

# Medtronic

# YOUR TRUSTED SOLUTION. BECAUSE POSTERIOR CERVICAL SHOULD BE EASIER.



IMPLANTS DESIGNED FOR EASY CONSTRUCT CONNECTIONS



THE RIGHT TOOLS, FOR SMALL SPACES



FULLY ENABLED PROCEDURES

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# IMPLANT **FEATURES**

# **Multi-Axial Screws**

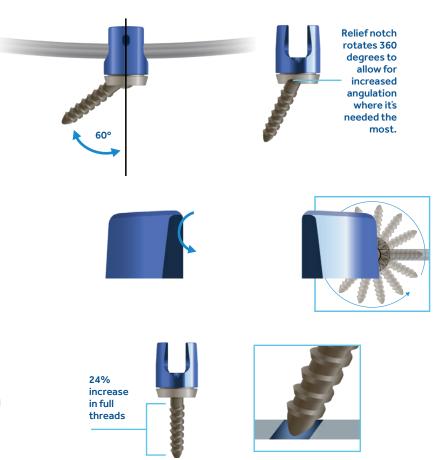
- Sixty degrees of angulation in ANY direction when positioned in notch on rotating base
- Thirty degrees of angulation in any direction when notch on base is not utilized
- Direct the additional angulation where it's needed with clear identification markers on the Increased Angle Positioner Tool
- Friction fit saddle to maintain position to facilitate rod placement and construct assembly
- Tapered tip facilitates screw insertion and location of pilot hole
- Finer thread pitch increases engagement with bone
- Increased thread run out to aid in tactile feedback at full depth of thread
- Tapered saddle base reduces profile by allowing the saddle to be positioned closer to bone
- Accepts 3.2mm and 3.5mm rods
- Variety of sizes:
  - 3.0mm × 8mm-34mm (2mm increments)\*
  - 3.5mm × 8mm-42mm (2mm increments)
  - 4.0mm × 8mm-42mm (2mm increments)
  - 4.5mm × 8mm-42mm (2mm increments)
  - 5.5mm × 15mm-40mm (5mm increments)

# **Note**

The thread spacing of the 5.5mm MAS is different from the smaller diameter screws, and is only compatible with the 5.0mm tap.

# **Partially Threaded Screws**

- Variety of diameters and lengths to accommodate unique anatomy of the C1 lateral mass
  - 3.5mm × 18mm 40mm (2mm increments)
  - 4.0mm × 18mm 40mm (2mm increments)
- Uniform 10mm of unthreaded screw shank length throughout all screw sizes



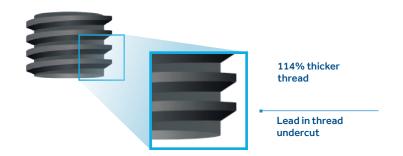




<sup>\*</sup>The 3.0mm multi-axial screw (MAS) requires the use of MAS Crosslink $^{\mathbb{M}}$  at each level in which the 3.0mm screw is intended to be used.

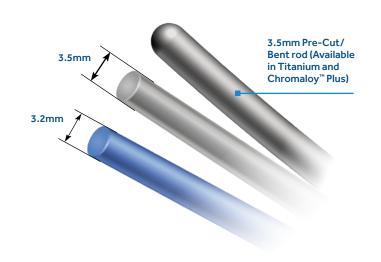
# **Locking Set Screw**

 Modified buttress thread and lead in thread undercut helps to minimizes cross threading



# Rods

- Surgeon choice of 3.2mm and 3.5mm rod diameters (Titanium and Chromaloy<sup>™</sup> Plus)
- Pre-Cut/Bent Rods in 3.5mm diameter (Titanium and Chromaloy<sup>™</sup> Plus)
- Cervical-thoracic transition rods available in various diameters in Titanium and Chromaloy™ Plus (see Cervical/Thoracic section for additional information)
- Occipital Rods available in Titanium and Chromaloy<sup>™</sup> Plus (see OccipitoCervical section for additional information)
- UNiD<sup>™</sup> Patient-Specific Cervical rods are available in 3.5mm or dual-diameter transition options (see Cervical/Thoracic section for additional information)



# **Laminar Hooks/Offset Laminar Hooks**

- Accepts 3.2mm and 3.5mm diameter rods
- Available in 4.5mm and 6.0mm openings
- Available in standard and offset designs





Laminar Hook, Standard

Laminar Hook, Offset

# **Cervical Thoracic Transition Options**

## **Offset Domino**

- Allows for medial/lateral offset of rods at the transition point
- Wide range of sizes for flexibility in construct planning. Enables connection from:
  - 3.2mm/3.5mm to 3.2mm/3.5mm
  - 3.2mm/3.5mm to 4.5mm/4.75mm
  - 3 2mm/3 5mm to 5 5mm/6 0mm

# **Open to Open Offset Domino**

- Allows for medial/lateral offset of rods at the transition point
- Open feature on both sides facilitates connection to existing rod without revising construct connections
- Wide range of sizes for flexibility in construct planning. Enables connection from:
  - 3.2mm/3.5mm to 3.2mm/3.5mm
  - 3.2mm/3.5mm to 4.5mm/4.75mm
  - 3.2mm/3.5mm to 5.5mm/6.0mm/6.35mm

## **Axial Domino**

- Allows for axial alignment of rods at the transition point
- Wide range of sizes for flexibility in construct planning. Enables connection from:
  - 3.2mm/3.5mm to 3.2mm/3.5mm
  - 3.2mm/3.5mm to 4.5mm/4.75mm
  - 3.2mm/3.5mm to 5.5mm/6.0mm
- Stepped design feature to accommodate dorsal height differences between rods
- Positive internal stop to facilitate rod assembly

# **Multi-axial Screw Extension Connector**

- Connects directly to the multi-axial screw to allow for extension of adjacent constructs without revising the existing construct
- "Zero Run on the Rod" transition option to allow for maximum fixation area
- Stepped design feature to accommodate dorsal height differences between rods
- Allows for medial/lateral offset of rods at the transition point
- Enables "dual rod" constructs at levels in which more construct rigidity is desired
- Wide range of sizes for flexibility in construct planning. Enables connection from:
  - 3.2mm/3.5mm to 3.2mm/3.5mm
  - 3.2mm/3.5mm to 4.5mm/4.75mm
  - 3.2mm/3.5mm to 5.5mm/6.0mm/6.35mm





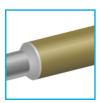




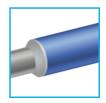
The MAS extension connectors are intended to be used with 3.5mm and larger diameter multi-axial screws. The MAS extension connectors are not intended to be used with 3.0mm screws.

# **Tapered Rods**

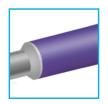
- One piece connection and allows for axial alignment of rods at the cervical-thoracic transition point
- Wide range of sizes for flexibility in construct planning:
  - Enable connection from a 3.5mm rod diameter to 4.75mm, 5.5mm, and 6.0mm rod diameters
- Available in Titanium and Chromaloy<sup>™</sup> Plus
- UNiD<sup>™</sup> Patient-Specific Cervical rods are available in 3.5mm transition options (3.5mm transitioning to either 5.5mm or 6.0mm)



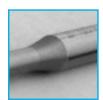
3.5mm-4.75mm Tapered rod



3.5mm-5.5 Tapered Rod



3.5mm-6.0 Tapered Rod



UNiD<sup>™</sup> Cervical Rods (dual diameter)

# **Rod Connector Options**

# **Lateral Offset Connectors**

- Allows for medial/lateral offset to accommodate nonlinear screws patterns
- Dorsal height adjustment capabilities to accommodate screw height differences
- Open, closed, and angled connector options:
  - Open and Closed lateral connectors available in:
    - 10mm, 13mm, and 19mm lengths
  - Angled lateral connector available in:
    - 19mm length
- The lateral offset connectors are intended to be used with 3.5mm and larger diameter multi-axial screws. The lateral offset connectors are not intended to be used with 3.0mm screws.







**Open Lateral Connector** 



**Closed Lateral Connector** 



**Open Angled Connector** 

# **Crosslink**<sup>™</sup> **Connector Options**

# Crosslink™ Connector, Rod to Rod Design

- Adjustable design and various sizes to accommodate varying distances between rods
- Lower profile at the apex of the crosslink arch
- Internal center set screw and ability to use the MAS Counter Torque improves screwdriver interface during final tightening of the central lock.

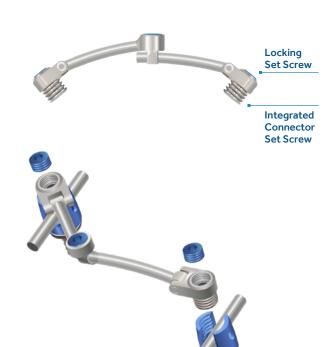
# **Crosslink™ Connector, MAS to MAS Design**

- Connects to the top of a multi-axial screw head in cases where adjacent screw heads are in close proximity to one another
- Integrated connector set screw reduces implantation steps
- Ability to attach to a different level above or below on each side of construct
- Lower profile at the apex of the crosslink arch
- Adjustable design and various sizes to accommodate varying distances between rods
- Internal center set screw and ability to use the MAS Counter Torque improves screwdriver interface during final tightening of the central lock.
- Utilizes a locking set screw to secure into position





## **Footprint**

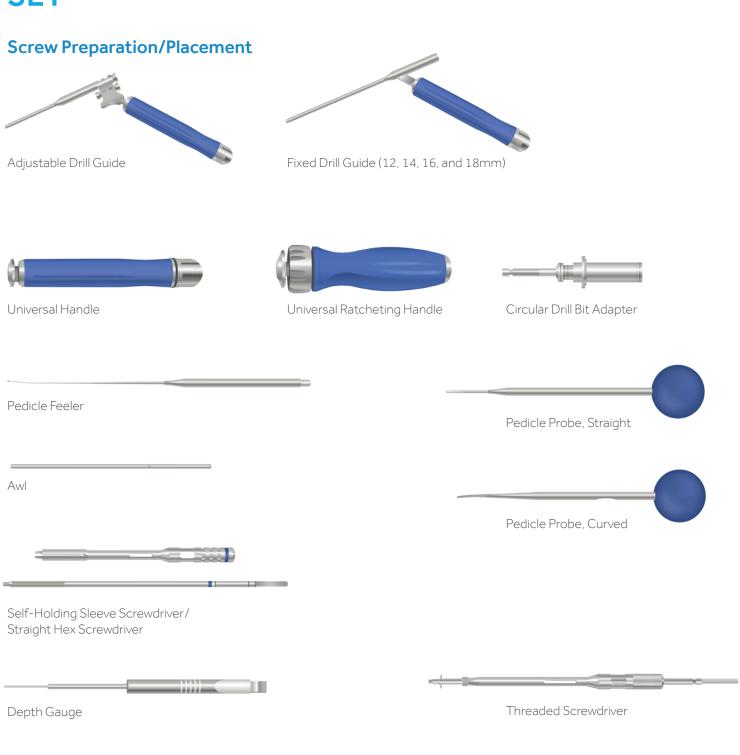


# **Crosslink™ Connector Sizing**

	Small	Medium	Large
Crosslink, Rod to Rod Design	23.5mm-30.3mm	29.5mm-40.5mm	39.5mm-56.5mm
Crosslink, MAS to MAS Design	23.5mm-30.3mm	29.5mm-40.5mm	39.5mm-56.5mm

# INSTRUMENT SET

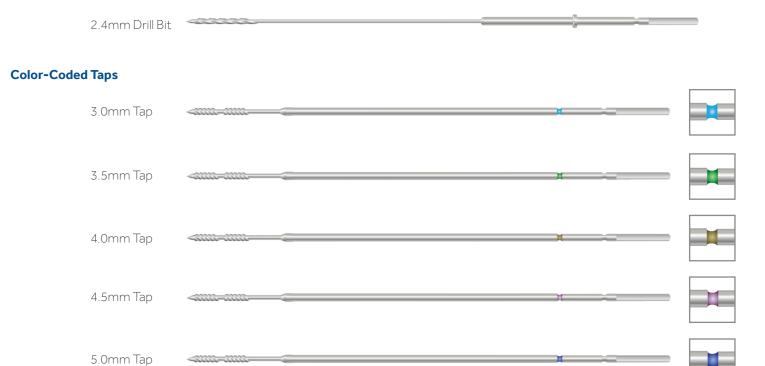
Plug Introducer



6

Self-Holding Tapered Screwdriver

# Screw Preparation/Placement continued



# Note

The 5.0mm Tap does not have a color code epoxy, to avoid confusion with the Occipital 4.5mm Tap, which does have a blue epoxy ring. Tap Sleeve not intended for 5.0mm Tap.

# Note

The 5.0mm tap should only be used with the 5.5mm MAS due to a different thread spacing with the 5.5mm MAS.

# **Color Coding Reference**

Tap Sleeve

	Screw Size	Color	Drill Bit	Тар
Infinity™ Multi-axial Screws	3.0mm × 8mm–34mm	Light Blue	2.4mm	3.0mm
	3.5mm × 8mm–42mm	Green	2.4mm	3.5mm
	4.0mm × 8mm–42mm	Gold	2.4mm	4.0mm
	4.5mm × 8mm–42mm	Magenta	2.4mm	4.5mm
	5.5mm × 15mm–40mm	Dark Blue	2.4mm	5.0mm
Infinity™ Partially Threaded Multi-axial Screws	3.5mm × 18–40mm	Green	2.4mm	3.5mm
	4.0mm × 18mm–40mm	Gold	2.4mm	4.0mm











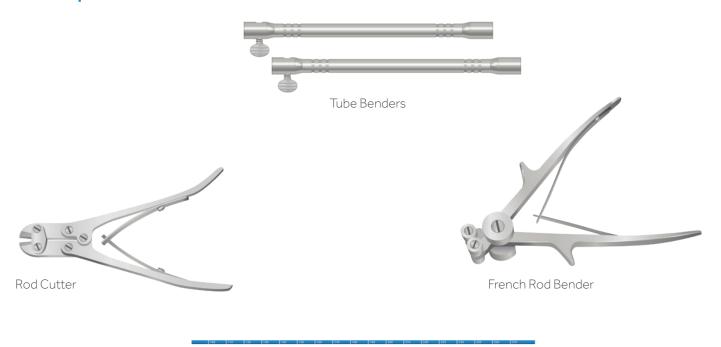
# **Hook Placement**



Laminar Elevator



# **Rod Preparation**



Rod Template

# Saddle Alignment/Rod Insertion



Increased Angled Positioner



# **Rod Reduction/Correction**





# **Final Tightening**



Torque-limiting Screwdriver

# **Alternate Final Tightening**

2.5mm Straight Hex Screwdriver

# PATIENT POSITIONING/ POSTERIOR APPROACH

The patient is placed prone in an appropriate manner to avoid specific pressure points. A midline incision is made, and dissection is carried down to the spinous processes of the appropriate vertebrae. Dissection is carried laterally to expose the facets and the transverse processes (Figure 1).



Figure 1

# MULTI-AXIAL SCREW **FIXATION**

# **Drilling**

Two drill guide designs are available for use based on surgeon preference, either the Fixed Drill Guides or the Adjustable Drill Guide.

The Fixed Drill Guides are available for drilling depths of 12mm, 14mm, 16mm, or 18mm (3606012, 6014, 6016, 6018mm, respectively).

The Adjustable Drill Guide (3606005) can be used for drilling depths of 6mm up to 40mm. The depth of the Adjustable Drill Guide can be adjusted in 2mm increments to allow for the desired drill depth that will correspond with the screw length.

To set the drilling depth of the Adjustable Drill Guide, use the index finger and thumb to press the two buttons simultaneously, and adjust the depth indicator barrel to the desired drilling depth (Figures 2 and 3). Release the two buttons and the guide will automatically lock into position. Prior to drilling, ensure lock engagement.

Attach the 2.4mm Drill Bit (G3606010) to either the Universal Handle (G850000) or the Universal Ratcheting Handle (G852402). All shafted instruments with tri-flat s can be inserted directly into the handles with a one-step insertion motion (Figure 4). Confirm connection into the handle, then insert the 2.4mm Drill Bit into the Adjustable Drill Guide to prepare for drilling (Figure 5).

# **Note**

For specific drilling trajectories for various C1-T3 screw fixation options, see Pages 33-56.

# Note

If power drilling is preferred, the tri-flat end of the drill bit can be connected to power drills with a Jacobs Chuck, or the Circular Drill Bit Adapter (6905715) can be used to convert the tri-flat to an AO connection.



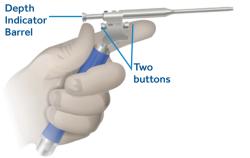


Figure 2



Figure 3



Figure 4



Figure 5

# **Tapping (Optional)**

Infinity™ Multi-axial Screws are self-tapping; therefore, this surgical step is considered optional. If tapping is desired, attach the appropriate size tap to either Universal Handle (G850000) or the Universal Ratcheting Handle (G852402). See the color code and sizing chart on page 8 to determine the appropriate size tap. Use the thread section indicators on the distal end of the tap to monitor the depth of tap in bone (Figure 6). The first section of threads represents 10mm of depth. The second section of threads starts at 14mm and ends at 25mm. The tap can be used to tap up to 42mm.

The trajectory of the tap should follow the same trajectory as outlined for drilling. For specific trajectories for various C1-T3 screw fixation options, see Pages 34 to 56. For illustration purposes, tapping is shown here for a C1 lateral mass screw (Figure 7).

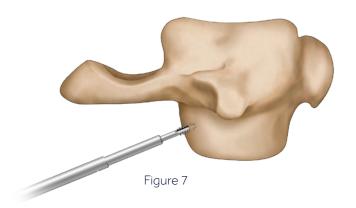
## **Note**

The Tap Sleeve (3606032) can be used for soft tissue protection. To use the Tap Sleeve, place it over the tri-flat end of the tap and allow it to dock on the bone.

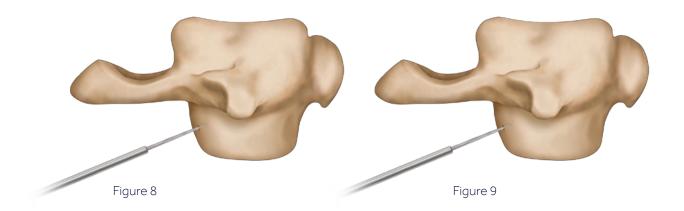
# **Screw Measurement**

The Pedicle Feeler (3602102) may be used to gently palpate the screw hole to assure no breach (Figure 8). The Depth Gauge (6956020) may be used to determine the appropriate screw length (Figure 9).









# **Screw Insertion**

Once the desired screw length is selected, engage the screw using one of the three screwdriver options:

- Self-Holding Tapered Screwdriver (3605772)
- Threaded Screwdriver (3606195)
- Self-Holding Sleeve Screwdriver
  - The Self-Holding Sleeve Screwdriver comprises the Sleeve (3606194) and the Straight Hex Screwdriver (3606193). This is indicated by the blue epoxy ring located on both of these instruments (Figure 10).
  - Place the Sleeve over the tri-flat end of the Straight Hex Screwdriver.
  - Attach the Sleeve/Straight Hex Screwdriver combination to either the Universal Handle (G850000) or the Universal Ratcheting Handle (G852402) and confirm connection (Figure 11).
  - Align and insert the Straight Hex Screwdriver into the bone screw hex (Figure 12).
  - Slide the sleeve down into the saddle rod slot to retain the screw (Figure 13).
  - After the bone screw has been inserted, pull the Sleeve upward to release and disengage the screw (Figure 14).

# Note

When inserting the multi-axial screw, do not bottom out the saddle onto the bone, as the saddle will tilt, and the driver may wedge and become difficult to disengage.

# **Note**

If the screwdriver becomes difficult to disengage, back the screw out a quarter turn to free the saddle from the bone.



Figure 12 Figure 13



### Threaded Screwdriver





Self-Holding Sleeve Screwdriver



Figure 10



Figure 11

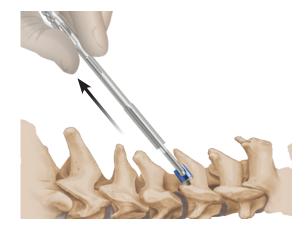


Figure 14

# MULTI-AXIAL SCREW **ALIGNMENT**

After all the screws have been placed, various tools are available to assist in aligning the MAS saddles to facilitate rod placement.

# 1) Alignment Tool (3605785)

Place the tool into the rod slot of the saddle and rotate into desired position (Figure 15). If additional angulation is required, see next step.

## Note

Friction within the saddle will maintain position after adjustments have been made.



When patient anatomy requires challenging screw trajectories and presents the need for additional angulation of the screw, the Infinity™ MAS has the ability to angulate up to 60 degrees in ANY direction, when positioned in the notch located on the underside of the base. The base rotates independently of the saddle, thus enabling the notch to be positioned in 360 degrees of rotation.

The triangle at the distal end of the IAP indexes with the screw to locate the notch (Figure 16).





Figure 15

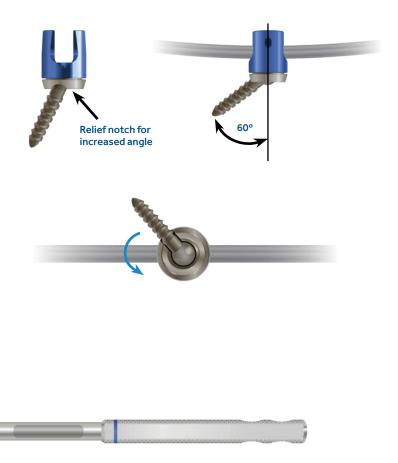


Figure 16

To use the IAP to locate the notch, position the instrument in the MAS saddle and rotate the knurled handle portion clockwise using a light finger grip motion until the IAP engages the screw (Figure 17). An audible click and/or tactile "drop" will indicate engagement. Note that this could require a full rotation of the instrument before engagement occurs.

# Note

No downward pressure is required, rather the weight of the instrument will facilitate engagement.

Once engaged, the FLAT portion on the knurled handle (with the blue ring) and the laser etched arrow on top of the handle serve as visual indicators of the position of the notch on the underside of the base (Figure 18).



Figure 17



Figure 18

The FLAT portion of knurled handle (with the blue ring) and the arrow on the top of the handle indicate the position of the notch on the underside of the saddle base.

Rotate handle and use the indicators to position the notch into the direction of the screw trajectory until the saddle is in the desired position.

While rotating handle toward the screw trajectory, simultaneously use slight pressure to move the handle in a "gearshift" type motion, so that the notch falls into position over the bone screw (Figure 19).

# Note

The spinal anatomy around the screw should be taken into consideration, as it may limit ability to achieve maximum angulation.

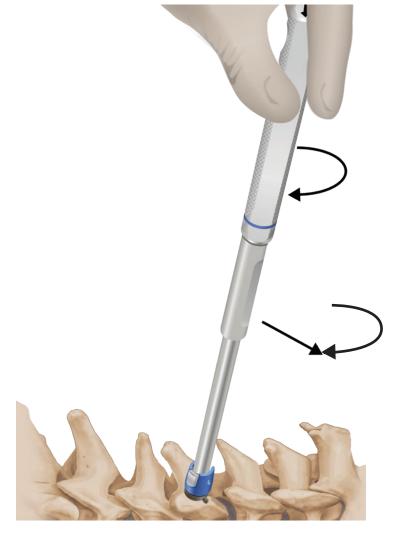
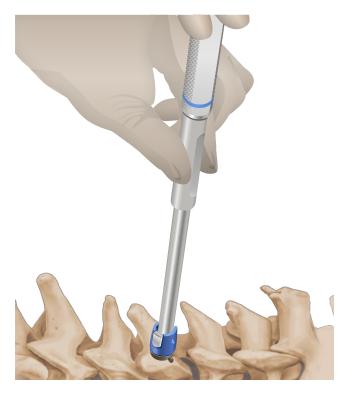


Figure 19

Once desired angulation is achieved, the middle portion ("sleeve") of the IAP can be used to rotate the saddles and align the rod slots prior to rod placement (Figures 20 and 21).

# Note

Friction within the saddle will maintain position after adjustments have been made.





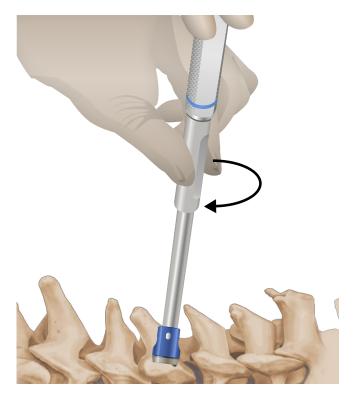


Figure 21

# LAMINAR HOOK **PLACEMENT**

When using Laminar Hooks in the cervical and upper thoracic spine, lamina preparation and ligamentum flavum dissection are performed using the Laminar Elevator (6956158) (Figure 22).

If desired, dissection may also be achieved using a hook in the Hook Holder (3606160).

The appropriate hook is selected based on the thickness of the lamina and placed at the desired position (Figure 23).





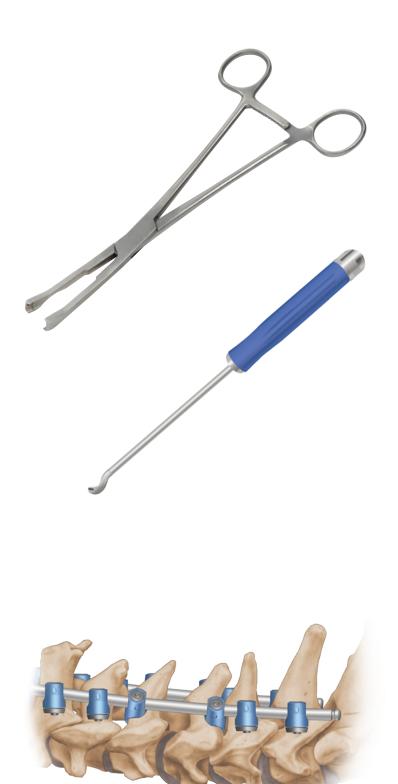


Figure 23

# ROD **SELECTION**

Straight rods are available in 3.2mm and 3.5mm diameters, in both Titanium and Chromaloy™ Plus.

Pre-Cut/Bent rods are available in 3.5mm Titanium and 3.5mm Chromaloy™ Plus.

Pre-Cut/Bent rods may reduce the surgical steps associated with measuring, cutting, and bending straight rods (Figure 24).

Cervical Thoracic Tapered Rods and Occipital Rods are described in the Cervical Thoracic and Occipital Cervical Sections of this technique.

UNiD<sup>™</sup> Patient Specific rods are available in 3.5mm Titanium and Cobalt Chrome.

# ROD **TEMPLATING**

The Rod Template (7757270) is used to determine the curvature and length of the rod needed based on the screw or hook positions (Figure 25).

Fit the Rod Template into the desired area and mold into proper shape. Remove the template and use to shape the rod to match.

# Note

The Rod Template has markings that can help determine the appropriate length of the entire construct (Figure 26).

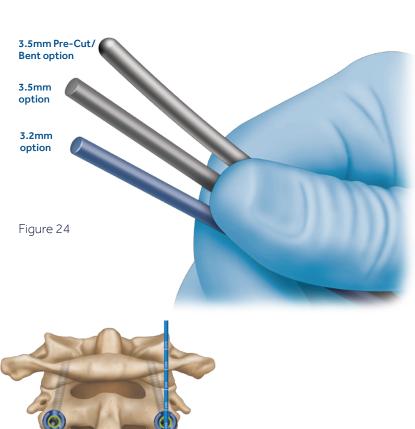




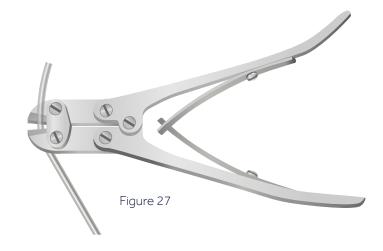
Figure 26

# ROD **CUTTING**

Use the Rod Cutter (6905784) to cut the rod to the desired length (Figure 27).

# Note

Use caution to secure both ends of the rod during cutting.



# ROD **BENDING**

Contour the rod to the sagittal contour of the spine and the medial/lateral orientation of the implants using either the French Rod Bender (3605782) (Figure 28).

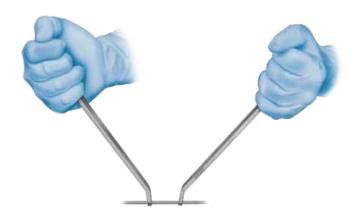
# Note

Avoid repeated or reverse bending motions to the implants, as excessive bending will decrease the integrity of the implant.

If in situ bending is needed, the rod can be contoured in the sagittal plane with the Left and Right Sagittal Bending Irons (3606290 and 3606291) (Figure 29) and in the medial/lateral plane with the Left and Right Coronal Benders (7756197L and 7756198R) (Figure 30).



Figure 28





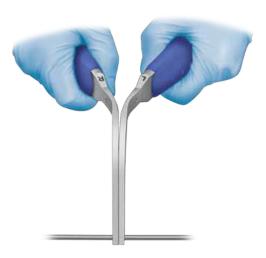


Figure 30

# USING LATERAL OFFSET CONNECTORS

If additional medial/lateral offset is required, beyond the 60 degrees of angulated, Lateral Connectors can facilitate rod attachment of the non-linear screws patterns and can adjust for screw height differences.

Closed Lateral Connectors are provided for placement before rod insertion (Figure 31), and Open Lateral Connectors are side loading to accommodate placement before or after rod insertion (Figure 32). Closed-ended Lateral Connectors and Open-ended Lateral Connectors are available in various lengths.

Provisionally tighten the set screw on the lateral connector to prevent migration on the rod by using the Self-Holding Screwdriver (3605772) with the Universal Handle (G850000) or the Plug Introducer (7756241).

All Lateral Connectors can be final tightened using the Torque-limiting Screwdriver (3606201) and Torque-limiting T-Handle (G851100) in conjunction with the Universal Rod Pusher/Counter Torque (3606172) (Figure 33).

# Note

The lateral offset connectors are intended to be used with 3.5mm and larger diameter multi-axial screws. The lateral offset connectors are not intended to be used with 3.0mm screws.



Featuring RodSync Technology with 60 degrees of angulation, the Infinity™ MAS provides 8.7mm of medial / lateral offset without the use of lateral connectors.

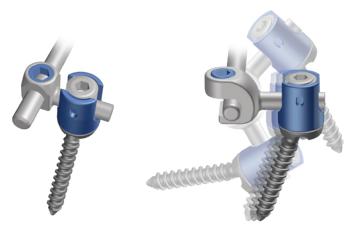
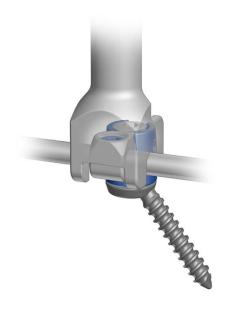


Figure 31 Figure 32



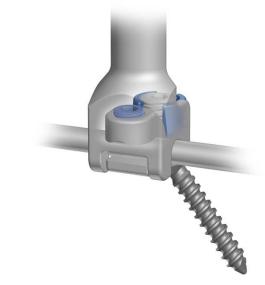


Figure 33

# ROD **PLACEMENT**

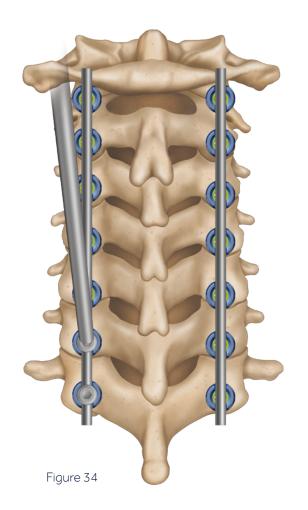
Place the rod into the implant heads using the Rod Holder (6905774).

With the rod fully seated in the screw heads, a set screw can be loaded onto the Self-Holding Screwdriver (3606194) or the Plug Introducer (7756241) and provisionally tightened into each screw head (Figure 34).

# Note

If a MAS Crosslink<sup>™</sup> Connector or a MAS Extension Connector will be used, a separate assembly is required and use of a standard set screw at the chosen level is not needed during this procedural step. Refer to the MAS Crosslink<sup>™</sup> Connector and MAS Extension Connector section for more information.





# ROD **REDUCTION**

If the rod is not easily captured in the screw head, the Rod Rocker (3606167) or Rod Reducer (3606175) can be used to fully seat the rod and facilitate set screw introduction.

To use the Rod Rocker, place over the rod and grasp the screw head reduction slots (Figure 35a). Gently squeeze and tilt the Rod Rocker to reduce the rod into the screw saddle (Figure 35b).

To use the Rod Reducer, place it over the rod and grasp the screw head reduction slots from above. As the handle is squeezed, the Rod Reducer sleeve will slide down and seat the rod).

To secure the rod, load a set screw onto the Self-Holding Tapered Screwdriver (3605772) and Universal Handle (G850000) or the Plug Introducer (7756241), and insert through the Rod Reducer or Rod Rocker into the MAS saddle and provisionally tighten to hold the rod in place (Figures 36a, 36b, and 36c).

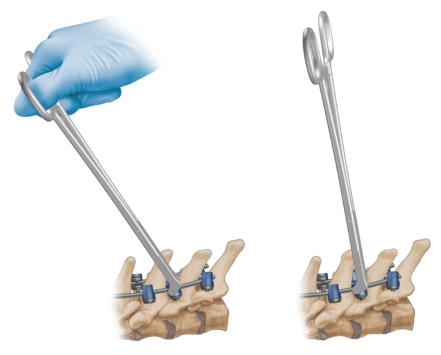


Figure 35a

Figure 35b



Figure 36b

Figure 36c

# COMPRESSION AND DISTRACTION

Once the rod is provisionally secured into the implants, distraction and/or compression may be performed to place the implants in the final position using the Distraction Forceps (G602050) and Compression Forceps (G601050). Once distraction and/or compression is achieved, tighten set screws to maintain position (Figure 37).

A Rod Gripper (6956163) is also included for additional rod manipulation (Figure 38).



Figure 37



# FINAL TIGHTENING

After the compression and distraction maneuvers are complete, all set screws should be final tightened using the Torque Limiting Driver (3606201) and Torque Limiting Handle (G851100 with Gray Handle) in conjunction with the MAS Rod Pusher/Counter torque (3606170) or the Universal Rod Pusher/Counter Torque (3606172) (Figure 39).

The MAS Rod Pusher/Counter Torque is for use on the MAS saddles and crosslink central lock set screw (see the following section on crosslink implantation for more information).

The Universal Rod Pusher/Counter Torque is for use on all other implants in the construct.

# Note

Use the 5.5mm Rod Pusher / Counter Torque to final tighten set screws in all 5.5mm MAS.

Care should be taken to fully engage Hex driver prior to final tightening.

## Note

Care should be taken not to inadvertently depress the torque limiting handle release mechanism during handling.

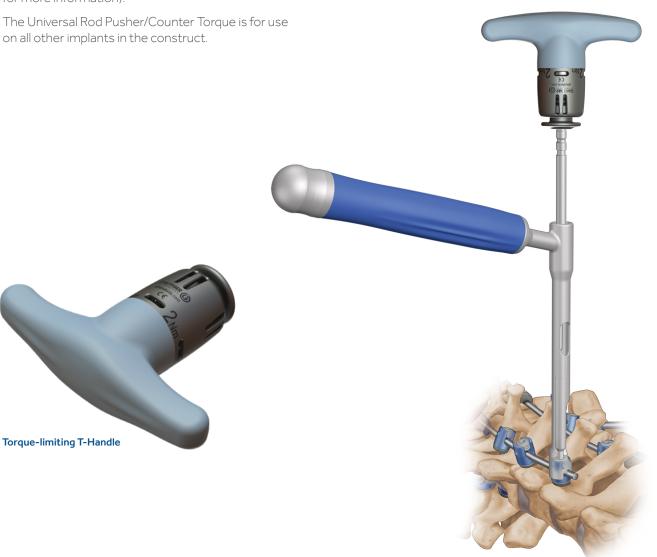


Figure 39

# CERVICAL THORACIC ROD TRANSITION OPTIONS

Rod transition options allow for a transition from the cervical to the thoracic spine or at any location where it is necessary to move from a smaller rod diameter to a large rod diameter.

Various designs are available depending on the alignment and anatomical requirements.

- Tapered Rods
- Offset Dominos
- UNiD<sup>™</sup> Patient Specific Rods
- Open to Open Offset Dominos
- Axial Dominos
- Multi-axial Screw Extension Connectors
  - Refer to the following section for special implantation instructions for the MAS Extension Connector.

All set screws of the rod transition options can be final tightened using the Torque-limiting Driver (3606201) and Torque-limiting Handle (G851100) in conjunction with the Universal Rod Pusher/Counter Torque (3606172).

## Note

During all final tightening steps, care should be taken not to inadvertently depress the torque limiting handle release mechanism during handling.









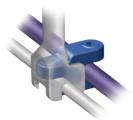
**Tapered Rod** 





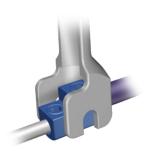
**Offset Dominos** 



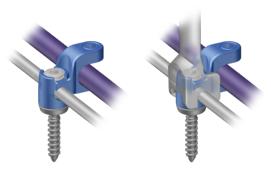


Open to Open Offset Domino





**Axial Domino** 



Multi-Axial Screw (MAS) Extension Connector

# USING THE MULTI-AXIAL SCREW (MAS) EXTENSION CONNECTOR

The MAS extension Connector will allow for a "zero run on the rod" transition option between various rod diameters by connecting directly to the head of a multi-axial screw. It also will allow for dual rod constructs, as well as extension of a previous construct by connecting directly on an existing multi-axial screw saddle.

Select the appropriate size connector based on the desired connecting rod diameter. Position the MAS Extension Connector over the lateral side of the MAS saddle and insert the connector into the rod slot (Figure 40).

While holding the MAS Extension Connector in place, provisionally tighten a set screw into the saddle using either the Self-Holding Tapered Screwdriver (3605772) and Universal Handle (G850000) or the Plug Introducer (7756241) (Figure 41). The Universal Rod Pusher/Counter Torque (3606172) can be used for seating the rod to aid in set screw insertion.

Final tighten the set screw using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100) in conjunction with the Universal Rod Pusher/ Counter Torque (3606172) (Figure 42).

Insert the desired connecting rod into the lateral opening of the MAS Extension Connector. Final tighten the set screw on the lateral arm of the MAS Extension Connector to lock the rod in place, using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100) with the Universal Rod Pusher/Counter Torque positioned over the MAS saddle (Figure 43).

# Note

An alternative technique would be to pre-load the connecting rod into the MAS Extension Connector prior to placement of the connector in the MAS saddle.

## Note

The MAS extension connectors are intended to be used with 3.5mm and larger diameter multi axial screws. The MAS extension connectors are not intended to be used with 3.0mm screws.

## **Note**

During all final tightening steps, care should be taken not to inadvertently depress the torque limiting handle release mechanism during handling.



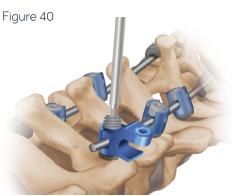


Figure 41

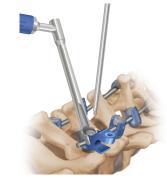




Figure 42



Figure 43

# CROSSLINK™ CONNECTOR **OPTIONS**

Once decortication is thoroughly performed and bone graft material is placed, Crosslink Connectors are recommended for the top and bottom thirds of the construct to increase rigidity. Two Crosslink Connector designs are available, the MAS Crosslink Connector and the Rod Crosslink Connector.



MAS Crosslink™ Connector



Rod Crosslink™ Connector



The Rod Crosslink  $^{\text{\tiny M}}$  Connector enables connection directly on the rod.

Before positioning the crosslink on the rods, it may be helpful to provisionally tighten the center set screw using the Self-Holding Tapered Screwdriver (3605772) and Universal Handle (G850000) or the Plug Introducer (7756241) in order to hold the crosslink in the desired position during implantation.

After placing the crosslink on the rods, final tighten both crosslink locking set screws using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100) in conjunction with the Universal Rod Pusher/Counter Torque (3606172) (Figure 44).

Final tighten the center set screw using the Torque-limiting Driver (3606201) and Torque-limiting Handle (G851100) in conjunction with the MAS Rod Pusher/Counter Torque (3606170) (Figure 45).

# Note

During all final tightening steps, care should be taken not to inadvertently depress the Torque Limiting Handle release mechanism during handling.



Figure 44



Figure 45

# MULTI-AXIAL SCREW (MAS) CROSSLINK™ CONNECTOR PLACEMENT

The MAS Crosslink™ Connector has the ability to connect directly to the head of two multi-axial screws in cases where adjacent screw heads are in close proximity to one another, as well as the ability to span various levels.

Before positioning the MAS Crosslink™ Connector on the rods, it may be helpful to provisionally tighten the center set screw using the Self-Holding Tapered Screwdriver (3605772) and Universal Handle (G850000) or the Plug Introducer (7756241) in order to hold the Crosslink in the desired position during implantation.

To use the MAS Crosslink<sup>™</sup>, first place two Plug Introducers (7756241) into each of the two lateral set screws of the Crosslink (Figure 46).

While holding the crosslink in slight tension and in the fully extended position with the Plug Introducers, lower one side of the Crosslink into a MAS saddle and provisionally tighten the internal Crosslink set screw (Figure 47).

Figure 46

## Note

Applying tension will minimize motion of the Crosslink during installment

After the first internal set screw has been placed, lower the opposite side and provisionally tighten the second internal Crosslink set screw into the contralateral MAS saddle (Figure 48).

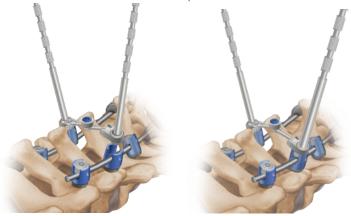
Remove the Plug Introducers, and final tighten both internal crosslink set screws using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100) in conjunction with the Universal Rod Pusher/ Counter Torque (3606172) (Figure 49).

## Note

During all final tightening steps, care should be taken not to inadvertently depress the torque limiting handle release mechanism during handling.

## Note

As an alternative technique for challenging anatomies and screw proximities, the MAS Counter Torque could be placed on the adjacent rod segment above or below the Crosslink to counter torque the construct.



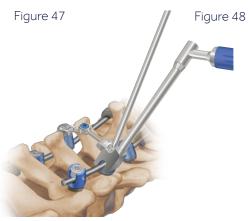


Figure 49

# INFINITY™ OCCIPITOCERVICAL-UPPER THORACIC SYSTEM MULTI-AXIAL SCREW (MAS) CROSSLINK™ CONNECTOR PLACEMENT

Insert a MAS Crosslink Locking Screw into the crosslink and provisionally tighten using the Self-Holding Screwdriver (3605772) and Universal Handle (G8500000) or the Plug Introducer (7756241) (Figure 50).

Final tighten both crosslink locking set screws using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100 with Gray handle) in conjunction with the Universal Rod Pusher/ Counter Torque (3606172) (Figure 51).

Once the crosslink is in position, final tighten the center set screw using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100) in conjunction with the MAS Rod Pusher/Counter Torque (3606170) (Figure 52).

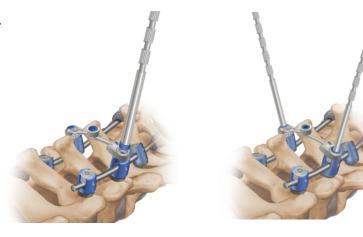


Figure 50 Figure 51

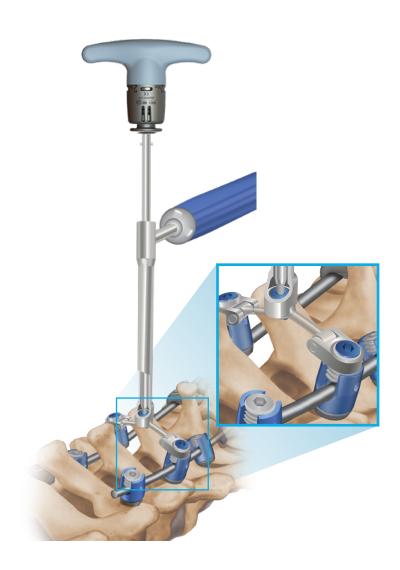


Figure 52

# Note

During all final tightening steps, care should be taken not to inadvertently depress the torque limiting handle release mechanism during handling.

# FINAL CONSTRUCT **ASSEMBLY**

# **Decortication and Fusion Bed Prep**

After implants have been placed, and alignment/correction of the spine has been achieved, prepare the fusion bed by decorticating the posterior cervical elements.

# **Bone Graft Preparation**

There are multiple biologics solutions available for posterior cervical fusions, based on surgeon preference of pre-formed or moldable mixable bone graft extenders, construct demands, and procedural levels involved. The following is a list of recommended biologics options:



Magnifuse™ Bone Graft



Mastergraft™ Matrix EXT







Grafton™ DBF



Mastergraft<sup>™</sup> Putty

Retain locally recovered autograft or autograft recovered from a second site.

Lay the autograft bone on top of the decorticated surfaces. Pack well and ensure there are no gaps in the bone graft.

Prepare the bone graft extender according to its instructions for use.

Place prepared bone graft on top of the autograft.

Retain locally recovered autograft or autograft recovered from a second site.

Prepare the bone graft extender according to its instructions for use.

Mix locally recovered bone graft with autograft and create a homogenous mix of autograft and bone graft extender.

Place composite graft mix on decorticated surfaces. Pack well and ensure there are no gaps in the bone graft.

Refer to the Magnifuse<sup>™</sup> Bone Graft, Mastergraft<sup>™</sup> Matrix EXT, Grafton<sup>™</sup> DBF, or Mastergraft<sup>™</sup> Putty Instructions for Use Manuals for further product information.

# **Final Construct**

An intraoperative image of the final construct should be made to verify proper connection is achieved. Confirm all connections prior to wound closure (Figure 53).



Figure 53

# **Explantation**

To remove any of the Infinity<sup>™</sup> System implants described throughout this technique, engage the set screw with the 2.5mm Straight Hex Screwdriver (3606193) and turn counterclockwise until the set screw is disengaged from the implant. Use 2.5mm Straight Hex Screwdriver (3606193) or the Threaded Screwdriver (3606195) to remove the bone screw.

C1-T3 SCREW
FIXATION
TECHNIQUES
ENTRY POINTS,
SCREW
TRAJECTORIES,
AND FINAL
SCREW
POSITIONING

# C1 LATERAL MASS SCREW FIXATION

#### **Pre-Operative Planning**

When placing C1 lateral mass screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C1 lateral mass screw fixation as described by Harms and Melcher.<sup>1,2</sup>

#### **Determining Entry Points**

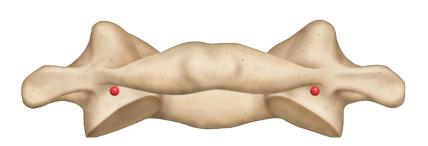
The dorsal root ganglion of C2 must be carefully retracted caudally to expose the starting point for the C1 lateral mass screw.

The entry point is the middle of the junction of the C1 posterior arch and the midpoint of the posterior inferior part of the C1 lateral mass (Figure 55). An indentation should be made at this entry point so that the drill bit will have a starting point and not skive off the bone.



Posterior View of C1

Figure 54



Posterior view of C1

Figure 55

# C1 LATERAL MASS SCREW FIXATION

#### C1 LATERAL MASS SCREW FIXATION

## **Drilling Trajectory**

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

The drill bit should be angled straight or slightly convergent, approximately 5-10 degrees medial (Figure 56), and parallel to the underside of the C1 posterior arch (Figure 57). When drilling under fluoroscopic control, additional orientation can be obtained by directing the tip of the drill bit toward the caudal half of the anterior tubercle of C1.

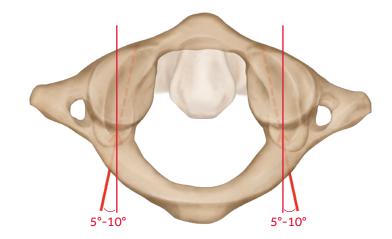


Figure 56

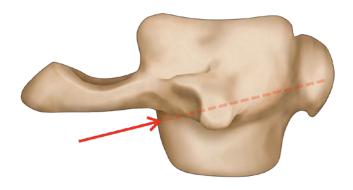
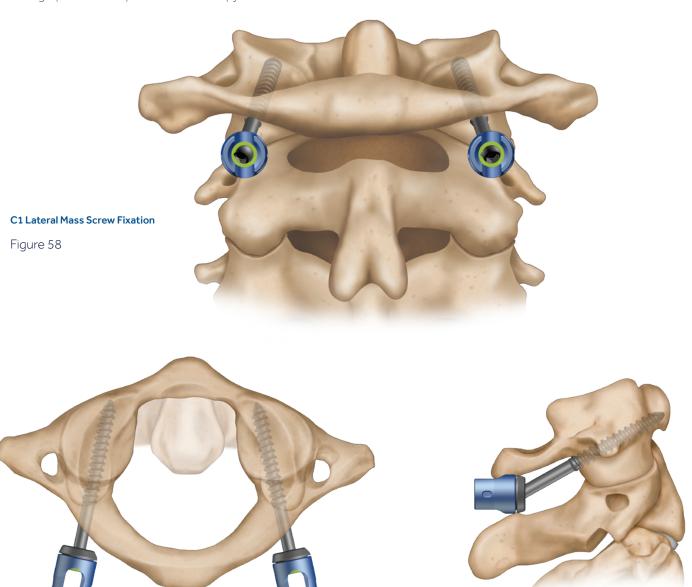


Figure 57

## **Screw Positioning**

Refer to Figure 58 for final screw positioning.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.



# C2 PEDICLE AND PARS INTERARTICULARIS SCREW FIXATION

# C2 PEDICLE AND PARS INTERARTICULARIS SCREW FIXATION

#### **Pre-Operative Planning**

The unique anatomy at C2 allows for placement of a screw in the pedicle or pars interarticularis.

When placing C2 screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C2 pedicle screw fixation as described by Dickman,<sup>3</sup> and C2 pars interarticularis screw fixation as described by Mummaneni<sup>4</sup> and Foley.<sup>5</sup>

#### **Determining Entry Points**

For screw placement in the C2 pedicle, the entry point is 3mm-4mm above the C2 inferior facet (Figure 21).

For screw placement in the C2 pars interarticularis, the entry point is approximately 3mm superior to the C2-C3 facet joint line and 3mm lateral to the lamina-lateral mass junction (Figure 60).

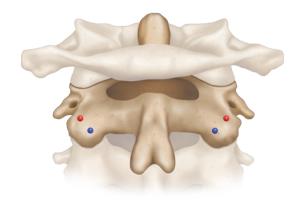
Indentations should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.



Posterior view of C2

Figure 59

- C2 Pedicle Screw
- C2 Pars Screw



#### Posterior view of C2

Figure 60

#### **Drilling Trajectory**

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

For screw placement in the C2 pedicle, the drill bit should be angled 20–30 degrees medial and directed into the central axis of the C2 pedicle (Figure 61). In the sagittal plane, the drill bit is angled approximately 20–30 degrees cephalad (Figure 62).

For screw placement in the C2 pars interarticularis, the drill bit should be angled slightly medial (10-15 degrees) (Figure 61). In the sagittal plane, the drill bit is angled approximately 35 degrees cephalad, assessed fluoroscopically by aiming toward the anterior tubercle of C1 (Figure 62).

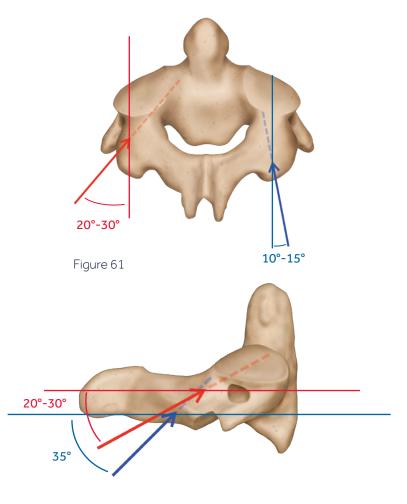
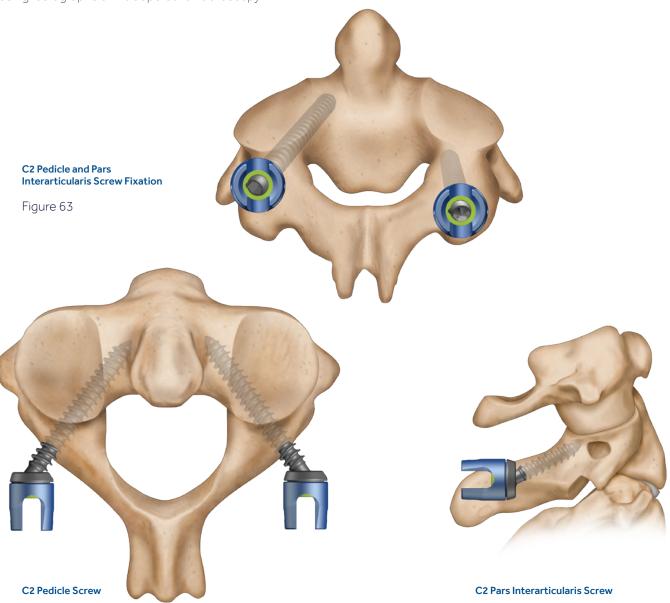


Figure 62

## **Screw Positioning**

Refer to Figure 63 for final screw positioning for a C2 Pedicle and Pars Interarticularis Screw.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.



# C2 TRANSLAMINAR SCREW FIXATION

# C2 TRANSLAMINAR **SCREW FIXATION**

#### **Pre-Operative Planning**

When placing C2 translaminar screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C2 translaminar screw fixation as described by Wright.<sup>6</sup>

#### **Determining Entry Points**

For placement of C2 Translaminar screws, the first entry point is at the junction of the C2 spinous process and lamina on either the left or right side (surgeon preference), close to the rostral margin of the C2 lamina (Figure 65).

The second entry point is at the junction of the C2 spinous process and lamina on the contralateral side, close to the caudal margin of the C2 lamina (Figure 16).

Indentations should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.



Posterior view of C2

Figure 64

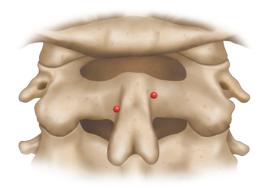


Figure 65

#### **Drilling Trajectory**

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

Once entry points on either side have been established, the contralateral lamina are then drilled, with the drill visually aligned along the angle of the exposed contralateral laminar surface (Figure 66). The trajectory is slightly less than the downslope of the lamina to ensure that any possible cortical breakthrough would occur dorsally through the laminar surface rather than ventrally into the spinal canal.

#### **Screw Positioning**

Refer to Figure 67 for final screw positioning.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.

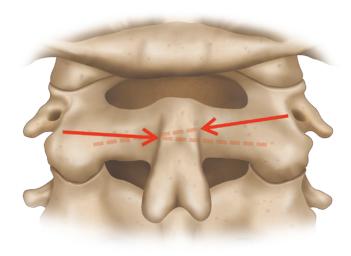
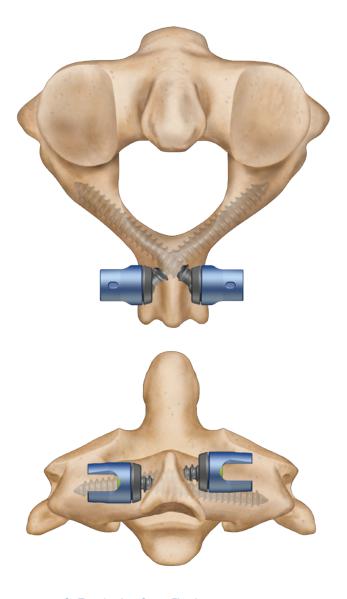


Figure 66



C2 Translaminar Screw Fixation

# C1-C2 TRANSARTICULAR SCREW FIXATION

#### **Pre-Operative Planning**

When placing C1- C2 transarticular screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C1-C2 transarticular screw fixation as described by Foley $^5$  and Fassett and Apfelbaum $^7$ 

#### **Determining Entry Points**

For placement of C1-C2 transarticular screws, the entry point is 2mm-3mm superior to the C2-C3 facet joint line and 3mm lateral to the lamina-lateral mass junction (Figure 69).

Indentations should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.



Posterior view of C1 – C2

Figure 68

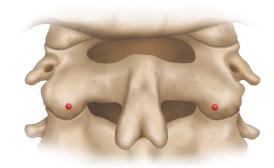


Figure 69

#### **Drilling Trajectory**

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

Once entry points have been established, the medial/ lateral trajectory is determined by visualizing the pars interarticularis and manipulating to make the drill bit coaxial with the sagittal axis of the pars, typically 10-15 degrees medial (Figure 70).

The cephalad/caudal trajectory is assessed fluoroscopically by aiming toward the anterior tubercle of C1. The drill is advanced slowly through the pars of C2, crosses the C1-C2 joint space, enters the lateral mass of C1, and ends 3mm-4mm posterior to the C1 anterior tubercle (Figure 71).

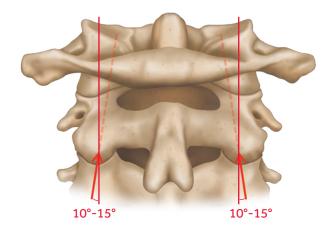


Figure 70

### **Screw Positioning**

Refer to Figure 72 for final screw positioning.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.

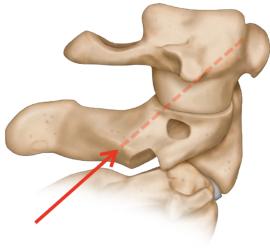


Figure 71

C1-C2 Transarticular Screw Fixation

Figure 72

# C3-C7 LATERAL MASS SCREW FIXATION

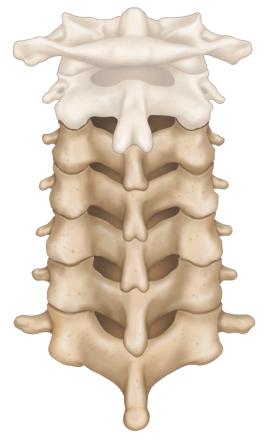
# C3-C7 LATERAL MASS SCREW **FIXATION**

#### **Pre-Operative Planning**

When placing lateral mass screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published for the placement of lateral mass screws and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C3-C7 lateral mass screw fixation as described by Dickman.<sup>3</sup>



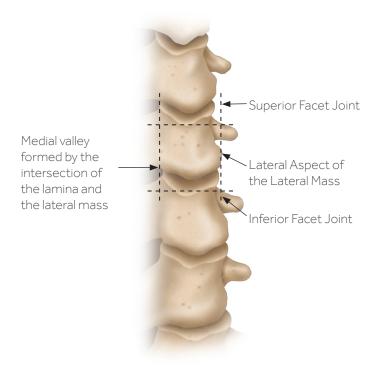
Posterior view of C3 - C7

Figure 73

## **Determining Entry Points**

The lateral mass screw entry point is determined by visualizing the "box" of the lateral mass, which is outlined by the facet joints inferiorly and superiorly, by the medial valley formed where the lamina and lateral mass intersect, and by the lateral aspect of the lateral mass (Figure 74).

The entry point is 1mm medial to the center of the lateral mass (Figures 75). An indentation should be made at this intersection so that the drill bit will have a starting point and not skive off the lateral mass.



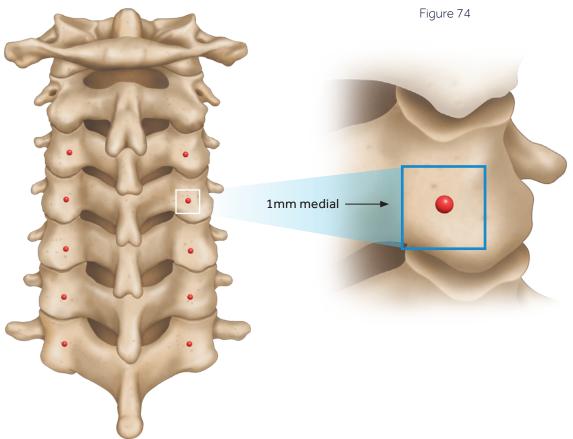


Figure 75

## **Drilling Trajectory**

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot  $% \left( 1\right) =\left( 1\right) \left( 1\right) \left($ hole for screw insertion.

Once the entry point has been established, the drill should be placed perpendicular to the lateral mass and then angled 20–30 degrees laterally (Figure 76) and approximately 20-30 degrees cephalad (Figure 77).

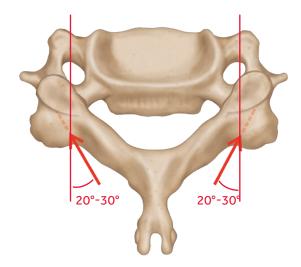


Figure 76

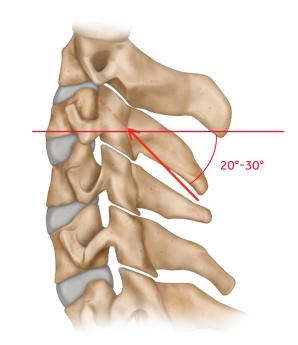


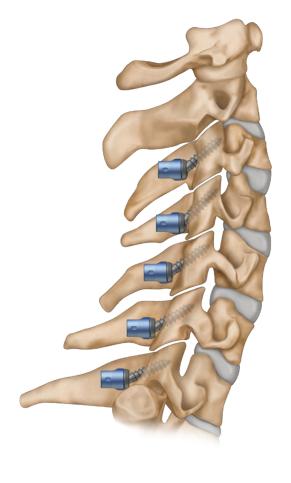
Figure 77

## **Screw Positioning**

Refer to Figure 78 for final screw placement.

Confirmation of screw positions can be made using radiographs or intraoperative fluoroscopy.





C3 – C7 Lateral Mass Screw Fixation Figure 78

# C3-T3 PEDICLE SCREW FIXATION

#### **Pre-Operative Planning**

When placing C3-T3 pedicle screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C3-C7 pedicle screw fixation as described by Abumi $^8$  and Moulton $^9$  and the technique for T1-T3 pedicle screw fixation as described by Fessler, et al. $^{10}$ 

#### **Determining Entry Points**

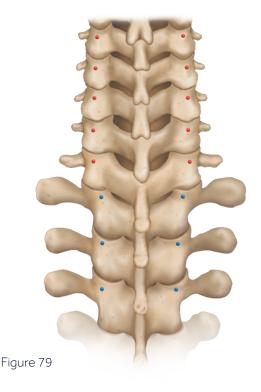
For screw placement in the pedicles of C3-C7, the entry point is just lateral to the midportion of the lateral mass, and 2mm-3mm below the inferior facet margin of the cephalad vertebra (Figure 79).

For screw placement in the pedicles of T1-T3, the entry point is identified by the intersection of a horizontal line connecting the transverse processes with a vertical line connecting the middle of the facet joints (Figure 79).

An indentation should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.



Posterior view of C3 - T3



54

#### **Drilling Trajectory**

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

For pedicle screw placement in C3-C7, the drill bit should be angled 25-45 degrees medial to the midline (Figure 80).

(Figure 81). The drill trajectory in the sagittal plane is parallel to the upper endplate of the pedicles (Figure 82).

For pedicle screw placement in T1-T3, the drill bit should

be angled 10–15 degrees medially and 5 degrees caudally

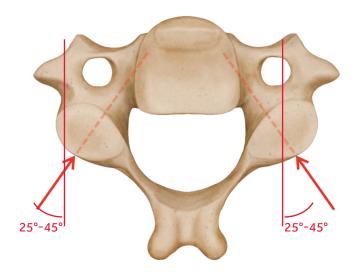


Figure 80

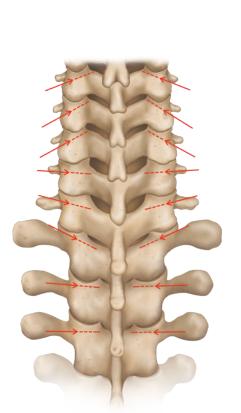
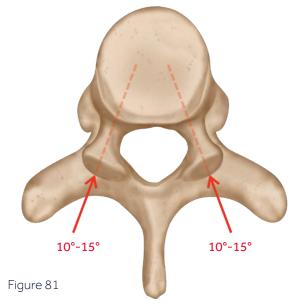
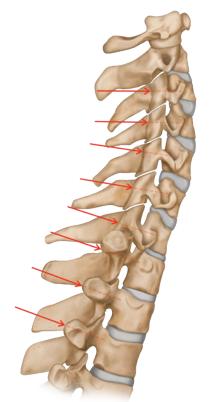


Figure 82

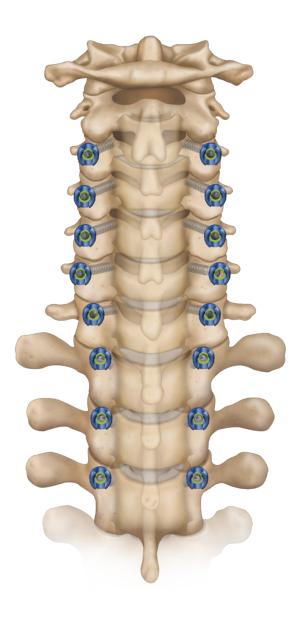




## **Screw Positioning**

Refer to Figure 83 for final screw positioning. Additional screws are placed using the same technique.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.





C3-C7 Pedicle Screw Fixation

Figure 83

# INFINITY™ OCCIPITOCERVICAL MODULE

# OCCIPITAL FIXATION IMPLANT FEATURES

#### **Occipitocervical Bone Screws**

#### **Screw Design**

Two different designs of OC bone screws are available:

#### Standard Tip:

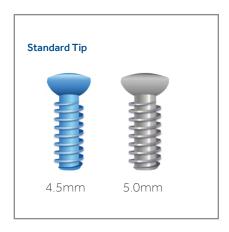
- 4.5mm × 6-14mm
- 5.0mm × 6-14mm
- Increased thread volume

#### Tapered Tip:

- 4.5mm × 6-14mm
- 5.0mm × 6-14mm

# Occipitocervical Screw Connectors

- Low-profile occipital fixation option
- Allow for six points of occipital midline fixation
- Flexibility in placement on the occiput in the cephalad/caudal directions
- Two lengths of screw connectors available for flexibility in the medial/lateral plane
- Dorsal height adjustment capabilities accommodate uneven bone surfaces





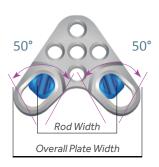




### **Occipital Adjustable Plates**

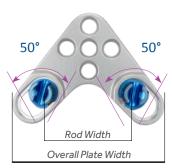
- Three hole midline fixation to the occiput to maximize bone-purchase in the midline
- Rotating and translating saddles allow for flexibility in rod placement
- Space between saddles of the plate for bone grafting on the occiput
- Pre-machined radius of curvature for proper fit onto the occipital anatomy
- Lateral screw holes for torsional stability
- Contoured with the Occipital Plate Bender
- Multiple sizes available to match patient anatomy

#### **Small OC Adjustable Plate Dimensions**



Width	Width	Width	
24mm	32mm	46.9mm	
Min Rod	Max Rod	Overall Plate	

#### Standard OC Adjustable Plate Dimensions



Min Rod	Max Rod	Overall Plate	
Width	Width	Width	
32mm	40mm	54.75mm	









50° of Rotation



4mm of Cephalad Caudal Translation

4mm of Medial Lateral Translation

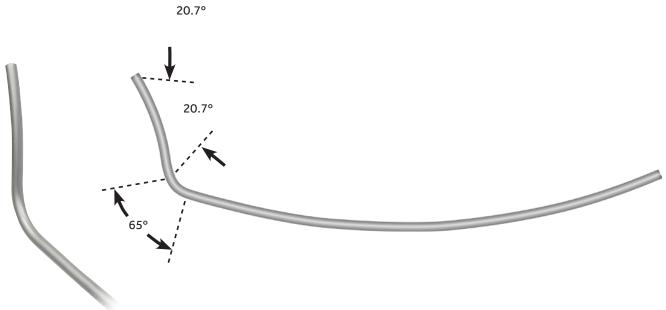
### Occipitocervical Adjustable Rods

- Hinge portion of rod adjusts to accommodate various anatomical angles in the occipitocervical junction
- Reduced profile of hinge portion for improved fit at the OC junction
- Angulation can be adjusted intraoperatively
- Requires less rod bending to fit difficult anatomy
- 360 degrees of rotation
- Available in 3.5mm/3.5mm diameter and 100mm and 200mm lengths
- Available in in Titanium and Chromaloy™ Plus

#### **Occipitocervical Pre-curved Rods**

- Pre-contoured to match anatomy of the occipitocervical junction
- Available in 3.5mm diameters and 100mm and 200mm lengths
- Available in Titanium and Chromaloy™ Plus



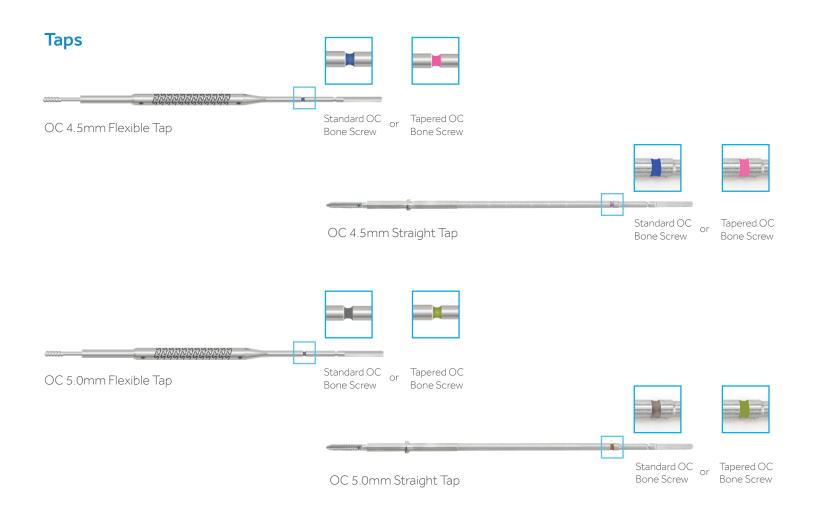


# OC INSTRUMENT **SET**

#### **Drill-Tap (DT) Screw Guides**



OC 3.2mm Flexible Drill Bit (for both Standard and Tapered Tip OC Bone Screws)



## **Screwdrivers**



OC Self-Holding Screwdriver, Flexible Shaft



OC Self-Holding Screwdriver, Straight Shaft

### **Occipital Midline Plate and Rod Benders**



Occipital Plate Bender



Tube Benders

## **Final Tightening**



OC Torque-limiting Flexible Screwdriver



 ${\tt OC\ Torque-limiting\ Straight\ Screwdriver}$ 



OC Torque-limiting Ratchet Screwdriver



OC Rod Pusher/Counter Torque

INFINITY™
OCCIPITOCERVICAL MODULE
USING THE OCCIPITAL
SCREW CONNECTORS
AND OCCIPITAL
ADJUSTABLE RODS

# ROD **PLACEMENT**

For occipitocervical stabilization using the Occipital Screw Connectors, first select and insert the cervical multi-axial screw and/or laminar hooks at the desired levels of fixation.

Once the subaxial fixation points are in place, use the Rod Holder (6905774) to position the desired rod (see rod options below) to determine necessary adjustments to align the rod with the subaxial fixation. For illustration purposes, the OC Adjustable Rod will be shown throughout this section (Figure 84).

There are multiple rod options to choose from depending on patient anatomy and surgeon preference:

#### 1. OC Adjustable Rod

- Available in Titanium and Chromaloy<sup>™</sup> Plus
- Available in 3.5mm diameter
- Allows surgeon to pre-set the angle of the rod to best accommodate the anatomy and eliminates the need for excessive bending.
- To adjust the angle of the rod, use the Straight Hex Screwdriver (3606193) with the Universal Handle (G850000) to loosen the internal set screw located on the hinge. Adjust the angle as necessary and tighten the internal set screw to secure the rod into a locked position. There is friction in the hinge mechanism to prevent the two rods from disassembling (Figure 85).
- Note: The set screw can be placed on either side of the hinge to accommodate medial/lateral offsets in occipital and subaxial screw fixation points.

#### 2. OC Precurved Rods

- Available in Titanium and Chromaloy<sup>™</sup> Plus
- Available in 3.5mm diameter

#### 3. Straight Rods

- Available in Titanium and Chromaloy<sup>™</sup> Plus
- Available in 3.5mm diameter
- Acute bends can be performed using the set of Tube Benders (3606292). See following section for usage of the Tube Benders.

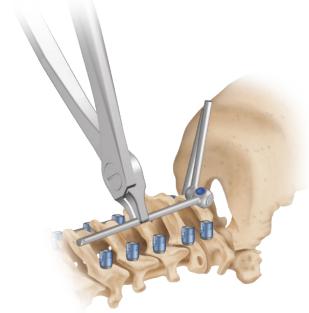


Figure 84



Figure 85



## ROD CONTOURING

For additional contouring to any of the rods, the French Bender (3605782), Left and Right Sagittal Benders (3606290 and 3606291), or Tube Benders (3606292) may be used.

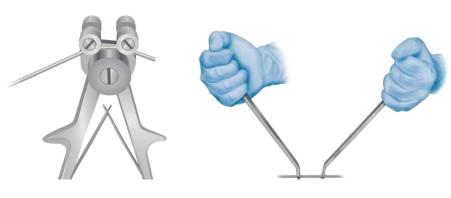
To use the Tube Benders, slide the rod into the opening on one Bender and lock rod into position using locking screw on the Bender. This will prevent the rod from slipping during bending.

Slide the second Tube Bender onto the other end of the rod and position rod segment for desired bend (Figure 86).

In one single motion, bend the rod to the desired angle (Figure 87).

#### Note

Avoid repeated bending motions or reverse bending motions to the implants, as excessive bending will decrease the integrity of the implant (Figure 51).



#### French Bender

Sagittal Benders

## ROD **CUTTING**

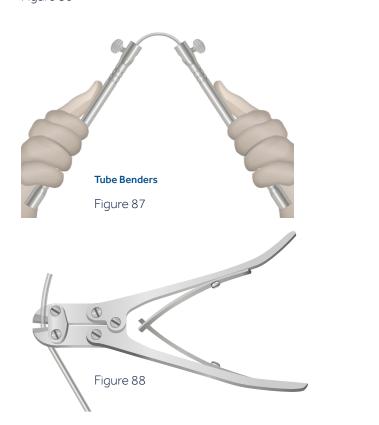
The Rod Cutter (6905784) may be used to cut the rods to the desired lengths (Figure 88).

#### Note

Use caution to secure both ends of the rod during cutting.



Figure 86



## OCCIPITAL BONE SCREW AND OCCIPITAL SCREW CONNECTOR PLACEMENT

Once all of the subaxial fixation points have been placed and the Occipital Adjustable Rods have been adjusted and contoured to match the patient's anatomy, determine the desired entry points for the OC Bone Screws. OC Bone Screw placement must be determined preoperatively using CT scans or lateral radiographs. Occipital bone thickness varies tremendously, and a clear understanding of the anatomy is required for safe screw placement. Anatomical landmarks should be identified and carefully reviewed to determine entry points in the thickest bone. Generally, the thickest bone in the suboccipital region is the occipital keel (internal occipital protuberance), near the midline.

After determining the desired location of the OC Bone Screw, place three Occipital Screw Connectors on each rod, for a total of six screw fixation points, and provisionally tighten on the rod by tightening the internal blue set screw with the Straight Hex Screwdriver (3606193) (Figure 89). The open portion of the connectors should be positioned medially on the rods (i.e., between the rods) so that midline fixation is achieved with the Occipital Bone Screws. Occipital Screw Connectors with longer offsets are available if additional length is needed to maximize screw purchase in the midline.

The Occipital Screw Connectors can be adjusted on the rod in the cephalad/caudal directions, as well as in the AP plane. This dorsal height adjustment capability will help accommodate uneven bone surfaces and facilitate positioning of the connectors so they lie flush with the bone (Figure 90).

Once the Screw Connectors have been provisionally placed on the Occipital Adjustable Rods in the desired position, place the rods in the subaxial fixation points and provisionally tighten the set screws to stabilize the rods.

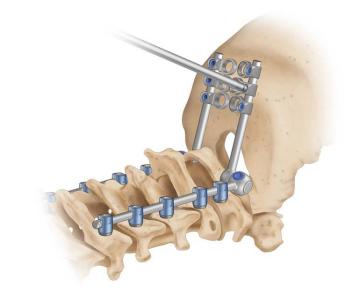


Figure 89



Figure 90

# OCCIPITAL BONE SCREW HOLE PREPARATION

For occipital fixation, 4.5mm (6mm to 14mm lengths) and 5.0mm (6mm to 14mm lengths) diameter Occipital Bone Screws are available in both a standard and tapered tip design. Select the appropriate drill bit and tap that match the desired screw design and diameter for occipital fixation (see the Color-Coding Reference Chart below).

#### Occipital Bone Screws—Color-Coding Reference

	Screw Size	Color	Drill Bit (one size for all; no color code)	Тар
Infinity <sup>™</sup> OC Bone Screws, Standard Design	4.5mm × 6mm–14mm	Blue	3.2mm (Straight Shaft or Flexible Shaft)	4.5mm (Straight Shaft or Flexible Shaft)
	5.0mm × 6mm–14mm		3.2mm (Straight Shaft or Flexible Shaft)	5.0mm (Straight Shaft or Flexible Shaft)
Infinity™ OC Bone Screws, Tapered Tip Design	4.5mm × 6mm–14mm	Magenta	3.2mm, Tapered (Straight Shaft or Flexible Shaft)	4.5mm,Tapered (Straight Shaft or Flexible Shaft)
	5.0mm × 6mm–14mm	Bronze	3.2mm, Tapered (Straight Shaft or Flexible Shaft)	5.0mm, Tapered (Straight Shaft or Flexible Shaft)

The occipital drill bits and taps are available in both straight and flexible shaft designs, based on surgeon preference and anatomical requirements. The straight shaft instruments transfer the energy more efficiently than the flexible shaft instruments, and should be considered the primary instrument choice. The flexible shaft instruments are reserved for use in cases where screw trajectories are difficult to achieve with straight shaft instruments.

For demonstration purposes, the following illustrations depict use of the flexible shaft instruments.

#### **Drilling**

Select the appropriate Drill-Tap (DT) Guide based on the desired drilling depth. The DT Guides are available with fixed drilling depths from 6mm to 14mm in 2mm increments. Both the Straight and Flexible Drill Bits must be used in conjunction with the DT Guide to achieve a fixed drilling depth (Figure 54). When the flexible drill bit is used, the DT Guide will help stabilize the flexible shaft and direct the drill bit in the proper position. Using the DT Guide to align the drill hole in the Occipital Screw Connector, insert the Flexible Drill Bit (G3600321) through the DT Guide, and drill to the desired depth (Figure 91). Drilling must be done through the Occipital Screw Connectors to ensure proper drilling depth.

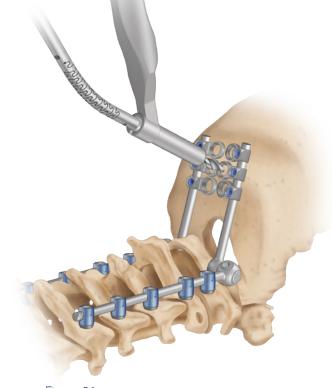


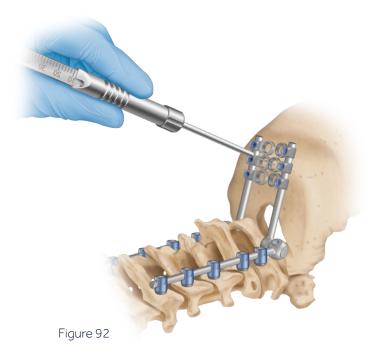
Figure 91

#### **Screw Measurement**

The Depth Gauge (6956020) should be used to verify the hole depth as well as the occipital bone thickness (Figure 92).

#### **Tapping**

Once a satisfactory depth has been achieved, the appropriate Straight or Flexible Tap can be used to prepare the screw hole. Select the appropriate DT Guide based on the desired tapping depth. Both the Straight and Flexible taps must be used in conjunction with the DT Guide to achieve a fixed tapping depth. When the Flexible Tap is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the tap in the proper position. Insert the Flexible Tap attached to the Universal Handle (G850000) through the DT Guide and tap to the desired depth (Figure 93). The occipital bone is very dense, and each hole should be completely tapped.



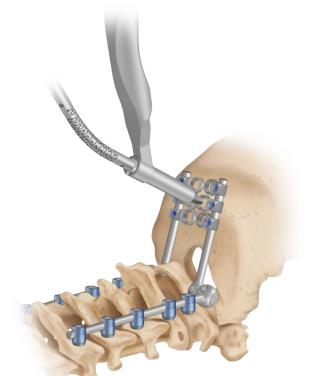


Figure 93

# OCCIPITAL BONE SCREW INSERTION

Choose the appropriate diameter and length screw for each screw location, and verify the diameter and length before placement using the screw gauge measuring tool located in the set.

To aid in bone screw insertion, there is a Screw Guide located on the opposite end of the 14mm DT guide (3600014), which serves as a "screw pusher" and provides additional control during screw insertion.

Load the OC Bone Screw onto the OC Self-Holding Screwdriver (straight or flexible shaft, 3600250 or 3600251), and using a reverse motion (bow and arrow style), pull the screwdriver through the distal opening of the Screw Guide so the guide surrounds the screwdriver shaft and seats behind screwdriver flange (Figures 94a, 94b, and 94c).

Insert the bone screw into the occipital bone and provisionally tighten. The remaining screws can be placed using this same technique (Figure 95).

#### Note

The OC Screwdriver and bone screws are not intended to be inserted through the guide as described with the drill and taps.

#### Note

The Screw Guide is optional when using the OC Straight Self-Holding Screwdriver. However, when using the OC Flexible Shaft Self-Holding Screwdriver, the use of the Screw Guide is necessary to prevent excessive motion of the flexible shaft and to direct the screwdriver into proper position.

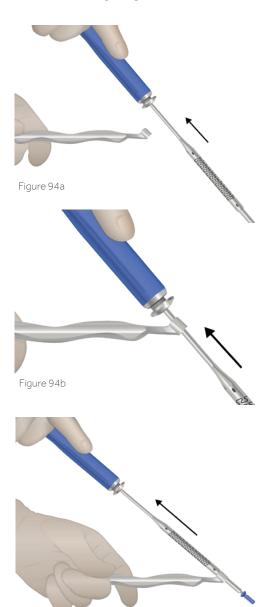


Figure 94c





Fixed Occipital Drill Tap Guide, 14mm/Screwdriver Guide

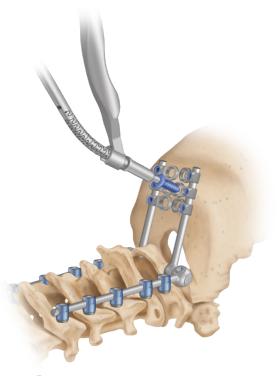


Figure 95

## FINAL TIGHTENING

After all the OC bone screws have been inserted and provisionally tightened, use 2.5mm Straight Hex Screwdriver (3606193) with the Universal Handle (G850000) to final tighten the screws into the occipital bone (Figure 96).

Securely tighten the Occipital Screw Connectors on the rod using the OC Torque-limiting Screwdriver (3600252) with the Torque-limiting Handle (G851100) in conjunction with either the 45 degree or 90 degree angled end of the OC Pusher/Counter Torque (3600170) (Figure 97).

Final tighten the set screw on the OC Adjustable Rod using the OC Straight or Flexible Torque-limiting Screwdriver (3600252 or 3600253) and the Torque-limiting T-Handle (G851100) in conjunction with either the MAS, Universal, or OC Rod Pusher/Counter Torque (3606170, 3606172, or 3600170, respectively) placed *adjacent* to the hinge (Figure 98).



Figure 96



Figure 98

Once all of the Occipital Bone Screws and Screw Connectors have been final tightened, all set screws in the subaxial fixation points should be final tightened using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100) in conjunction with the MAS Rod Pusher/Counter Torque (3606170) (Figure 99).

#### Note

During all final tightening steps, care should be taken not to inadvertently depress the torque limiting handle release mechanism during handling.



Figure 97



Figure 99

# FINAL CONSTRUCT

Confirm all connections of the final construct prior to wound closure (Figure 100).

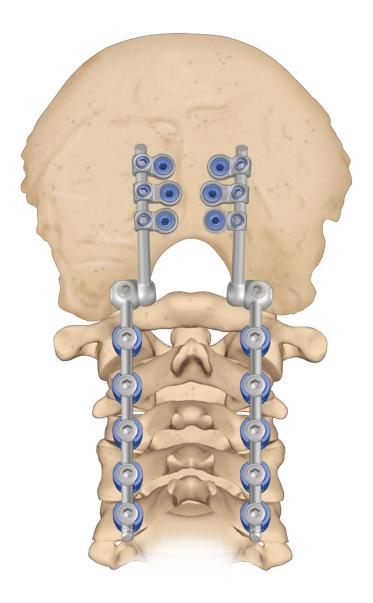


Figure 100

INFINITY™
OCCIPITOCERVICAL MODULE
USING THE OCCIPITAL
ADJUSTABLE MIDLINE PLATE
AND OCCIPITAL
ADJUSTABLE RODS

# OCCIPITAL ADJUSTABLE MIDLINE PLATE PLACEMENT

In general, the thickest bone in the suboccipital region is the occipital keel (internal occipital protuberance), near the midline. When positioning the Occipital Adjustable Plate, it should be centered in the midline between the external Occipital Protuberance (EOP) and the posterior border of the foramen magnum (Figure 101).

The goal is to maximize bone purchase, closer to the external Occipital Protuberance (EOP), while achieving a low profile. The geometry of the OC Adjustable Plate is designed to maximize bone graft placement in the midline.

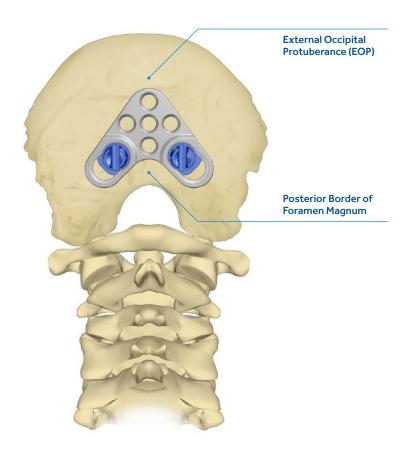
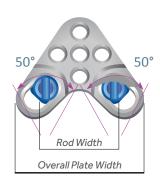


Figure 101

Once all of the subaxial fixation points have been placed, position the Occipital Adjustable Rod to determine the proper plate size, as well as any adjustments to align the rod properly (Figure 102). Instructions for use of the Occipital Adjustable Rod are described on page 65.

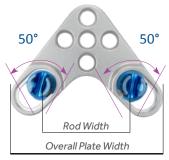
There are two sizes of the Occipital Adjustable Plate to accommodate varying anatomies, Small and Standard.

#### Small OC Adjustable Plate Dimensions

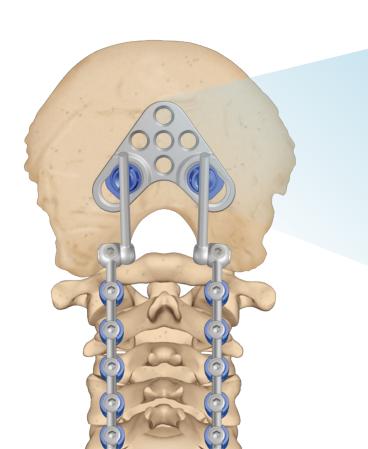


Min Rod	Max Rod	Overall Plate
Width	Width	Width
24mm	32mm	

#### Standard OC Adjustable Plate Dimensions



Min Rod	Max Rod	Overall Plate
Width	Width	Width
32mm	40mm	54.75mm



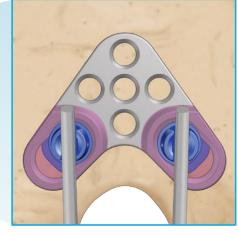


Figure 102a

#### **Note**

To ensure proper lock, the rods must extend beyond the shaded portion on the upper surface of the plate, as referenced in Figure 102a.

Figure 102

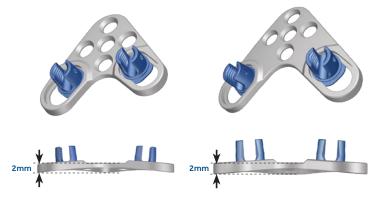
# OCCIPITAL ADJUSTABLE MIDLINE PLATE CONTOURING

The OC Adjustable Plates have a pre-machined radius of curvature for proper fit on the occiput. If necessary, additional contouring may be performed using the Occipital Plate Bender (3600230) for a more anatomic fit against the occiput (Figure 65). The OC Plate Bender may be oriented to create bends in both the cephalad/caudal planes and the medial/lateral planes (Figures 103a and 103b).

It also may be necessary to contour a small portion of uneven occipital bone with a high-speed drill to allow the plate to lie flush.

#### Note

Avoid repeated bending motions to the implants, as excessive bending will decrease the integrity of the implant. Do not bend in the area of the saddle slots.





Bending in the Cephalad/Caudal Plane

Figure 103a



Bending in the Medial/Lateral Plane

Figure 103b

### OCCIPITAL SCREW HOLE PREPARATION

For occipital fixation, 4.5mm (6mm to 14mm lengths) and 5.0mm (6mm to 14mm lengths) diameter Occipital Bone Screws are available in both a standard and tapered tip design. Select the appropriate drill bit and tap that match the desired screw design and diameter for occipital fixation (see the Color-Coding Reference Chart below).

#### Occipital Bone Screws—Color-Coding Reference

	Screw Size	Color	Drill Bit (one size for all; no color code)	Тар
Infinity <sup>™</sup> OC Bone Screws, Standard Design	4.5mm × 6mm–14mm	Blue	3.2mm (Straight Shaft or Flexible Shaft)	4.5mm (Straight Shaft or Flexible Shaft)
	5.0mm × 6mm-14mm		3.2mm (Straight Shaft or Flexible Shaft)	5.0mm (Straight Shaft or Flexible Shaft)
Infinity™ OC Bone Screws, Tapered Tip Design	4.5mm × 6mm–14mm	Magenta	3.2mm, Tapered (Straight Shaft or Flexible Shaft)	4.5mm,Tapered (Straight Shaft or Flexible Shaft)
	5.0mm × 6mm-14mm	Bronze	3.2mm, Tapered (Straight Shaft or Flexible Shaft)	5.0mm, Tapered (Straight Shaft or Flexible Shaft)

The occipital drill bits and taps are available in both straight and flexible shaft designs, based on surgeon preference and anatomical requirements. The straight shaft instruments transfer the energy more efficiently than the flexible shaft instruments, and should be considered the primary instrument choice. The flexible shaft instruments are reserved for use in cases where screw trajectories are difficult to achieve with the straight shaft instruments.

For demonstration purposes, the following illustrations depict use of the flexible shaft instruments.

#### **Drilling**

Select the appropriate Drill-Tap (DT) Guide based on the desired drilling depth. The DT Guides are available with fixed drilling depths from 6mm to 14mm in 2mm increments. Both the Straight and Flexible Drill Bits must be used in conjunction with the DT Guide to achieve a fixed drilling depth (Figure 54). When the flexible drill bit is used, the DT Guide will help stabilize the flexible shaft and direct the drill bit in the proper position. Using the DT Guide to align the drill hole in the Occipital Adjustable Plate, insert the Flexible Drill Bit (G3600321) through the DT Guide, and drill to the desired depth (Figure 104). Drilling must be done through the Occipital Adjustable Plate to ensure proper drilling depth.

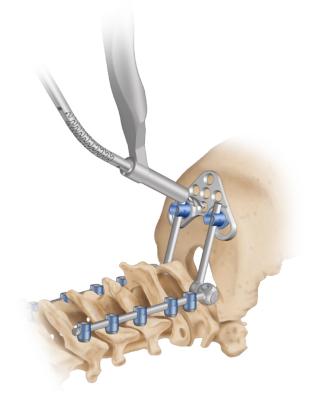


Figure 104

#### **Screw Measurement**

The Depth Gauge (6956020) should be used to verify the hole depth as well as the occipital bone thickness (Figure 105).

#### **Tapping**

Once a satisfactory depth has been achieved, the appropriate Straight or Flexible Tap can be used to prepare the screw hole. Select the appropriate DT Guide based on the desired tapping depth. Both the Straight and Flexible taps must be used in conjunction with the DT Guide to achieve a fixed tapping depth. When the Flexible Tap is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the tap in the proper position. Insert the Flexible Tap attached to the Universal Handle (G850000) through the DT Guide and tap to the desired depth (Figure 106). The occipital bone is very dense, and each hole should be completely tapped.

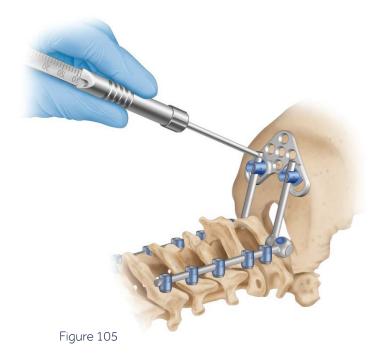




Figure 106

### OCCIPITAL BONE SCREW INSERTION

Choose the appropriate diameter and length screw for each screw location, and verify the diameter and length before placement using the screw gauge measuring tool located in the set.

To aid in bone screw insertion, there is a Screw Guide located on the opposite end of the 14mm DT guide (3600014), which serves as a "screw pusher" and provides additional control during screw insertion.

Load the OC Bone Screw onto the OC Self-Holding Screwdriver (straight or flexible shaft, 3600250 or 3600251), and using a reverse motion (bow and arrow style), pull the screwdriver through the distal opening of the Screw Guide so the guide surrounds the screwdriver shaft and seats behind screwdriver flange (Figures 107a, 107b, and 107c).

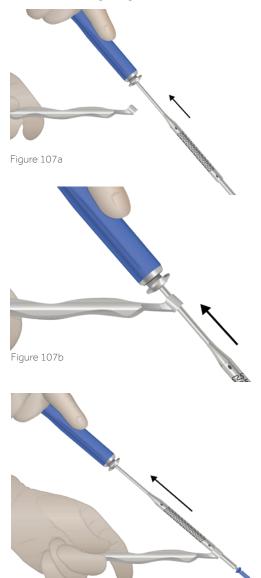


Figure 107c

Insert the bone screws into the occipital bone through the plate and provisionally tighten (Figure 108). The remaining screws can be placed using the same technique.

#### Note

The OC Screwdriver and bone screws are not intended to be inserted through the guide as described with the drill and taps.

#### Note

The Screw Guide is optional when using the OC Straight Self-Holding Screwdriver. However, when using the OC Flexible Shaft Self-Holding Screwdriver, the use of the Screw Guide is critical to prevent excessive motion of the flexible shaft and to direct the screwdriver into proper position.





Fixed Occipital Drill Tap Guide, 14mm/Screwdriver Guide

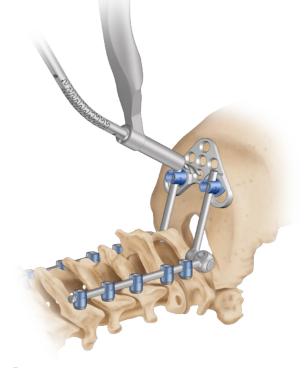


Figure 108

## FINAL TIGHTENING OF OC BONE SCREWS

After all the OC bone screws have been inserted and provisionally tightened, use 2.5mm Straight Hex Screwdriver (3606193) with the Universal Handle (G850000) to final tighten the screws into the occipital bone (Figure 109).

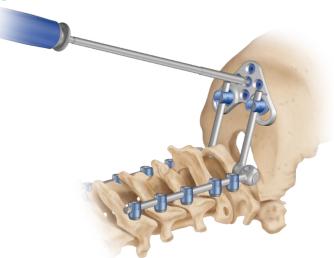


Figure 109

# SET SCREW INSERTION INTO OC PLATE SADDLES

Once all of the Occipital Bone Screws have been final tightened, use the OC Self-Holding Tapered Screwdriver (3600250) to insert and provisionally tighten the set screws in the saddles of the Occipital Adjustable Plate to stabilize the rod. If the patient's anatomical position requires use of angled instruments for the set screws in the saddles of the OC Plate, the OC Self-Holding Flexible Screwdriver (3600251) and the Screw Guide (3600014) may be used to insert the set screws (Figure 110).

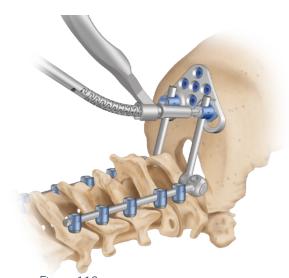


Figure 110

## FINAL TIGHTENING OF CONSTRUCT

Once all of the set screws have been provisionally tightened and the rods are secured in the implants, final tighten the set screws in the OC Adjustable Plate saddles using the OC Torque-limiting Screwdriver (3600252) with the Torque-limiting Handle (G851100 with Gray handle) in conjunction with either the 45-degree or 90-degree angled end of the OC Rod Pusher/Counter Torque (3600170). If the patient's anatomical position requires use of the angled instruments, the OC Flexible Shaft Torque-limiting Screwdriver (3600252) (Figure 111) or the OC Torque-limiting Ratchet Screwdriver (G700251) either in conjunction with the OC Rod Pusher/ Counter Torque, may be used for final tightening (Figure 112).

#### **Note**

The OC Torque-limiting Ratchet Screwdriver requires use of the 90-degree angled end of the OC Rod Pusher/ Counter Torque. The OC Straight or Flexible Torque-limiting Screwdrivers can utilize either the 45-degree or 90-degree angled end, but the 45-degree angled end is recommended for additional support and control during final tightening.

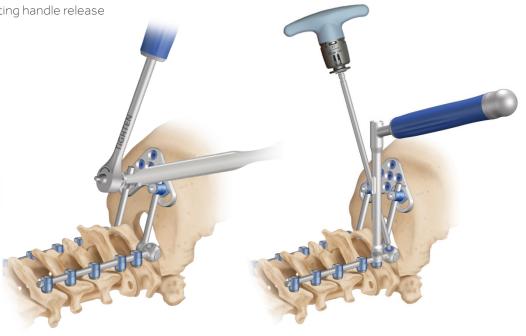
#### Note

During all final tightening steps, care should be taken not to inadvertently depress the torque limiting handle release mechanism during handling.

To use the OC Torque-limiting Ratchet Screwdriver (G700251), refer to the arrows on the instrument to position the tightening side of the wrench so it is facing outwards. Insert the hex into the set screw, and use a ratchet motion to final tighten the set screw (Figure 112). If loosening of the set screw is needed at any point, refer to the arrows on the instrument to reverse the hex and position the "loosen" facing outwards.

Final tighten the set screw on the OC Adjustable Rod using the OC Straight or Flexible Torque-limiting Screwdriver (3600252 or 3600253) and the Torque-limiting T-Handle (G851100 with Gray handle) in conjunction with either the MAS, Universal, or OC Rod Pusher/Counter Torque (3606170, 3606172, or 3600170, respectively) placed adjacent to the hinge (Figure 113).

Set screws in the subaxial fixation points should also be final tightened using the Torque-limiting Screwdriver (3606201) and Torque-limiting Handle (G851100) in conjunction with the MAS Rod Pusher/Counter Torque (3606170).



Option A: Use of OC Flexible Torquelimiting Driver with the 45 degree angled end of the OC Rod Pusher/ Counter Torque.

Figure 111 Figure 112

Option B: Use of OC Torquelimiting Ratchet Wrench with the 90 degree angled end of the OC Rod Pusher/Counter Torque

Figure 113

# FINAL CONSTRUCT

Confirm all connections of the final construct prior to wound closure (Figure 114).

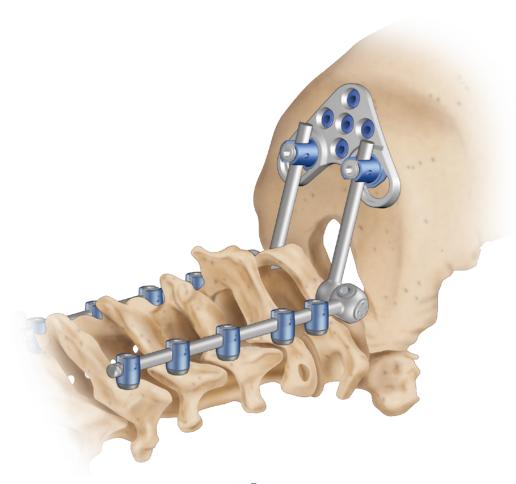


Figure 114

### **EXPLANTATION**

To remove any of the Infinity<sup>™</sup> System implants described throughout this technique, engage the set screws and the occipital bone screws with a 2.5mm Hex Straight Screwdriver and turn counterclockwise until the set screw is disengaged from the implant, and the bone screw until it is disengaged from the bone. The implants can then be freely removed from the bone.

# PART NUMBERS & SET CONFIGURATIONS



		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
Part Number	Description	C3-( Ster	C3-(	2.4n	OC- Mod	100	Cerv	Con (Nor	Out	3.0n	5.5n	Lam	Lam (Nor	OC Bit P	OC -	Loos
Multi-axial Sc	rews															
G3603008	Multi-axial X-Small Screw 3.0 × 8mm									4						
G3603010	Multi-axial X-Small Screw 3.0 × 10mm									4						
G3603012	Multi-axial X-Small Screw 3.0 × 12mm									4						
G3603014	Multi-axial X-Small Screw 3.0 × 14mm									4						
G3603016	Multi-axial X-Small Screw 3.0 × 16mm									4						
G3603018	Multi-axial X-Small Screw 3.0 × 18mm									4						
G3603020	Multi-axial X-Small Screw 3.0 × 20mm															X
G3603022	Multi-axial X-Small Screw 3.0 × 22mm															X
G3603024	Multi-axial X-Small Screw 3.0 × 24mm															X
G3603026	Multi-axial X-Small Screw 3.0 × 26mm															×
G3603028	Multi-axial X-Small Screw 3.0 × 28mm															X
G3603030	Multi-axial X-Small Screw 3.0 × 30mm															X
G3603032	Multi-axial X-Small Screw 3.0 × 32mm															Х
G3603034	Multi-axial X-Small Screw 3.0 × 34mm															X
G3603508	Multi-axial Screw 3.5 × 8mm															Х
G3603510	Multi-axial Screw 3.5 × 10mm															X
3603512	Multi-axial Screw 3.5 × 12mm	8														
3603514	Multi-axial Screw 3.5 × 14mm	14														
3603516	Multi-axial Screw 3.5 × 16mm	8														
3603518	Multi-axial Screw 3.5 × 18mm	6														
3603520	Multi-axial Screw 3.5 × 20mm	4														
3603522	Multi-axial Screw 3.5 × 22mm	2			2		2									
3603524	Multi-axial Screw 3.5 × 24mm	2			2		2									



		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
Part Number	Description	C3-C7 In Sterile)	C3-C7 In Sterile)	2.4mm D	OC-C2 Ir Module (	OC Drill I	Cervical Implant	Complex (Non Ste	Outlier Ir	3.0mm X	5.5 mm T	Laminar	Laminar (Non Ste	OC Tape Bit Modu	OC Tape Instrume	Loose G
3603526	Multi-axial Screw 3.5 × 26mm	2			2		2									
3603528	Multi-axial Screw 3.5 × 28mm	2			2		2									
3603530	Multi-axial Screw 3.5 × 30mm				2		2									
3603532	Multi-axial Screw 3.5 × 32mm				2		2									
3603534	Multi-axial Screw 3.5 × 34mm				2		2									
G3603536	Multi-axial Screw 3.5 × 36mm															X
G3603538	Multi-axial Screw 3.5 × 38mm															Х
G3603540	Multi-axial Screw 3.5 × 40mm															х
G3603542	Multi-axial Screw 3.5 × 42mm															х
G3604008	Multi-axial Screw 4.0 × 8mm															Х
G3604010	Multi-axial Screw 4.0 × 10mm															Х
3604012	Multi-axial Screw 4.0 × 12mm	4														
3604014	Multi-axial Screw 4.0 × 14mm	4														
3604016	Multi-axial Screw 4.0 × 16mm	4														
3604018	Multi-axial Screw 4.0 × 18mm	4														
3604020	Multi-axial Screw 4.0 × 20mm	4														
3604022	Multi-axial Screw 4.0 × 22mm	2			2		2									
3604024	Multi-axial Screw 4.0 × 24mm	2			2		2									
3604026	Multi-axial Screw 4.0 × 26mm	2			2		2									
3604028	Multi-axial Screw 4.0 × 28mm	2			2		2									
3604030	Multi-axial Screw 4.0 × 30mm				2		4									
3604032	Multi-axial Screw 4.0 × 32mm				2		4									
3604034	Multi-axial Screw 4.0 × 34mm				2		4									



		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5 mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	od (Sterile)
Part Number	Description	C3-C7 Imp Sterile)	C3-C7 Inst Sterile)	2.4mm Dri	OC-C2 Im Module (No	OC Drill Bit	Cervical Th Implant Mo	Complex Ir (Non Steril	Outlier Imp	3.0mm X-5	5.5mm Tra	Laminar H	Laminar H (Non Steril	OC Tapere Bit Module	OC Tapere Instrumen	Loose Good (Sterile)
G3604036	Multi-axial Screw 4.0 × 36mm															×
G3604038	Multi-axial Screw 4.0 × 38mm															Х
G3604040	Multi-axial Screw 4.0 × 40mm															х
G3604042	Multi-axial Screw 4.0 × 42mm															×
G3604508	Multi-axial Screw 4.5 × 8mm															×
G3604510	Multi-axial Screw 4.5 × 10mm															×
G3604512	Multi-axial Screw 4.5 × 12mm															X
G3604514	Multi-axial Screw 4.5 × 14mm															×
G3604516	Multi-axial Screw 4.5 × 16mm															X
G3604518	Multi-axial Screw 4.5 × 18mm															Х
G3604520	Multi-axial Screw 4.5 × 20mm															Х
3604522	Multi-axial Screw 4.5 × 22mm						2									
3604524	Multi-axial Screw 4.5 × 24mm						2									
3604526	Multi-axial Screw 4.5 × 26mm						2									
3604528	Multi-axial Screw 4.5 × 28mm						2									
3604530	Multi-axial Screw 4.5 × 30mm						4									
3604532	Multi-axial Screw 4.5 × 32mm						4									
3604534	Multi-axial Screw 4.5 × 34mm						4									
G3604536	Multi-axial Screw 4.5 × 36mm															×
G3604538	Multi-axial Screw 4.5 × 38mm															×
G3604540	Multi-axial Screw 4.5 × 40mm															X
G3604542	Multi-axial Screw 4.5 × 42mm															×
G3605515	Multi-axial Transition Screw 5.5 × 15mm															X



		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
Part Number	Description	0 ts	ದಿ ಜ	2.	ŌΣ	Ō	ŏ≞	ŏΖ	Ō	ώ.	.5	ت	22	Ōä	ŌΞ	۲
G3605520	Multi-axial Transition Screw 5.5 × 20mm															×
G3605525	Multi-axial Transition Screw 5.5 × 25mm										4					
G3605530	Multi-axial Transition Screw 5.5 × 30mm										4					
G3605535	Multi-axial Transition Screw 5.5 × 35mm										4					
G3605540	Multi-axial Transition Screw 5.5 × 40mm										4					
Partially Thre	aded Multi-axial Screws															
G360PT3518	Partially Threaded Multi- axial Screw 3.5 × 18mm															×
G360PT3520	Partially Threaded Multi- axial Screw 3.5 × 20mm															Х
360PT3522	Partially Threaded Multi- axial Screw 3.5 × 22mm				2											
360PT3524	Partially Threaded Multi- axial Screw 3.5 × 24mm				2											
360PT3526	Partially Threaded Multi- axial Screw 3.5 × 26mm				2											
360PT3528	Partially Threaded Multi- axial Screw 3.5 × 28mm				2											
360PT3530	Partially Threaded Multi- axial Screw 3.5 × 30mm				2											
G360PT3532	Partially Threaded Multi- axial Screw 3.5 × 32mm															Х
G360PT3534	Partially Threaded Multi- axial Screw 3.5 × 34mm															Х
G360PT3536	Partially Threaded Multi- axial Screw 3.5 × 36mm															X
G360PT3538	Partially Threaded Multi- axial Screw 3.5 × 38mm															×
G360PT3540	Partially Threaded Multi- axial Screw 3.5 × 40mm															Х
G360PT4018	Partially Threaded Multi- axial Screw 4.0 × 18mm															Х
G360PT4020	Partially Threaded Multi- axial Screw 4.0 × 20mm															Х
360PT4022	Partially Threaded Multi- axial Screw 4.0 × 22mm				2											-
360PT4024	Partially Threaded Multi- axial Screw 4.0 × 24mm				2											
360PT4026	Partially Threaded Multi- axial Screw 4.0 × 26mm				2											
360PT4028	Partially Threaded Multi Axial Screw 4.0 × 28mm				2											
360PT4030	Partially Threaded Multi Axial Screw 4.0 × 30mm				2											
G360PT4032	Partially Threaded Multi-axial Screw 4.0 × 32mm															X
G360PT4034	Partially Threaded Multi-axial Screw 4.0 × 34mm															X

Part																	
Section   Sect	Part Number	Description	C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
Score 140-24 Server																	
Scew 4.0 × 38mm	G360P14036	Screw 4.0 × 36mm															X
Laminar Hooks   Screw Ad 9- 40mm	G360PT4038																×
G3606073	G360PT4040	Partially Threaded Multi-axial Screw 4.0 × 40mm															×
Hook Laminar 4.5mm	Laminar Hook	KS															
March   Marc	G3606073	Hook Laminar 4.5mm											2				
Hook Laminar 4 5mm	G3606073L												2				
G3606074 Hook Laminar 6.0mm	G3606073R	Hook Laminar 4.5mm											2				
G3606074L	C7606074												2				
G5606074R																	
Pre-Cut Rods	G3606074L	Offset L											2				
3603725   Rod Pre-Cut 3.5mm × 25mm   2	G3606074R												2				
3603730       Rod Pre-Cut 3.5mm × 40mm       2         3603740       Rod Pre-Cut 3.5mm × 50mm       2         3603750       Rod Pre-Cut 3.5mm × 60mm       2         3603760       Rod Pre-Cut 3.5mm × 70mm       2         3603770       Rod Pre-Cut 3.5mm × 70mm       2         3603780       Rod Pre-Cut 3.5mm × 80mm       2         G7753870       Rod Pre-Cut 3.5mm × 80mm       2         G7753880       Rod Pre-Cut 3.5mm × 80mm CCM       2         3.5mm × 80mm CCM       2       2         G7753890       Rod Pre-Cut 3.5mm × 90mm CCM       2         3.5mm × 90mm CCM       2       2         G7753890       Rod Pre-Cut 3.5mm × 90mm CCM       2         3.5mm × 100mm CCM       2       2         WINID T Rod 2.5mm × 100mm CCM       2         B33123500       UNID T Rod 2.5mm       3         B33143500       UNID T Rod Dual Diameter 2.5mm / 2.5mm       3         B33243500       UNID CoCr Rod Dual Diameter 2.5mm / 2.5mm       3         B33243600       UNID CoCr Rod Dual Diameter 2.5mm / 2.5mm / 2.5mm       3         B3524400       Rod 3.5mm × 240mm       2         Straight Rods       2         G7755088       Rod 3.5Mm Chromaloy Plus <td>Pre-Cut Rods</td> <td></td>	Pre-Cut Rods																
3603740 Rod Pre-Cut 3.5mm × 40mm 2 3603750 Rod Pre-Cut 3.5mm × 50mm 2 3603760 Rod Pre-Cut 3.5mm × 50mm 2 3603770 Rod Pre-Cut 3.5mm × 60mm 2 3603770 Rod Pre-Cut 3.5mm × 80mm 2 3603780 Rod Pre-Cut 3.5mm × 80mm CCM 3.5mm × 90mm CCM 3.5mm × 100mm CCM 3.5mm × 80mm / 85.5mm 8 33123500 UNID TiRod Dual Diameter 2.55mm / 65.5mm 8 33123500 UNID CoCr Rod 0.35mm 8 33123500 UNID CoCr Rod 0.315mm 8 33123500 UNID CoCr Rod 0.315mm 8 33123500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm / 65.5mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm 8 33223500 UNID CoCr Rod Dual Diameter 2.55mm 8 3223500 UNID CoCr Rod Du	3603725	Rod Pre-Cut 3.5mm × 25mm	2														
3603750     Rod Pre-Cut 3.5mm × 50mm     2       3603760     Rod Pre-Cut 3.5mm × 60mm     2       3603770     Rod Pre-Cut 3.5mm × 70mm     2       3603780     Rod Pre-Cut     3.5mm × 80mm     2       G7753870     Rod Pre-Cut     3.5mm × 80mm CCM     2       G7753880     Rod Pre-Cut     2     2       3.5mm × 90mm CCM     2     2       G7753890     Rod Pre-Cut     2     2       3.5mm × 90mm CCM     2     2       G7753900     Rod Pre-Cut     2     2       3.5mm × 100mm CCM     2     2       UNID Tervical Rods       B33123500     UNID TiRod Dual Diameter     2     3.5mm / 95.5mm       B33143500     UNID TiRod Dual Diameter     2     3.5mm / 96.0mm       B33223500     UNID CoCr Rod Dual Diameter     2     3.5mm / 96.0mm       B33243500     UNID CoCr Rod Dual Diameter     2     3.5mm / 96.0mm       Straight Rods       Straight Rods       Straight Rods       3.5mm × 240mm     2       67750088     Rod 3.5Mm Chromaloy Plus     2	3603730	Rod Pre-Cut 3.5mm × 30mm	2														
3603760       Rod Pre-Cut 3.5mm × 70mm       2         3603770       Rod Pre-Cut 3.5mm × 70mm       2         3603780       Rod Pre-Cut 3.5mm × 80mm       2         G7753870       Rod Pre-Cut       3.5mm × 70mm CCM         G7753880       Rod Pre-Cut       3.5mm × 80mm CCM         G7753890       Rod Pre-Cut       3.5mm × 90mm CCM         G7753900       Rod Pre-Cut       2         3.5mm × 100mm CCM       2       2         UNID*** Text Post Post Post Post Post Post Post Pos	3603740	Rod Pre-Cut 3.5mm × 40mm	2														
3603770       Rod Pre-Cut 3.5mm × 70mm       2         3603780       Rod Pre-Cut 3.5mm × 80mm       2         G7753870       Rod Pre-Cut       3.5mm × 70mm CCM         G7753880       Rod Pre-Cut       3.5mm × 80mm CCM         G7753890       Rod Pre-Cut       3.5mm × 90mm CCM         G7753900       Rod Pre-Cut       3.5mm × 100mm CCM         B33123500       UNID TiRod Ø3.5mm         B33143500       UNID TiRod Dual Diameter Ø3.5mm Ø3.5mm Ø3.5mm Ø3.5mm Ø3.5mm Ø40.0mm         B33143600       UNID TiRod Dual Diameter Ø3.5mm Ø40.0mm         B33223500       UNID CoCr Rod Ø3.5mm         B33243500       UNID CoCr Rod Qual Diameter Ø3.5mm Ø40.0mm         B33243600       UNID CoCr Rod Qual Diameter Ø3.5mm Ø40.0mm         B33243600       UNID CoCr Rod Qual Diameter Ø3.5mm Ø40.0mm         B302240       Rod 3.2 × 240mm Ti       2         3605240       Rod 3.5mm × 240mm       2         G7750088       Rod 3.5mm Chromaloy Plus	3603750	Rod Pre-Cut 3.5mm × 50mm	2														
3603780       Rod Pre-Cut 3.5mm × 80mm 2       2       3	3603760	Rod Pre-Cut 3.5mm × 60mm	2														
Rod Pre-Cut   3.5mm × 70mm CCM   2   2   3   3   3   3   3   3   3   3	3603770	Rod Pre-Cut 3.5mm × 70mm	2														
3.5mm × 70mm CCM   2	3603780	Rod Pre-Cut 3.5mm × 80mm	2														
3.5mm × 80mm CCM   2   2   3   3   5   5   5   5   5   5   5   5	G7753870									2							
3.5mm × 90mm CCM   2   2   3   3   5   5   5   5   5   5   5   5	G7753880									2							
Rod Pre-Cut   3.5mm × 100mm CCM   2	G7753890									2							
UNID Ti Rod Ø3.5mm	G7753900	Rod Pre-Cut								2							
B33123500       UNID Ti Rod ø3.5mm       9.5mm       9.5	UNiD™ Corvie																
B33143500   UNiD Ti Rod Dual Diameter																	
B33143600 UNID Ti Rod Dual Diameter		UNiD Ti Rod Dual Diameter															
B33223500 UNiD CoCr Rod Ø3.5mm  B33243500 UNiD CoCr Rod Dual Diameter Ø3.5mm Ø5.5mm  UNiD CoCr Rod Dual Diameter Ø3.5mm Ø6.0mm  Straight Rods  3602240 Rod 3.2 × 240mm Ti 2 3 3605240 Rod 3.5mm × 240mm 2 2 3 3605240 Rod 3.5m	B33143600	UNiD Ti Rod Dual Diameter															
B33243500 UNID CoCr Rod Dual Diameter																	
B33243600 UNiD CoCr Rod Dual Diameter		UNiD CoCr Rod Dual Diameter															
Straight Rods       3602240     Rod 3.2 × 240mm Ti     2       3605240     Rod 3.5mm × 240mm     2       G7750088     Rod 3.5Mm Chromaloy Plus     2		UNiD CoCr Rod Dual Diameter															
3602240 Rod 3.2 × 240mm Ti 2 3605240 Rod 3.5mm × 240mm 2 3605240 Rod 3.5mm × 240mm 2 3605240 Rod 3.5Mm Chromaloy Plus 3																	
3605240 Rod 3.5mm × 240mm 2																	
G7750088 Rod 3.5Mm Chromaloy Plus																	
	3605240	Rod 3.5mm × 240mm	2														
	G7750088									2							





	Part Number	Description	C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
	Crosslink <sup>™</sup> Co	onnectors and Lateral Connec	tors														
	3602510	Connector Lateral Open 10mm	2														
5	G3602513	Connector Lateral Open 13mm								2							
	G3602519	Connector Lateral Open 19mm															Х
3-	3602519A	Connector Lateral Open Angled 19mm				2											
	3601510	Connector Lateral Closed 10mm	2														
	G3601513	Connector Lateral Closed 13mm								2							
	G3601519	Connector Lateral Closed 19mm															Х
	G3602525	Crosslink MAS to MAS S								1							
» «	3602526	Crosslink MAS to MAS M	2														
	G3602527	Crosslink MAS to MAS L								1							
	G3602535	Crosslink Rod to Rod S								1							
	3602536	Crosslink Rod to Rod M	2														
	G3602537	Crosslink Rod to Rod L								1							
	Set Screws																
	3600215	Set Screw Standard	26														
	3602615	Set Screw Closed Connector Flat	6														
	Cervical to Th	noracic Transition Options															
	3601350	Domino Offset 3.2/3.5 to 3.2/3.5mm						3									
	3601475	Domino Offset 3.2/3.5 to 4.5/4.75mm						3									
	3601550	Domino Offset 3.2/3.5 to 5.5/6.0mm						3									
_	3603350	Domino Offset O/O 3.2/3.5 to 3.2/3.5mm						3									
	3603475	Domino Offset O/O 3.2/3.5 to 4.5/4.75mm						3									
	3603635	Domino Offset O/O 3.2/3.5 - 5.5/6.0/6.35mm						3									
	G3602350	Domino Axial 3.2/3.5 to 3.2/3.5mm								3							
	G3602475	Domino Axial 3.2/3.5 to 4.5/4.75mm								3							
	G3602550	Domino Axial 3.2/3.5 to 5.5/6.0mm								3							
	G3606069	MAS Extension Connector 3.2/3.5mm								3							

		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
		s-C7 erile)	3-C7 erile)	4mm	C-C2 odule	C Dril	ervice	omple Ion St	utlier	0mm	5mm	mina	mina Ion St	C Tap t Moo	C Tap strum	ose (
Part Number	Description	S 22	ದಿ ಜ	2.	ŌΣ	Ō	ٽڬ	ŏΖ	Ō	ω̈́	.5	ت	22	Ōä	ŌΞ	7
G3606071	MAS Extension Connector 4.75mm								3							
G3606072	MAS Extension Connector 5.5/6.0/6.35mm								3							
3603706	Rod Tapered 3.5/4.75mm × 420mm						3									
3603707	Rod Tapered 3.5/5.5mm × 420mm						3									
3603806	Rod Tapered 3.5/4.75 × 420mm CCM						3									
3603807	Rod Tapered 3.5/5.5 × 420mm CCM						3									
G3603709	Tapered Rod 3.5/6.0 × 420mm Ti															х
G3603809	Tapered Rod 3.5/6.0 × 420mm CCM+															х
G3603708	Tapered Rod 3.5/6.0 × 600mm Ti															X
G3603808	Tapered Rod 3.5/6.0 × 600mm CCM+															Х
7753704	Tapered Rod 3.5mm/4.75mm 600mm															Vertex Shelf Item
7753705	Tapered Rod 3.5mm/5.5mm 600mm															Vertex Shelf Item
7753804	Tapered Rod 3.5mm/4.75mm CCM+ 600mm															Vertex Shelf Item
7753805	Tapered Rod 3.5mm/5.5mm CCM+ 600mm															Vertex Shelf Item
Occipital Scre	ew Connectors															
3600300	Connector OC Eyelet Standard				4											
3600301	Connector OC Eyelet Offset				4											
Occipital Adju	ustable Plate															
3600600	OC Adjustable Plate, Small				1											
3600601	OC Adjustable Plate				1											
Occipital Bon	e Screws															
3600406	OC Screw 4.5 × 6mm				5											
3600408	OC Screw 4.5 × 8mm				5											
3600410	OC Screw 4.5 × 10mm				5											
3600412	OC Screw 4.5 × 12mm				5											











		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
Part Number	Description	Oß	OS	2		O	0 =	02	O	м	Ω.		75	0 m	0 =	
3600414	OC Screw 4.5 × 14mm				4											
3600506	OC Screw 5.0 × 6mm				4											
3600508	OC Screw 5.0 × 8mm				4											
3600510	OC Screw 5.0 × 10mm				4											
3600512	OC Screw 5.0 × 12mm				4											
3600514	OC Screw 5.0 × 14mm				2											
G360T0406	OC Bone Screw Tapered 4.5 × 6mm													5		
G360T0408	OC Bone Screw Tapered 4.5 × 8mm													5		
G360T0410	OC Bone Screw Tapered 4.5 × 10mm													5		
G360T0412	OC Bone Screw Tapered 4.5 × 12mm													5		
G360T0414	OC Bone Screw Tapered 4.5 × 14mm													4		
G360T0506	OC Bone Screw Tapered 5.0 × 6mm													4		
G360T0508	OC Bone Screw Tapered 5.0 × 8mm													4		
G360T0510	OC Bone Screw Tapered 5.0 × 10mm													4		
G360T0512	OC Bone Screw Tapered 5.0 × 12mm													4		
G360T0514	OC Bone Screw Tapered 5.0 × 14mm													2		
Occipital Rod	S															
G3600100	OC Adjustable Rod Ti 3.5 × 100mm															Х
G3600110	OC Adjustable Rod 3.5 × 100 CCM															Х
3600200	OC Adjustable Rod Ti 3.5 × 200				3											
3600210	OC Adjustable Rod 3.5 × 200 CCM				3											
3600201	OC Precurved Rod 3.5 × 200mm				3											
3600211	OC Precurved Rod 3.5 × 200mm CCM				3											
Instruments																
G850000	Universal Handle		2													
G852402	Ratcheting Handle		3													
3606005	Adjustable Drill Guide		1													
3606012	Fixed Drill Guide, 12mm		1													





													ejr	E .		
		uo	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	ent	(e)	u o	anle	Outlier Implant Module (Sterile)	ale	odule	erile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	
		C3-C7 Implant Module (Non Sterile)	Modul	lule (S	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	dule (S	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	nmen	crew	crew (Non	(II)
		it Moc	ment	it Moc	nt & In Sterile	odule	acic Ti Ile	rumer	nt Mod	all MA:	tion M	Mod	< Instr	one S terile)	odule	Loose Good (Sterile)
		mplar	nstru	Dri∥ B	Implai (Non	Bit M	Thor	x Inst erile)	Implai	X-Sm	Transi	Hool	Hool erile)	ered B Iule (S	ered B	) poos
		s-C7 I erile)	s-C7 I erile)	4mm	C-C2	C Drill	ervica	on St	utlier	Jmm.	, Emm.	mina	mina on St	C Tape t Mod	C Tape strum	ose (
Part Number	Description	\(\frac{1}{2}\)	చ్ చ	7.7	ŎΣ	ŏ	ತಿ ೬	రికే	ŏ	3.0	5.6	Ľ	ŠĽ	ŏ ä	ŎΞ̈́	
3606014	Fixed Drill Guide, 14mm		1													
3606016	Fixed Drill Guide, 16mm															Х
3606018	Fixed Drill Guide, 18mm															Х
G3606010	2.4mm Drill Bit			2												
3606030	Tap, 3.0mm		1													
3606035	Tap, 3.5mm		1													
3606040	Tap, 4.0mm							1								
3606045	Tap, 4.5mm							1								
3606055	Tap, 5.0mm							1								
3606032	Tap sleeve															X
3602102	Pedicle Feeler		1													
6956020	Depth Gauge		1													
3606003	Pedicle Probe, Standard		1													
3606004	Pedicle Probe, Curved							1								
3606195	Threaded Screwdriver		2													
3605772	Self-Holding Screwdriver		2													
3606193	Straight Hex Screwdriver		2													
3606194	Self-Holding Sleeve Screwdriver		2													
7756241	Plug Introducer		2													
3605786	Increased Angled Positioner /Alignment Tool		1													
3605785	Alignment tool		1													
7757270	Rod Template		1													
6905774	Rod Holder		1													
3605782	Rod Bender		1													
6905784	Rod Cutter		1													
3606175	Rod Reducer		1													
3606167	Rod Rocker							1								
6956163	Rod Gripper							1								
3606290	Sagittal Bending Iron, Left				1			1								
3606291	Sagittal Bending Iron, Right				1			1								
7756197L	Coronal Bending Iron, Left							1								
7756198R	Coronal Bending Iron, Right							1								
G601050	Compression Forceps							1								
G602050	Distraction Forceps							1								
3606201	Torque-limiting Screwdriver		2													

		ule (Non	Module (Non	ule (Sterile)	strument !)	(Sterile)	ansition	it Module	dule (Sterile)	S Module	AS Module	ule (Sterile)	Laminar Hook Instrument Module (Non Sterile)	crew and Drill	crew (Non Sterile)	
		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	nar Hook Instr Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
Part Number	Description	C3-C Steril	C3-C Steril	2.4m	DC-C	OC D	Cervi	Com (Non	Outli	3.0m	5.5m	Lami	Lamii (Non	OC T	OC T	Loos
G851100	Torque-limiting Handle, T-Handle		1													
3606170	Rod Pusher/Counter Torque, MAS		1													
3606172	Rod Pusher /Counter Torque, Universal		1													
3606171	Counter torque/Rod Pusher, 5.5mm MAS							1								
3605787	Screw Gauge		1													
6905715	Circular Drill Bit Adapter		1													
3606160	Hook Holder												1			
7754073	Laminar Hook Trial, 4.5/6.0mm												1			
7754074	Laminar Offset Hook Trial 4.5mm												1			
7754075	Laminar Offset Hook Trial 6.0mm												1			
6956158	Laminar elevator												1			
Occipital Fixa	tion Instruments										1	1	1			
G3600320	OC 3.2mm Drill Bit					1										
G3600321	OC 3.2mm Drill Bit, Flexible					1										
3600450	OC Tap, 4.5mm				1											
3600451	OC Tap, 4.5mm, Flexible				1											
3600500	OC Tap, 5.0mm				1											
3600501	OC Tap, 5.0mm, Flexible				1											
3600006	OC DT Guide 6mm-8mm				1											
3600010	OC DT Guide 10mm-12mm				1											
3600014	OC DT Guide 14mm- Screw Guide				1											
3600250	OC Self-Holding Screwdriver				1											
3600251	OC Self-Holding Screwdriver, Flexible				1											
G700251	OC Torque-limiting Ratchet Screwdriver				1											
3600252	OC Torque-limiting Screwdriver				1											
3600253	OC Torque-limiting Screwdriver, Flexible				1											
3600230	OC Plate Bender				1											
3600170	OC Rod Pusher/Counter Torque				1											
3606292	Tube Bender				2											
	OC 3.3mm Drill Bit, Tapered													1		

		C3-C7 Implant Module (Non Sterile)	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	Loose Good (Sterile)
Part Number	OC 3.3mm Drill Bit, Tapered,	0 0	0 65	8	02	0	0 =	UE		м	. υ		75		0 =	
G360T0321	Flexible													1		
3600334	OC Tap 4.5mm, Tapered														1	
3600383	OC Tap 4.5mm, Tapered, Flexible														1	
3600337	OC Tap 5.0mm, Tapered														1	
3600384	OC Tap 5.0mm, Tapered, Flexible														1	
Cases and Tra	ays															
3607000	Hook Instrument Tray												1			
1850049	Standalone Case Lid												1			
3607001	OC - C2 Instrument Tray				1											
3607002	OC-C2 Implant Tray				1											
3607003	OC - C2 Module: MAS Caddy				1											
3607004	OC - C2 Module: MAS Caddy Lid				2											
3607005	OC Screw Caddy				1											
3607006	OC Screw Caddy Lid				2											
3607007	OC Plate and Screw Connector Caddy				1											
3607008	OC Plate and Screw Connector Caddy Lid				1											
3607009	OC-C2 Implant and Instrument Module Label				2											
3607010	C3-C7 Instrument Tray 1 of 2		1													
3607011	C3-C7 Instrument Tray 2 of 2		1													
3607012	C3-C7 Instrument Module Label		2													
1850079	Lid 1850079 Generic Outer Lid	1	1		1		1									
1850078	Case 1850078 Triple Generic Outer Case	1	1		1		1									
3607013	C3-C7 Implant Tray 1 of 2	1														
3607014	C3-C7 Implant Tray 2 of 2	1														
3607015	C3-C7 Implant Module: 3.5 MAS Caddy	1														
3607016	C3-C7 Implant Module: 3.5 MAS Caddy Lid	1														
3607017	C3-C7 Implant Module: 4.0 MAS Caddy	1														

			_										e e	≡	~	
		Von	C3-C7 Instrument Module (Non Sterile)	2.4mm Drill Bit Module (Sterile)	nent	ile)	noi	qule	Outlier Implant Module (Sterile)	dule	odule	terile)	Laminar Hook Instrument Module (Non Sterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Non Sterile)	
		C3-C7 Implant Module (Non Sterile)	t Modu	dule (S	OC-C2 Implant & Instrument Module (Non Sterile)	OC Drill Bit Module (Sterile)	Cervical Thoracic Transition Implant Module	Complex Instrument Module (Non Sterile)	odule (\$	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	rumer	Screw e)	Screw e (Non	( <u>e</u>
		ant Mo	ument	Bit Mo	lant & l n Steri	Moduli	oracic dule	strume	lant Mo	mall M	sition	ok Mo	ok Inst	Bone (Sterile	i Bone Modul	Loose Good (Sterile)
		:7 Impl e)	:7 Instr e)	m Drill	22 lmp lle (No	vill Bit	ical Th	plex In Sterile	erImp	m X-Sı	m Trar	nar Ho	nar Ho Sterile	aperec Iodule	apered	е Gooc
Part Number	Description	C3-C Steril	C3-C Steril	2.4m	Joc-C Modu	OCD	Cervi	Com (Non	Outli	3.0m	5.5m	Lami	Lami (Non	OC T Bit M	OC T Instru	Loos
3607018	C3-C7 Implant Module: 4.0 MAS Caddy Lid	1														
3607019	C3-C7 Implant Module: Connector Caddy	1														
3607020	C3-C7 Implant Module: Connector Caddy Lid	1														
3607021	C3-C7 Implant Module: Set Screw Caddy	1														
3607022	C3-C7 Implant Module: Set Screw Caddy Lid	1														
3607023	C3-C7 Implant Module: Pre-Cut Rod Caddy	1														
3607024	C3-C7 Implant Module: Pre-Cut Rod Caddy Lid	1														
3607025	C3-C7 Implant Module Label	2														
3607026	Complex Instrument Tray							1								
1850095	Standalone Case Lid							1								
3607028	Cervical Thoracic Implant Tray 1 of 2						1									
3607029	Cervical Thoracic Implant Tray 2 of 2						1									
3607030	Cervical Thoracic Implant Module: 3.5mm MAS Caddy						1									
3607031	Cervical Thoracic Implant Module: 3.5mm MAS Caddy Lid						1									
3607032	Cervical Thoracic Implant Module: 4.0mm/4.5mm MAS Caddy						1									
3607033	Cervical Thoracic Implant Module: 4.0mm/4.5mm MAS Caddy Lid						1									
3607034	Cervical Thoracic Implant Module: Domino Caddy						1									
3607035	Cervical Thoracic Implant Module: Domino Caddy Lid						1									
3607036	Cervical Thoracic Implant Module Label						2									
3607100	Sterile Suitcase								1							
3607038	OC Tapered Bone Screw Instrument Tray														1	
3607039	OC Tapered Screw and Drill Bit Sterile Suitcase													1		
176-530	Sterile Drill Bit Caddy			1		1										
9790901	Sterile Drill Bit Caddy Lid			1		1										
8657021	Sterile Suitcase									1	1	1				
1850460	Standalone Case Lid														1	

### IMPORTANT INFORMATION

#### **Infinity<sup>™</sup> OCT System**

#### **PURPOSE**

IMPORTANT INFORMATION ON THE INFINITY™ OCT SYSTEM

The Infinity  $^{\text{TM}}$  Occipitocervical-Upper Thoracic System (OCT System) is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the craniocervical, cervical, and/or upper thoracic spine (occiput-T3).

#### **DESCRIPTION**

The Infinity  $^{\text{TM}}$  OCT System is a posterior occipitocervical-upper thoracic system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case

The Infinity  $^{\text{TM}}$  OCT System is fabricated from medical grade titanium alloy and medical grade cobalt chromium. Medical grade titanium alloy and medical grade cobalt chromium may be used together. Never use titanium alloy and/or cobalt chromium with stainless steel in the same construct. No warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

To achieve best results, do not use any of the Infinity  $^{\text{TM}}$  OCT System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another Medtronic document. As with all orthopedic and neurosurgical implants, Infinity  $^{\text{TM}}$  OCT System components should never be reused under any circumstances.

#### INDICATIONS

The Infinity  $^{TM}$  OCT System is 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 to C7), and the thoracic spine from T1-T3:

- Traumatic spinal fractures and/or traumatic dislocations.
- Instability or deformity.
- Failed previous fusions (e.g. pseudarthrosis).
- Tumors involving the cervical spine.
- 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.

The Infinity  $^{\text{TM}}$  OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Infinity<sup>TM</sup> OCT System may be used with PASS OCT Patient Specific UNID OCT rods. In order to achieve additional levels of fixation, the Infinity<sup>TM</sup> OCT System may be connected to the CD Horizon<sup>TM</sup> Spinal System and Vertex<sup>TM</sup> Reconstruction System rods with the Infinity<sup>TM</sup> OCT System rod connectors. Transition rods with differing diameters may also be used to connect the Infinity<sup>TM</sup> OCT System to the CD Horizon<sup>TM</sup> Spinal System. Refer to the CD Horizon<sup>TM</sup> Spinal System package insert, Vertex<sup>TM</sup> Reconstruction System and PASS OCT Spinal System package insert for a list of the indications of use.

Note: The 3.0mm multi axial screw (MAS) requires the use of MAS CROSSLINK  $^{\text{TM}}$  at each level in which the 3.0mm screw is intended to be used.

The lateral offset connectors and MAS extension connectors are intended to be used with 3.5mm and larger diameter multi axial screws. The lateral offset connectors and MAS extension connectors are not intended to be used with 3.0mm screws.

 $Note: Segmental\,fixation\,is\,recommended\,for\,these\,constructs.$ 

#### **CONTRAINDICATIONS**

Contraindications include:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the
  potential benefit of spinal implant surgery, such as the presence
  of congenital abnormalities, elevation of sedimentation rate
  unexplained by other diseases, elevation of white blood count (WBC),
  or a marked left shift in the WBC differential count.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

#### **POTENTIAL ADVERSE EVENTS**

All of the adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing
- skin penetration, irritation, fibrosis, necrosis, and/or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
- Loss of neurological function (e.g. sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis,
- and/or muscle loss.

#### IMPORTANT INFORMATION

- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body), and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (pseudarthrosis), delayed union, or mal-union.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction or loss of bowel control, or other types of gastrointestinal system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Change in mental status.
- Death.

Note: additional surgery may be necessary to correct some of these potential adverse events.

#### WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or patients who abuse alcohol are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

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

This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device

and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal 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 and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle 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.

Physician note: although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

#### !USA For US Audiences Only

 ${\bf Caution}:$  Federal law (USA) restricts these devices to sale by or on the order of a physician.

#### **FURTHER INFORMATION**

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, contact Medtronic.

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#### Magnifuse™ DBM and Magnifuse™ II

#### **INDICATIONS**

Magnifuse™ Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., spine, pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone.

Magnifuse  $^{\text{TM}}$  Bone Graft may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse  $^{\text{TM}}$  Bone Graft may be mixed with fluid such as bone marrow aspirate, blood, sterile water, or sterile saline in order to adjust the consistency and handling characteristics of the bone graft material. Magnifuse  $^{\text{TM}}$  Bone Graft is resorbed/remodeled and replaced by host bone during the healing process.

Magnifuse<sup>TM</sup> II Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. Magnifuse<sup>TM</sup> II Bone Graft is resorbed/remodeled and replaced by host bone during the healing process.

#### **CONTRAINDICATIONS**

The following are contraindications for the use of Magnifuse  $^{\text{TM}}$  DBM Bone Graft and Magnifuse  $^{\text{TM}}$  II Bone Graft:

- The presence of infection at the transplantation site.
- Treatment of spinal insufficiency fractures.

#### **CAUTION**

This product may contain trace amounts of antibiotics (gentamicin), surfactant, and other solutions used in processing the bone tissue as well as the PGA mesh. Caution should be exercised if the patient is allergic to these antibiotics or chemicals.

#### **PRECAUTIONS**

Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the qualification of all tissue donors. Despite the viral inactivation and extensive tissue donor selection and qualifications process used in providing this tissue graft, transmission of an infectious disease through the use of this tissue graft is still possible. Bacterial infection at the graft site may also occur. Any adverse outcomes potentially attributable to Magnifuse<sup>TM</sup> or Magnifuse<sup>TM</sup> II Bone Graft must be reported promptly to Medtronic (i.e., spine, pelvis, and extremities). Adequate fixation should be used to stabilize the implant site during bone formation and healing in bony voids or gaps of the skeletal system.

#### Mastergraft<sup>™</sup> Putty

#### **INDICATIONS**

Mastergraft<sup>™</sup> Putty combined with either autogenous bone marrow, and/ or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, Mastergraft<sup>™</sup> Putty can be used with autograft as a bone graft extender. Mastergraft<sup>™</sup> Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Mastergraft<sup>™</sup> Putty resorbs and is replaced with bone during the healing process.

#### **CONTRAINDICATIONS**

This product is not intended to provide structural support during the healing process; therefore, Mastergraft Putty is contraindicated where the device is intended as structural support in the skeletal system. Conditions representing relative contraindications include:

- Severe neurological or vascular disease.
- Uncontrolled diabetes.
- Hypercalcemia.
- Pregnancy.
- Where stabilization of fracture is not possible.
- Segmental defects without supplemental fixation.
- Where there is significant vascular impairment proximal to the graft site.
- When there are systemic and/or metabolic disorders that affect the bone or wound healing.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

 $Master graft^{\intercal M} \ Putty \ should \ not \ be \ used \ in \ patients \ with \ a \ known \ history \ of \ hypersensitivity \ to \ bovine \ derived \ materials.$ 

#### **POTENTIAL ADVERSE EVENTS**

A listing of potential adverse events includes, but is not limited to:

- Deformity of the bone at the surgical site.
- Fracture or extrusion of Mastergraft<sup>TM</sup> Putty, with or without generation of particulate debris.
- Wound complications including hematoma, site damage, infection, bone fracture, and other complications common to any surgical procedure.
- Incomplete, or lack of, osseous ingrowth into bone void, as possible with any bone filler.

#### WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.

As with any surgical procedure, care should be demonstrated in treating patients with preexisting conditions that may impact the success of the surgical procedure. This includes patients with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy, or high dosage radiation therapy.

Mastergraft<sup>™</sup> Putty does not possess sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation methods are recommended as needed to ensure stabilization of the defect. Complete postoperative wound closure is essential.

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

This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Warning: Never use this device if the packaging is compromised.

**PHYSICIAN NOTE**: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

#### !USA FOR US AUDIENCES ONLY

**CAUTION:** FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

#### Mastergraft™ Matrix EXT

#### **INDICATIONS**

Mastergraft $^{\text{TM}}$  Matrix EXT is to be combined with autogenous bone marrow and is indicated for bony voids or gaps not intrinsic to the stability of the bony structure and can be used as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

#### **CONTRAINDICATIONS**

This product is not intended to provide structural support during the healing process. Therefore, Mastergraft Matrix EXT is contraindicated where the device is intended as structural support in the skeletal system. Conditions representing relative contraindications include:

- Severe neurological or vascular disease.
- Uncontrolled diabetes.
- Hypercalcemia.
- Pregnancy.
- Where stabilization of fracture is not possible.
- Segmental defects without supplemental fixation.
- Where there is significant vascular impairment proximal to the graft site.
- When there are systemic and/or metabolic disorders that affect the bone or wound healing.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.
- Should not be used in patients with a known history of hypersensitivity to bovine derived materials.

#### **POTENTIAL ADVERSE EVENTS**

A listing of potential adverse events includes, but is not limited to:

Deformity of the bone at the surgical site.

Fracture or extrusion of Mastergraft  $^{TM}$  Matrix EXT with or without generation of particulate debris.

Wound complications including hematoma, site damage, infection, bone fracture, and other complications common to any surgical procedure.

Incomplete or lack of osseous in-growth into bone void, as possible with any bone filler.

#### WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. As with any surgical procedure, care should be demonstrated in treating patients with preexisting conditions that may impact the success of the surgical procedure. This includes patients with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

Mastergraft $^{\text{TM}}$  Matrix EXT does not possess sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation methods are recommended as needed to ensure stabilization of the defect. Complete postoperative wound closure is essential.

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

This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Warning: Never use this device if the packaging is compromised.

**PHYSICIAN NOTE:** Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

#### **!USA FOR US AUDIENCES ONLY**

**CAUTION:** FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

#### Grafton™ DBF

#### **INDICATIONS**

Caution: GRAFTON™ DBM DBF is restricted to use by a physician, podiatrist, or dentist. GRAFTON™ DBM DBF can be used in orthopedic or reconstructive bone grafting procedures. The product can also be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or alone as a bone graft. The contents of an individual GRAFTON™ DBM DBF container are intended for single patient use only. Do not use the contents of any container for multiple patients. Empty or partially used containers should be disposed of in accordance with recognized procedures for discarding medical waste materials. Preparation of the bone graft bed is important for graft incorporation and bone formation, as are other factors such as blood supply, source of marrow elements, loading, stability, and absence of infection at the graft site. The volume of graft material used in each procedure is determined by the judgment of the clinician.

#### **CAUTION**

This allograft may contain trace amounts of antibiotics (gentamicin) and processing solutions. Caution should be exercised if the patient is allergic to these antibiotics or processing solutions.

#### **PRECAUTIONS**

Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the qualification of all tissue donors. Despite the viral inactivation and extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of a communicable disease through the use of this tissue graft is still possible. Bacterial infection at the graft site may also occur. Any adverse outcomes potentially attributable to GRAFTON™ DBM DBF must be reported promptly to Medtronic.

#### CONTRAINDICATIONS

The presence of infection at the transplantation site is a contraindication for the use of this allograft.

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(901) 396-3133 (800) 876-3133 Customer Service: (800) 933-2635 The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.



Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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