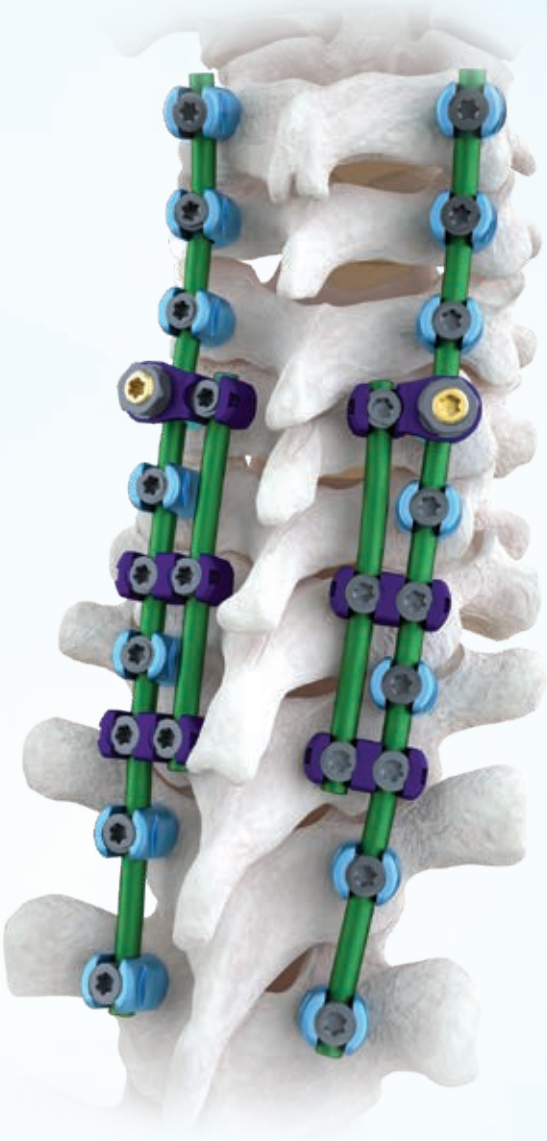

QUARTEX® ADDITION®-C

Cervico-Thoracic Complex Primary and Revision Implants

SURGICAL TECHNIQUE GUIDE

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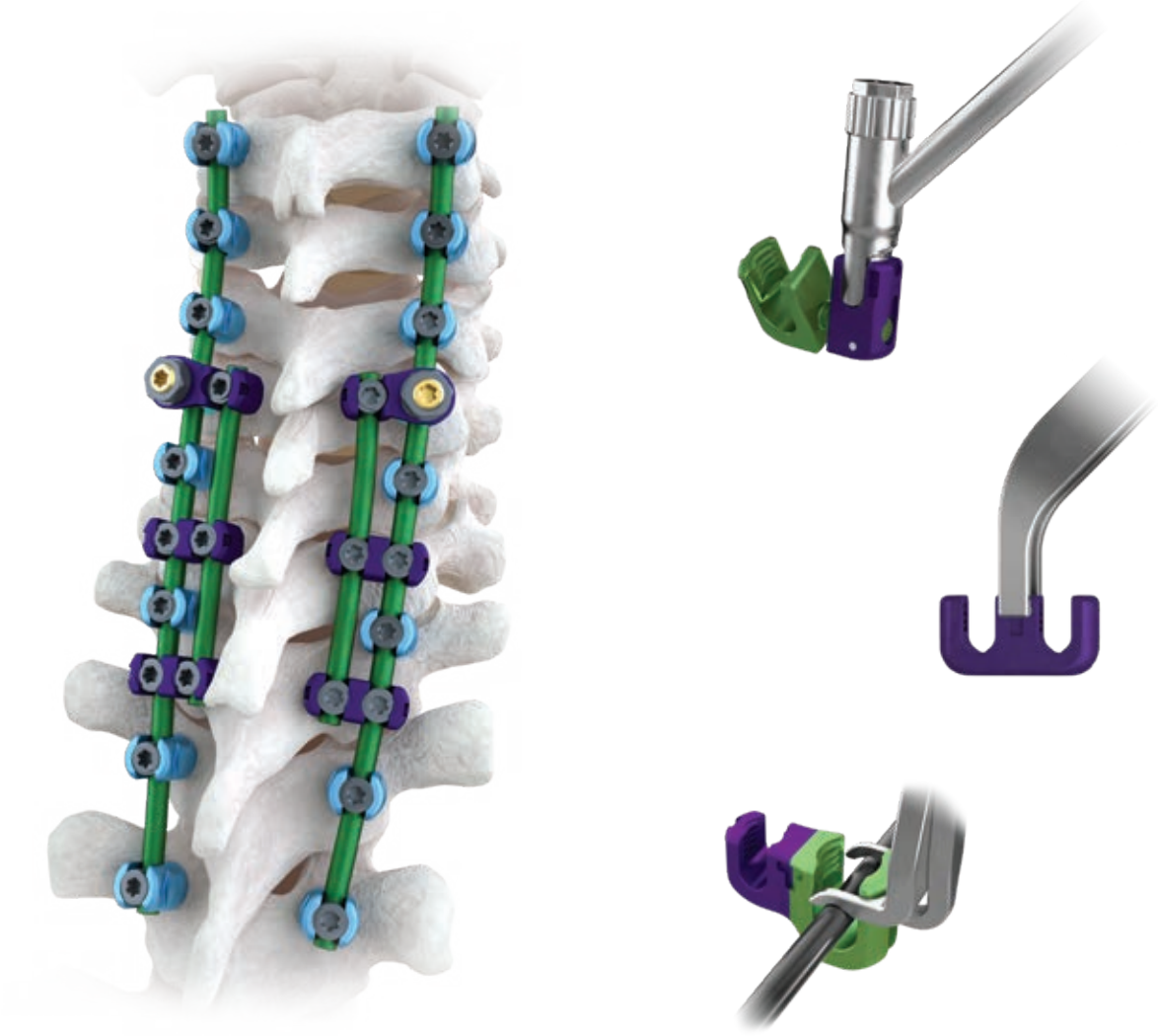
SURGICAL TECHNIQUE GUIDE

QUARTEX® ADDITION®-C

QUARTEX® ADDITION®-C

Cervico-Thoracic Complex Primary and Revision Implants

QUARTEX® ADDITION®-C offers an unparalleled portfolio of adapters to facilitate revision, deformity, and complex cervico-thoracic surgeries. QUARTEX® ADDITION®-C accommodates hardware from 3.2-6.35mm rod systems to fit individual patient needs. Designed with a robust grip, the QUARTEX® ADDITION®-C inserters securely hold the implant for complete control during difficult revision and complex deformity surgeries. The inserters feature angled handles for easy maneuvering within deep muscular walls and to keep out of the way during locking cap insertion.



IMPLANT OVERVIEW

Swivel

- Unique design translates medial-lateral and rotates cephalad-caudal to facilitate rod placement at the cervico-thoracic junction
- Reducer fits to headed feature
- QUARTEX® (cervical) head accepts 3.2-4.0mm rods
- CREO® 4.75 (thoraco-lumbar) head accepts 4.5-4.75mm rods
- CREO® Threaded (thoraco-lumbar) head accepts 5.5-6.0mm rods

Headed

- Couples parallel rods using QUARTEX® Threaded and CREO® Threaded Locking Caps
- Reducer fits to headed feature
- QUARTEX® (cervical) head accepts 3.2-4.0mm rods
- CREO® 4.75 (thoraco-lumbar) head accepts 4.5-4.75mm rods
- CREO® Threaded (thoraco-lumbar) head accepts 5.5-6.0mm rods

Zero-Run-on-Rod

- Allows for rod connection when space is limited between screw heads
- QUARTEX® Threaded Locking Cap technology
- Includes reduction feature
- Accepts 3.2-4.0mm rods

CREO AMP QUAD®

- Unique polyaxial CREO AMP QUAD® head allows ±30° of angulation
- Connects a CREO® Threaded head to a QUARTEX® head
- Allows CREO® screw shank insertion prior to head attachment
- Designed to be in-line with the lamina in the upper thoracic region
- Accepts 5.5-6.0mm rod in CREO AMP QUAD® head and 3.2-4.0mm in QUARTEX® head

Open and Closed Combinations

- Securely couple two parallel rods
- Accept 3.2-4.0mm, 4.5-5.0mm, and 5.5-6.35mm rods
- Open and closed geometry gives wide variety of connection options

Inserter Options

Pin

- Engages with implant in vertical or horizontal orientations
- Angled handle to facilitate locking and tightening, and to avoid the muscular wall during insertion
- Ratcheting forceps provide a robust connection

Threaded

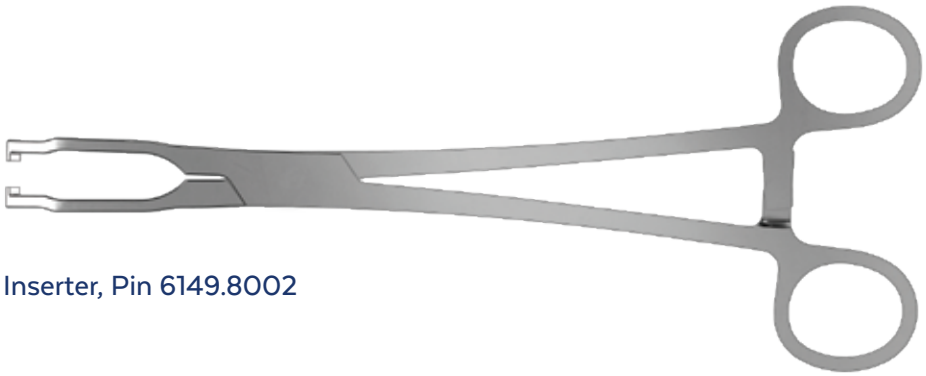
- Engages with QUARTEX® Headed and Zero-Run-on-Rod adapters
- Angled handle to facilitate locking and tightening, and to avoid the muscular wall during insertion
- Threaded tip engagement provides a robust connection to implant

Reducer

- Attaches to Swivel, Zero-Run-on-Rod, and Headed implants
- Reduces 3.2-6.35mm rods with one instrument
- Allows 5mm of reduction

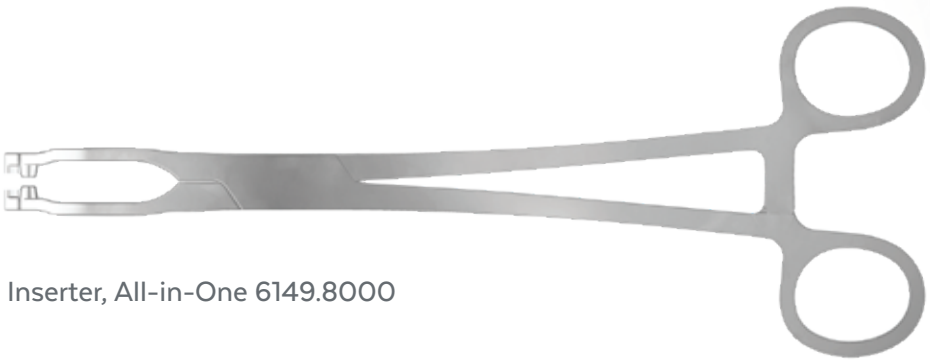
INSTRUMENT OVERVIEW

INSERTER INSTRUMENTS



Inserter, Pin 6149.8002

Inserter, Threaded 6149.8010



Inserter, All-in-One 6149.8000

Inserter, Cone 6149.8001

Items in gray are additionally available.

REDUCER

Reducer 6149.8020

FINAL TIGHTENING INSTRUMENTS

QUARTEX® Threaded Locking Cap Inserter 6149.4000

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

Nut Inserter 682.312

Torque-Limiting Quick-Connect Handle, 2.0Nm 6149.4220

Threaded Locking Cap Driver, Fixed 6120.5004

4.75 Threaded Locking Cap Driver 6067.5000

Ratcheting Torque-Limiting Handle, 8Nm, ¼" Quick-Connect 634.611

Driver Shaft, ¼" Quick-Connect, Short 6067.0050

SURGICAL TECHNIQUE

QUARTEX® ADDITION®-C

Refer to the product insert printed at the back of the technique guide for complete description, indications, contraindications, precautions, and warnings.

QUARTEX® ADDITION®-C implants are used in conjunction with QUARTEX®, CREO®, REVERE®, or ELLIPSE® screws and rods. Refer to the QUARTEX® Surgical Technique Guide (GMTGD172) for QUARTEX® screw and rod insertion. Refer to the appropriate CREO®, REVERE®, or ELLIPSE® Surgical Technique Guide for connecting to these systems. This technique provides instructions for inserting various QUARTEX® ADDITION®-C implants for primary or revision surgery.

A posterior approach is used to implant QUARTEX ADDITION-C implants.

STEP 1 PREPARATION

Remove any interfering bone. Expose the rod and levels planned for surgery.

STEP 2 IMPLANT SELECTION

QUARTEX® ADDITION®-C offers multiple options for hardware connection. Implant selection depends on the following:

- Rod diameter
- Revision approach (e.g., inline, lateral), if applicable
- Number of levels
- Available rod spacing
- Surgeon preference

Implant colors correspond with the rod diameter accepted into each side of the implant. A dual tone indicates that each side accepts different diameter rods.

Select the appropriate size adapter and insert onto the rod or into the screw with a corresponding inserter. See the chart at right for color-coding.

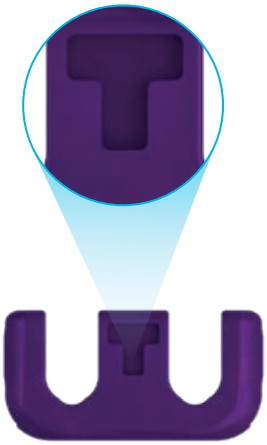
Implant Color		Rod Sizes Accepted (mm)
Purple		3.2-4.0
Light Blue		4.5-5.0
Light Blue (Headed)		4.5-4.75
Medium Green		5.5-6.0
Gold		5.5-6.35

STEP 3 IMPLANT INSERTION

A pin-style or threaded-style inserter may be used to insert the implants.

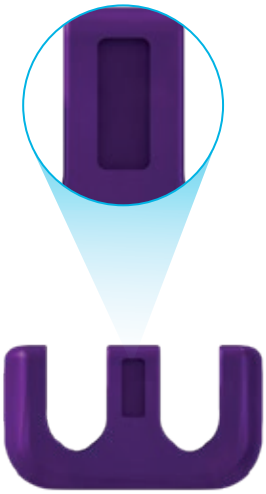
All QUARTEX® ADDITION®-C adapters have either a T-slot or vertical slot feature in the central portion of the implant.

The **Inserter, Pin** can be inserted into the T-slot either vertically or horizontally, and into the vertical slot vertically. To release the inserter from the implant, open the forceps.



T-slot

Pin oriented vertically



Vertical slot

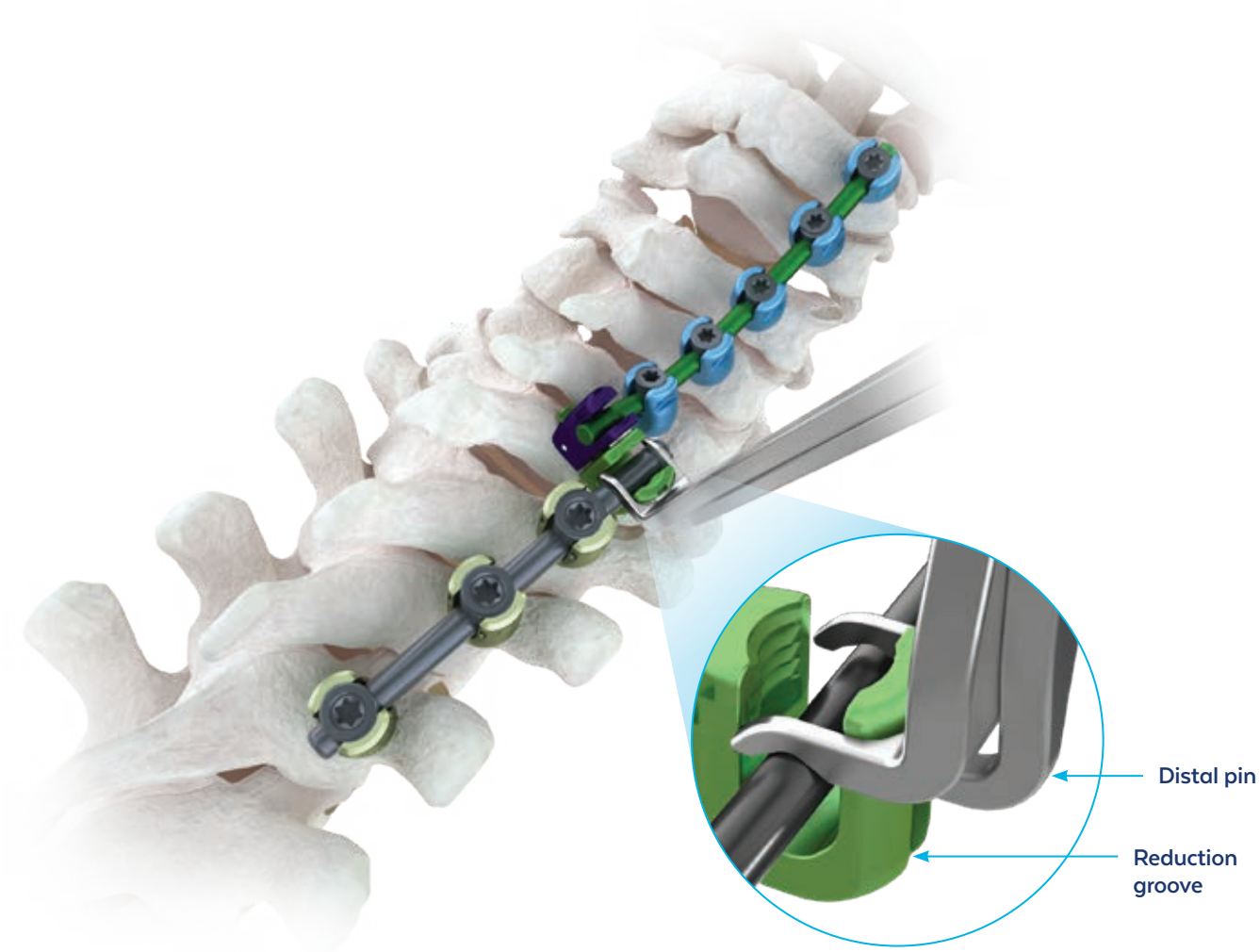
Pin oriented horizontally

IMPLANT INSERTION (CONT'D)

The **Inserter, Threaded** is used to connect with a QUARTEX® head. To load, align the prongs in the rod slots of the QUARTEX® head and rotate the knurled knob clockwise until finger-tight. Multiple drive features on the knob may be used to tighten and release the inserter from the implant, including the #15 hexalobe, #25 hexalobe, #27 hexalobe, and 8mm hex. Do not overtighten the knurled knob to avoid damaging the threads.

The **Adapter Reducer** may be used to reduce rods ranging from 3.2-6.35mm into a headed-style implant. Insert the distal pin into the rod reduction groove on the Headed connector. Compress the grip handle to reduce.

Note that the reducer is designed to seat the rod into the screw, not to bend the rod. Ensure the rod is properly contoured prior to reduction.



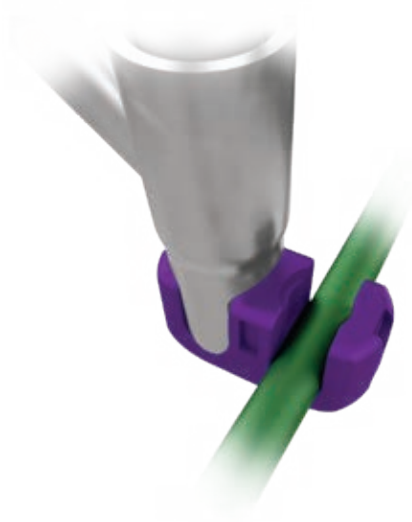
Headed Side

Select the connection point and slide the QUARTEX® head portion onto the rod. The implants may be inserted using the Inserter, Threaded. Secure by inserting and provisionally tightening a QUARTEX® Locking Cap, CREO® 4.75 Locking Cap, or CREO® Threaded Locking Cap using the corresponding cap inserter (see chart).

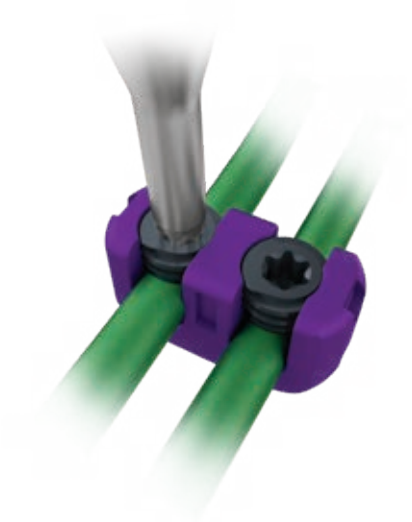
On the opposite side, insert a rod and provisionally tighten the cap or set screw using the corresponding cap inserter.

Locking Cap	Inserter Part No.	Inserter Description
QUARTEX®	6149.4000	QUARTEX® Threaded Locking Cap Inserter
CREO® 4.75	6067.5000	4.75 Threaded Locking Cap Driver
CREO® Threaded	6120.5004	Threaded Locking Cap Driver, Fixed

The construct is not completely locked until final tightening. Follow the final tightening instructions on page 16 for each type of locking cap.



Threaded inserter engaged in Headed adapter



QUARTEX® locking cap insertion

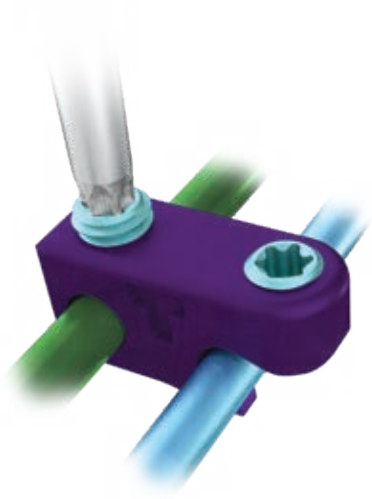
Open Side

Before insertion, ensure the set screw is not obstructing the rod slot by using the locking cap inserter to rotate the set screw counterclockwise until it stops.

Select the attachment site. Secure the open end of the implant to the rod by provisionally tightening the set screw with the Screwdriver, #15, Final Tightening, Quick-Connect and Torque-Limiting Quick-Connect Handle, 2.0Nm assembly. Final tighten all set screws using the driver and 2.0Nm torque-limiting assembly.

Closed Side

Slide the adapter opening onto the end of the rod. Provisionally tighten the corresponding set screws using the Screwdriver, #15, Final Tightening, Quick-Connect and Torque-Limiting Quick-Connect Handle, 2.0Nm assembly. Slide the adjacent rod into the remaining opening. Final tighten all set screws using the driver and 2.0Nm torque-limiting assembly.



Connector with closed and open rod sides

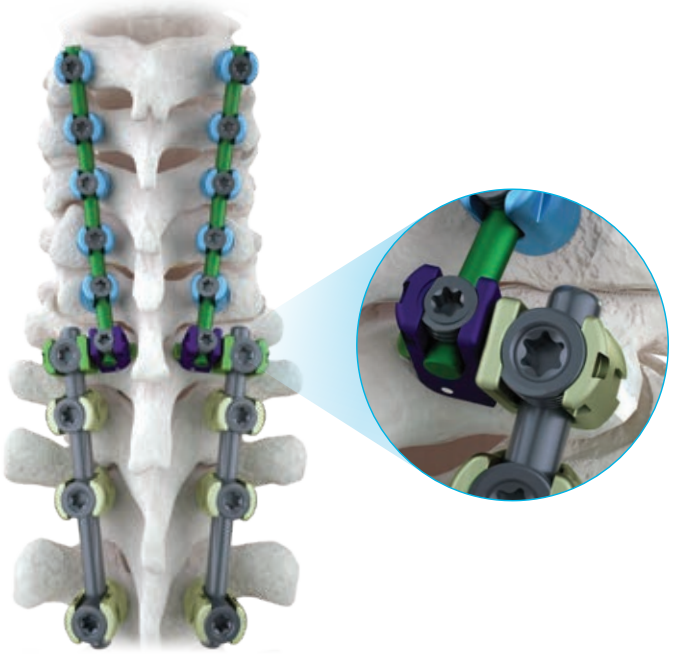
IMPLANT INSERTION (CONT'D)

Swivel Adapters

Select the connection point and slide the QUARTEX® head of the swivel adapter onto the rod. Secure by inserting and provisionally tightening a QUARTEX® Locking Cap, CREO® 4.75 Locking Cap, CREO® Threaded Locking Cap, or set screw using the corresponding cap inserter (see chart below).

On the opposite side, insert a rod and provisionally tighten with the appropriate CREO® 4.75 or CREO® Threaded locking cap using the corresponding locking cap driver.

Note that provisionally tightening the QUARTEX® headed side may lock the angulation of the adapter. Slightly loosen the locking cap to adjust angulation.



Connection Type	Locking Cap Part No.	Locking Cap Description	Final Tightening Torque
QUARTEX® Head	1149.0001	QUARTEX® Threaded Locking Cap	2.0Nm
CREO® Threaded Head	1119.0010	CREO® Threaded Locking Cap	8.0Nm
CREO® 4.75mm Head	1067.0000	CREO® 4.75 Locking Cap	8.0Nm
Open and Closed	-	Set screw	2.0Nm

The construct is not completely locked until final tightening. Follow the final tightening instructions on page 16 for each type of locking cap or set screw.

QUARTEX® locking cap insertion

CREO® Threaded locking cap insertion

Zero-Run-on-Rod Adapter

The Zero-Run-On-Rod implant is attached to a QUARTEX® polyaxial screw and an accessory rod (3.2-4.0mm diameter). **Note: 3.2mm rods are not intended for use with QUARTEX® polyaxial screws.**

Insert the posted Zero-Run-on-Rod Locking Cap into a QUARTEX® screw using the QUARTEX® Threaded Locking Cap Inserter and final tighten using the Screwdriver, #15, Final Tightening, Quick-Connect and Torque-Limiting Quick-Connect Handle, 2.0Nm assembly.

Zero-Run-on-Rod Locking Cap final tightened

Place the adapter over the posted locking cap. Insert an accessory rod (3.2-4.0mm) into the adapter.

Insert the QUARTEX® Locking Nut above the adapter onto the posted locking cap using the **Nut Inserter** to provisionally secure the adapter and insert the QUARTEX® Threaded Locking Cap into the adapter to provisionally secure the rod.

Zero-Run-on-Rod adapter with rod

Final tighten the Locking Nut using the Nut Inserter and Torque-Limiting Quick-Connect Handle, 2.0Nm. Final tighten the Locking Cap using the Screwdriver, #15, Final Tightening, Quick-Connect and Torque-Limiting Quick-Connect Handle, 2.0Nm.

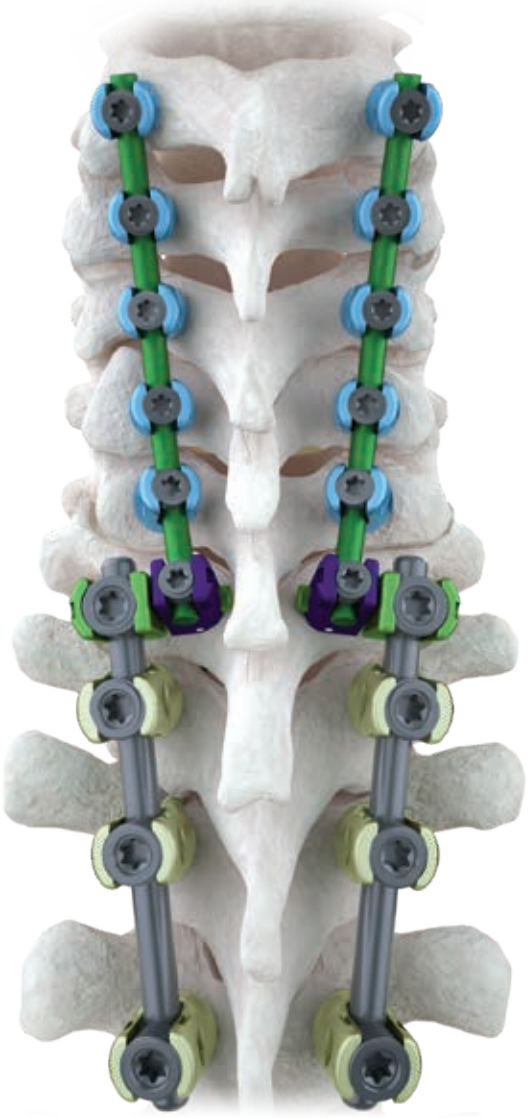
QUARTEX® Locking Cap in adapter final tightened

STEP 4 FINAL TIGHTENING

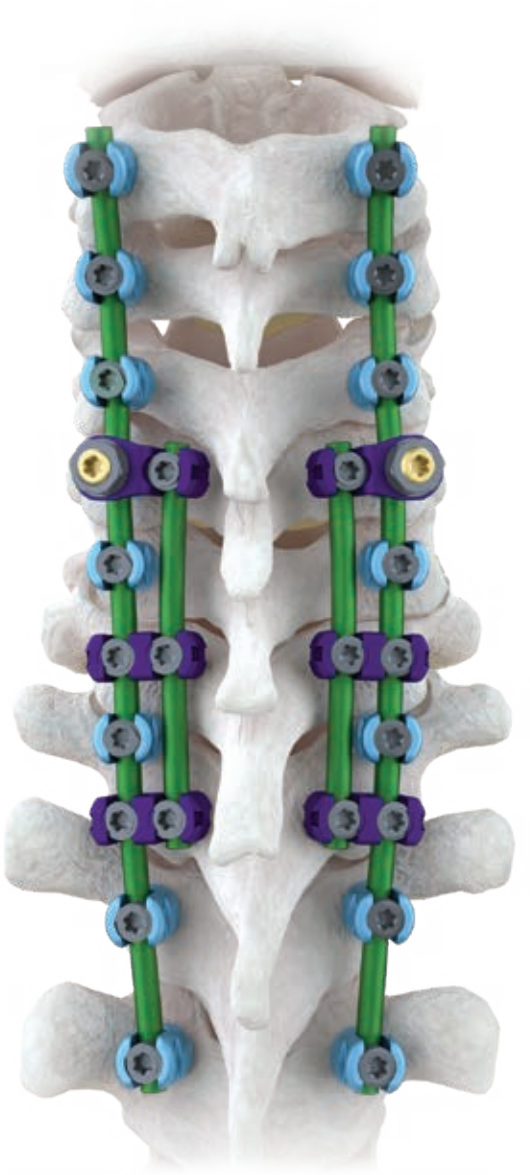
For final tightening, attach the corresponding driver and torque-limiting handle, as listed in the table below. Insert the driver into the locking cap (or set screw) and rotate the assembly until it reaches the torque limit.

Locking Cap	Final Tightening Instruments
QUARTEX® head	• Screwdriver, #15, Final Tightening, Quick-Connect • Torque-Limiting Quick-Connect Handle, 2.0Nm 
CREO® 4.75 head	• Driver Shaft, ¼" Quick-Connect, Short • Ratcheting Torque-Limiting Handle, 8Nm, ¼" Quick-Connect 
CREO® Threaded head	• Driver Shaft, ¼" Quick-Connect, Short • Ratcheting Torque-Limiting Handle, 8Nm, ¼" Quick-Connect 
Open and Closed	• Screwdriver, #15, Final Tightening, Quick-Connect • Torque-Limiting Quick-Connect Handle, 2.0Nm 

FINAL CONSTRUCTS

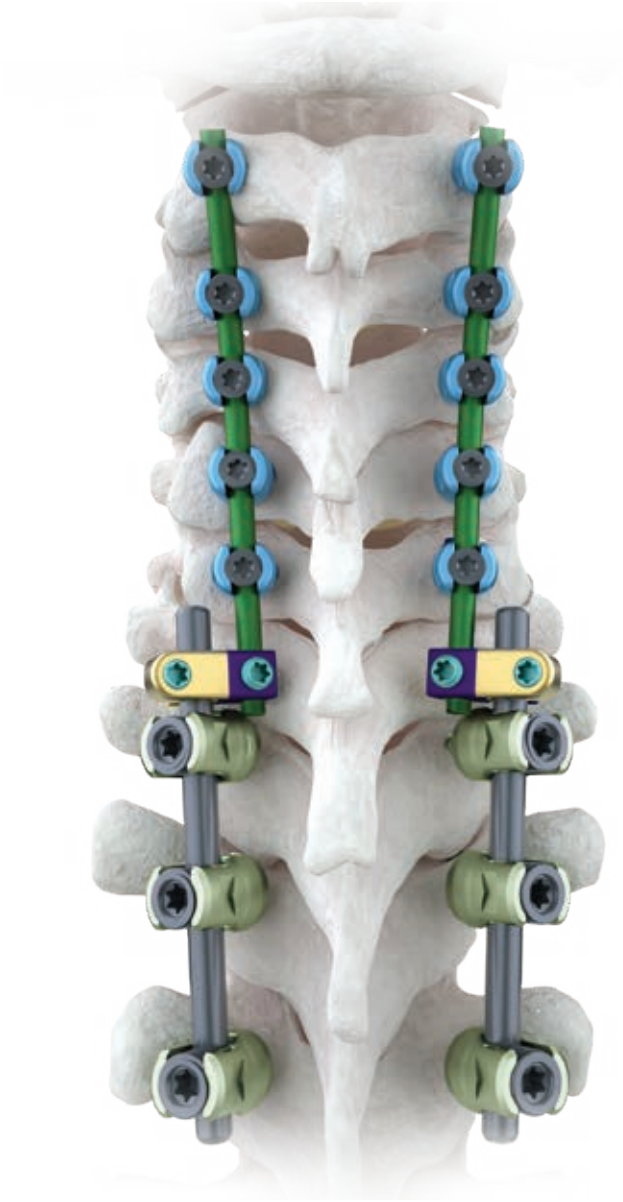


Swivel

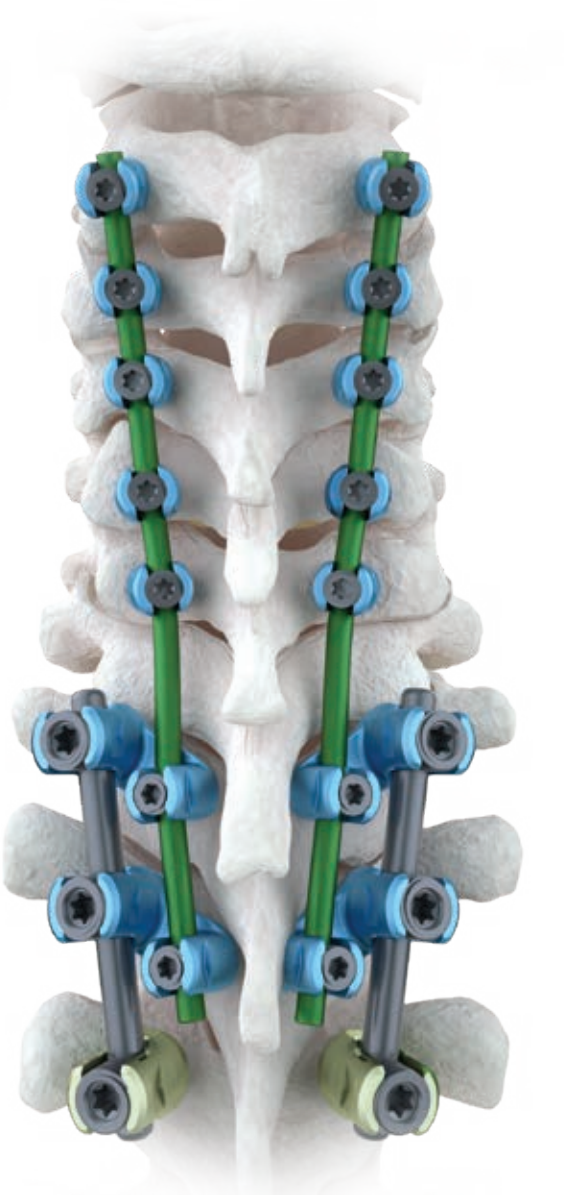


Headed and
Zero-Run-on-Rod

FINAL CONSTRUCTS (CONT'D)



Open and Closed



CREO AMP QUAD®
CREO® Threaded - QUARTEX®

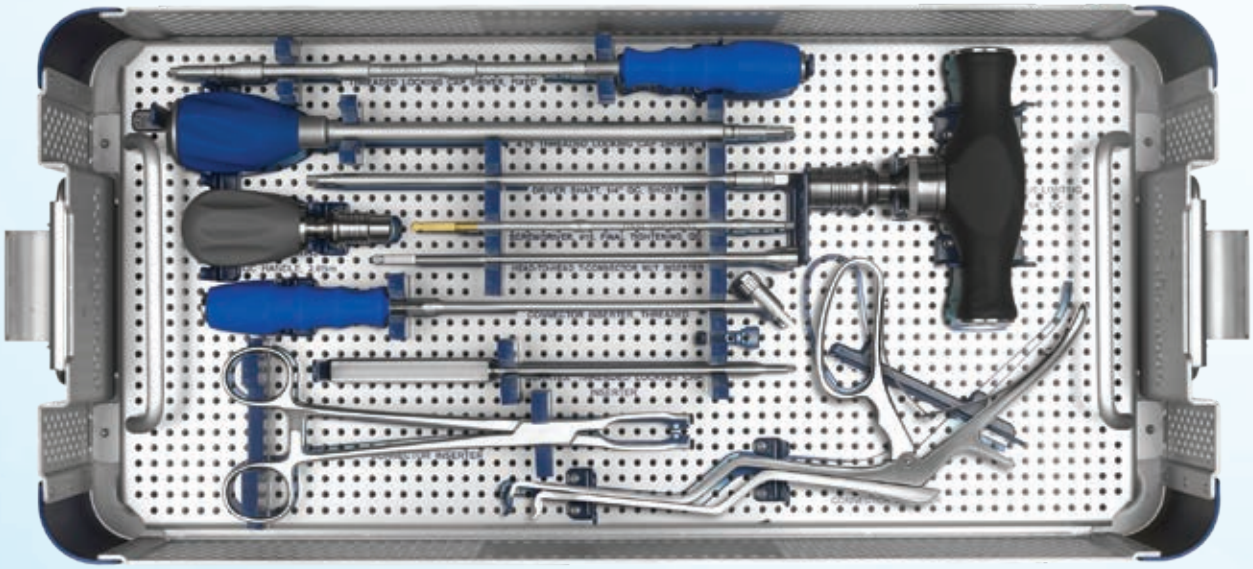
OPTIONAL: REMOVAL

For removal, reverse the insertion steps until the desired implants may be removed. Loosen all set screws with the corresponding driver. Once the set screws are loosened and the caps are removed, grasp the rod and remove from the screws or hooks. Adapters/connectors may remain connected on the rods for removal, or may be removed separately.

QUARTEX® ADDITION®-C
ADAPTER AND INSTRUMENT SET 9149.9013

Part No.	Description	Qty
1149.8500	QUARTEX® 3.2-4.0mm to QUARTEX® 3.2-4.0mm, Dual Headed Adapter	4
1149.8501	QUARTEX® 3.2-4.0mm to QUARTEX® 3.2-4.0mm, Narrow Offset, Dual Headed Adapter	4
1149.8504	QUARTEX® 3.2-4.0mm to CREO® Threaded 5.5-6.0mm, Dual Headed Adapter	4
1149.8505	QUARTEX® 3.2-4.0mm to CREO® Threaded 5.5-6.0mm, Narrow Offset, Dual Headed Adapter	4
1149.8570	Open CT 3.2-4.0mm to Open CT 3.2-4.0mm, Rod Adapter	4
1149.8571	Open CT 3.2-4.0mm to Open CT 3.2-4.0mm, Narrow Offset, Rod Adapter	4
1149.8574	Open CT 3.2-4.0mm to Open TL 5.5-6.35mm, Rod Adapter	4
1149.8575	Open CT 3.2-4.0mm to Open TL 5.5-6.35mm, Narrow Offset, Rod Adapter	4
1149.8600	Zero-Run-on-Rod Adapter	4
1149.8602	Zero-Run-on-Rod Locking Cap	4
1149.0003	QUARTEX® Locking Nut	4
1149.8650	QUARTEX® Headed to CREO® Threaded, Swivel Adapter	4
1149.0001	QUARTEX® Locking Cap	8
1067.0010	CREO® 4.75 Threaded Locking Cap	8
1119.0010	CREO® Threaded Locking Cap	8
6149.8002	Adapter Inserter, Pin	1
6149.8010	Adapter Inserter, Threaded	1
6149.8020	Adapter Lateral Reducer	1
6149.4000	QUARTEX® Threaded Locking Cap Inserter	1
6149.4200	Screwdriver, #15, Final Tightening, Quick-Connect	1
6149.4220	Torque-Limiting Quick-Connect Handle, 2.0m	1
634.611	Ratcheting Torque-Limiting Handle, 8Nm, 1/4” Quick-Connect	1
682.312	Nut Inserter	1
6067.0050	Driver Shaft, 1/4” Quick-Connect, Short	1
6067.5000	4.75 Threaded Locking Cap Driver	1
6120.5004	Threaded Locking Cap Driver, Fixed	1
9149.1130	QUARTEX® ADDITION®-C Cervical to Cervical Adapter Module	
9149.1132	QUARTEX® ADDITION®-C Cervical to 5.5-6.35mm Thoraco-Lumbar Adapter Module	
9149.1133	QUARTEX® ADDITION®-C Locking Cap Module	
9149.0013	QUARTEX® ADDITION®-C Graphic Case	

QUARTEX® ADDITION®-C
ADAPTER AND INSTRUMENT SET 9149.9013 (CONT'D)



QUARTEX® ADDITION®-C
ADAPTER AND INSTRUMENT SET 9149.9013 (CONT'D)

Additionally Available

Headed-Headed

Part No.	Description
1149.8510	QUARTEX® 3.2-4.0mm to QUARTEX® 3.2-4.0mm, Dual Headed Inline Adapter
1149.8511	QUARTEX® 3.2-4.0mm to QUARTEX® 3.2-4.0mm, Double, Dual Headed Inline Adapter
1149.8514	QUARTEX® 3.2-4.0mm to CREO® Threaded 5.5-6.0mm, Dual Headed Inline Adapter
1149.8515	QUARTEX® 3.2-4.0mm to CREO® Threaded 5.5-6.0mm, Double, Dual Headed Inline Adapter

Headed-Open

Part No.	Description
1149.8526	CREO® Threaded Headed to Open CT 3.2-4.0mm, Rod Adapter
1149.8527	CREO® Threaded Headed to Open CT 3.2-4.0mm, Narrow Offset, Rod Adapter

Headed-Closed

Part No.	Description
1149.8530	QUARTEX® Headed 3.2-4.0mm to Closed CT 3.2-4.0mm, Rod Adapter
1149.8531	QUARTEX® Headed 3.2-4.0mm to Closed CT 3.2-4.0mm, Narrow Offset, Rod Adapter
1149.8534	QUARTEX® Headed 3.2-4.0mm to Closed TL 5.5-6.35mm, Rod Adapter
1149.8535	QUARTEX® Headed 3.2-4.0mm to Closed TL 5.5-6.35mm, Narrow Offset, Rod Adapter
1149.8536	CREO® Threaded Headed to Closed CT 3.2-4.0mm, Rod Adapter
1149.8537	CREO® Threaded Headed to Closed CT 3.2-4.0mm, Narrow Offset, Rod Adapter

Closed-Open

Part No.	Description
1149.8560	Closed CT 3.2-4.0mm to Open CT 3.2-4.0mm, Rod Adapter
1149.8561	Closed CT 3.2-4.0mm to Open CT 3.2-4.0mm, Narrow Offset, Rod Adapter
1149.8564	Closed CT 3.2-4.0mm to Open TL 5.5-6.35mm, Rod Adapter
1149.8565	Closed CT 3.2-4.0mm to Open TL 5.5-6.35mm, Narrow Offset, Rod Adapter

Closed-Closed

Part No.	Description
1149.8580	Closed CT 3.2-4.0mm to Closed CT 3.2-4.0mm, Rod Adapter
1149.8581	Closed CT 3.2-4.0mm to Closed CT 3.2-4.0mm, Narrow Offset, Rod Adapter
1149.8584	Closed CT 3.2-4.0mm to Closed TL 5.5-6.35mm, Rod Adapter
1149.8585	Closed CT 3.2-4.0mm to Closed TL 5.5-6.35mm, Narrow Offset, Rod Adapter

Swivel

Part No.	Description
1149.8651	QUARTEX® Headed to Open TL 5.5-6.35mm, Swivel Adapter
1149.8652	QUARTEX® Headed to Closed TL 5.5-6.35mm, Swivel Adapter

Instruments and Module

Part No.	Description
6149.8000	Adapter Inserter, All-In-One
6149.8001	Adapter Inserter, Cone
9149.1135	QUARTEX® ADDITION®-C Auxiliary Adapter Module

QUARTEX® ADDITION®-C
4.5-5.0MM ADAPTER MODULE SET 9149.9014

Part No.	Description	Qty
1149.8502	QUARTEX® 3.2-4.0mm to CREO® 4.75, Dual Headed Adapter	4
1149.8503	QUARTEX® 3.2-4.0mm to CREO® 4.75, Narrow Offset, Dual Headed Adapter	4
1149.8572	Open CT 3.2-4.0mm to Open TL 4.5-5.0mm, Rod Adapter	4
1149.8573	Open CT 3.2-4.0mm to Open TL 4.5-5.0mm, Narrow Offset, Rod Adapter	4
1149.8653	QUARTEX® Headed to CREO® 4.75, Swivel Adapter	4
9149.1131	QUARTEX® ADDITION®-C Cervical to 4.5-5.0mm Thoraco-Lumbar Adapter Module	

QUARTEX® ADDITION®-C
4.5-5.0MM ADAPTER MODULE SET 9149.9014 (CONT'D)

Additionally Available

Headed-Headed

Part No.	Description
1149.8512	QUARTEX® 3.2-4.0mm to CREO 4.75, Dual Headed Inline Adapter
1149.8513	QUARTEX® 3.2-4.0mm to CREO 4.75, Double, Dual Headed Inline Adapter

Headed-Open

Part No.	Description
1149.8528	CREO® 4.75 Headed to Open CT 3.2-4.0mm, Rod Adapter
1149.8529	CREO® 4.75 Headed to Open CT 3.2-4.0mm, Narrow Offset, Rod Adapter

Headed-Closed

Part No.	Description
1149.8532	QUARTEX® Headed 3.2-4.0mm to Closed TL 4.5-5.0mm, Rod Adapter
1149.8533	QUARTEX® Headed 3.2-4.0mm to Closed TL 4.5-5.0mm, Narrow Offset, Rod Adapter
1149.8538	CREO® 4.75 Headed to Closed CT 3.2-4.0mm, Rod Adapter
1149.8539	CREO® 4.75 Headed to Closed CT 3.2-4.0mm, Narrow Offset, Rod Adapter

Closed-Open

Part No.	Description
1149.8562	Closed CT 3.2-4.0mm to Open TL 4.5-5.0mm, Rod Adapter
1149.8563	Closed CT 3.2-4.0mm to Open TL 4.5-5.0mm, Narrow Offset, Rod Adapter

Closed-Closed

Part No.	Description
1149.8582	Closed CT 3.2-4.0mm to Closed TL 4.5-5.0mm, Rod Adapter
1149.8583	Closed CT 3.2-4.0mm to Closed TL 4.5-5.0mm, Narrow Offset, Rod Adapter

Swivel

Part No.	Description
1149.8654	QUARTEX® Headed to Open TL 4.5-5.0mm, Swivel Adapter
1149.8655	QUARTEX® Headed to Closed TL 4.5-5.0mm, Swivel Adapter

CREO AMP QUAD® – QUARTEX®
MODULE SET 9149.9027

Part No.	Description	Qty
1149.8544	CREO AMP QUAD®, CREO® Threaded to QUARTEX®, Right	4
1149.8545	CREO AMP QUAD®, CREO® Threaded to QUARTEX®, Left	4
9149.1270	CREO AMP QUAD® Threaded Double Screw Head 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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