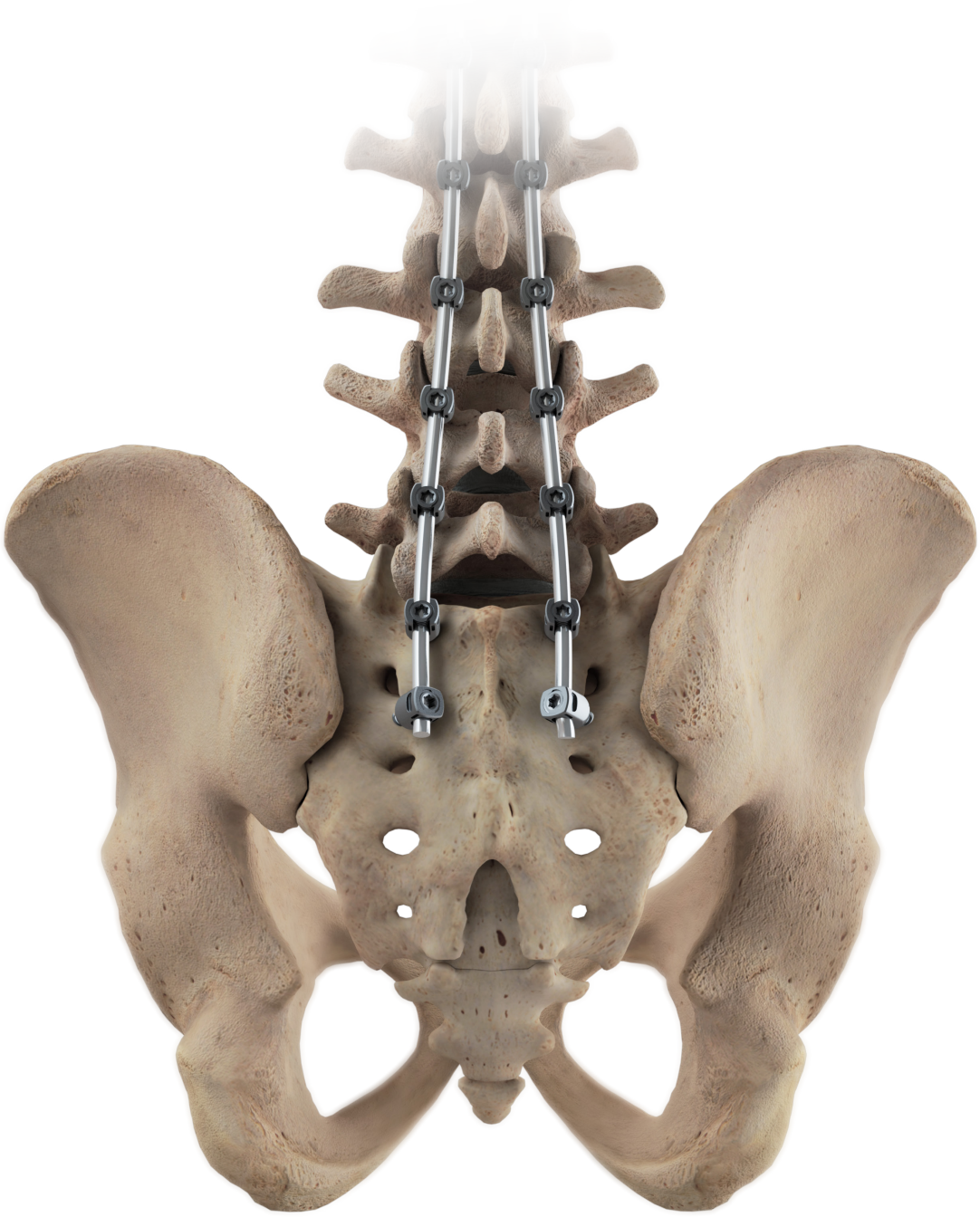
RESPONSE™ Spine 5.5/6.0 Closed Screw System

SURGICAL TECHNIQUE - Extension ST 1301-01-03



OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

CLOSED PEDICLE SCREWS

5.5/6.0 Polyaxial Pedicle Screws	
00-1301-5650	6.5mm x 50mm
00-1301-5655	6.5mm x 55mm
00-1301-5660	6.5mm x 60mm
00-1301-5670	6.5mm x 70mm
00-1301-5680	6.5mm x 80mm
00-1301-5750	7mm x 50mm
00-1301-5755	7mm x 55mm
00-1301-5760	7mm x 60mm
00-1301-5770	7mm x 70mm
00-1301-5780	7mm x 80mm
00-1301-5790	7mm x 90mm
00-1301-5710	7mm x 100mm
00-1301-5850	8mm x 50mm

5.5/6.0 Polyaxial Pedicle Screws	
00-1301-5855	8mm x 55mm
00-1301-5860	8mm x 60mm
00-1301-5870	8mm x 70mm
00-1301-5880	8mm x 80mm
00-1301-5890	8mm x 90mm
00-1301-5810	8mm x 100mm
00-1301-5950	9mm x 50mm
00-1301-5955	9mm x 55mm
00-1301-5960	9mm x 60mm
00-1301-5970	9mm x 70mm
00-1301-5980	9mm x 80mm
00-1301-5990	9mm x 90mm
00-1301-5910	9mm x 100mm

5.5/6.0 Cannulated Polyaxial Pedicle Screw	
00-1301-4650	6.5mm x 50mm
00-1301-4655	6.5mm x 55mm
00-1301-4660	6.5mm x 60mm
00-1301-4665	6.5mm x 65mm
00-1301-4670	6.5mm x 70mm
00-1301-4675	6.5mm x 75mm
00-1301-4680	6.5mm x 80mm
00-1301-4750	7mm x 50mm
00-1301-4755	7mm x 55mm
00-1301-4760	7mm x 60mm
00-1301-4765	7mm x 65mm
00-1301-4770	7mm x 70mm
00-1301-4775	7mm x 75mm
00-1301-4780	7mm x 80mm
00-1301-4790	7mm x 90mm
00-1301-4710	7mm x 100mm
00-1301-4850	8mm x 50mm

5.5/6.0 Cannulated Polyaxial Pedicle Screw	
00-1301-4855	8mm x 55mm
00-1301-4860	8mm x 60mm
00-1301-4865	8mm x 65mm
00-1301-4870	8mm x 70mm
00-1301-4875	8mm x 75mm
00-1301-4880	8mm x 80mm
00-1301-4890	8mm x 90mm
00-1301-4810	8mm x 100mm
00-1301-4950	9mm x 50mm
00-1301-4955	9mm x 55mm
00-1301-4960	9mm x 60mm
00-1301-4965	9mm x 65mm
00-1301-4970	9mm x 70mm
00-1301-4975	9mm x 75mm
00-1301-4980	9mm x 80mm
00-1301-4990	9mm x 90mm
00-1301-4910	9mm x 100mm

INSTRUMENTS

WARNING: Cannulated pedicle screw drivers are only to be used with the Response Cannulated Pedicle Screw System. The hexalobe geometry is different than that of the standard pedicle screw drivers. Similarly, the standard Response Spine pedicle screw drivers are only to be used with the standard Response 5.5/6.0 Pedicle Screw System. The differing of hexalobe geometry can lead to difficulty inserting screws or stripping of the drivers hexalobe features.

5.5/6.0 Closed Cannulated Pedicle Screw Driver, Zimmer Hudson
01-1301-6040

Description	Item#
5.5/6.0 Closed Cannulated Pedicle Screw Driver, Zimmer Hudson	01-1301-6040
5.5/6.0 Closed Cannulated Pedicle Screw Driver, Square	01-1301-6041
5.5/6.0 Closed Pedicle screw driver, T20, Square	01-1301-6042
5.5/6.0 Closed Pedicle screw driver, T20, Zimmer Hudson	01-1301-6043

Pedicle Screwdriver Application

Attach Pedicle Screwdriver 01-1301-6043 to the axial handle 01-1003-6033 or palm handle 01-1003-6034.

Attach Cannulated Pedicle Screwdriver, 01-1301-6035, to Zimmer Hudson Handle, 01-1071-005.

Place hexalobe tip of either the pedicle screwdriver or cannulated driver into the pedicle screw. Engage the hex with the driver tip.

See sections “Pedicle Screwdriver Application” and “Place Screws” in ST-1300-01-01 for pedicle screw and pedicle screwdriver assembly.

Upon insertion of the standard closed or cannulated pedicle screws, proceed with rod reduction, deformity correction, and set screw insertion per ST-1300-01-01 using the RESPONSE 5.5/6.0 standard instrumentation

Tap Sizing	
Screw Size	Tap Size
6.0mm Screw	5.0mm Tap
6.5mm Screw	5.5mm Tap
7.0mm Screw	6.0mm Tap
8.0mm Screw	7.0mm Tap
9.0mm Screw	8.0mm Tap

Tapping Pedicles

Cannulated System drivers and taps utilize the Zimmer Hudson handle, part 01-1071-005.

Following the placement of guide wire, prepare pedicles via placement of cannulated system taps over the guide wires.

NOTE: Etching on the taps indicate the screw size and corresponding Tap sizes.

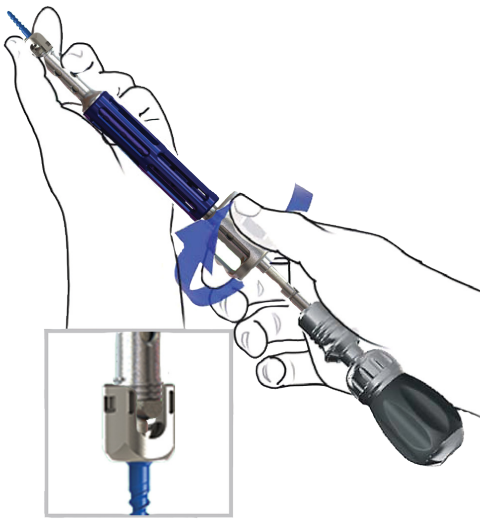
Ensure there is no damage to the wire prior to tap placement as damage may result causing patient complications if there are impinging interactions between mating devices.

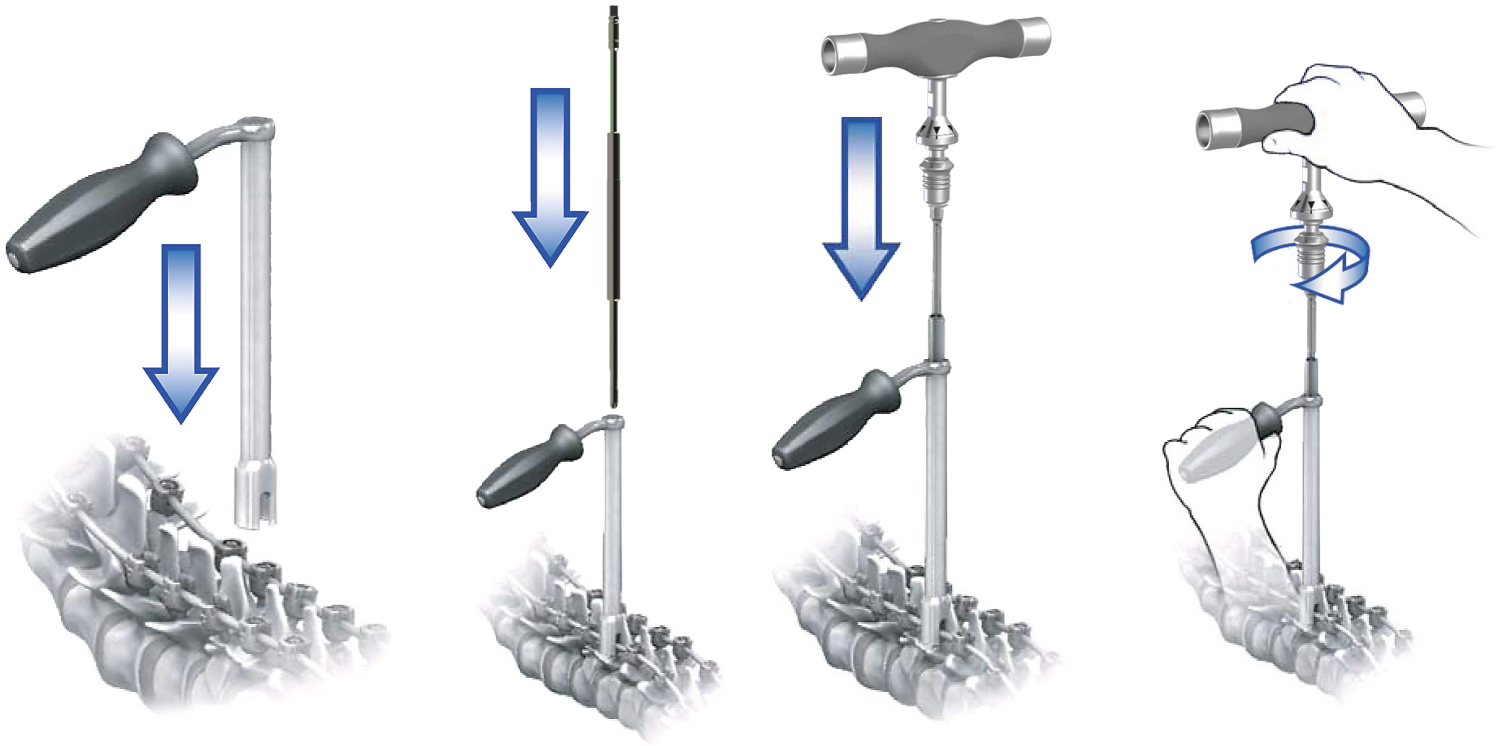
See section “Prepare Pedicles” from ST-1300-01-01 for further details in pedicle preparation and tap insertion.

WARNING: Cannulated System taps should ONLY be used with Cannulated System pedicle screws and SHOULD NOT be used with Response 5.5/6.0 solid pedicle screws. Similarly, Response 5.5/6.0 pedicle screw drivers SHOULD NOT be used with the Response Cannulated Screw System.

WARNING: Guide wires are designated as single use only and should not be reused between cases.

CAUTION: Ensure appropriate size screw is selected prior to tapping as selection of incorrect screw size can lead to damage to pedicle.





Final Tightening

To final tighten all open pedicle screw assemblies, seat the Counter Torque Wrench and the Final Set Screw Driver Shaft (01-1300-9100) onto the open screw, saddle, and set screw.

Place the gray Set Screw Torque Limiter T-Handle (13 N-m) on the Driver Shaft, and turn the handle clockwise while firmly holding the Counter Torque Wrench.

Turn the T-handle until two audible clicks are heard, indicating that proper torque has been met.

NOTE: The Gray T-handle (13 N-m) or the 14 N-m (Dark Gray Collar) Single Use Torque Limiter is only to be used with the large set screw driver for large set screws using the 5.5mm/6.0mm system.

WARNING: Ensure set screw is properly tightened with provided Gray Set Screw Torque Limiter T-Handle, or with the 14 N-m (Dark Gray Collar) Single Use Torque Limiter attached to Fixed Ratcheting T-Handle. Failure to fully seat the torque driver in the set screw can lead to damage or disassociation of set screw postoperatively

When final torque is complete a squeaking sound is often heard. This is by design and part of the science of the RESPONSE Spine System thread technology. This squeaking is caused by an effect called “galling” or cold welding. By utilizing this science, the large set screw and tulip head interface self-locks upon final torque.

Ensure set screw is properly seated within the pedicle screw following final torque (Figure 3). When utilizing a 6.0mm rod, the set screw will be flush with the pedicle screw head. When utilizing a 5.5mm rod, the set screw will be slightly recessed within the pedicle screw head.

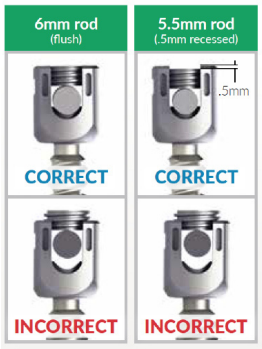
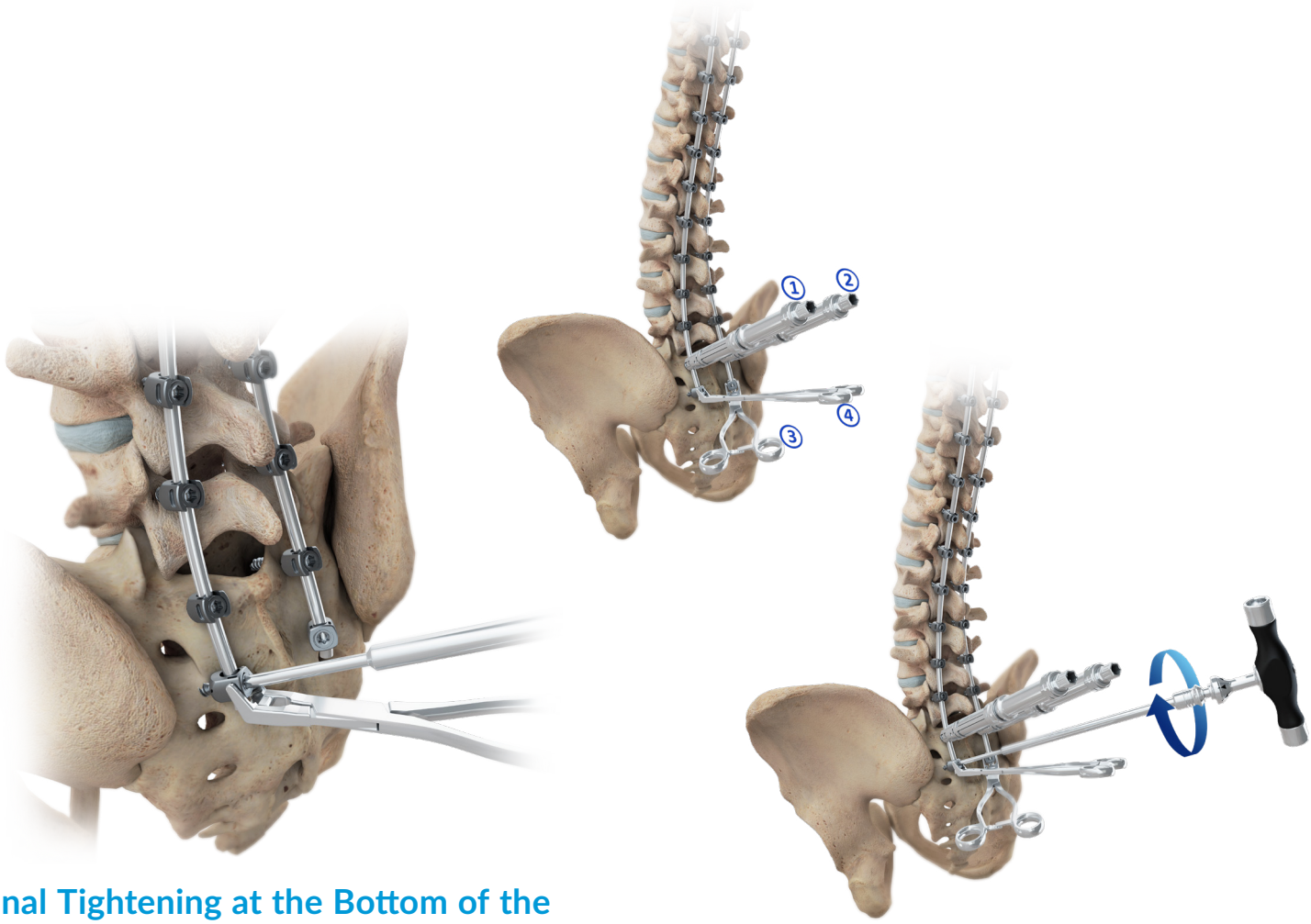


FIGURE 3: Proper seating of set screw within pedicle screw showing using the 5.5mm/6.0mm system.

NOTE: when using the 5.5mm ONLY system, the set screw is flush upon final torque.

NOTE: Set screw location on closed screws is same as open screws shown in image above



Final Tightening at the Bottom of the Construct

In the context of the OrthoPediatrics RESPONSE system, use the towers in the lower two levels, as shown below. This will ensure that the rod is fully seated.

1. Tighten towers 1 and 2 to ensure that the rod is properly seated in the tulip head.
2. Utilizing the rocker ensure that the rod is properly seated in the Closed Pedicle Screw tulip head.
3. While keeping pressure down on the rocker tighten the set screw through the tower utilizing the gray T-Handle (13 N-m) on the same side where pressure is being applied with the rocker.
4. Turn the gray T-handle (13 N-m) until two audible clicks are heard, indicating that proper torque has been met.
5. Ensure that the rod is properly seated in the Closed Pedicle Screw tulip head with the rocker and tighten the set screw utilizing the gray T-Handle (13 N-m) on the same side per step 4.
6. Repeat Steps 2 through 5 on the opposite side.

NOTE: the illustration shown is using the 5.5mm/6.0mm system.

**See ST-1300-01-01, Page 36, for Final Tightening - Alternate Instruments.*

Notes

Notes

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile Clean and sterilize before use according to instructions

CAUTION: Only those instruments and implants contained within the Response™ Surgical Techniques; ST-1300-01-01 and ST-1600-01-01 are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended, unless otherwise stated.

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