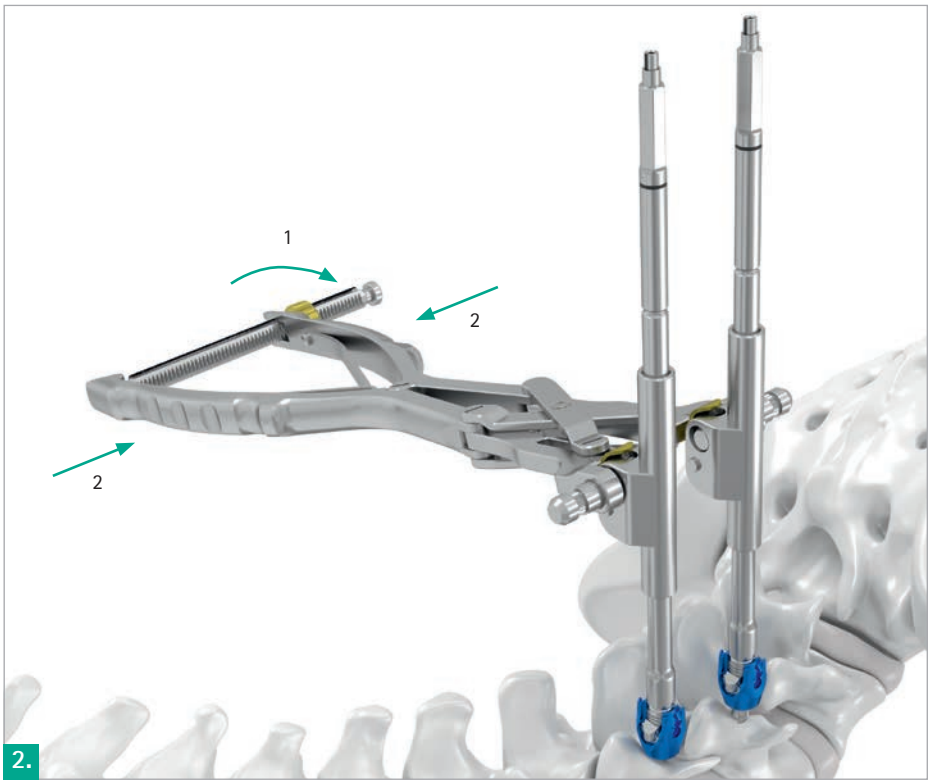
- Disengage the Downtube from the screw head by pulling the Alignment Sleeve off the patient.
- If needed, repeat this step for all relevant Downtubes.

H



COMPRESSION AND DISTRACTION

- Attach the Cage Sleeves onto the Compression / Distraction Forceps by sliding the connection pins of the forceps into the coupling of the Cage Sleeves.
- Ensure that the distance of the Downtubes is taken into account while attaching the Cage Sleeves to the forceps.
- Release the ratchet bar from the forceps handle (1), slide the Cage Sleeves onto the PolyLock® Sleeves (2) and slide the assembly further down until it touches the skin surface.



- Engage the ratchet bar to the forceps handles (1) and squeeze (2) them until the aimed manipulation is achieved.
- As a result, the distance between the loaded elements decreases / increases evenly.
- Once the desired manipulation is achieved, secure the manipulation by turning the golden ratchet bar nut until it contacts the forceps handle.

AESCULAP® Ennovate®

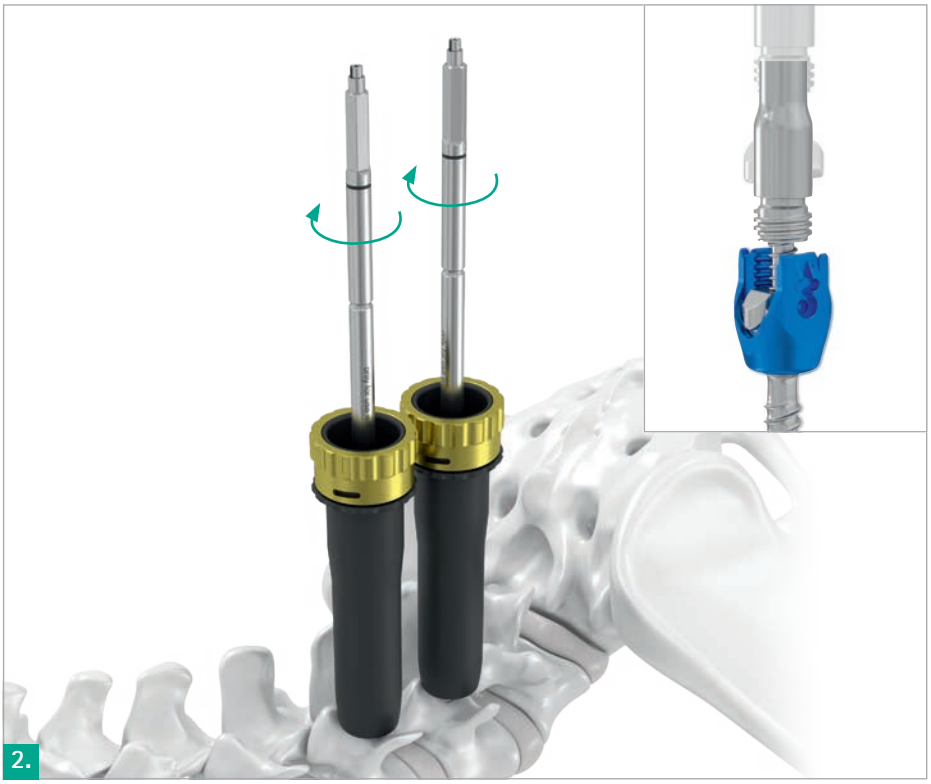
DEGENERATIVE SPINE

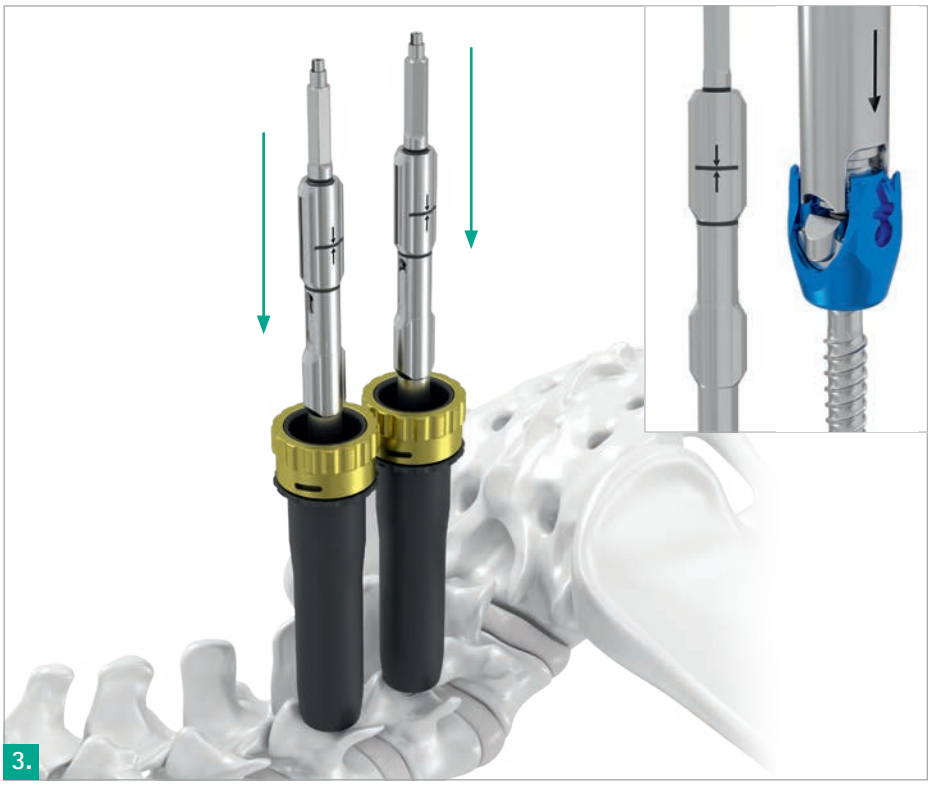
H. IN-SITU DOWNTUBE REMOVAL AND ATTACHMENT

MIS DOWNTUBE ATTACHMENT

- Place the Working Port in the existing incision of the detached Downtube and ensure that the tissue is dilated for an unobstructed access to the pedicle screw.

- Prior to the upcoming steps, remove the Alignment Sleeve from the rest of the Alignment Tool.
- Place the Centralizer interface (with the PolyLock® Sleeve attached to it) into the pedicle screw head.
- Turn the hexagon shaped portion of the PolyLock® Sleeve clockwise until the set screw thread of the PolyLock® Sleeve engages with the screw head.
- Proper fixation is reached when the pedicle screw is restricted polyaxially.





- Slide the Alignment Sleeve over the PolyLock® Sleeve until the stop.
- Proper attachment is reached when the line marking on the PolyLock® Sleeve is flush with the top of the Alignment Sleeve and the hexagon shaped portion of the PolyLock® Sleeve is fully exposed. Additionally, the Alignment Sleeve shall show restricted rotational movement.

- Turn the golden ring of the Downtube clockwise and pull the outer sleeve backwards until the golden ring touches the silver crown.
- Guide the Downtube over the Alignment Sleeve while the golden ring remains pulled back until the stop.
- Push the Downtube towards the screw until an acoustic signal sounds. The acoustic signal is an indicator that the connection arms of the Downtube have attached to the screw head. Visual and tactile confirmation of the connection is recommended.

AESCULAP® Ennovate®

DEGENERATIVE SPINE

H. IN-SITU DOWNTUBE REMOVAL AND ATTACHMENT

- Release the outer sleeve of the Downtube and turn the golden ring counter-clockwise until the upper portion of the golden ring is flush with the line marking.
- If needed, the Tightening Key may be used to enhance the tightening. Slide the Tightening Key over the Downtube and turn it counter-clockwise until a positive stop is perceived.

- Turn the golden ring of the Working Port clockwise (1) until the stop and pull it upwards (2).

7.

- The two half-shells of the Working Port can be removed from the Downtube by pulling them away from the patient.

8.

- Engage the Counter Torque Handle to the coupling geometry on the Downtube (1).
- Attach the Torque Wrench Handle 10 Nm handle to the hexagon shaped portion of the PolyLock® Sleeve by sliding the hexagonal shaped portion of the shaft into the handle coupling until the stop (2).
- Turn the Torque Wrench counter-clockwise (3) while firmly holding the Counter Torque Handle until the PolyLock® Sleeve and the Centralizer detach from the screw head.

AESCULAP® Ennovate®

DEGENERATIVE SPINE

I. Ennovate® INSTRUMENTS

HANDLES

SZ222R
Ennovate® Ratchet Handle, Straight

SZ224R
Ennovate® Ratchet Handle, T-Shape

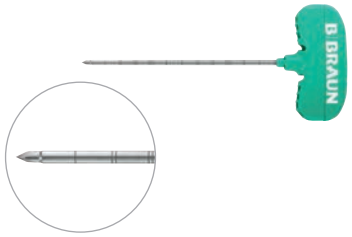
SZ225R
Ennovate® Ratchet Handle, Drop Shape

SZ228R
Ennovate® Torque Wrench Handle, 10 Nm

SZ390R
Ennovate® Reduction/Tightenting Handle

SZ392R
Ennovate® MIS/FRI Counter Torque Handle

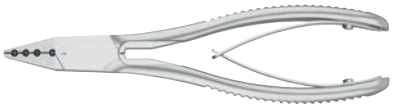
PREPARATION INSTRUMENTS



SZ364SU
Ennovate® Bone Acess Needle, Single-Use

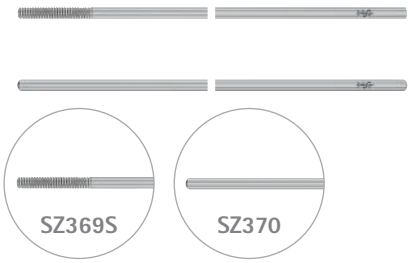
SZ466R
Ennovate® Bone Acess Needle Handle, Reusable

SZ465R
Ennovate® Bone Access Needle Trocar, Reusable



SZ367R
Ennovate® Guide Wire Forceps

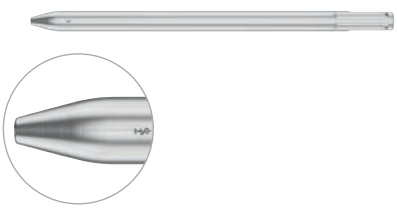
SZ368R
Ennovate® Hammer, Slotted



SZ369S/SZ370
Ennovate® Guide Wire, Stainless Steel/Nitinol

SZ371R
Ennovate® MIS Skin Incision Guide

BB540
AESCULAP® Scalpel Blade, Double Cutting



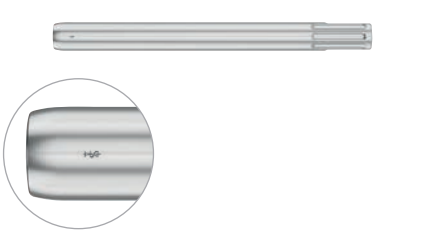
SZ372T
Ennovate® MIS Dilator, Small

AESCULAP® Ennovate®

DEGENERATIVE SPINE

I. Ennovate® INSTRUMENTS

PREPARATION INSTRUMENTS



SZ373T
Ennovate® MIS Dilator, Medium

SZ374T
Ennovate® MIS Dilator, Large

SZ375T
Ennovate® MIS Dilator, Handle

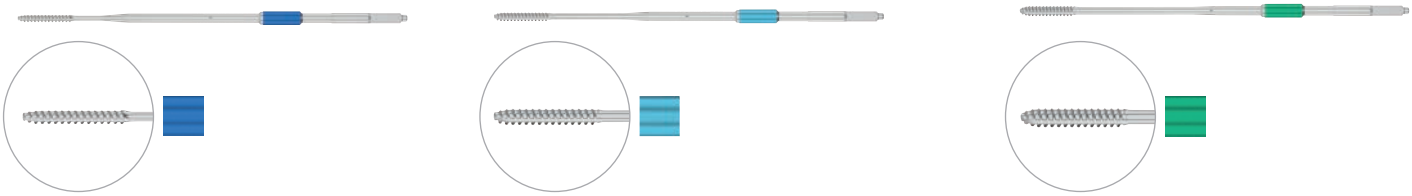
SZ376R
Ennovate® Lumbar Pedicle Probe, Straight, Canulated

SZ377R
Ennovate® MIS Screw Length Gauge

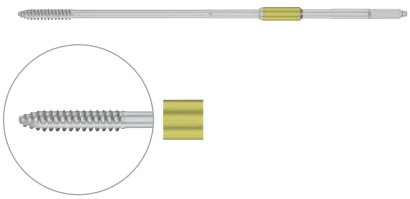
SZ254R
Ennovate® Screw Tap for Ø 4.5 mm, Canulated

SZ255R
Ennovate® Screw Tap for Ø 5.5 mm, Canulated

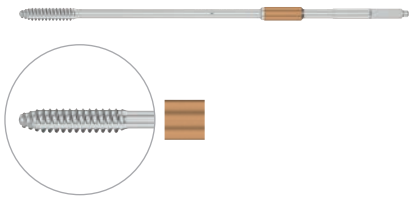
SZ256R
Ennovate® Screw Tap for Ø 6.5 mm, Canulated



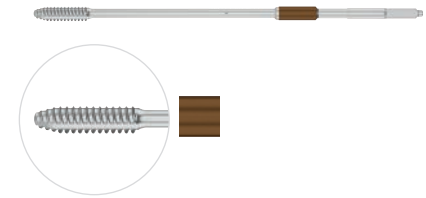
SZ257R
Ennovate® Screw Tap for Ø 7.5 mm, Canulated



SZ258R
Ennovate® Screw Tap for Ø 8.5 mm, Canulated



SZ259R
Ennovate® Screw Tap for Ø 9.5 mm, Canulated



SZ260R
Ennovate® Screw Tap for Ø 10.5 mm, Canulated

AESCULAP® Ennovate®

DEGENERATIVE SPINE

I. Ennovate® INSTRUMENTS

IMPLANTATION INSTRUMENTS

SZ378R
Ennovate® MIS Downtube

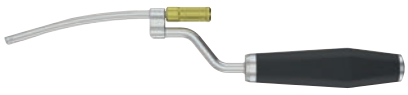
SZ379R
Ennovate® Tightening Key for MIS/FRI Downtube

SZ381R
Ennovate® MIS/FRI Screwdriver

SR138SU
Ennovate® MIS/FRI Injection Cannula

SR139R
Ennovate® MIS/FRI Cannula Sleeve

SZ382R
Ennovate® MIS/FRI Rod Length Gauge



SZ384R
Ennovate® MIS/FRI Rod Inserter, Tilted

SZ385R
Ennovate® MIS/FRI Rod Inserter, Straight

SZ387R
Ennovate® MIS/FRI Rod Indicator

REDUCTION AND MANIPULATION INSTRUMENTS

SZ270R
Ennovate® Rod Bender

SZ389R
Ennovate® MIS Rod Pusher

SZ393R
Ennovate® PolyLock® Key

SZ397R
Ennovate® MIS Quick Rod Pusher

SZ391R
Ennovate® Set Screw Driver

SZ380R
Ennovate® Removal Key for MIS/FRI Downtube

SZ398P
Ennovate® MIS Working Port

SZ399R
Ennovate® MIS/FRI Alignment Tool

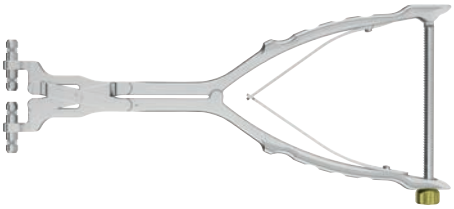
FW692R
Ennovate® Instrument Cleaning Device

AESCULAP® Ennovate®

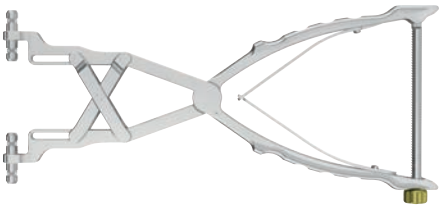
DEGENERATIVE SPINE

I. Ennovate® INSTRUMENTS

COMPRESSION AND DISTRACTION INSTRUMENTS



SZ231R
Ennovate® MIS/FRI Parallel Distractor Handle



SZ232R
Ennovate® MIS/FRI Parallel Compressor Handle

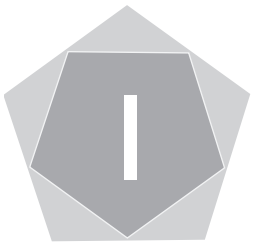
SZ396R
Ennovate® Cage Sleeves for MIS/FRI Parallel Distractor/Compressor Handle

SZ388R
Ennovate® Parallel Sleeves for MIS/FRI Parallel Distractor/Compressor Handle

SZ395R
Ennovate® C-Rings for MIS/FRI Parallel Distractor/Compressor Handle

SZ394T
Ennovate® MIS/FRI Compression/Distraction Wedge

NOTES



AESCULAP® – a B. Braun brand

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