QUARTEX®

Occipito-Cervico-Thoracic Stabilization System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

QUARTEX®

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Occipito-Cervico-Thoracic Stabilization System

The QUARTEX® Occipito-Cervico-Thoracic (OCT) Stabilization System offers a variety of solutions to the challenges associated with posterior OCT fusion to aid in easier construct assembly.

With a comprehensive range of instruments, including threaded drivers and streamlined reduction tools, installation of implants is swift and simple in the midst of complex pathologies. The threaded locking cap design allows for single step locking for speed and efficiency.

Screw Head Capability

The QUARTEX® screw head accepts a 3.5 or 4.0mm rod and offers 90° of conical angulation.

Threaded Locking Cap

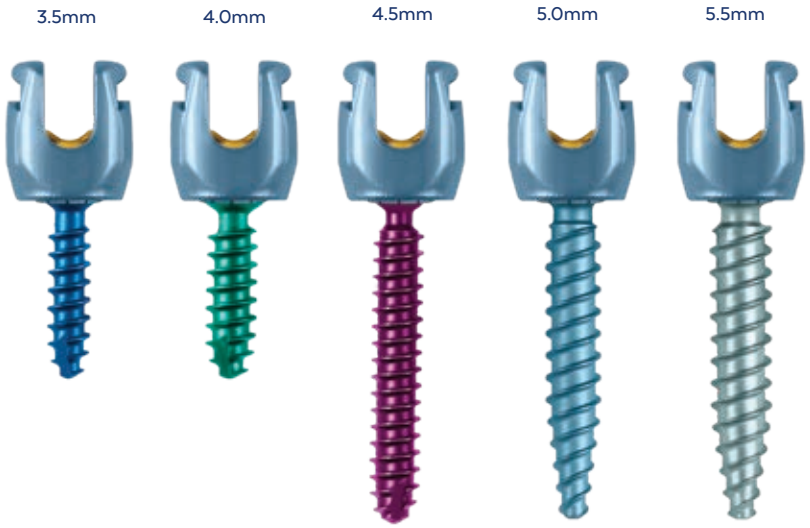
The low-torque, single step locking provides speed and efficiency.

Refined Instruments

Stable threaded drivers, efficient reduction options and flexible tools facilitate easy construct assembly.

True Thoracic Pedicle Screw Offerings

QUARTEX® offers true thoracic screws with diameters up to 5.5mm to accommodate patient anatomy.



IMPLANT OVERVIEW

Polyaxial Screw

- 90° conical screw angulation of 3.5, 4.0, and 4.5mm screws provides intraoperative versatility for complex pathologies
- Large diameter 5.0 and 5.5mm screws provide 70° conical screw angulation
- Screw head accepts a 3.5 or 4.0mm rod
- Screw lengths from 8–50mm
- Screw diameters from 3.5–5.5mm
- Shoulder screws available

Screw Thread

- Small diameter screws feature a tapered and fluted tip with a single lead thread
- Large diameter screws feature a tapered tip and a dual lead thread

Threaded Locking Cap

- Low-torque single step locking simplifies construct assembly

Rods

- 3.5 and 4.0mm rods in titanium alloy and cobalt chrome alloy
- Curved rods available in lengths from 25–120mm
- Tapered rod transitions from 3.5 or 4.0mm to 4.0, 4.5, 4.75, 5.0, 5.5, 6.0, 6.35 and 6.5mm diameters
- Pre-bent and hinged rod options for occipital fixation

Hooks

- Threaded low profile hooks in left, right and inline configurations

Head-to-Head T-Connector

- Allows insertion when screws are directly adjacent
- Low profile curved design accommodates patient anatomy
- Sizes ranging from 21–63mm

Rod-to-Rod T-Connector

- Low profile design
- Medial-lateral translation allows versatility in placement
- Clamp snaps over rod for controlled insertion
- Sizes ranging from 21–63mm

Lateral Connector

- 9, 20, 30mm, and angled options

Parallel Connectors

- Allow attachment of QUARTEX® to 3.5–6.5mm diameter rod systems

Occipital Plate

- Rod acceptors rotate and translate to accommodate rod position
- Utilizes the same threaded locking cap as polyaxial screws
- Five points of midline fixation
- Variable angle, self-tapping screws in 4.2 and 4.6mm diameters, in lengths from 6–16mm
- Bend zones for contouring
- Design allows plate to lag to the bone
- Multiple plate sizes available

INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS

Awl, 2.4mm 682.113

Pedicle Probe, Straight 6149.0050

Pedicle Probe, Curved 6149.0055

Drill Bits

Drill Bit 3.5mm (2.4mm diameter) 6149.1035
(S) Sterile Packed 6149.1036S

Drill Bit 3.5, Short 6149.1037
(S) Sterile Packed 6149.1038S

Drill Bit 4.0 (2.9mm diameter) 6149.1040
(S) Sterile Packed 6149.1041S

Drill Bit 4.0, Short 6149.1042
(S) Sterile Packed 6149.1043S

Drill Bit 4.5 (3.4mm diameter) 6149.1045
(S) Sterile Packed 6149.1046S

Additionally Available

Drill Guide with 14mm Stop 6149.1014

Drill Guide with Adjustable Stop,
3.5-4.5 Diameter, 6-50mm 6149.1000

Taps

3.0mm Screw	6149.1130
3.5mm Screw	6149.1135
4.0mm Screw	6149.1140
4.5mm Screw	6149.1145

5.0mm Screw	6149.1150
5.5mm Screw	6149.1155

Additionally Available

PREPARATION INSTRUMENTS (CONT'D)

Adjustable Depth Tap Sleeve 6149.1110

Ball Tip Probe 682.115

SCREW INSTRUMENTS

Rigid Driver 6149.2000

Spin Sleeve 6149.2001

Screwdriver, #15, Self-Retaining, Quick-Connect 6149.2100

Quick-Connect Handle, Swivel 636.450

Pushbutton Driver, #15 Hexalobe 6149.2700

Head Turner 6149.3000

ROD INSTRUMENTS

Rod Template 240mm 615.301

Tube Style Rod Bender 6149.3090

Rod Bender 615.304

In Situ Rod Cutter, 4.0mm 6149.3095

Rod Holding Forceps, 3.5mm Rod 682.308

Rod Holding Forceps, 4.0mm Rod 6149.3055

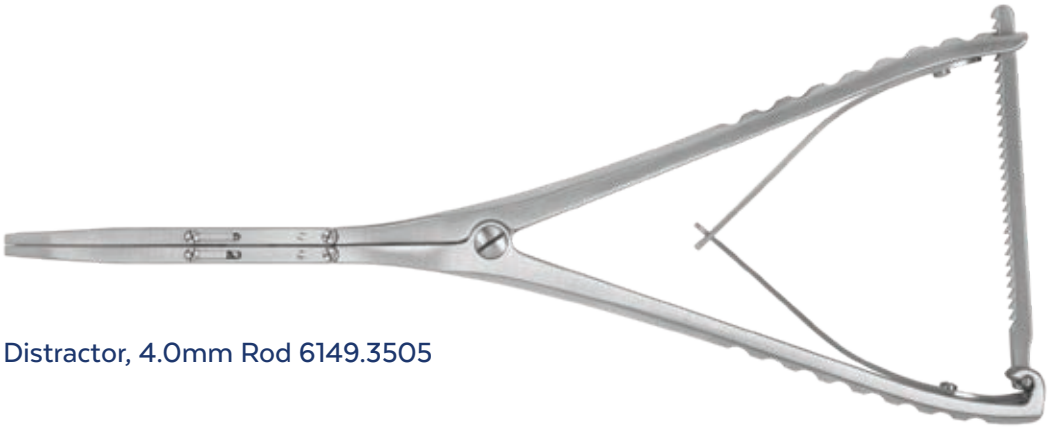
ROD INSTRUMENTS (CONT'D)

Tower Reducer 6149.3200

Tower Adapter, A/O Quick-Connect 6149.3210

Rocker Fork Reducer 6149.3250

Compressor, 4.0mm Rod 6149.3500



Distractor, 4.0mm Rod 6149.3505

Additionally Available

ROD INSTRUMENTS (CONT'D)

Heavy Duty Tower Reducer, 10mm 6149.3280

Heavy Duty Tower Reducer, 20mm 6149.3290

Top Loading Flip Ratcheting Reducer 6149.3260

Top Loading Ratcheting Reducer 6149.3220

LOCKING INSTRUMENTS

Threaded Locking Cap Inserter 6149.4000

Screwdriver, #15, Final Tightening, Quick-Connect 6149.4200

LOCKING INSTRUMENTS (CONT'D)

Counter-Torque 6149.4100

Torque-Limiting Quick-Connect Handle, 2.0Nm 6149.4220

OTHER INSTRUMENTS

Hook Forceps 6149.3040

Head-to-Head, Bender, Left 6149.5000

Head-to-Head, Bender, Right 6149.5001

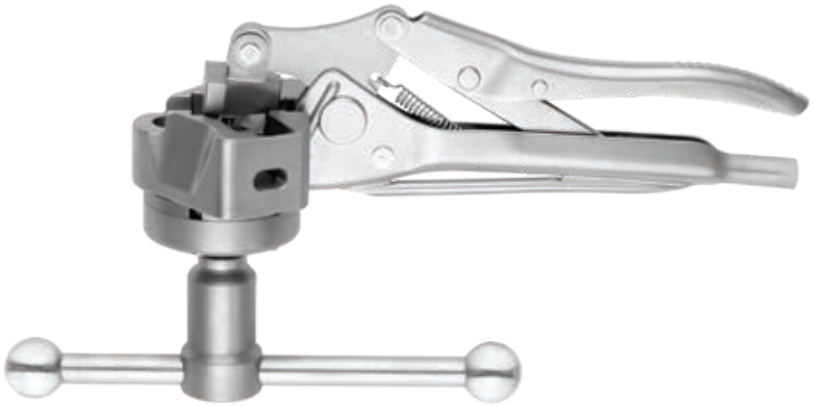
OTHER INSTRUMENTS (CONT'D)

Head-to-Head T-Connector Nut Inserter 682.312

2.5mm Hex Driver, Quick-Connect 610.831

OCCIPITAL INSTRUMENTS

Occipital Plate Holder 682.603



Occipital Plate Bender 6149.6800

Occipital Plate Tip Bender 682.662

OCCIPITAL INSTRUMENTS (CONT'D)

Occipital Adjustable Depth Drill Guide 6149.6300

Flexible Drill Bit, 2.9mm 682.622

Occipital U-Joint Sleeve 6149.6500

Occipital U-Joint Screwdriver, #15, Self-Retaining 6149.6555

Occipital U-Joint Caps for Driver 6149.6505

Occipital U-Joint Cap, Stop

6mm Stop	6149.6506
8mm Stop	6149.6508
10mm Stop	6149.6510
12mm Stop	6149.6512
14mm Stop	6149.6514*
16mm Stop	6149.6516*

Occipital U-Joint Tap, 4.2mm Screws 6149.6540
Occipital U-Joint Tap, 4.6mm Screws 6149.6545

Socket Driver 682.602

Offset Handle, Occipital CV Joint 682.620

Offset Handle, Locking Ring 682.619

*Additionally Available

OCCIPITAL INSTRUMENTS (CONT'D)

Occipital Rod Slot Positioner 6149.6010

Occipital Rocker Fork Reducer 6149.6250

Jointed Rod Holder 6149.3070

Occipital Counter-Torque 6149.6600

OCCIPITAL INSTRUMENTS (CONT'D)

Torque-Limiting 2.5mm Hex Driver, 2.5Nm 615.203

Screw Removal Tool 6149.6900

Angled Screw Removal Tool 6149.6910

Angled Screw Removal Tool Counter-Torque 682.657

SURGICAL TECHNIQUE

QUARTEX®

QUARTEX® Navigation Instruments, including drills, taps, pedicle probes and screwdrivers, may be used in conjunction with the Medtronic StealthStation®. Refer to the QUARTEX® Guided Instruments (GI1) Technique Guide (GMTGD228) for detailed instructions.

STEP 1 APPROACH

The patient is placed under general anesthesia and positioned prone. The operative area is carefully cleaned and an incision is made at the appropriate level(s). While there are various techniques for implant insertion, a standard midline approach and the assembly of an occipito-cervico-thoracic (OC-T3) construct is described for the purposes of this surgical technique guide. Lateral C-arm fluoroscopy or other radiographic methods may be utilized throughout surgery to ensure correct implant placement.

STEP 2 INSERTION SITE PREPARATION

Locate pedicles or lateral masses (C1-T3) and remove bone and/or soft tissue as needed using standard instruments.

Align the **Awl, 2.4mm** in the trajectory for the screw and perforate the cortex to create a pilot hole. The **Pedicle Probe, Straight** or **Pedicle Probe, Curved** may be used to open the pedicle or lateral mass pathway. The **Ball Tip Probe** may be used to verify that the walls of the prepared pathway are not violated.

Determine the appropriate screw diameter and length. Choose the corresponding drill bit for the selected screw diameter and length. The **Drill Guide with Adjustable Stop, 6-50mm** allows drill depths from 6-50mm, in 2mm increments. Rotate the gold ring and pull down the tapered sleeve to release the ratchet. Adjust the drill stop until the appropriate depth is indicated and release the sleeve. Rotate the gold ring until secure to lock the drill guide at the appropriate depth. If the required depth is 14mm, the **Drill Guide, Fixed Stop 14mm** may be used.

Attach the drill bit to the **Quick-Connect Handle, Swivel** and insert the assembly through the drill guide and drill to the stop. The **Depth Gauge** may be used to verify depth.

In dense bone, the hole should be tapped to the full length of the intended screw trajectory with the appropriate diameter tap for ease of insertion. If preparing the pedicles with a **Tap**, the **Adjustable Depth Tap Sleeve** may be used to indicate depth. Insert the tap into the sleeve to the desired depth and rotate the knob to lock in place.

Tap

Diameter (mm)				
Instrument	**3.0**	**3.5**	**4.0**	**4.5**
Drill	N/A	2.4	2.9	3.4
Tap	2.9	3.4	3.9	4.4

Tap

Diameter (mm)		
Instrument	**5.0**	**5.5**
Large Diameter Tap	4.9	5.4

STEP 3 SCREW INSERTION

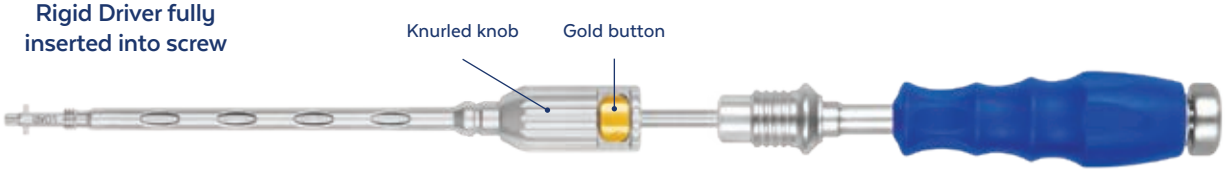
To assemble the **Rigid Driver**, connect the Quick-Connect Handle, Swivel onto the flat portion of the proximal end of the driver. Push the gold button on the knurled knob and retract towards the handle. If desired, the **Spin Sleeve** may be loaded onto the driver by inserting the driver into the cannulated portion of the sleeve and rotating the sleeve until it is fully captured. Snap the Spin Sleeve towards the knurled knob to position for loading the screw.

Prior to inserting, screw size can be verified by checking the length and diameter markings on the screw head, or by using the gauges provided in the screw module.

To load a QUARTEX® polyaxial screw onto the driver, press the gold button and retract the outer sleeve toward the handle and fully insert the hexalobe tip into the screw head. Advance the sleeve forward, toward the screw head, and rotate the knurled knob to thread the driver into the screw head until fully seated.

Inserting screw with Rigid Driver

Rigid Driver fully inserted into screw



Rigid Driver

Insert the screw into the prepared pedicle canal or lateral mass. Ensure that the screw head is free of bone obstruction. If required, a **Reamer** is additionally available to prepare the bone at the insertion site for optimal screw head mobility.

To disengage the driver, rotate the outer knurled knob counterclockwise until it releases the screw head.

Alternately, the **Screwdriver, #15 Self-Retaining** or **Pushbutton Driver** may be used for screw insertion. Once the screws are fully inserted, the screw heads can be oriented to receive the rod using the **Head Turner**.

To reposition a screw *in situ*, use the Screwdriver, #15, Final Tightening.

Polyaxial Screw loaded onto Screwdriver, #15, Self-Retaining

Polyaxial Screw loaded onto Pushbutton Driver

OPTIONAL: HOOK INSERTION

Hook Forceps can be used for controlled insertion of hooks. The construct is not fully locked until final tightening is completed.

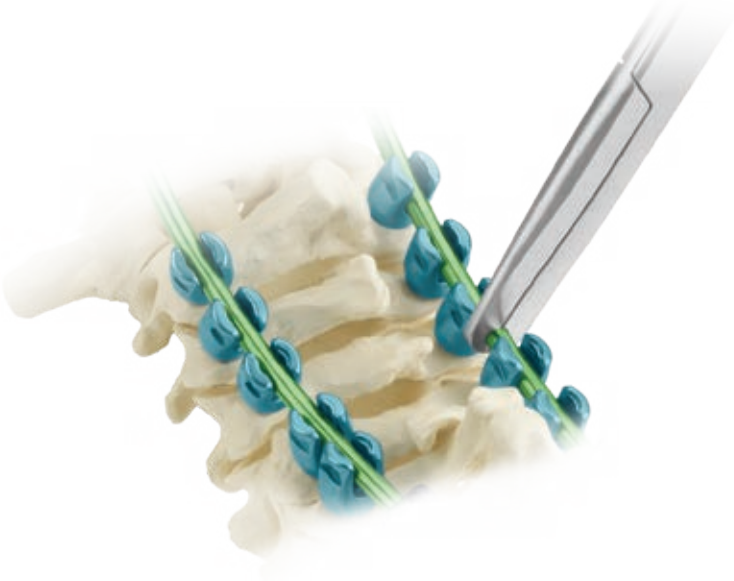
STEP 4 ROD AND CAP INSERTION

Rod Preparation

Determine the appropriate length and contour of the rod using the **Rod Template, 240mm**. Rods are available in a variety of lengths, and may be cut using the ***In Situ* Rod Cutter**. If necessary, bend or contour the rod using the **Rod Bender** by placing the rod into the bender and compressing the handles until the desired curvature is achieved. The ***In Situ* Benders, 4.0** can be used to bend 3.5 or 4.0mm diameter rods.

Rod Insertion

Insert the rod into the screw head or hook using the **Rod Holding Forceps**. If the rod cannot be inserted fully, the rod may need to be contoured or rod reduction may be necessary.



Rod insertion

Locking Cap Insertion

Thread the locking cap into the screw head to capture the rod using the **Threaded Locking Cap Inserter**. If necessary, compress or distract the screws or hooks along the rod using the **Compressor** or **Distractor** prior to final tightening the locking cap.

To final tighten the construct, position the **Counter-Torque** over the screw head and attach the **Screwdriver, #15, Final Tightening, Quick-Connect** to the **Torque-Limiting Quick-Connect Handle, 2.0Nm**. Rotate the screwdriver clockwise until it reaches its torque limit.

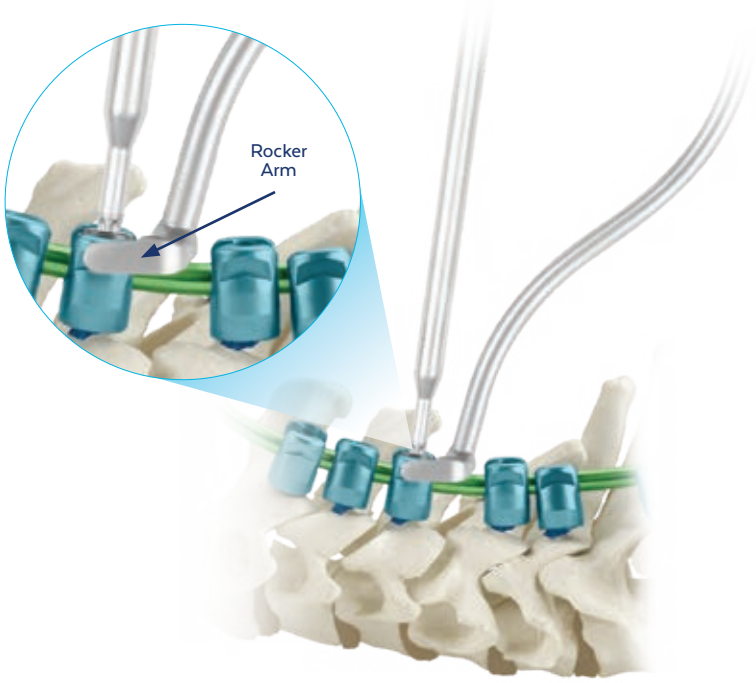
Threaded locking cap inserter with Counter-Torque

Rod Reduction

The QUARTEX® system includes multiple options for rod reduction. Please note that rod reduction instruments are designed to seat the rod into the screw, not to bend the rod. Ensure the rod is properly contoured prior to reduction.

Option A: Rocker Fork Reducer

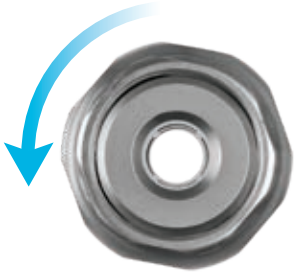
Tilt the **Rocker Fork Reducer** upwards so that the rocker arms are orientated vertically and slide the pins of the rocker fork into the chevrons of the screw head. Once engaged, rotate the handle downward to push the rod into the screw head as needed.



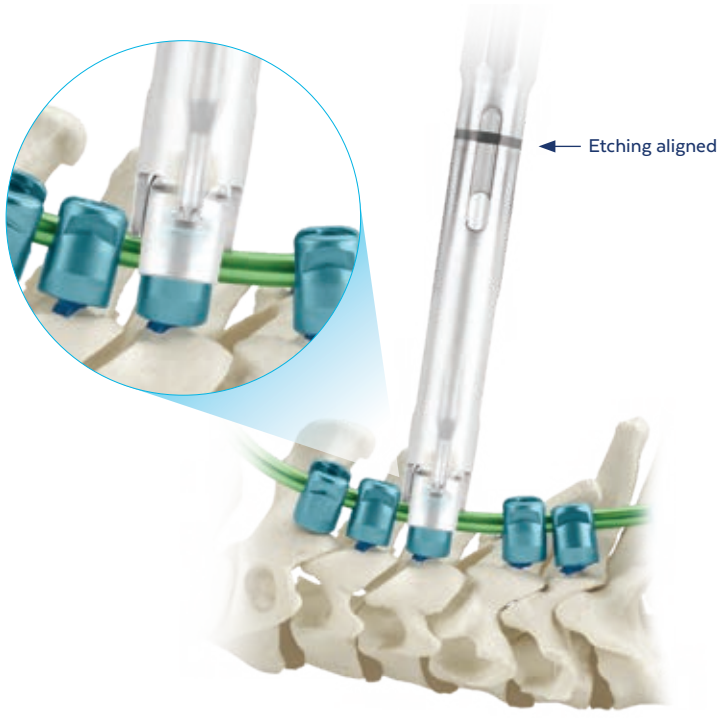
Inserting Threaded Locking Cap with Rocker Fork

Option B: Tower Reducer

To use the **Tower Reducer**, rotate the knob counterclockwise to ensure that it has been fully opened. Line up the rod with the slot on the reducer and click into the screw head. To reduce, rotate the knob clockwise until the rod is reduced by the desired amount. The etching on the reducer aligns when fully reduced. To disengage the instrument from the screw head, rotate the knob counterclockwise until it stops and then slightly rotate the instrument while pulling away from the implant. To aid in rotating the knob of the Tower Reducer, **the Tower Adapter, AO Quick-Connect** may be attached to a handle and placed over the rotating knob.



Rotate axially to disengage reducer from screw head



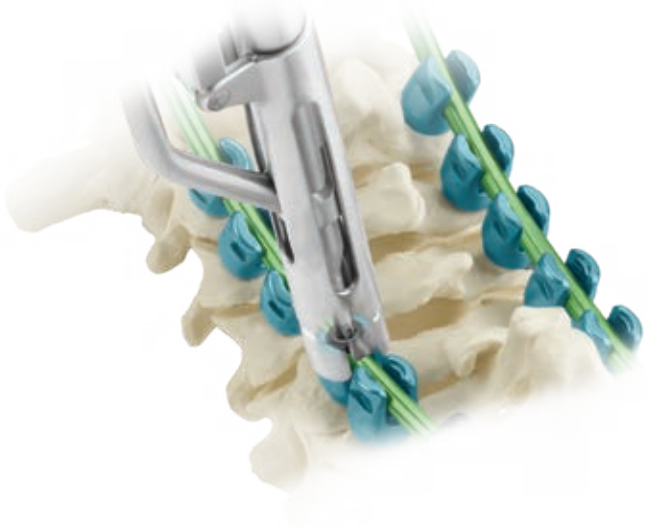
Inserting Threaded Locking Cap with Tower Reducer

ROD AND CAP INSERTION (CONT'D)

Option C: Grip Reducer

To prepare the **Top Loading Flip Ratcheting Reducer** for use, release the hinge on the handle and ensure that it is fully open. Line up the rod with the slot on the reducer and click onto the top of the screw head. To reduce, slowly compress the handle until the rod is reduced the desired amount. To disengage the instrument from the screw head, release the hinge on the handle to fully open, and then slightly rotate the instrument while pulling away from the implant.

Note: For tactile feedback during reduction, open the ratcheting lever while compressing the handle.



Inserting Threaded Locking Cap with Top Loading Flip Ratcheting Reducer

STEP 5 OCCIPITAL FIXATION

Occipital plates are secured to the occiput using bone screws. Screws up to 12mm in length may be safely inserted into the occipital bone, close to the external occipital protuberance (EOP). Longer screws up to 16mm may be used if they are angled medially close to the EOP. Care must be taken not to penetrate the far cortex of the occipital bone.

Use the **Occipital Plate Holder** to place the appropriate sized plate on the occiput. If it is necessary to increase the plate contour, the **Occipital Plate Bender** may be used to bend the plate within the indicated bend zone.

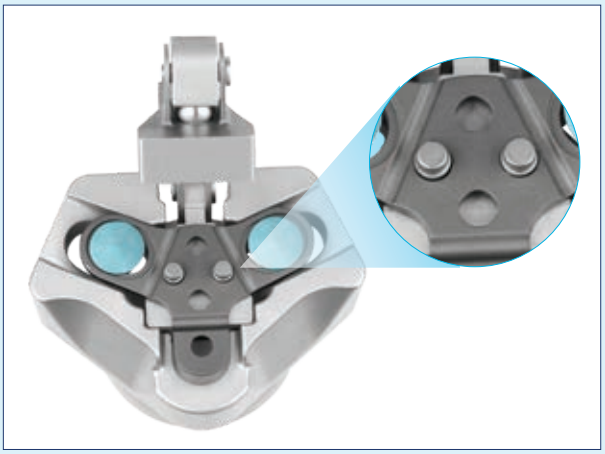
To use an occipital clamp, slide the rod into the rod acceptor of the clamp and hold in position by provisionally tightening the set screw with the Screwdriver, #15, Self-Retaining and Quick-Connect Handle, Swivel assembly. Prepare the screw hole(s) as described on page 26 and insert the appropriate length screw through the clamp hole(s). The set screw on the clamp must be final tightened using the Screwdriver, #15, Final Tightening, Quick-Connect with the Torque-Limiting Quick-Connect Handle, 2.0Nm.

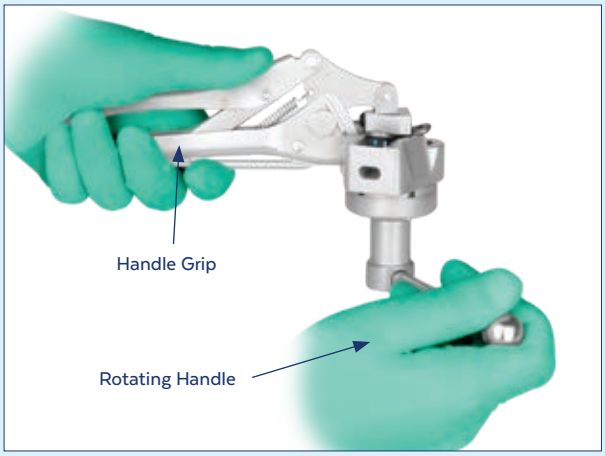
USING THE OCCIPITAL PLATE BENDER

Rotate the handle clockwise so that the metal insert of the plate bender elevates to receive the plate. Insert the plate into the bender so that the two locator pins fit into the two lateral holes on the plate.

For more convexity, install the plate's top surface facing down so the rod acceptors are within the instrument, as shown below. For more concavity, install the plate with the top surface facing up.

To securely hold the plate while bending, compress the handle grip. Rotate the rotating handle counterclockwise until the desired plate contour is achieved. The handle stops when the maximum contour is achieved.





USING THE OCCIPITAL PLATE TIP BENDER

To bend the tip of the plate, ensure that the plate is inserted with the top surface of the plate facing down so the rod acceptors are within the instrument as shown above. The metal insert of the plate bender should be elevated. Compress the handle grip to securely hold the plate.

Slide the **Occipital Plate Tip Bender** completely over the tip of the plate and compress until the tip bender reaches the handle grip.

The tip bender should only be compressed in line with the handle grip, as shown at right. Avoid twisting or tilting the tip bender while compressing. Follow these steps to ensure that bending does not compromise the structural integrity of the plate.

OCCIPITAL FIXATION (CONT'D)

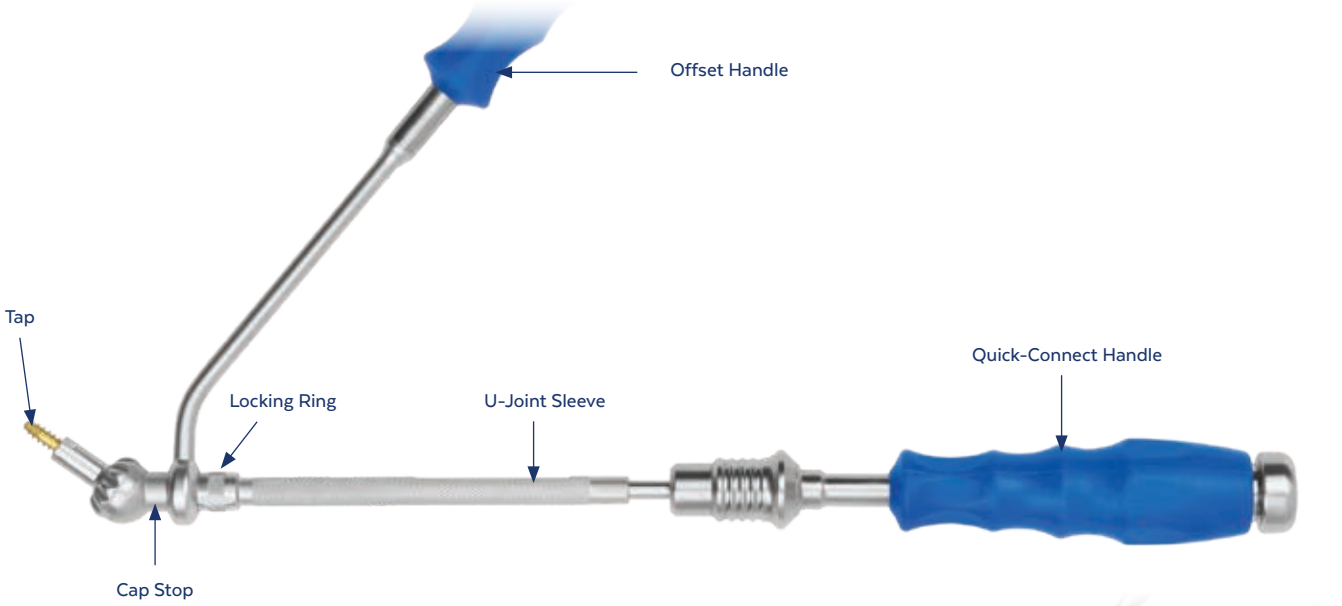
Screw Hole Preparation

The Awl 2.4mm may be used to perforate the cortex of the occiput. The **Occipital Adjustable Depth Drill Guide** allows drill depth from 6 to 16mm, in 2mm increments. To adjust the drill stop, rotate the gold ring and pull down the tapered sleeve to release the ratchet and adjust to desired depth. Release the sleeve and rotate the gold ring until secure to lock the drill guide at the appropriate depth.

The **Flexible Drill Bit, 2.9mm** allows up to 90° insertion angle when needed in the occiput. Insert the drill bit and drill through the Occipital Adjustable Depth Drill Guide.

Choose the **Occipital Joint Tap** of appropriate diameter and assemble with the **Occipital U-Joint Sleeve**. Select the desired depth for the **Occipital U-Joint Cap Stop** and thread onto the U-Joint sleeve. Attach the tap assembly to a Quick-Connect handle and tap to the desired depth. Tapping is recommended in occipital bone due to its density. QUARTEX® 6 and 8mm occipital screws do not have self-tapping flutes; 10 to 20mm occipital screws have self-tapping flutes.

An additional **Offset Handle** may be used to gain leverage during tapping or screw insertion. Assemble the offset handle to the U-Joint sleeve and thread the **Offset Handle, Locking Ring** to secure the offset handle.



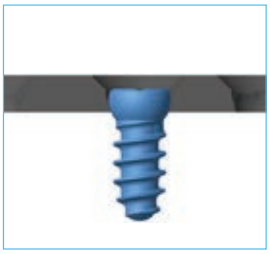
Flexible Drill

Tapping occiput

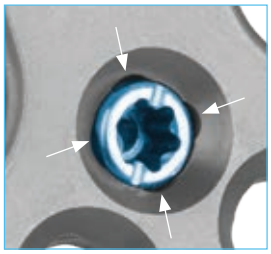
Screw Insertion and Locking

Select the desired occipital screw and insert using the **Occipital U-Joint Screwdriver, #15, Self-Retaining**. A joint sleeve is available to maintain the angle of the screw during insertion.

QUARTEX® occipital screws are designed to automatically lock to the occipital plate during insertion. The screw provides a tactile feel and four divots are visible around the screw when fully seated, as shown below. No additional tightening is necessary.



Screw fully seated



Four divots visible when fully seated

Offset Handle on Occipital U-Joint Screwdriver

Locking Cap Insertion

Use the **Occipital Rod Slot Positioner** to orient the rod acceptors to receive the rod. Place the rod in the acceptors. Thread the locking caps into the occipital tulips using the Threaded Locking Cap Inserter or hexalobe Occipital U-Joint Driver. The locking caps may be inserted with or without reduction instruments.

Two reduction tools are provided for use with the Occipital plate. The **Occipital Counter-Torque** and the **Occipital Rocker Fork Reducer** are used in the same manner as the QUARTEX® Rod Counter-Torque and QUARTEX® Rocker Fork Reducer, respectively.

The construct is not completely locked until final tightening. The Torque-Limiting Quick-Connect Handle, 2.0Nm, may be attached to the Screwdriver, #15, Final Tightening, Quick-Connect or Occipital U-Joint Driver.

Occipital Rocker Fork

Final Tightening Occipital Jointed Rods

The **Jointed Rod Holder** may be used for rod placement. Place the holder around the locking set screw of the jointed rod and insert the rod into position. With the holder still in place, use the **Torque-Limiting 2.5mm Hex Driver, 2.5Nm** to tighten the set screw of the jointed rod until it reaches the torque limit.

Using Jointed Rod Holder and Torque-Limiting Driver

STEP 6 OPTIONAL CONNECTORS

Various connectors may be used to connect rods or lengthen a construct, as described below. Stainless steel implants should not be connected to titanium alloy or cobalt chrome alloy implants due to the risk of galvanic corrosion.

Parallel Connectors

Parallel Connectors can be used to aid in transitioning between screw or hook locations and to minimize rod contouring. They also enable connections to pre-existing titanium rods systems of various diameters. The 3.5 and 4.0mm QUARTEX® rods may be connected to a 3.5, 4.0, 4.5, 4.75, 5.0, 5.5, 6.0, 6.35 or 6.5mm diameter rod system using the corresponding connectors.

Slide the Parallel Connectors onto the rods to be connected. Once the Parallel Connector is attached to both rods, the set screws should be final tightened using the Screwdriver, #15, Final Tightening, Quick-Connect, with the Torque-Limiting Quick-Connect Handle, 2.0Nm.

Lateral Connectors

Lateral Connectors are used to aid in transitioning between screw or hook locations to minimize rod contouring.

Slide the clamp of the lateral connector onto the rod. Introduce the rod portion of the connector into the opening of the polyaxial screw or hook. Insert the threaded locking cap onto the rod with the Threaded Locking Cap Inserter. The Lateral Connector is now connected to the construct, but is not completely locked until final tightening of both the locking cap and set screw.

Note: Lateral Connectors may be cut to length using the In Situ *Rod Cutter. Ensure that the desired rod length passes completely through the screw or hook head.*

Rod-to-Rod T-Connectors

The Rod-To-Rod T-Connectors are used to securely link the rods of the construct together.

Select the Rod-to-Rod T-Connector that corresponds with the rod diameter that is being implanted. Gently snap one side of the connector onto the rod. Adjust the sliding assembly to the desired width and snap the other side of the connector onto the contralateral rod. To final tighten the connector, install the **Head-to-Head T-Connector Nut Inserter** onto the 2.0Nm Torque Limiting Handle and final tighten the locking nut on each side of the connector.

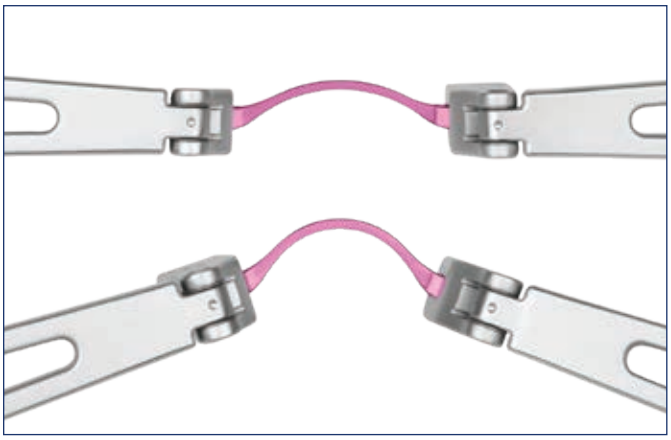
Head-to-Head T-Connectors

Head-to-Head T-Connectors attach to contralateral polyaxial screw heads only and are useful when screw heads are in close proximity and a traditional Rod-to-Rod connector cannot be used. These connectors use a special Head-to-Head Locking Cap and Head-to-Head Locking Nut.

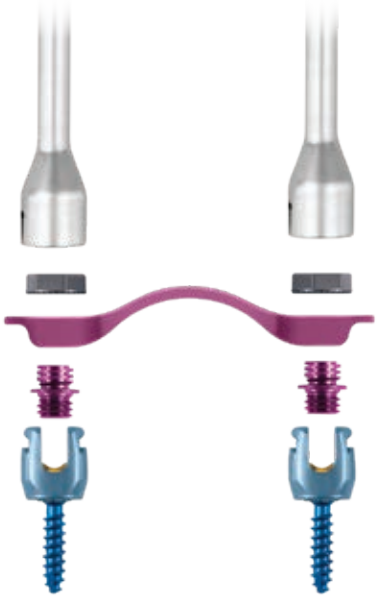
Install the Head-to-Head Threaded Locking Cap using the Threaded Locking Cap Inserter. Connect the Screwdriver, #15, Final Tightening, Quick-Connect to the Torque-Limiting Quick-Connect. Final tighten the Head-to-Head Locking Cap. Choose the appropriate length connector and place it onto the screw heads using a pair of forceps. Connect the **Head-to-Head T-Connector Nut Inserter** to the Torque-Limiting Quick-Connect Handle, 2.0Nm. Install a Head-to-Head Locking Nut onto the threaded portion of each locking cap until it reaches its torque limit (2.0Nm).

The Head-to-Head T-Connectors are pre-curved; however, if more curvature is desired, the **Head-to-Head Benders** (right and left) may be used. Place the lateral ends of the Head-To-Head T-Connector into the mating part of the Right and Left Benders and manually bend the T-Connector to the desired curvature.

Note: The Head-to-Head Locking Cap may be used with the Rocker Fork Reducer, but not with the Top Loading Ratcheting Reducer or Tower Reducer.



Head-to-Head T-Connector Benders



Placement of Head-to-Head T-Connector

QUARTEX® ADDITION®-C Implants

Refer to the QUARTEX® ADDITION®-C Technique Guide (GMTGD265) for instructions.

Headed-Headed

Headed-Headed

Open-Closed

Open-Open

Zero-Run-On-Rod

Swivel

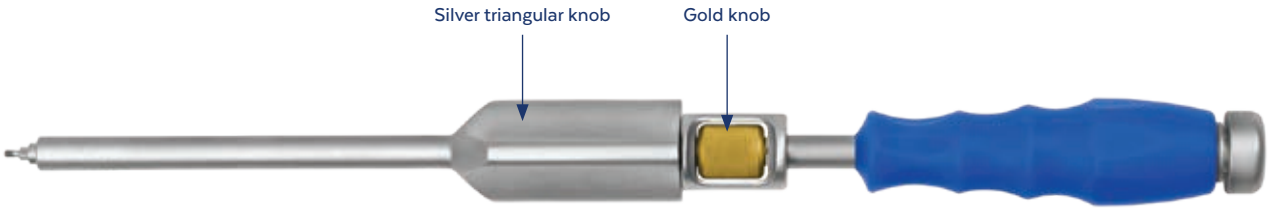
CREO AMP QUAD®

FINAL CONSTRUCT

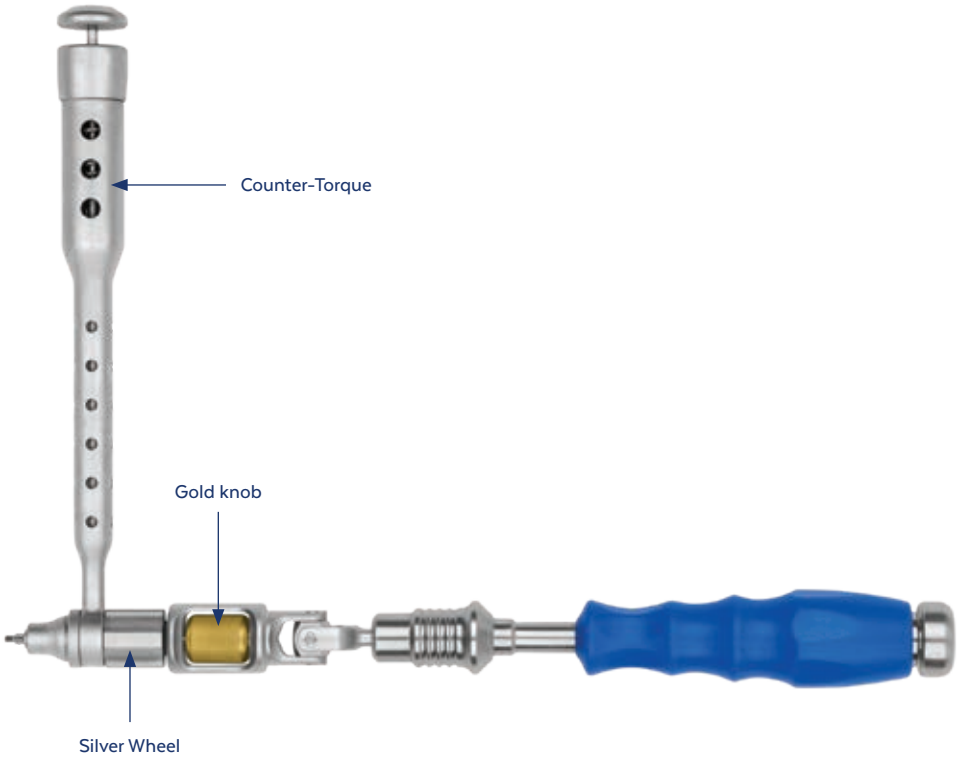
OPTIONAL: IMPLANT REMOVAL

For revision or removal of QUARTEX® implants, reverse the insertion steps until the desired implants are removed. Loosen and remove all threaded locking caps using the threaded locking cap driver. Once the threaded locking caps are loosened and removed, grasp the rods and remove from the screws or hooks. Remove all screws using a hexalobe driver. Connectors may remain connected on the rods for removal, or may be removed separately.

To remove occipital screws from an occipital plate or clamp that may have stripped in the bone, use either the **Screw Removal Tool** or the **Angled Screw Removal Tool**. For the straight option, prepare the screw removal tool by rotating the silver knob counter-clockwise, exposing the hexalobe tip. Attach the screw removal tool to the intended screw by aligning the drive feature and then rotating the gold knob clockwise to retain the screw's threaded connection. While holding the silver triangular knob stationary, rotate the blue handle counterclockwise to back the screw out of the plate or clamp.



If a steep approach angle is required to remove occipital screws, use the **Angled Screw Removal Tool** with the **Angled Screw Removal Tool Counter-Torque**. To assemble, insert the Angled Screw Removal Tool into the Angled Screw Removal Tool Counter-Torque and rotate the silver wheel until the wheel is finger-tight against the removal tool. Attach the Quick-Connect Handle, Swivel. Attach the removal tool to the intended screw by aligning the drive feature and then rotating the gold knob clockwise to retain the screw's threaded connection. Depress the button on the counter-torque and continuously hold while rotating the blue handle counterclockwise to back the screw out of the plate.



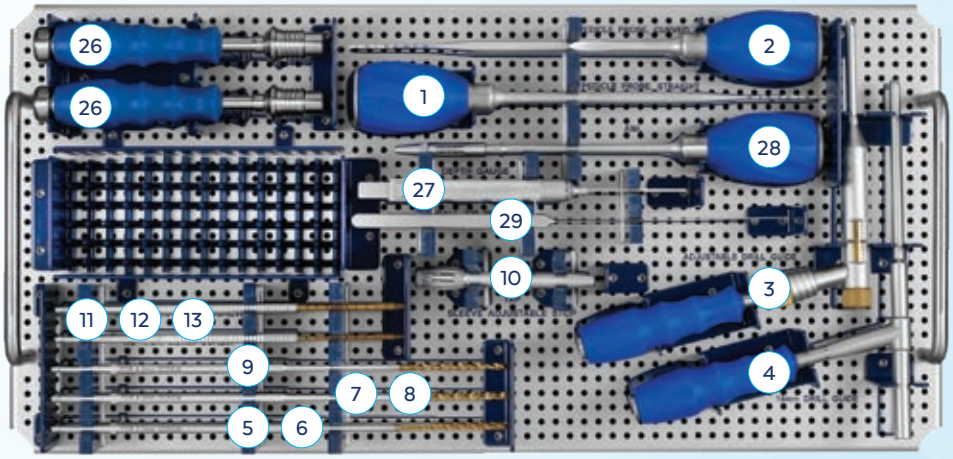
QUARTEX®
INSTRUMENT SET I 9149.9001

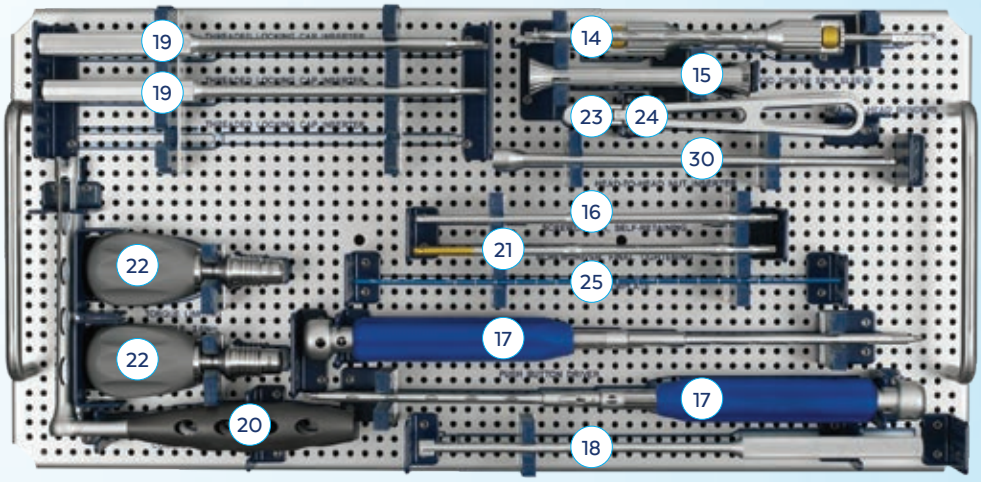
	Instruments		Qty
1	6149.0050	Pedicle Probe, Straight	1
2	6149.0055	Pedicle Probe, Curved	1
3	6149.1000	Drill Guide with Adjustable Stop, 3.5-4.5mm, 6-50mm	1
	6149.1010	Drill Guide with 10mm Stop	
	6149.1012	Drill Guide with 12mm Stop	
4	6149.1014	Drill Guide with 14mm Stop	1
	6149.1016	Drill Guide with 16mm Stop	
	6149.1018	Drill Guide with 18mm Stop	
	6149.1020	Drill Guide with 20mm Stop	
5	6149.1035	Drill Bit for 3.5mm Screw	1
	6149.1036S	Drill Bit for 3.5mm Screw	
6	6149.1037	Drill Bit for 3.5mm Screw, Short	1
	6149.1038S	Drill Bit for 3.5mm Screw, Short	
7	6149.1040	Drill Bit for 4.0mm Screw	1
	6149.1041S	Drill Bit for 4.0mm Screw	
8	6149.1042	Drill Bit for 4.0mm Screw, Short	1
	6149.1043S	Drill Bit for 4.0mm Screw, Short	
9	6149.1045	Drill Bit for 4.5mm Screw	1
	6149.1046S	Drill Bit for 4.5mm Screw	
10	6149.1110	Adjustable Depth Tap Sleeve	1
11	6149.1135	Tap for 3.5mm Screw	1
12	6149.1140	Tap for 4.0mm Screw	1
13	6149.1145	Tap for 4.5mm Screw	1
	6149.1500	Reamer	
14	6149.2000	Rigid Driver	2
15	6149.2001	Spin Sleeve	2
16	6149.2100	Screwdriver, #15, Self-Retaining, Quick-Connect	2
	6149.2105	Screwdriver, #15, Self-Retaining, Small Handle	
	6149.2500	Quick-Connect Handle, Small, Ratcheting	
17	6149.2700	Pushbutton Driver, #15 Hexalobe	2
18	6149.3000	Head Turner	1
19	6149.4000	Threaded Locking Cap Inserter	4

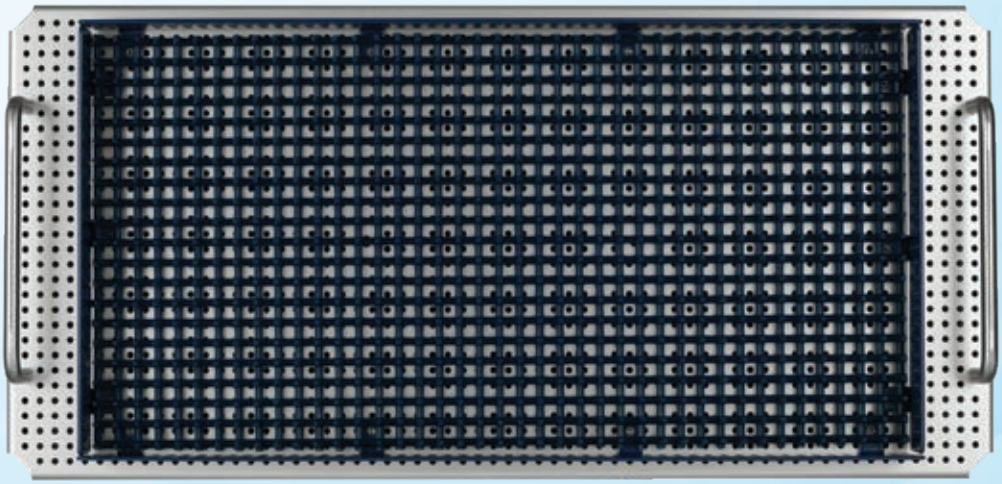
	Instruments		Qty
	6149.4020	Threaded Locking Cap Inserter, Dual Sided	
20	6149.4100	Counter-Torque	1
21	6149.4200	Screwdriver, #15, Final Tightening, Quick-Connect	2
	6149.4020	Threaded Locking Cap Inserter, Dual Sided	
22	6149.4220	Torque-Limiting Quick-Connect Handle, 2.0Nm	2
23	6149.5000	Head-to-Head Bender, Left	1
24	6149.5001	Head-to-Head Bender, Right	1
	615.111	Lamina Finder	
25	615.301	Rod Template, 240mm	1
26	636.450	Quick-Connect Handle, Swivel	2
27	682.112	Depth Gauge	1
28	682.113	Awl, 2.4mm	1
29	682.115	Ball Tip Probe	1
	682.123	Awl, 2.4mm, Long	
30	682.312	Head-to-Head T-Connector Nut Inserter	2
	9149.0001	QUARTEX® Instruments Graphics Case	

Items in gray are additionally available.

QUARTEX®
INSTRUMENT SET I 9149.9001 (CONT'D)





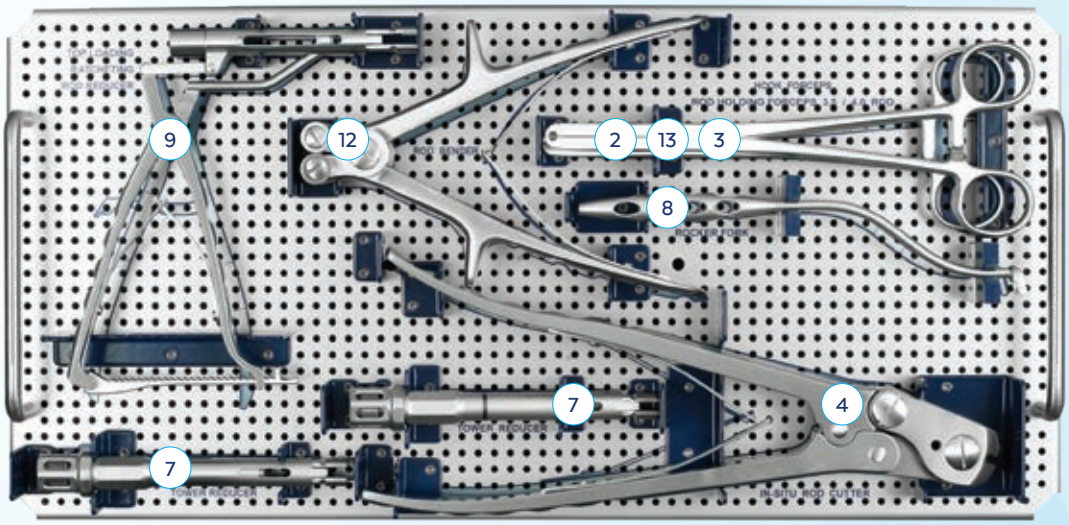


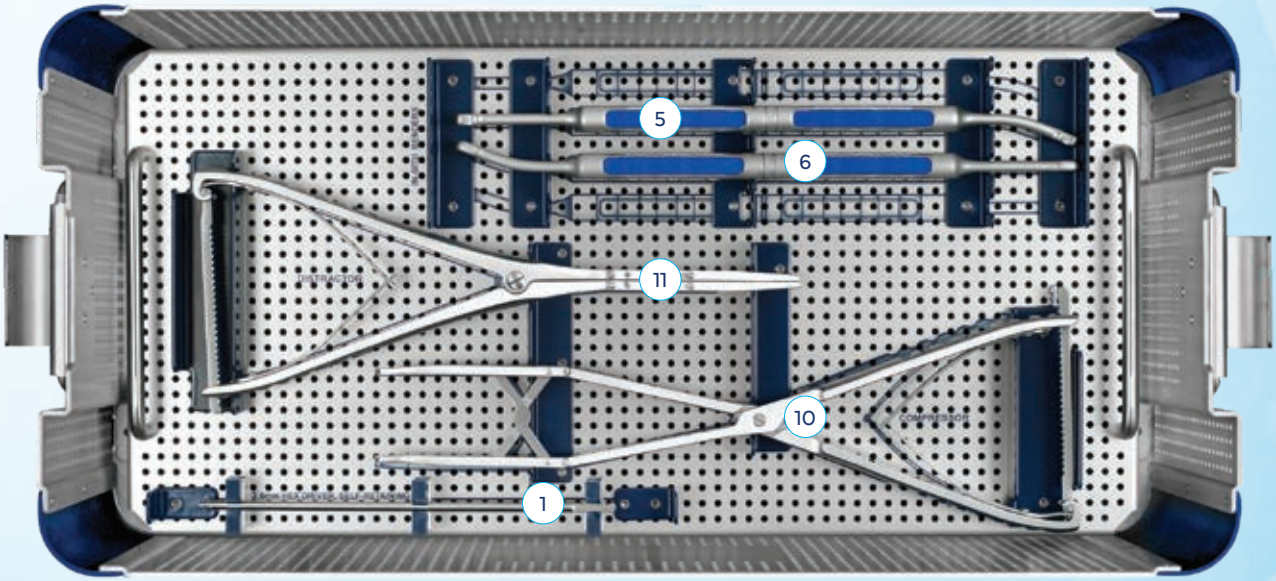
QUARTEX®
INSTRUMENT SET II 9149.9011

	Instruments		Qty
1	610.831	2.5mm Hex Driver, Quick-Connect	1
2	6149.3040	Hook Forceps	1
3	6149.3055	Rod Holding Forceps, 4.0mm Rod	1
	6149.3065	Rod Gripper, 4.0mm	
4	6149.3095	*In Situ* Rod Cutter, 4.0mm	1
5	6149.3100	*In Situ* Bender, 4.0mm Rod, Left	1
6	6149.3105	*In Situ* Bender, 4.0mm Rod, Right	1
	6149.3210	Tower Adapter, A/O Quick-Connect	
7	6149.3200	Tower Reducer	2
	6149.3220	Top Loading Ratcheting Reducer	
	6149.3230	Lateral Reducer	
	6149.3240	Inline Reducer	
8	6149.3250	Rocker Fork Reducer	1
9	6149.3260	Grip Reducer	1
	6149.3280	Heavy Duty Tower Reducer, 10mm	
	6149.3290	Heavy Duty Tower Reducer, 20mm	
10	6149.3500	Compressor, 4.0mm Rod	1
11	6149.3505	Distractor, 4.0mm Rod	1
12	615.304	Rod Bender	1
	682.306	*In Situ* bender, Left. 3.5mm Rod	
	682.307	*In Situ* Bender, Right, 3.5mm Rod	
13	682.308	Rod Holding Forceps, 3.5mm Rod	1
	682.310	3.5mm Rod Gripper	
	9149.0011	QUARTEX® Instruments II Graphic Case	

Items in gray are additionally available.

QUARTEX®
INSTRUMENT SET II 9149.9011 (CONT'D)



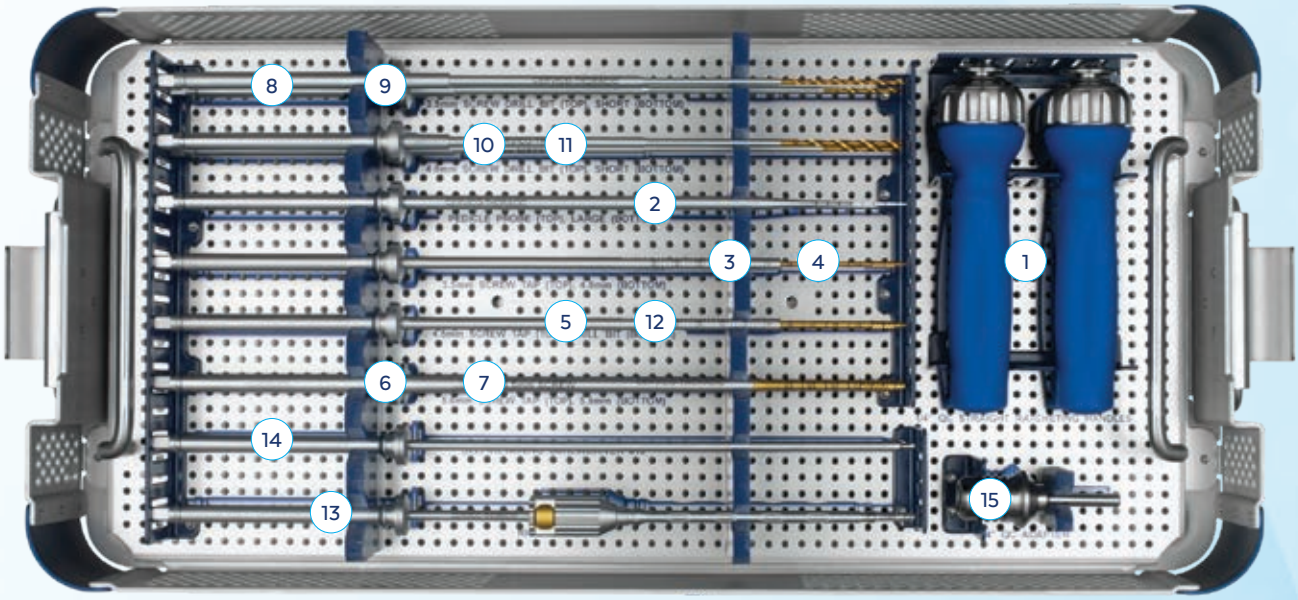


QUARTEX® GI1
GUIDED INSTRUMENT SET 9149.9012

	Instruments		Qty
1	6067.0010	Straight Handle, Ratcheting, 1/4" Quick-Connect	2
	6067.0030	Palm Handle, Ratcheting, 1/4" Quick-Connect	
2	6149.9122	Pedicle Probe, CT, GI1	1
	6149.9123	Pedicle Probe, Large, CT, GI1	
3	6149.9124	Tap for 3.5mm Screw, CT, GI1	1
4	6149.9125	Tap for 4.0mm Screw, CT, GI1	1
5	6149.9126	Tap for 4.5mm Screw, CT, GI1	1
6	6149.9127	Tap for 5.0mm Screw, CT, GI1	1
7	6149.9128	Tap for 5.5mm Screw, CT, GI1	1
8	6149.9135	Drill Bit for 3.5mm Screw, CT, GI1	1
9	6149.9136	Drill Bit for 3.5mm Screw, Short, CT, GI1	1
10	6149.9140	Drill Bit for 4.0mm Screw, CT, GI1	1
11	6149.9141	Drill Bit for 4.0mm Screw, Short, CT, GI1	1
12	6149.9145	Drill Bit for 4.5mm Screw, CT, GI1	1
	6149.9150	Drill Bit for 5.0mm Screw, CT, GI1	
	6149.9155	Drill Bit for 5.5mm Screw, CT, GI1	
13	6149.9200	Rigid Driver, CT, GI1	1
14	6149.9210	Screwdriver, #15, Self-Retaining, CT, GI1	1
15	639.407	1/4" Quick-Connect Adapter	1
	9149.0012	QUARTEX® Guided Instruments, GI1 Graphic Case	1
	999.040	QUARTEX® Guided Instruments Usage Code	

Items in gray are additionally available.

QUARTEX® GI1
GUIDED INSTRUMENT SET 9149.9012 (CONT'D)



QUARTEX®
IMPLANT SET 9149.9002

QUARTEX® Polyaxial Screws		Qty
1149.3508	3.5mm Polyaxial Screw, 8mm	8
1149.3510	3.5mm Polyaxial Screw, 10mm	16
1149.3512	3.5mm Polyaxial Screw, 12mm	16
1149.3514	3.5mm Polyaxial Screw, 14mm	16
1149.3516	3.5mm Polyaxial Screw, 16mm	16
1149.3518	3.5mm Polyaxial Screw, 18mm	8
1149.3520	3.5mm Polyaxial Screw, 20mm	8
1149.3522	3.5mm Polyaxial Screw, 22mm	8
1149.3524	3.5mm Polyaxial Screw, 24mm	8
1149.3526	3.5mm Polyaxial Screw, 26mm	8
1149.3528	3.5mm Polyaxial Screw, 28mm	
1149.3530	3.5mm Polyaxial Screw, 30mm	
1149.3532	3.5mm Polyaxial Screw, 32mm	
1149.3534	3.5mm Polyaxial Screw, 34mm	
1149.3536	3.5mm Polyaxial Screw, 36mm	
1149.3538	3.5mm Polyaxial Screw, 38mm	
1149.3540	3.5mm Polyaxial Screw, 40mm	
1149.3542	3.5mm Polyaxial Screw, 42mm	
1149.3544	3.5mm Polyaxial Screw, 44mm	
1149.3546	3.5mm Polyaxial Screw, 46mm	
1149.3548	3.5mm Polyaxial Screw, 48mm	
1149.3550	3.5mm Polyaxial Screw, 50mm	
1149.4010	4.0mm Polyaxial Screw, 10mm	8
1149.4012	4.0mm Polyaxial Screw, 12mm	8
1149.4014	4.0mm Polyaxial Screw, 14mm	8
1149.4016	4.0mm Polyaxial Screw, 16mm	8
1149.4018	4.0mm Polyaxial Screw, 18mm	8
1149.4020	4.0mm Polyaxial Screw, 20mm	8
1149.4022	4.0mm Polyaxial Screw, 22mm	8
1149.4024	4.0mm Polyaxial Screw, 24mm	4
1149.4026	4.0mm Polyaxial Screw, 26mm	4
1149.4028	4.0mm Polyaxial Screw, 28mm	4
1149.4030	4.0mm Polyaxial Screw, 30mm	4

QUARTEX® Polyaxial Screws (Cont'd)		Qty
1149.4032	4.0mm Polyaxial Screw, 32mm	
1149.4034	4.0mm Polyaxial Screw, 34mm	
1149.4036	4.0mm Polyaxial Screw, 36mm	
1149.4038	4.0mm Polyaxial Screw, 38mm	
1149.4040	4.0mm Polyaxial Screw, 40mm	
1149.4042	4.0mm Polyaxial Screw, 42mm	
1149.4044	4.0mm Polyaxial Screw, 44mm	
1149.4046	4.0mm Polyaxial Screw, 46mm	
1149.4048	4.0mm Polyaxial Screw, 48mm	
1149.4050	4.0mm Polyaxial Screw, 50mm	
1149.4510	4.5mm Polyaxial Screw, 10mm	
1149.4512	4.5mm Polyaxial Screw, 12mm	
1149.4514	4.5mm Polyaxial Screw, 14mm	
1149.4516	4.5mm Polyaxial Screw, 16mm	
1149.4518	4.5mm Polyaxial Screw, 18mm	
1149.4520	4.5mm Polyaxial Screw, 20mm	4
1149.4522	4.5mm Polyaxial Screw, 22mm	4
1149.4524	4.5mm Polyaxial Screw, 24mm	4
1149.4526	4.5mm Polyaxial Screw, 26mm	4
1149.4528	4.5mm Polyaxial Screw, 28mm	4
1149.4530	4.5mm Polyaxial Screw, 30mm	4
1149.4532	4.5mm Polyaxial Screw, 32mm	4
1149.4534	4.5mm Polyaxial Screw, 34mm	4
1149.4536	4.5mm Polyaxial Screw, 36mm	4
1149.4538	4.5mm Polyaxial Screw, 38mm	4
1149.4540	4.5mm Polyaxial Screw, 40mm	
1149.4542	4.5mm Polyaxial Screw, 42mm	
1149.4544	4.5mm Polyaxial Screw, 44mm	
1149.4546	4.5mm Polyaxial Screw, 46mm	
1149.4548	4.5mm Polyaxial Screw, 48mm	
1149.4550	4.5mm Polyaxial Screw, 50mm	

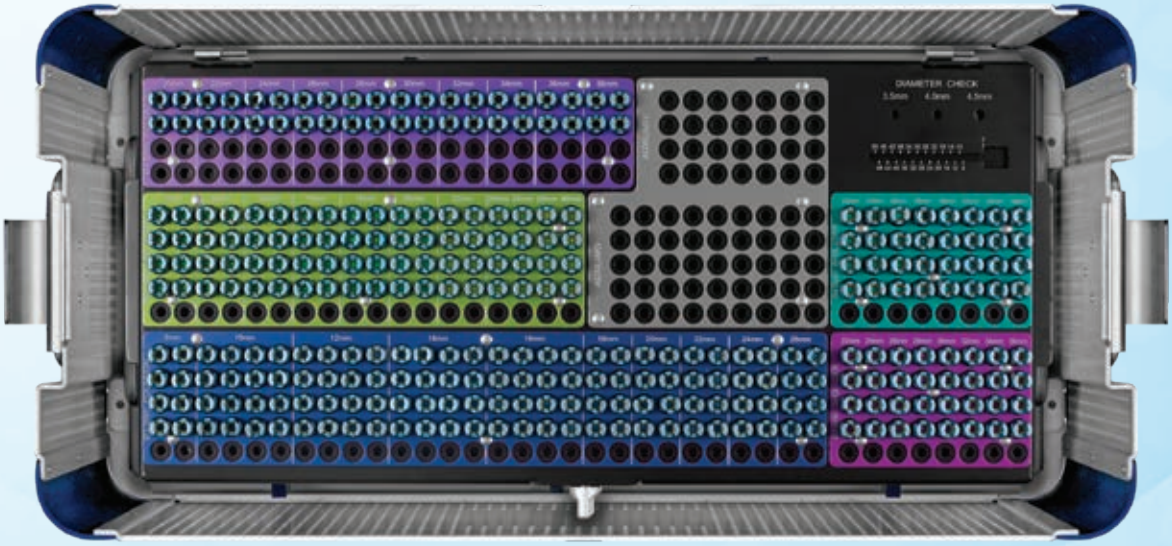
Items in gray are additionally available.

QUARTEX®
IMPLANT SET 9149.9002 (CONT'D)

QUARTEX® Polyaxial Shoulder Screws		Qty
1149.3722	3.5mm Polyaxial Shoulder Screw, 22mm	4
1149.3724	3.5mm Polyaxial Shoulder Screw, 24mm	4
1149.3726	3.5mm Polyaxial Shoulder Screw, 26mm	4
1149.3728	3.5mm Polyaxial Shoulder Screw, 28mm	4
1149.3730	3.5mm Polyaxial Shoulder Screw, 30mm	4
1149.3732	3.5mm Polyaxial Shoulder Screw, 32mm	4
1149.3734	3.5mm Polyaxial Shoulder Screw, 34mm	4
1149.3736	3.5mm Polyaxial Shoulder Screw, 36mm	4
1149.3738	3.5mm Polyaxial Shoulder Screw, 38mm	
1149.3740	3.5mm Polyaxial Shoulder Screw, 40mm	
1149.3742	3.5mm Polyaxial Shoulder Screw, 42mm	
1149.3744	3.5mm Polyaxial Shoulder Screw, 44mm	
1149.3746	3.5mm Polyaxial Shoulder Screw, 46mm	
1149.3748	3.5mm Polyaxial Shoulder Screw, 48mm	
1149.3750	3.5mm Polyaxial Shoulder Screw, 50mm	
1149.4222	4.0mm Polyaxial Shoulder Screw, 22mm	4
1149.4224	4.0mm Polyaxial Shoulder Screw, 24mm	4
1149.4226	4.0mm Polyaxial Shoulder Screw, 26mm	4

QUARTEX® Polyaxial Shoulder Screws		Qty
1149.4228	4.0mm Polyaxial Shoulder Screw, 28mm	4
1149.4230	4.0mm Polyaxial Shoulder Screw, 30mm	4
1149.4232	4.0mm Polyaxial Shoulder Screw, 32mm	4
1149.4234	4.0mm Polyaxial Shoulder Screw, 34mm	4
1149.4236	4.0mm Polyaxial Shoulder Screw, 36mm	4
1149.4238	4.0mm Polyaxial Shoulder Screw, 38mm	
1149.4240	4.0mm Polyaxial Shoulder Screw, 40mm	
1149.4242	4.0mm Polyaxial Shoulder Screw, 42mm	
1149.4244	4.0mm Polyaxial Shoulder Screw, 44mm	
1149.4246	4.0mm Polyaxial Shoulder Screw, 46mm	
1149.4248	4.0mm Polyaxial Shoulder Screw, 48mm	
1149.4250	4.0mm Polyaxial Shoulder Screw, 50mm	

Locking Cap and Nuts		Qty
1149.0001	QUARTEX® Threaded Locking Cap	24
1149.0002	QUARTEX® Threaded Locking Cap for Head-to- Head T-Connector	4
1149.0003	QUARTEX® Locking Nut for Head-to-Head T-Connector	4



Items in gray are additionally available.

QUARTEX®
IMPLANT SET 9149.9002 (CONT'D)

Curved Rods		Qty
111.825	3.5mm Curved Rod, 25mm	
111.830	3.5mm Curved Rod, 30mm	
111.835	3.5mm Curved Rod, 35mm	
111.840	3.5mm Curved Rod, 40mm	
111.845	3.5mm Curved Rod, 45mm	
111.850	3.5mm Curved Rod, 50mm	
111.855	3.5mm Curved Rod, 55mm	
111.860	3.5mm Curved Rod, 60mm	2
111.865	3.5mm Curved Rod, 65mm	
111.870	3.5mm Curved Rod, 70mm	
111.875	3.5mm Curved Rod, 75mm	
111.880	3.5mm Curved Rod, 80mm	
111.885	3.5mm Curved Rod, 85mm	
111.890	3.5mm Curved Rod, 90mm	
111.895	3.5mm Curved Rod, 95mm	
111.900	3.5mm Curved Rod, 100mm	
111.905	3.5mm Curved Rod, 105mm	
111.910	3.5mm Curved Rod, 110mm	
111.915	3.5mm Curved Rod, 115mm	
111.920	3.5mm Curved Rod, 120mm	2
1149.7525	4.0mm Curved Rod, 25mm	
1149.7530	4.0mm Curved Rod, 30mm	
1149.7535	4.0mm Curved Rod, 35mm	
1149.7540	4.0mm Curved Rod, 40mm	
1149.7545	4.0mm Curved Rod, 45mm	
1149.7550	4.0mm Curved Rod, 50mm	
1149.7555	4.0mm Curved Rod, 55mm	
1149.7560	4.0mm Curved Rod, 60mm	2
1149.7565	4.0mm Curved Rod, 65mm	
1149.7570	4.0mm Curved Rod, 70mm	
1149.7575	4.0mm Curved Rod, 75mm	
1149.7580	4.0mm Curved Rod, 80mm	
1149.7585	4.0mm Curved Rod, 85mm	
1149.7590	4.0mm Curved Rod, 90mm	
1149.7595	4.0mm Curved Rod, 95mm	

Curved Rods		Qty
1149.7600	4.0mm Curved Rod, 100mm	
1149.7605	4.0mm Curved Rod, 105mm	
1149.7610	4.0mm Curved Rod, 110mm	
1149.7615	4.0mm Curved Rod, 115mm	
1149.7620	4.0mm Curved Rod, 120mm	2

Straight Rods		Qty
1149.7040	4.0mm Rod, Straight, 40mm	4
1149.7080	4.0mm Rod, Straight, 80mm	4
1149.7120	4.0mm Rod, Straight, 120mm	2
1149.7240	4.0mm Rod, Straight, 240mm	2
1149.7250	4.0mm Rod, Straight, 500mm	
182.805	3.5mm Rod, 500mm	

3.5mm Cobalt Chrome Straight Rods

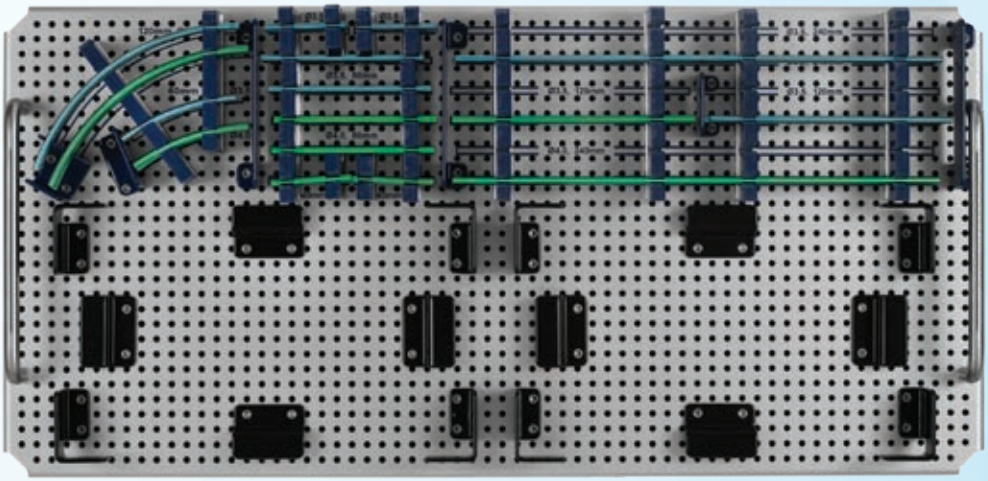
782.801	3.5mm CoCr Rod, 80mm
782.802	3.5mm CoCr Rod, 120mm
782.803	3.5mm CoCr Rod, 240mm
782.804	3.5mm CoCr Rod, 40mm
782.805	3.5mm CoCr Rod, 500mm

4.0mm Cobalt Chrome Straight Rods

7149.7040	4.0mm Straight Rod, 40mm, CoCr
7149.7080	4.0mm Straight Rod, 80mm, CoCr
7149.7120	4.0mm Straight Rod, 120mm, CoCr
7149.7240	4.0mm Straight Rod, 240mm, CoCr
7149.7250	4.0mm Straight Rod, 500mm, CoCr

Items in gray are additionally available.

QUARTEX®
IMPLANT SET 9149.9002 (CONT'D)



QUARTEX®
IMPLANT SET 9149.9002 (CONT'D)

QUARTEX® In-Line Hooks		Qty
1149.1900	In-Line Hook	2
1149.1901	In-Line Hook, Left	1
1149.1902	In-Line Hook, Right	1

Titanium Tapered Rods - 350mm		Qty
182.980	3.5mm (175mm)-4.0mm (175mm) Tapered Rod, Titanium, 350mm Length	
182.981	3.5mm (175mm)-4.5mm (175mm) Tapered Rod, Titanium, 350mm Length	
182.982	3.5mm (175mm)-5.0mm (175mm) Tapered Rod, Titanium, 350mm Length	
182.983	3.5mm (175mm)-5.5mm (175mm) Tapered Rod, Titanium, 350mm Length	2
182.984	3.5mm (175mm)-6.0mm (175mm) Tapered Rod, Titanium, 350mm Length	
182.985	3.5mm (175mm)-6.35mm (175mm) Tapered Rod, Titanium, 350mm Length	
182.986	3.5mm (175mm)-6.5mm (175mm) Tapered Rod, Titanium, 350mm Length	
182.987	Tapered Rod, 3.5mm (175mm) - 4.75mm (175mm), Titanium, 350mm Length	
1149.7460	4.0mm (175mm)-4.5mm (175mm) Tapered Rod, Titanium, 350mm Length	
1149.7461	4.0mm (175mm)-4.75mm (175mm) Tapered Rod, Titanium, 350mm Length	
1149.7462	4.0mm (175mm)-5.0mm (175mm) Tapered Rod Titanium, 350mm Length	
1149.7463	4.0mm (175mm)-5.5mm (175mm) Tapered Rod Titanium, 350mm Length	2
1149.7465	4.0mm (175mm)-6.0mm (175mm) Tapered Rod Titanium, 350mm Length	
1149.7466	4.0mm (175mm)-6.35mm (175mm) Tapered Rod Titanium, 350mm Length	
1149.7467	4.0mm (175mm)-6.5mm (175mm) Tapered Rod Titanium, 350mm Length	

Cobalt Chrome Tapered Rods - 350mm	
782.979	3.5mm (175mm)-3.7mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
782.980	3.5mm (175mm)-4.0mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
782.981	3.5mm (175mm)-4.5mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length

Cobalt Chrome Tapered Rods - 350mm (Cont'd)	
782.982	3.5mm (175mm)-5.0mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
782.983	3.5mm (175mm)-5.5mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
782.984	3.5mm (175mm)-6.0mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
782.985	3.5mm (175mm)-6.35mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
782.986	3.5mm (175mm)-6.5mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
7149.7460	4.0mm (175mm)-4.5mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
7149.7461	4.0mm (175mm)-4.75mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
7149.7462	4.0mm (175mm)-5.0mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
7149.7463	4.0mm (175mm)-5.5mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
7149.7465	4.0mm (175mm)-6.0mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
7149.7466	4.0mm (175mm)-6.35mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length
7149.7467	4.0mm (175mm)-6.5mm (175mm) Tapered Rod, Cobalt Chrome, 350mm Length

Tapered Rods - 500mm	
182.989	3.5mm (250mm)-5.5mm (250mm) Tapered Rod, Titanium, 500mm Length
782.989	3.5mm (250mm)- 5.5mm (250mm) Tapered Rod, Cobalt Chrome, 500mm Length
1149.7464	4.0mm (250mm)-5.5mm (250mm) Tapered Rod Titanium, 500mm Length
7149.7464	4.0mm (250mm)-5.5mm (250mm) Tapered Rod, Cobalt Chrome, 500mm Length

Tapered Rods - 550mm	
182.988	Tapered Rod, 3.5mm (50mm) - 5.5mm (500mm), Titanium, 550mm Length

Tapered Rods - 600mm	
182.978	Tapered Rod, 3.5mm (100mm)-4.5mm (500mm), Titanium, 600mm Length

Tapered Rods - 700mm	
182.977	Tapered Rod, 3.5mm (200mm)-5.5mm (500mm), Titanium, 700mm Length
782.977	CoCr Tapered Rod, 3.5mm to 5.5mm, 700mm

Items in gray are additionally available.

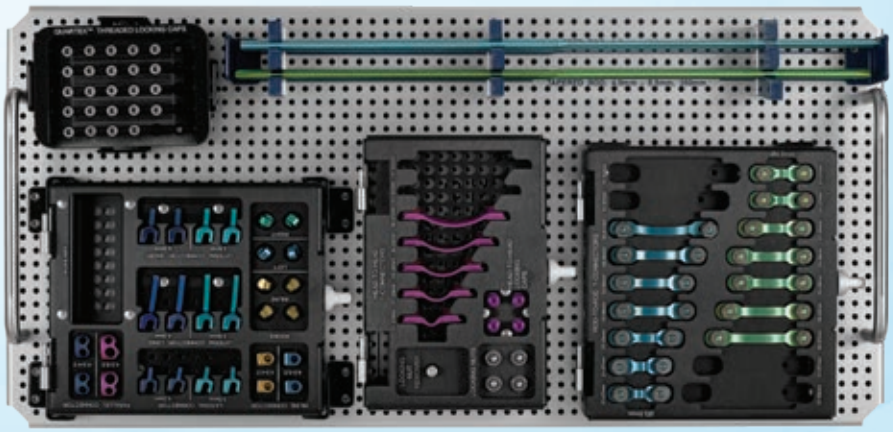
QUARTEX®
IMPLANT SET 9149.9002 (CONT'D)

Titanium Tapered Rods - 800mm

182.940	Tapered Rod, 3.5mm (200mm)-4.5mm (600mm), Titanium, 800mm Length
182.941	Tapered Rod, 3.5mm (200mm)-4.75mm (600mm), Titanium, 800mm Length
182.942	Tapered Rod, 3.5mm (200mm)-5.0mm (600mm), Titanium, 800mm Length
182.943	Tapered Rod, 3.5mm (200mm)-5.5mm (600mm), Titanium, 800mm Length
182.944	Tapered Rod, 3.5mm (200mm)-6.0mm (600mm), Titanium, 800mm Length
182.945	Tapered Rod, 3.5mm (200mm)-6.35mm (600mm), Titanium, 800mm Length
182.946	Tapered Rod, 3.5mm (200mm)-6.5mm (600mm), Titanium, 800mm Length
1149.7440	Tapered Rod, 4.0mm (200mm)-4.5mm (600mm), Titanium, 800mm Length
1149.7441	Tapered Rod, 4.0mm (200mm)-4.75mm (600mm), Titanium, 800mm Length
1149.7442	Tapered Rod, 4.0mm (200mm)-5.0mm (600mm), Titanium, 800mm Length
1149.7443	Tapered Rod, 4.0mm (200mm)-5.5mm (600mm), Titanium, 800mm Length
1149.7444	Tapered Rod, 4.0mm (200mm)-6.0mm (600mm), Titanium, 800mm Length
1149.7445	Tapered Rod, 4.0mm (200mm)-6.35mm (600mm), Titanium, 800mm Length
1149.7446	Tapered Rod, 4.0mm (200mm)-6.5mm (600mm), Titanium, 800mm Length

Cobalt Chrome Tapered Rods - 800mm

782.940	Tapered Rod, 3.5mm (200mm)-4.5mm (600mm), Cobalt Chrome, 800mm Length
782.941	Tapered Rod, 3.5mm (200mm)-4.75mm (600mm), Cobalt Chrome, 800mm Length
782.942	Tapered Rod, 3.5mm (200mm)-5.0mm (600mm), Cobalt Chrome, 800mm Length
782.943	Tapered Rod, 3.5mm (200mm)-5.5mm (600mm), Cobalt Chrome, 800mm Length
782.944	Tapered Rod, 3.5mm (200mm)-6.0mm (600mm), Cobalt Chrome, 800mm Length
782.945	Tapered Rod, 3.5mm (200mm)-6.35mm (600mm), Cobalt Chrome, 800mm Length
782.946	Tapered Rod, 3.5mm (200mm)-6.5mm (600mm), Cobalt Chrome, 800mm Length
7149.7440	Tapered Rod, 4.0mm (200mm)-4.5mm (600mm), Cobalt Chrome, 800mm Length
7149.7441	Tapered Rod, 4.0mm (200mm)-4.75mm (600mm), Cobalt Chrome, 800mm Length
7149.7442	Tapered Rod, 4.0mm (200mm)-5.0mm (600mm), Cobalt Chrome, 800mm Length
7149.7443	Tapered Rod, 4.0mm (200mm)-5.5mm (600mm), Cobalt Chrome, 800mm Length
7149.7444	Tapered Rod, 4.0mm (200mm)-6.0mm (600mm), Cobalt Chrome, 800mm Length
7149.7445	Tapered Rod, 4.0mm (200mm)-6.35mm (600mm), Cobalt Chrome, 800mm Length
7149.7446	Tapered Rod, 4.0mm (200mm)-6.5mm (600mm), Cobalt Chrome, 800mm Length



Items in gray are additionally available.

QUARTEX®
IMPLANT SET 9149.9002 (CONT'D)

QUARTEX® Parallel Connectors		Qty
1149.8000	Parallel Connector 4.0mm Rod to 4.0mm Rod	2
1149.8001	Parallel Connector 4.0mm Rod to 4.5mm Rod	
1149.8002	Parallel Connector 4.0mm Rod to 4.75mm Rod	
1149.8003	Parallel Connector 4.0mm Rod to 5.0mm Rod	
1149.8004	Parallel Connector 4.0mm Rod to 5.5mm Rod	2
1149.8005	Parallel Connector 4.0mm Rod to 6.0mm Rod	
1149.8006	Parallel Connector 4.0mm Rod to 6.35mm Rod	
1149.8007	Parallel Connector 4.0mm Rod to 6.5mm Rod	

QUARTEX® Lateral Connectors		Qty
1149.8050	Lateral Connector, 4.0mm Rod	2
1149.8051	Lateral Connector, Long, 4.0mm Rod	2
1149.8052	Lateral Connector, Short, 4.0mm Rod	2
1149.8053	Lateral Connector, Angled, 4.0mm Rod	
1149.8054	Lateral Connector, 3.5mm Rod	2
1149.8055	Lateral Connector, Long, 3.5mm Rod	2
1149.8056	Lateral Connector, Short, 3.5mm Rod	2
1149.8057	Lateral Connector, Angled, 3.5mm Rod	
1149.8058	Lateral Connector, Extra Long, 4.0mm Rod	
1149.8059	Lateral Connector, Extra Long, 3.5mm Rod	
1149.8060	Lateral Connector, Closed, Short, 3.5mm Rod	
1149.8061	Lateral Connector, Closed, Long, 3.5mm Rod	
1149.8062	Lateral Connector, Closed, Short, 4.0mm Rod	
1149.8063	Lateral Connector, Closed, Long, 4.0mm Rod	

QUARTEX® In-Line Connectors		Qty
1149.8070	In-Line Connector, Single, 4.0-4.0mm	2
1149.8071	In-Line Connector, Double, 4.0-4.0mm	
1149.8072	In-Line Connector, Single, 4.0-6.5mm	2
1149.8073	In-Line Connector, Double, 4.0-6.5mm	

QUARTEX® Rod-to-Rod T-Connectors		Qty
1149.8100	3.5mm Rod-to-Rod T-Connector, 21-27mm	2
1149.8101	3.5mm Rod-to-Rod T-Connector, 27-33mm	1
1149.8102	3.5mm Rod-to-Rod T-Connector, 33-39mm	2
1149.8103	3.5mm Rod-to-Rod T-Connector, 39-45mm	1

QUARTEX® Rod-to-Rod T-Connectors		Qty
1149.8104	3.5mm Rod-to-Rod T-Connector, 45-51mm	1
1149.8105	3.5mm Rod-to-Rod T-Connector, 51-57mm	
1149.8106	3.5mm Rod-to-Rod T-Connector, 57-63mm	
1149.8200	4.0mm Rod-to-Rod T-Connector, 21-27mm	2
1149.8201	4.0mm Rod-to-Rod T-Connector, 27-33mm	1
1149.8202	4.0mm Rod-to-Rod T-Connector, 33-39mm	2
1149.8203	4.0mm Rod-to-Rod T-Connector, 39-45mm	1
1149.8204	4.0mm Rod-to-Rod T-Connector, 45-51mm	1
1149.8205	4.0mm Rod-to-Rod T-Connector, 51-57mm	
1149.8206	4.0mm Rod-to-Rod T-Connector, 57-63mm	

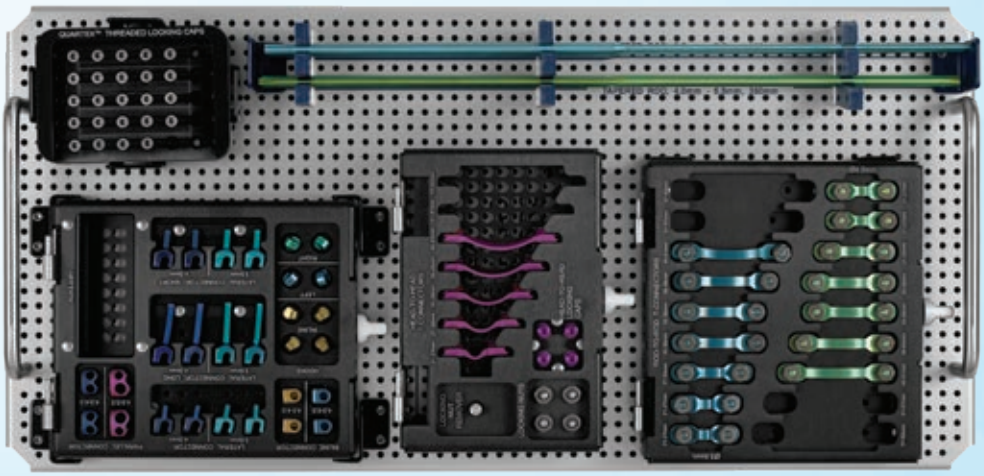
Items in gray are additionally available.

QUARTEX®
IMPLANT SET 9149.9002 (CONT'D)

QUARTEX® Head-to-Head T-Connectors		Qty
1149.8300	Head-to-Head T-Connector, 21-27mm	1
1149.8301	Head-to-Head T-Connector, 27-33mm	1
1149.8302	Head-to-Head T-Connector, 33-39mm	1
1149.8303	Head-to-Head T-Connector, 39-45mm	1
1149.8304	Head-to-Head T-Connector, 45-51mm	1
1149.8305	Head-to-Head T-Connector, 51-57mm	
1149.8306	Head-to-Head T-Connector, 57-63mm	

Graphic Cases

9149.0002	QUARTEX® Implants Graphics Case
9149.1200	QUARTEX® Screw Module
9149.1201	QUARTEX® Locking Cap Module
9149.1202	QUARTEX® Rod-to-Rod T-Connector Module
9149.1203	QUARTEX® Head-to-Head T-Connector Module
9149.1204	QUARTEX® Hooks and Connectors Module
9149.1205	3.5mm Curved Rod Module
9149.1206	4.0mm Curved Rod Module



Items in gray are additionally available.

QUARTEX®
OCCIPITAL SET 9149.9003

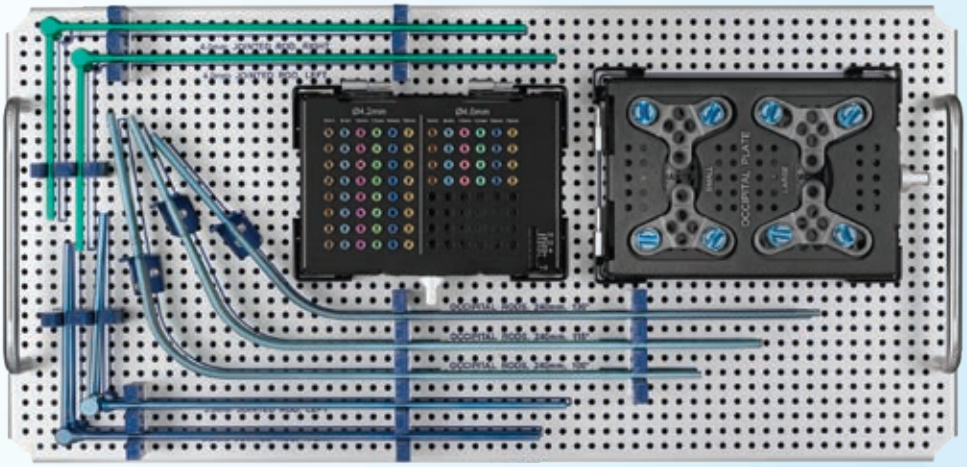
	Occipital Instruments		Qty
1	6149.3070	Jointed Rod Holder	1
2	6149.6010	Occipital Rod Slot Positioner	1
3	6149.6250	Occipital Rocker Fork Reducer	1
4	6149.6300	Occipital Adjustable Depth Drill Guide	1
5	6149.6500	Occipital U-Joint Sleeve	2
6	6149.6505	Occipital U-Joint Cap for Driver	1
7	6149.6506	Occipital U-Joint Cap for 6mm Stop	1
8	6149.6508	Occipital U-Joint Cap for 8mm Stop	1
9	6149.6510	Occipital U-Joint Cap for 10mm Stop	1
10	6149.6512	Occipital U-Joint Cap for 12mm Stop	1
	6149.6514	Occipital U-Joint Cap for 14mm Stop	
	6149.6516	Occipital U-Joint Cap for 16mm Stop	
11	6149.6540	Occipital U-Joint Tap, 4.2mm Screws	1
12	6149.6545	Occipital U-Joint Tap, 4.6mm Screws	1
13	6149.6555	Occipital U-Joint Screwdriver, #15, Self-Retaining	1
14	6149.6600	Occipital Counter-Torque	1
15	6149.6800	Occipital Plate Bender	1
16	6149.6900	Screw Removal Tool	1
17	6149.6910	Angled Screw Removal Tool	1
18	615.203	Torque-Limiting 2.5mm Hex Driver, 2.5Nm	1
	636.450	Quick-Connect Handle, Swivel	1
19	682.602	Socket Driver	1
20	682.603	Occipital Plate Holder	1
21	682.619	Offset Handle Locking Ring	2
22	682.620	Offset Handle, Occipital CV Joint	2
23	682.622	Flexible Drill Bit, 2.9mm	1
24	682.657	Angled Screw Remover Tool Counter-Torque	1
25	682.662	Occipital Plate Tip Bender	1

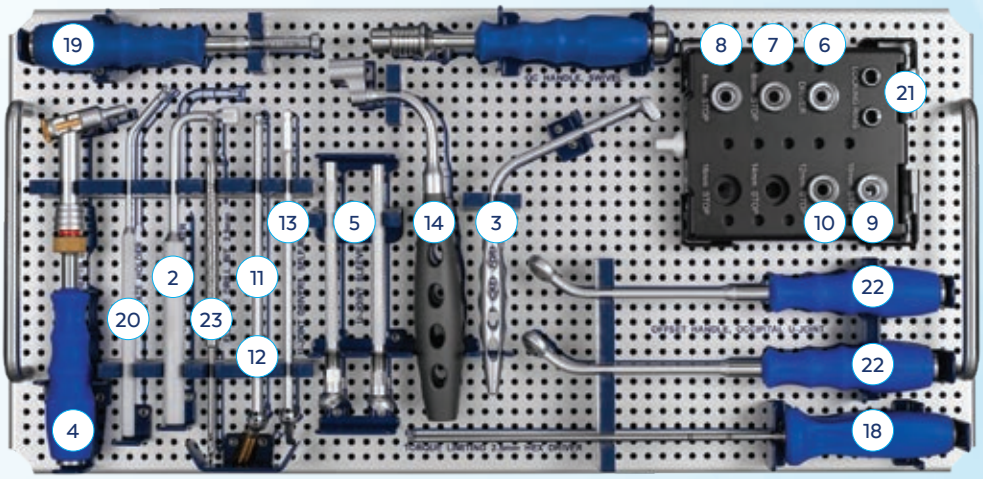
	QUARTEX® Occipital Screws	Qty
1149.9006	4.2mm Occipital Screw, 6mm	8
1149.9008	4.2mm Occipital Screw, 8mm	8
1149.9010	4.2mm Occipital Screw, 10mm	8
1149.9012	4.2mm Occipital Screw, 12mm	8
1149.9014	4.2mm Occipital Screw, 14mm	8
1149.9016	4.2mm Occipital Screw, 16mm	8
1149.9106	4.6mm Occipital Screw, 6mm	4
1149.9108	4.6mm Occipital Screw, 8mm	4
1149.9110	4.6mm Occipital Screw, 10mm	4
1149.9112	4.6mm Occipital Screw, 12mm	4
1149.9114	4.6mm Occipital Screw, 14mm	4
1149.9116	4.6mm Occipital Screw, 16mm	4

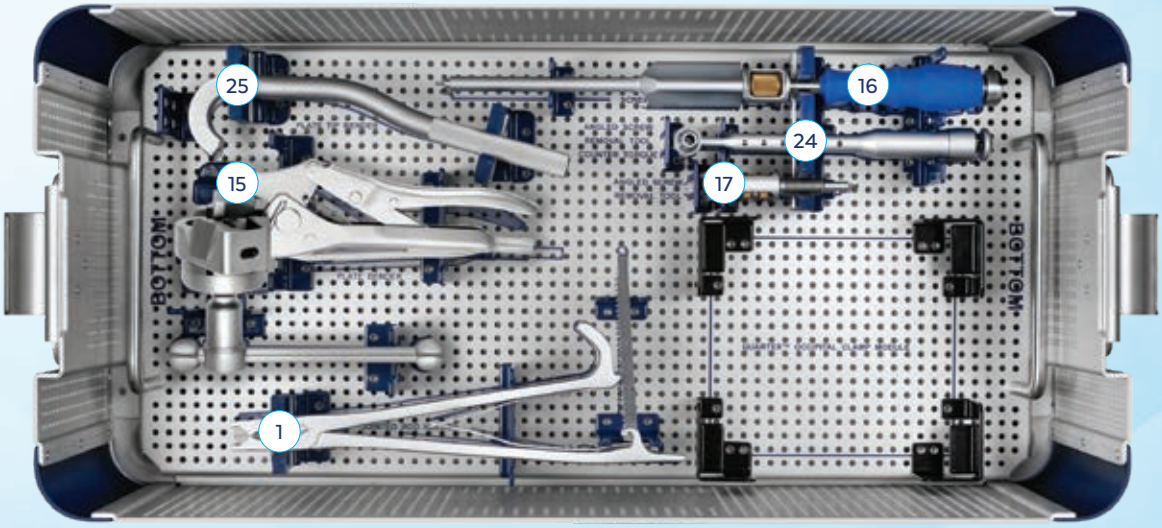
	QUARTEX® Occipital Plates	Qty
1149.9200	Occipital Plate, Small	2
1149.9210	Occipital Plate, Large	2

Items in gray are additionally available.

QUARTEX®
OCCIPITAL SET 9149.9003 (CONT'D)







QUARTEX®
OCCIPITAL SET 9149.9003 (CONT'D)

Occipital Screws		Qty
1149.9300	QUARTEX® 4.0mm Occipital Rod 240mm, 100	2
1149.9315	QUARTEX® 4.0mm Occipital Rod 240mm, 115	2
1149.9330	QUARTEX® 4.0mm Occipital Rod 240mm, 130	2
1149.9450	QUARTEX® 4.0mm Occipital Jointed Rod, Right	2
1149.9455	QUARTEX® 4.0mm Occipital Jointed Rod, Left	2
182.953	3.5mm ELLIPSE® Occipital Rod, 240mm, 100°	2
182.954	3.5mm ELLIPSE® Occipital Rod, 240mm, 115°	2
182.955	3.5mm ELLIPSE® Occipital Rod, 240mm, 130°	2
182.956	Occipital Jointed Rod, Right	2
182.957	Occipital Jointed Rod, Left	2
7149.9300	4.0mm Occipital Rod, 240mm, 100, CoCr	
7149.9315	4.0mm Occipital Rod, 240mm, 115, CoCr	
7149.9330	4.0mm Occipital Rod, 240mm, 130, CoCr	
782.953	3.5mm CoCr Occipital Rod 240mm, 100°	
782.954	3.5mm CoCr Occipital Rod 240mm, 115°	
782.955	3.5mm CoCr Occipital Rod 240mm, 130°	

Occipital Clamps

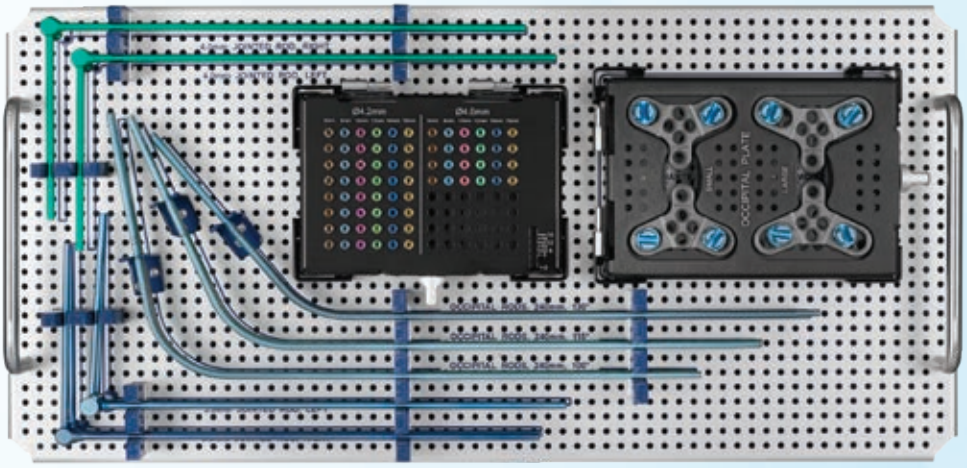
1149.9511	QUARTEX® 3.5mm Occipital Clamp, Single, Short
1149.9512	QUARTEX® 3.5mm Occipital Clamp, Single, Long
1149.9521	QUARTEX® 3.5mm Occipital Clamp, Double, Short
1149.9522	QUARTEX® 3.5mm Occipital Clamp, Double, Long
1149.9531	QUARTEX® 3.5mm Occipital Clamp, Triple, Short
1149.9532	QUARTEX® 3.5mm Occipital Clamp, Triple, Long
1149.9611	QUARTEX® 4.0mm Occipital Clamp, Single, Short
1149.9612	QUARTEX® 4.0mm Occipital Clamp, Single, Long
1149.9621	QUARTEX® 4.0mm Occipital Clamp, Double, Short
1149.9622	QUARTEX® 4.0mm Occipital Clamp, Double, Long
1149.9631	QUARTEX® 4.0mm Occipital Clamp, Triple, Short
1149.9632	QUARTEX® 4.0mm Occipital Clamp, Triple, Long

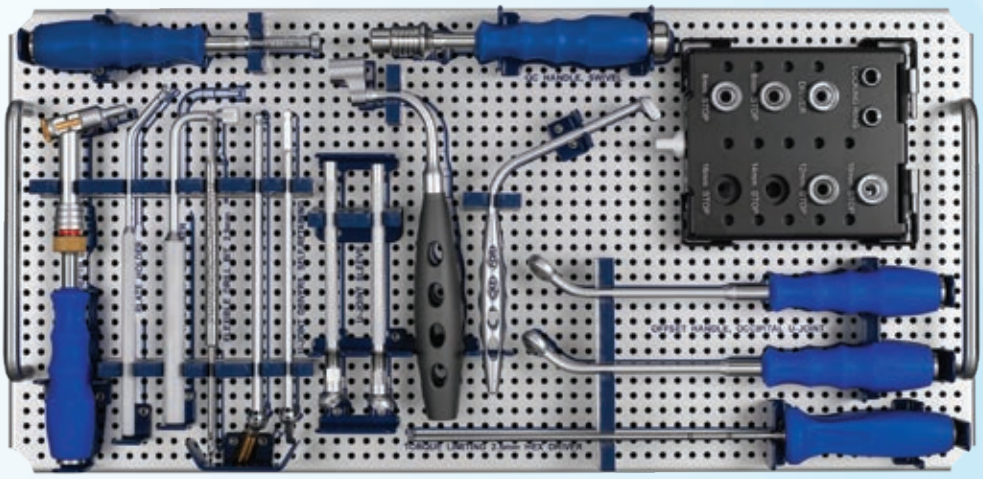
Graphic Cases

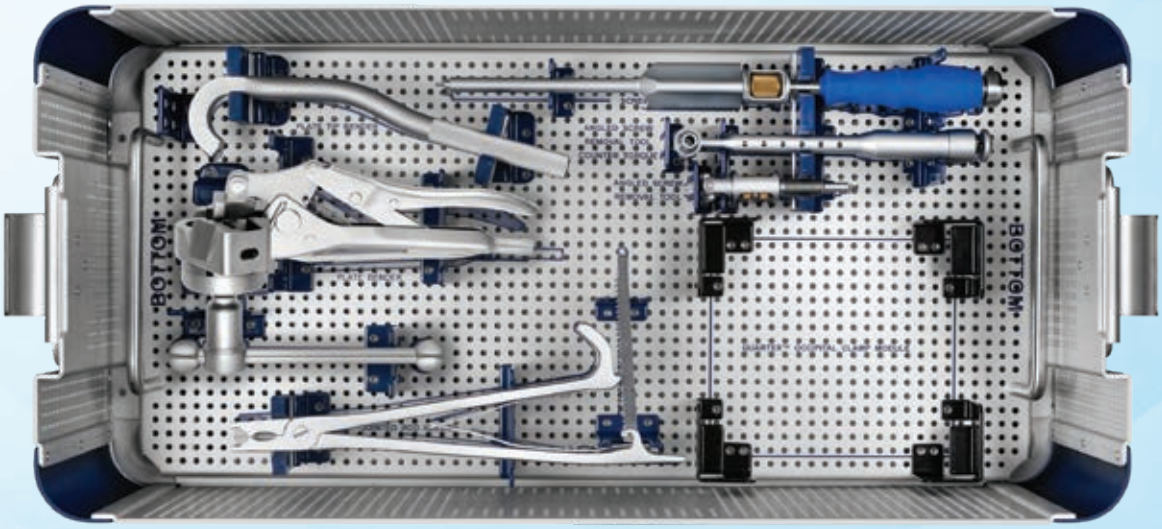
9149.0003	QUARTEX® Occipital System Graphics Case
9149.1300	QUARTEX® Occipital Screw Module
9149.1301	QUARTEX® Occipital Plate Module
9149.1302	QUARTEX® Occipital Clamp Module
9149.2300	QUARTEX® U-Joint Accessory Module

Items in gray are additionally available.

QUARTEX®
OCCIPITAL SET 9149.9003 (CONT'D)







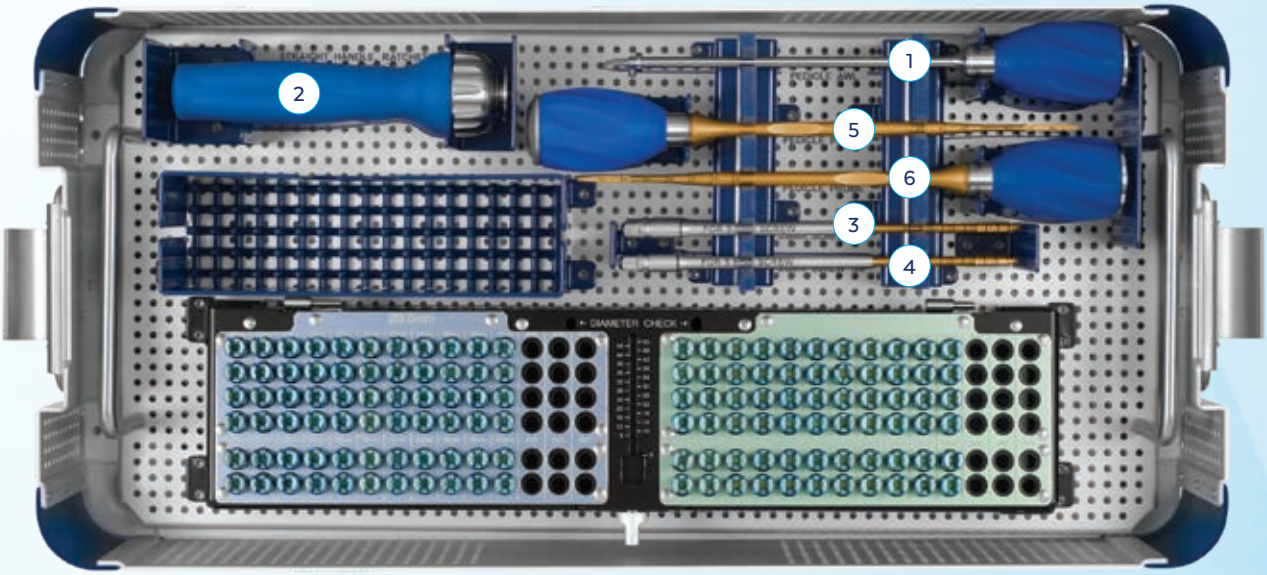
QUARTEX® LARGE DIAMETER SCREW SET 9149.9004

QUARTEX® Large Diameter Screws		Qty
1149.5020	5.0mm Polyaxial Screw, 20mm	6
1149.5022	5.0mm Polyaxial Screw, 22mm	6
1149.5024	5.0mm Polyaxial Screw, 24mm	6
1149.5026	5.0mm Polyaxial Screw, 26mm	6
1149.5028	5.0mm Polyaxial Screw, 28mm	6
1149.5030	5.0mm Polyaxial Screw, 30mm	6
1149.5032	5.0mm Polyaxial Screw, 32mm	6
1149.5034	5.0mm Polyaxial Screw, 34mm	6
1149.5036	5.0mm Polyaxial Screw, 36mm	6
1149.5038	5.0mm Polyaxial Screw, 38mm	6
1149.5040	5.0mm Polyaxial Screw, 40mm	6
1149.5042	5.0mm Polyaxial Screw, 42mm	
1149.5044	5.0mm Polyaxial Screw, 44mm	
1149.5046	5.0mm Polyaxial Screw, 46mm	
1149.5048	5.0mm Polyaxial Screw, 48mm	
1149.5050	5.0mm Polyaxial Screw, 50mm	
1149.5520	5.5mm Polyaxial Screw, 20mm	6
1149.5522	5.5mm Polyaxial Screw, 22mm	6
1149.5524	5.5mm Polyaxial Screw, 24mm	6
1149.5526	5.5mm Polyaxial Screw, 26mm	6
1149.5528	5.5mm Polyaxial Screw, 28mm	6
1149.5530	5.5mm Polyaxial Screw, 30mm	6
1149.5532	5.5mm Polyaxial Screw, 32mm	6
1149.5534	5.5mm Polyaxial Screw, 34mm	6
1149.5536	5.5mm Polyaxial Screw, 36mm	6
1149.5538	5.5mm Polyaxial Screw, 38mm	6
1149.5540	5.5mm Polyaxial Screw, 40mm	6
1149.5542	5.5mm Polyaxial Screw, 42mm	
1149.5544	5.5mm Polyaxial Screw, 44mm	
1149.5546	5.5mm Polyaxial Screw, 46mm	
1149.5548	5.5mm Polyaxial Screw, 48mm	
1149.5550	5.5mm Polyaxial Screw, 50mm	

	Instruments		Qty
1	6067.0001	Pedicle Awl	1
2	6067.0010	Straight Handle, Ratcheting, 1/4" Quick-Connect	1
3	6149.1150	Tap for 5.0mm Screw	1
4	6149.1155	Tap for 5.5mm Screw	1
5	624.113	Pedicle Probe, Thoracic, Curved	1
6	624.114	Pedicle Probe, Thoracic, Straight	1
	9149.0004	QUARTEX® Large Diameter Graphics Case	
	9149.1400	QUARTEX® Large Diameter Screw Module	

Items in gray are additionally available.

QUARTEX® LARGE DIAMETER
SCREW SET 9149.9004 (CONT'D)



3.5mm CURVED ROD
SET 9149.9005

Part No.	Description	Qty
111.825	3.5mm Curved Rod, 25mm	2
111.830	3.5mm Curved Rod, 30mm	2
111.835	3.5mm Curved Rod, 35mm	2
111.840	3.5mm Curved Rod, 40mm	2
111.845	3.5mm Curved Rod, 45mm	2
111.850	3.5mm Curved Rod, 50mm	2
111.855	3.5mm Curved Rod, 55mm	2
111.860	3.5mm Curved Rod, 60mm	2
111.865	3.5mm Curved Rod, 65mm	2
111.870	3.5mm Curved Rod, 70mm	2
111.875	3.5mm Curved Rod, 75mm	2
111.880	3.5mm Curved Rod, 80mm	2
111.885	3.5mm Curved Rod, 85mm	2
111.890	3.5mm Curved Rod, 90mm	2
111.895	3.5mm Curved Rod, 95mm	2
111.900	3.5mm Curved Rod, 100mm	2
111.905	3.5mm Curved Rod, 105mm	2
111.910	3.5mm Curved Rod, 110mm	2
111.915	3.5mm Curved Rod, 115mm	2
111.920	3.5mm Curved Rod, 120mm	2
9149.1205	QUARTEX® 3.5mm Curved Rod Module	

4.0mm CURVED ROD
SET 9149.9006

Part No.	Description	Qty
1149.7525	4.0mm Curved Rod, 25mm	2
1149.7530	4.0mm Curved Rod, 30mm	2
1149.7535	4.0mm Curved Rod, 35mm	2
1149.7540	4.0mm Curved Rod, 40mm	2
1149.7545	4.0mm Curved Rod, 45mm	2
1149.7550	4.0mm Curved Rod, 50mm	2
1149.7555	4.0mm Curved Rod, 55mm	2
1149.7560	4.0mm Curved Rod, 60mm	2
1149.7565	4.0mm Curved Rod, 65mm	2
1149.7570	4.0mm Curved Rod, 70mm	2
1149.7575	4.0mm Curved Rod, 75mm	2
1149.7580	4.0mm Curved Rod, 80mm	2
1149.7585	4.0mm Curved Rod, 85mm	2
1149.7590	4.0mm Curved Rod, 90mm	2
1149.7595	4.0mm Curved Rod, 95mm	2
1149.7600	4.0mm Curved Rod, 100mm	2
1149.7605	4.0mm Curved Rod, 105mm	2
1149.7610	4.0mm Curved Rod, 110mm	2
1149.7615	4.0mm Curved Rod, 115mm	2
1149.7620	4.0mm Curved Rod, 120mm	2
9149.1206	QUARTEX® 4.0mm Curved Rod Module	

QUARTEX®
OCCIPITAL CLAMP SET 9149.9007

Part No.	Description	Qty
1149.9511	QUARTEX® 3.5mm Occipital Clamp, Single, Short	4
1149.9512	QUARTEX® 3.5mm Occipital Clamp, Single, Long	4
1149.9521	QUARTEX® 3.5mm Occipital Clamp, Double, Short	4
1149.9522	QUARTEX® 3.5mm Occipital Clamp, Double, Long	4
1149.9531	QUARTEX® 3.5mm Occipital Clamp, Triple, Short	4
1149.9532	QUARTEX® 3.5mm Occipital Clamp, Triple, Long	4
1149.9611	QUARTEX® 4.0mm Occipital Clamp, Single, Short	4
1149.9612	QUARTEX® 4.0mm Occipital Clamp, Single, Long	4
1149.9621	QUARTEX® 4.0mm Occipital Clamp, Double, Short	4
1149.9622	QUARTEX® 4.0mm Occipital Clamp, Double, Long	4
1149.9631	QUARTEX® 4.0mm Occipital Clamp, Triple, Short	4
1149.9632	QUARTEX® 4.0mm Occipital Clamp, Triple, Long	4
9149.1302	QUARTEX® Occipital Clamp Module	

QUARTEX®
AUXILIARY SCREW MODULE 9149.9008

QUARTEX® 3.5mm Polyaxial Screw		Qty
1149.3528	28mm	4
1149.3530	30mm	4
1149.3532	32mm	4
1149.3534	34mm	4
1149.3536	36mm	4
1149.3538	38mm	4
1149.3540	40mm	4
1149.3542	42mm	2
1149.3544	44mm	2
1149.3546	46mm	2
1149.3548	48mm	2
1149.3550	50mm	2

QUARTEX® 3.5mm Polyaxial Shoulder Screw		Qty
1149.3738	38mm	4
1149.3740	40mm	4
1149.3742	42mm	2
1149.3744	44mm	2
1149.3746	46mm	2
1149.3748	48mm	2
1149.3750	50mm	2

QUARTEX® 4.0mm Polyaxial Screw		Qty
1149.4032	32mm	4
1149.4034	34mm	4
1149.4036	36mm	4
1149.4038	38mm	4
1149.4040	40mm	4
1149.4042	42mm	2
1149.4044	44mm	2
1149.4046	46mm	2
1149.4048	48mm	2
1149.4050	50mm	2

QUARTEX® 4.0mm Polyaxial Shoulder Screw		Qty
1149.4238	38mm	4
1149.4240	40mm	4
1149.4242	42mm	2
1149.4244	44mm	2
1149.4246	46mm	2
1149.4248	48mm	2
1149.4250	50mm	2

QUARTEX® 4.5mm Polyaxial Screw		Qty
1149.4510	10mm	4
1149.4512	12mm	4
1149.4514	14mm	4
1149.4516	16mm	4
1149.4518	18mm	4
1149.4540	40mm	2
1149.4542	42mm	2
1149.4544	44mm	2
1149.4546	46mm	2
1149.4548	48mm	2
1149.4550	50mm	2

9149.1500	QUARTEX® Auxiliary Screw Module

IMPORTANT INFORMATION ON QUARTEX® OCCIPITO-CERVICO-THORACIC SPINAL SYSTEM

DESCRIPTION

The QUARTEX® Occipito-Cervico-Thoracic Spinal System consists of 3.5mm-4.0mm jointed, straight and pre-bent rods, tapered rods, polyaxial screws, hooks, locking caps, t-connectors, lateral connectors, parallel connectors, in-line connectors, rod-to-rod connectors, rod extension clamps and occipital plates. The implants are composed of titanium alloy (per ASTM F136, F1472, or F1295), stainless steel (per ASTM F138) or cobalt chromium molybdenum alloy (CoCr) (per ASTM F1537).

QUARTEX® constructs may be connected to stabilization systems including ELLIPSE®, PROTEX® CT, PROTEX®, CREO®, REVERE®, or BEACON® Systems using corresponding connectors.

The QUARTEX® system include manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, reusable instruments that can be operated manually or under power using a power drill such as POWEREASE™ and are intended to be used with the Medtronic StealthStation® System.

INDICATIONS

The QUARTEX® Occipito-Cervico-Thoracic Spinal System implants are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1-C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. These implants are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, rods may be connected to occipital cervical thoracic or thoracolumbar stabilization systems ranging in diameter from 3.2mm to 6.5mm, using corresponding connectors.

Globus Navigation Instruments are intended to be used during the preparation and placement of QUARTEX® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Possible adverse effects which may occur and may require additional surgery include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

The components of this system are manufactured from titanium alloy, stainless steel or cobalt chromium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components of titanium or cobalt chromium with stainless steel is not recommended, for metallurgical, mechanical and functional reasons.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS

The implantation of posterior screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this posterior screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

The implants are for single use only. Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

MRI SAFETY INFORMATION

The QUARTEX® Occipito-Cervico-Thoracic Spinal System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of QUARTEX® Occipito-Cervico-Thoracic Spinal System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use

IMPORTANT INFORMATION ON QUARTEX® OCCIPITO-CERVICO-THORACIC SPINAL SYSTEM

or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All implants, instruments, and instrument trays and cases should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double foil pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature). Sterile implants meet pyrogen limit specifications.

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

Do not stack trays during sterilization. These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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NOTES

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Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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