HPS^{™2.0} - Open Posterior Dynamic Stabilization and Fusion



Surgical Technique





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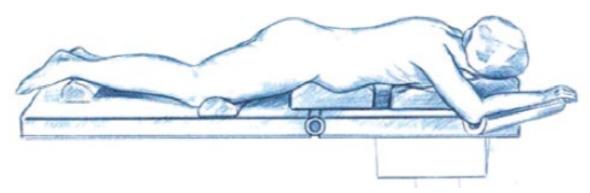
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Open Surgical Technique - General

Step 1: Patient Positioning

Place the patient in a prone position. Clean the operative area and make an incision at the appropriate level(s). Apply lateral C-arm fluoroscopy or other radiographic techniques during surgery to ensure correct implant placement.



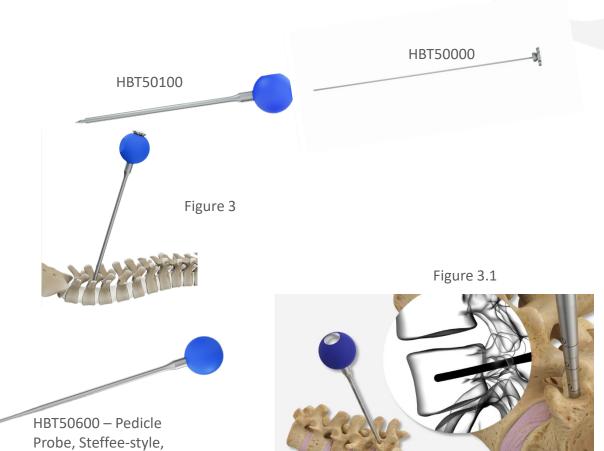


Open Surgical Technique - General

Step 2: Pedicle Preparation

- Assemble the awl by inserting the Trocar awl (HBT50000) through the cannulated awl (HBT50100) and tighten clockwise.
- Use the awl to perforate the cortex overlying the pedicle. (Figure 3)

 Use the pedicle probe (HBT50600) to dissect through the cancellous bone to the appropriate depth for tapping and screw insertion. Etched markings on the pedicle finder indicate its depth (Figure 3.1).





curved

Open Surgical Technique - General

Step 2: Pedicle Preparation

- Using the flexible Pedicle Ball Tip Probe
 (HBT50300), advance the instrument to the base
 (floor) of the hole to confirm five distinct bony
 borders: the floor and four walls (medial, lateral,
 superior, and inferior Figure 4 and 4.1). Give
 special care to the first 10 mm to 15 mm of the
 tract.
- Measuring the screw length: The Ball Tip Probe is advanced to the anterior cortex of the vertebral body. A distinctive change will be felt as cancellous bone is passed and cortical bone is encountered.
- This step measures the length of the screw. With
 the ball tip probe at the anterior cortex, the
 image will show the tip of the probe to be at the
 center of the vertebra. The probe is grasped with
 a clamp, and the length of the screw is
 Confidential For Internal Use Only Do not Distribute MKT-XXXXX REV. A
 determined. (Figure 4.1 and 4.2)



Figure 4.1

Figure 4

HBT50300



PARADIGM SPINE

Figure 4.2

Open Surgical Technique - General

Step 2: Pedicle Preparation

 Note: Optimal screw placement allows the creation of a "triangle" (Figure 5), i.e. screws placed in a convergent fashion will increase the rotational stability of the construct (Figure 6) and lead to stronger screw fixation.

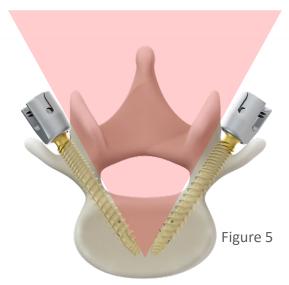




Figure 6



Open Surgical Technique – General

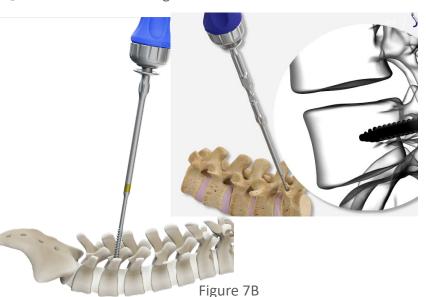
Step 3: Pedicle tapping – Optional

- HPS ™ 2.0 pedicle screws are self-tapping. However, in the case of sclerotic bone quality taps are available for all screw diameters (Figure 7A).
- Attach the appropriate tap to a handle (HBT40126) or HBT40112), insert the tap into the hole prepared in the pedicle and rotate the handle clockwise to tap a thread in the pedicle (Figure 7B). The taps are marked to indicate depth and have colored rings corresponding to the screw sizes.
- Note: The taps are undersized by 0.5 mm and have a thread length of 36.0 mm (Figure 7C).





Figure 7A





HBT40112

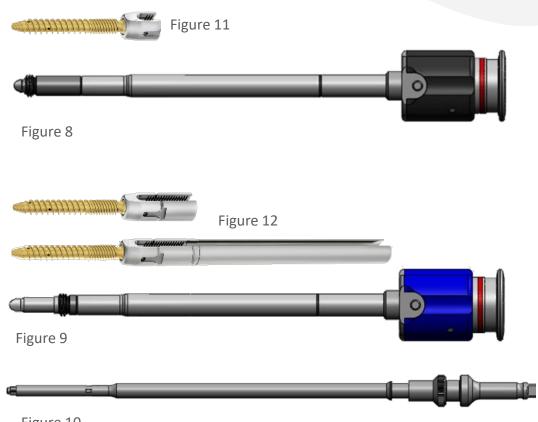




Open Surgical Technique – General

Step 4: Screw Inserter assembly

- All HPS [™] 2.0 implants are sterile packaged, and the set screw is included in the same packaging as the screw. There are two different screwdrivers available:
- Figure 8: HBT80102 HPS ™ 2.0 Polyaxial Screwdriver. The Screwdriver "Short Tulip" (Figure 8) is for the Standard Screws (Figure 11).
- Figure 9: HBT80100 HPS ™ 2.0 Polyaxial Screwdriver Reduction Tulip. The screwdriver "Reduction Tulip" (Figure 9) is for the Reduction and MIS Screws (Figure 12).
- Figure 10: Both Screwdrivers require the HBT80105
 HPS ™ 2.0 Inner Shaft.







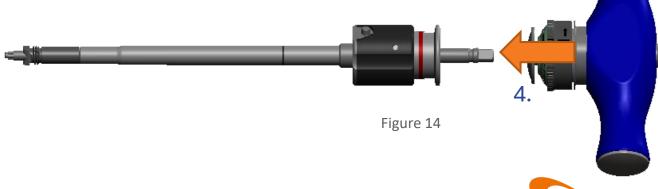
Open Surgical Technique - General

Step 4: Screw Inserter assembly

• Assembly is identical for both Screwdrivers:



- 1. Rotational lock must be unlocked (red line visible), Figure 13
- 2. For smooth attachment unlock axial lock (pin in handle), Figure 13
- 3. Stick inner shaft (HBT80105) into outer sleeve (HBT80100 or HBT80102), Figure 13
- 4. Attach T-(HBT40112) or straight- (HBT40126) handle, Figure 14



PARADIGM SPINE

Open Surgical Technique - General

Step 5: Screw insertion

 Assembly is identical for both Screwdrivers: Figure 15





Figure 16

- 1. Stick screwdriver (drive feature T25) in screw shank, Figure 15 Make sure the T25 drive feature is completely recessed in the tulip, Figure 16
- Tighten the connection by truing the handle at the outer shaft clockwise
- Lock rotational lock sleeve (no visible red marking)
- Insert screw into pedicle, Figure 17

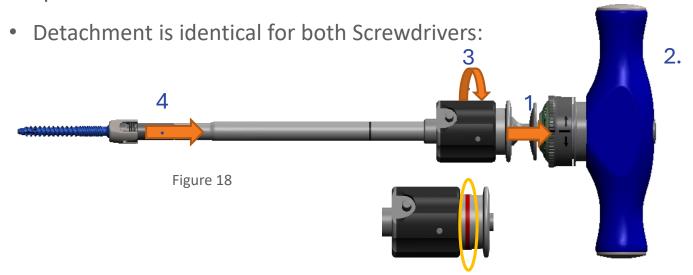


Figure 17



Open Surgical Technique - General

Step 6: Screw detachment



- 1. Unlock rotational lock sleeve (visible red marking), Figure 18
- 2. Hold handle, Figure 18
- 3. Untighten the connection by truing the handle at the outer shaft counterclockwise, Figure 18
- 4. Pull back screwdriver, Figure 18



Open Surgical Technique – Monosegmental dynamic Instrumentation

Step 7: Coupler assembly

- Note: In case of monosegmental dynamic instrumentation, the interpedicular space can be assessed using the "Coupler Template" (HBT90176). This ensures that the coupler will fit in between the two pedicle screws and can be positioned in a neutral position i.e. non-flexed (Figure 19).
- Note: If the coupler template doesn't fit in between the two pedicle screws, an HPS ™ coupler cannot be used, and fusion may have to be performed.

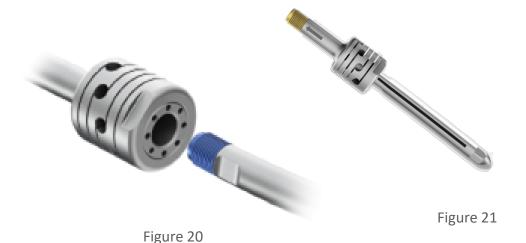




Open Surgical Technique – Monosegmental dynamic Instrumentation

Step 7: Coupler assembly

- The caudal rod length should be most likely between 20mm and 30mm for a monosegmental treatment. For assembling the rod coupler with the rod (Figure 20), turn the rod into the rod coupler clock-wise until the blue-colored thread grooves respectively are hidden then turn back minimum half a turn to keep threads exposed. The line on the rod should be aligned with the arrow on the coupler, (Figure 21).
- Important: Do not turn in the thread entirely. Leaving the coupler loose avoids torsion forces during insertion and stabilization of the segment!





Open Surgical Technique – Monosegmental dynamic Instrumentation

Step 8: Coupler insertion and positioning

- The retaining forceps, small (DAT40560) (Figure 22) can be used for easier insertion of the coupler with the attached rod into the aligned screw tulips (Figure 23). Pay attention, that the assembled rod doesn't rotate in a kyphotic position during the insertion procedure.
- Important: The arrows on the couplers must point precisely posterior and be aligned in the frontal plane (Figure 24).
- Note: The coupler must be placed in a neutral position. Bending, compression and distraction forces must be avoided. Care has to be taken that the coupler slots are parallel (Figure 25)!
- Note: The total rod length should project a minimum overhang of 5 mm on both sides once the implant has been placed in the screw tulips!
- After placing the coupler-rod-construct move on to step "set screw insertion" Slide 38

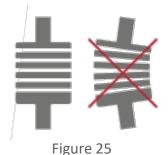


Figure 23



Figure 22

Figure 24





Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 1 to 6: Approach and Screw Insertion, see slides 3-11

Step 7: Coupler Assembly

- For multi-segment dynamic instrumentation, the option of connecting up to two couplers can be selected. Therefore, the interpedicular distance has to be measured with the "Template for Coupler Bending" (Figure 30) that is available in three different radii (300, 200 and 100) to measure also the lordosis at the same time that has to be adjusted later for the coupler rods.
- The length of the attached rods is the same for all three templates! (Figure 31).



Figure 30



Figure 31



Open Surgical Technique – **Multisegmental** dynamic Instrumentation

Step 7: Coupler Assembly

- All three templates have laser marks on the rod for measuring the needed coupler length. The second line is for the 27 mm coupler (Figure 32).
- For using more than one coupler, use the "Coupler Template" (HBT90170) (Figure 33) connected to the cranial rod (second line) of the "Template for Coupler Bending" (Figure 26) to check the interpedicular distance and if the coupler fits in between.
- The "Coupler Template" (HBT90170+HBT9019x) (Figure 34) has to be positioned in the screw tulips with the laser mark "cranial" facing to cranial. The overlapping rod length for the 27 mm rod coupler will be the effective rod length (Figure 32).

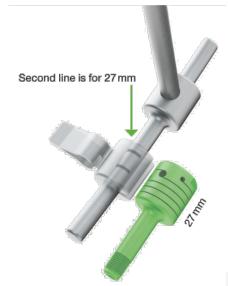


Figure 32





Figure 34



Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 7: Coupler Assembly

• In the following case (Figure 35/36), there is three-segmental instrumentation (L3/L4 and L4/L5 dynamic with two couplers and fusion at L5/S1) procedure. The approximate lordosis is measured with a radius of 200 (Radius Template 2). The coupler length is measured—with sufficient length of rod overhang. The whole template construct is shown in figure 35 and 36:



Figure 36



Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 7: Coupler Assembly

 Note: For measuring the correct lordosis (1, 2 or 3), make sure that the appropriated "Template for Coupler Bending" is not bobbing while pressing the template into the screw tulips! (Figure 37)



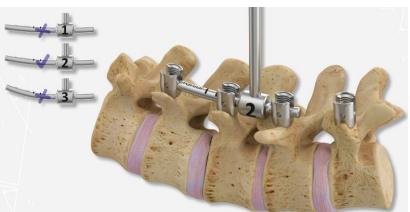


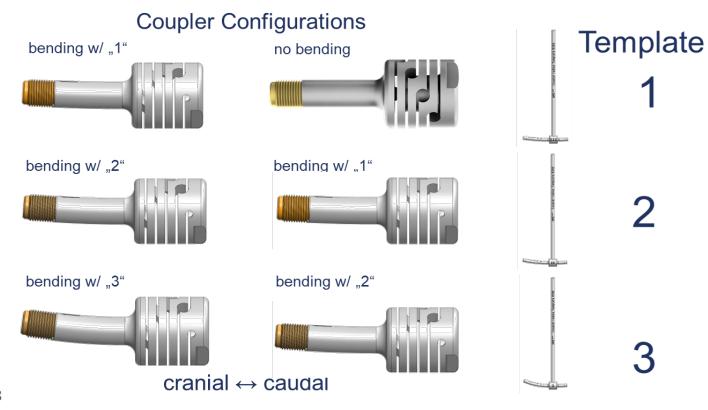
Figure 37



Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 7: Coupler Assembly

• The following coupler configurations are recommended (Figure 38):





Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 7: Coupler Assembly

- Assemble the couplers, after bending, due to the recommendation on slide 19/Figure 38. The less bent coupler should be threaded in the more bent coupler.
- **Important**: Do not turn in the threads entirely. Leaving the coupler loose avoids torsion forces during insertion and stabilization of the segment!
- Note: If the required rod curvature cannot be clearly matched to the templates, always start bending with the largest radius Template No.1 (R300)! If the radius is not small enough, the coupler rod can be bent with the next smaller radius (Template 2). A bending back must be avoided under all circumstances!



Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 8: Coupler bending

• (Figure 39) Assemble the Handles (HBT90250) to the Coupler Bender (HBT90220) and fold out the Stabilization Plates (Figure 40). Make sure the Coupler Rod Bender has a stable base for the bending procedure!



Figure 40

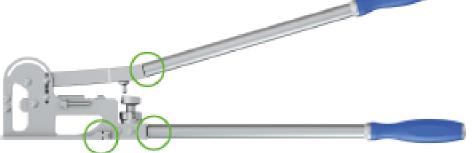


Figure 39



Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 8: Coupler bending

- Rotate down the handles of the coupler holder (Figure 41)
- Take the appropriated coupler implant that has to be bent and screw it into the coupler holder. Make sure that the coupler is not screwed in tight and the two laser marks (two arrows) will face each other in line (Figure 42)!

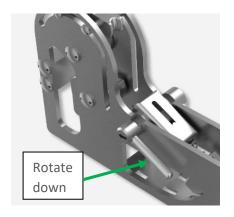


Figure 41



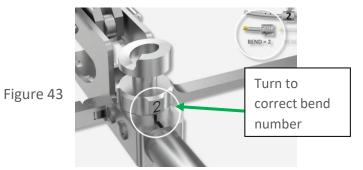
Figure 42



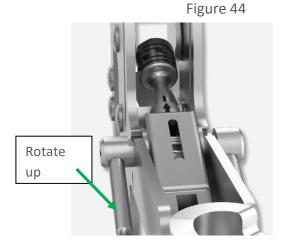
Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 8: Coupler bending

• Set the measured radius (1, 2 or 3) on the bender. (Figure 43)



• Swivel the coupler into the coupler safety box.(Figure 44)





Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 8: Coupler bending

• Push down the handle to the stop to ensure the set bending (Figure 45). The Pin should be in full contact to the stop. (Figure 46)

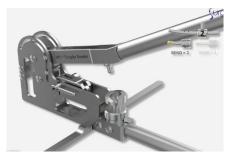


Figure 45

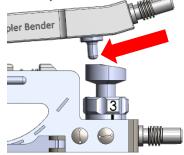


Figure 46

• Swivel the handle and coupler holder back and turn out the bent coupler.

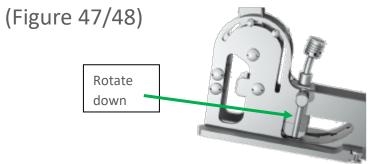


Figure 47



Figure 48



Open Surgical Technique – **Multisegmental** dynamic Instrumentation

Step 9: Rod Measurement

 To determine the rod length for the fusion length, use the Measurement Tool (HBT90140). Insert one arm of the Measurement Tool into the first tulip immediately caudal to the coupler and the second arm into the most caudal tulip until each leg is fully seated in the screw heads (Figure 49/50).

 Length markings indicate rod length, including rod overhang (Figure 51). No additional rod length allowance is required.
 Select the rod that corresponds with the stated rod length. If the measurement is between two lengths, it is recommended to select the longer rod.

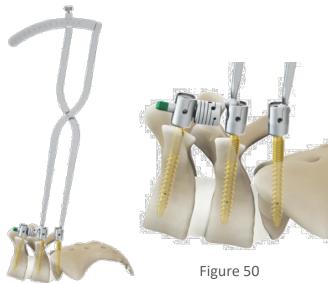


Figure 49

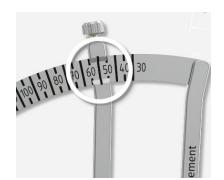


Figure 51



Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 10: Implant assembly and Insertion

- To assemble the two coupler with the fusion rod, turn the rod into the coupler until all blue-colored thread grooves are hidden. Then turn back half a turn to keep threads exposed (Figure 20).
- **Important**: Do not tighten the thread completely! Leaving the coupler loose avoids torsion forces during coupler insertion and stabilization of the segment.
- The Retaining Forceps Small (DAT40560) can be used for easier insertion of the coupler with the attached rod into the aligned screw tulips. Pay attention, that the assembled rod doesn't rotate in a kyphotic position during the insertion procedure. (Figure 52).
- Important: The arrows on the couplers must point precisely posterior and be aligned in the frontal plane (Figure 53).







Figure 52





Open Surgical Technique – Multisegmental dynamic Instrumentation

Step 10: Implant assembly and Insertion

- The coupler must be placed in a neutral position. Bending, compression and distraction forces must be avoided. Care has to be taken that the coupler slots are parallel (Figure 25). After placing the coupler-rod-construct move on to step "set screw insertion". (Figure 54)
- After placing the coupler-rod-construct move on to step "set screw insertion" Slide 38



Figure 54



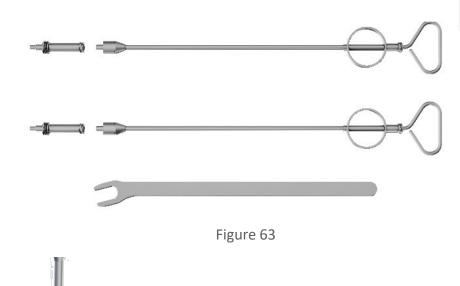
Figure 25

Open Surgical Technique - Fusion: Optional Screw Augmentation

Step 1 to 6: Approach and Screw Insertion see slides 3-11 Step 7: Screw Augmentation

- All HPS 2.0 screws are canulated and fenestrated. The cement injection Set (HCD80800) consists of two Cement Injection Adapter for the connection on the screw, two cement injection cannulae with a plunger and a counter torque holder for removing the Instruments (Figure 63).
- Connect the Cement Injection adapter with the Set screw Driver (HBT80162) and insert it into the tulip. The thread of the adapter must be completely screwed in the tulip (Figure 64/65)
- Important: Lateral X-ray control absolutely necessary.









Open Surgical Technique - Fusion: Optional Screw Augmentation

Step 7: Screw Augmentation

• Cement preparation according to the manufacturer's instructions.

• Thread the standard Luer syringe from the cement delivery system onto the cement injection cannulae. Fill the cement injection cannulae with cement (Figure 66).

Connect the cement injection cannulae with the cement adapter

(Figure 67).



Figure 67



Figure 66

Open Surgical Technique - Fusion: Optional Screw Augmentation

Step 7: Screw Augmentation

- With the plunger the cement can now applicated into the vertebrae (Figure 68)
- Important: Use x-ray throughout the procedure to verify and monitor cement flow.
- Note: The amount of cement can be measured with the scaling on the plunger in 0.5ml steps up to max 1.5ml (Figure 69).

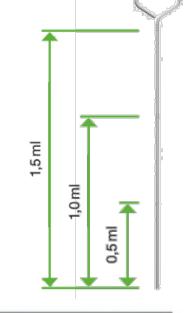




Figure 68



Figure 69

• After application remove the injection cannulae and the Cement injection adapter under the support of the counter torque holder (Figure 70).



Figure 70





Open Surgical Technique – Fusion

Step 1 to 6: Approach and Screw Insertion see slides 3-11.

Step 8: Rod Measurement

- Optional: to align the tulips you can use the aligner (HBT80150)
- To determine the rod length for the fusion length, use the Measurement Tool (HBT90140). Insert one arm of the Measurement Tool into the cranial Head and the most caudal Head until each leg is fully seated in the screw heads (Figure 55).
- Length markings indicate rod length, including rod overhang. No additional rod length allowance is required. Select the rod that corresponds with the stated rod length. If the measurement is between two lengths, it is recommended to select the longe
- Option The Template Rod (HAT90150) can be used to determine rod length and for rod contouring



Figure 55

HAT90150



Open Surgical Technique – Fusion

Step 9:Rod Contouring - Optional

• The HPS 2.0 rods are precontoured but if further contouring is required the bending pliers (HAT90200) can be used.

Step 10: Rod Cutting – Optional

- The HPS 2.0 rods are available in different lengths but if needed the rods can be shortened with the rod cutter (HBT90300) assembled with the Coupler Bender Handles (HBT90250).
 - Note: the rod must be held on both sides during cutting to prevent it from flying uncontrollably through the air.

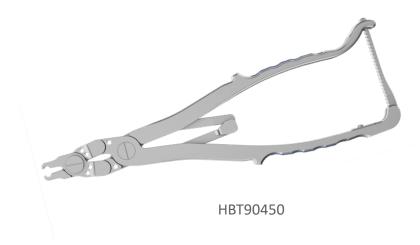




Open Surgical Technique – Fusion

Step 11: Rod insertion

- Once a rod is selected the handle for coupler template (HBT90180) can be used to insert the rod to the screw heads (Figure 63).
- Optional the HPS Vice Grip (HBT90450) can be used for rod insertion.
- After placing the rod move on to step "set screw insertion" Slide 38



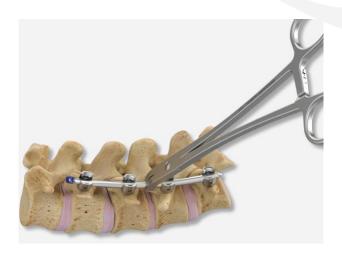


Figure 63



Open Surgical Technique – Fusion

Step 12: Rod Reduction – Optional

Within the HPS 2.0 System are several instruments for rod reduction:

	Rocker	Persuader	Rod- Pusher	Reduction & MIS screw
	8			
Article number	HAT90800	HAT90500	НВТ90552	HAI6xxyy Reduction HAI4xxyy MIS
Reduction way	5 mm	20mm	unlimited	20 mm

Table 1



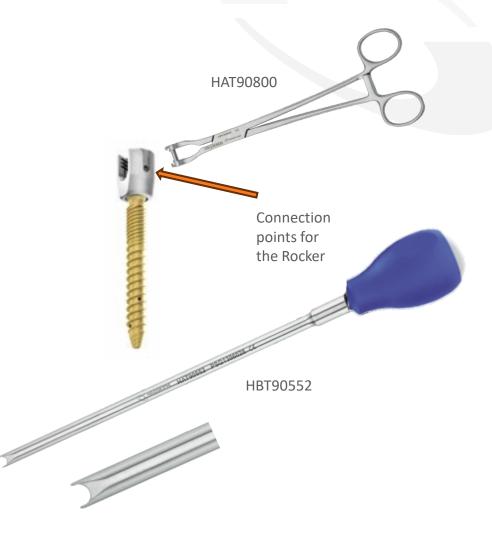
Open Surgical Technique – Fusion

Step 12: Rod Reduction Rocker – Optional

- Connect the HPS Rocker (HAT90800) over the rod with the HPS 2.0 screw.
- Use the rocker (HAT90800) to lever the rod into the screw head of the pedicle screw.

Step 12: Rod Reduction Pusher – optional

 If the rod is not fully seated within the Head of the screw the Rod pusher (HBT90552) can be used to manipulate the rod until it's fully seated within the screw head and a set screw can be inserted.





Open Surgical Technique – Fusion

Step 12: Rod Reduction Persuader – Optional

- Ensure that the ratchet handle is fully open. Place the persuader (HAT90500) over rod and onto the screw head. Press down firmly until the tips engage the head of the screw (Figure 56).
- Persuader encloses screw head completely. Ensure right angle (90°) to rod axis and correct alignment on screw head (Figure 57)
- Squeeze the handle to seat the rod into the head of the pedicle screw.
- For the detachement of the instrument when having a tight fit on the screwhead, simultanously:
 - => Pull small lever, Push big lever, Repeat (Figure 58)



Figure 56



Figure 57

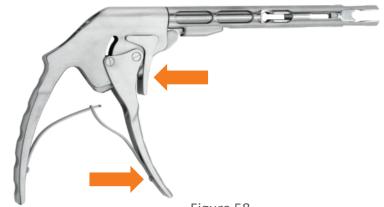


Figure 58



Open Surgical Technique – General

Step 13: Set Screw Insertion

- Note: All HPS ™ 2.0 implants are sterile packed, and the set screw is included in the same packaging as the screw.
- Insert the tip of the Lock screwdriver (HBT80162) into the set screw. Press down firmly. The Lock screwdriver is self-retaining.
 With the rod engaged with the screw head insert the set screw and turn clockwise until finger tight to pre-lock the set screw to the head of the screw, (Figure 26)
- Note: At this stage the system is still not locked and will require Final tightening to complete the procedure.



HBT80162



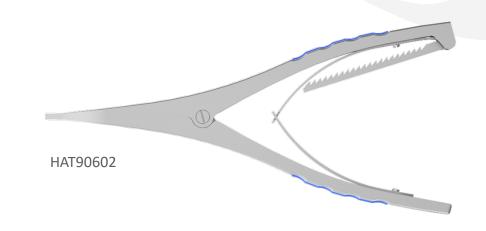
Figure 26



Open Surgical Technique - General

Step 14: Compression/Distraction - optional

- The distractor is used to widen the distance between the vertebrae to prepare the disc space .
- After locking the rod in one pedicle screw, place the distractor (HAT90602) over the rod and use the locked part as a counterpoint to distract. Note: At this stage the system is still not locked and will require Final tightening to complete the procedure.
- After preparing the disc space use the compressor (HAT90702) to minimize the disc space and then do the final tightening on the second screw.









HAT90702



Open Surgical Technique - General

Step 15: Final Tightening

- Place the Counter-Torque holder (HBT80500) over the screw head until the slots at the distal end of the instrument are completely seated over the rod.
- With the Torque T-handle (HBT40112) engaged, insert the Torque shaft (HBT80160) through the Counter-Torque holder until it is securely seated into the set screw and tighten the set screw with the Torque Limiter (Figure 27).
- If the coupler is twisted by this maneuver, use the Counter Torque to turn the screw Head back until the coupler is in a neutral position, (Figure 28/29)
- The set screw is fully tightened, with 12Nm, when the you hear an audible click.



Figure 28



Figure 29



Figure 27



Open Surgical Technique - Removal

Removal:

- For removal of the spinal construct will be a separate reduced instrument set available, which includes the following instruments:
 - HBT80160 HPS 2.0 Torque shaft
 - HBT40112 HPS 2.0 Torque T-Handle
 - HBT80500 HPS 2.0 Counter Torque Holder
 - DAT40560 Retaining forceps small
 - HBT80105 HPS 2.0 Screwdriver shaft
 - HBT80102 HPS 2.0 Polyaxial screwdriver

