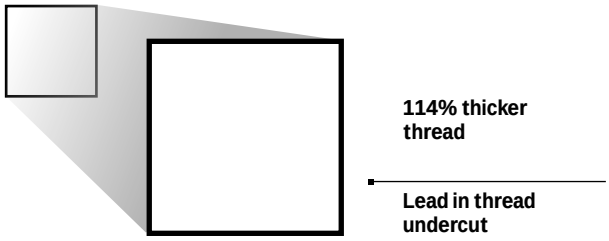
SURGICAL TECHNIQUE

Medtronic

MICHELSO

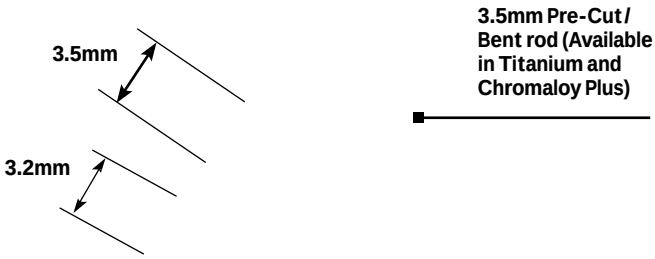
Locking Set Screw

- 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 Plus)
- Pre-Cut/Bent Rods in 3.5mm diameter (Titanium and Chromaloy Plus)
- Cervical-thoracic transition rods available in various diameters in Titanium and Chromoloy™ Plus (see Cervical/Thoracic section for additional information)
- Occipital Rods available in Titanium and Chromoloy™ Plus (see OccpitoCervical 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

Offset Domino

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

Open to Open Offset Domino

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

Axial Domino

Multi Axial Screw Extension Connector

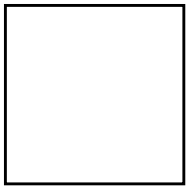
- Connects directly to the multi axial screw to allow for extension of adjacent constructs without revising the existing construct
- "Zero Run on the Rod" transition option to allow for maximum fixation area
- Stepped design feature to accommodate dorsal height differences between rods
- Allows for medial/lateral 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

MAS Extension Connector

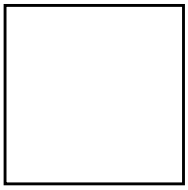
The MAS extension connectors are intended to be used with 3.5mm and larger diameter multi axial screws.
The MAS extension connectors are not intended to be used with 3.0mm screws.

Tapered Rods

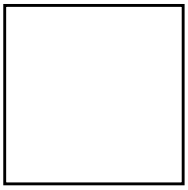
- One piece connection and allows for axial alignment of rods at the cervical-thoracic transition point
- Wide range of sizes for flexibility in construct planning:
  - Enable connection from a 3.5mm rod diameter to 4.75mm, 5.5mm, and 6.0mm rod diameters
- Available in Titanium and Chromaloy Plus



3.5mm-4.75mm Tapered rod



3.5mm-5.5 Tapered Rod



3.5mm-6.0 Tapered Rod

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

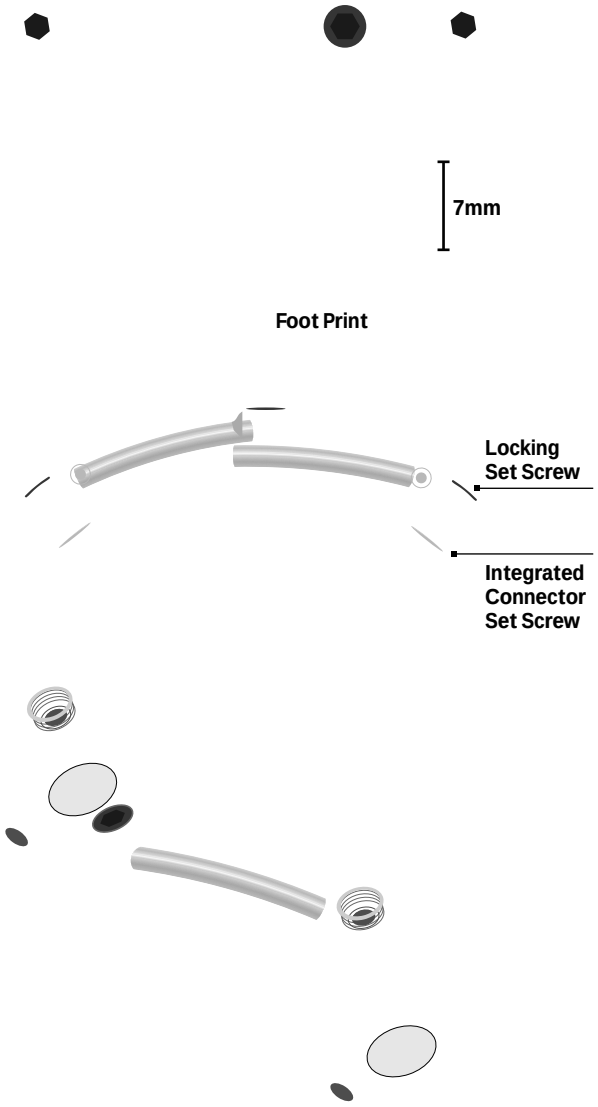
CROSSLINK™ Connector Options

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.



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

Screw Preparation/Placement continued

2.4mm Drill Bit

Color-Coded Taps

3.0mm tap

3.5mm tap

4.0mm tap

4.5mm tap

5.0mm tap

Tap Sleeve

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.

Color Coding Reference

	Screw Size	Color	Drill Bit	Tap
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

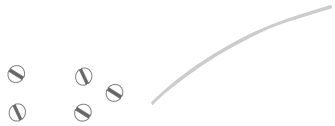
Hook Placement

Laminar elevator

Hook Holder

Rod Preparation

Tube Benders



Rod Cutter

French Rod Bender

rod template

Saddle Alignment / Rod Insertion

Alignment tool

Increased Angled Positioner

Rod Holder

Rod Reduction/Correction

Rod Reducer

Rod Gripper

Bending Iron right

Bending Iron Left

Rod Rocker

Coronal Benders

Compression/Distraction

Compressor Forceps

Distractor Forceps

Final Tightening

MAS
Rod Pusher/
Counter torque

Universal
Rod Pusher/
Counter Torque

5.5mm MAS
Rod Pusher/
Counter Torque

Torque Limiting Handle

Torque Limiting Screw Driver

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 flats can be inserted directly into the handles with a one-step insertion motion. (Figure 4) 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 adaptor (6905715) can be used to convert the tri flat to an AO connection.

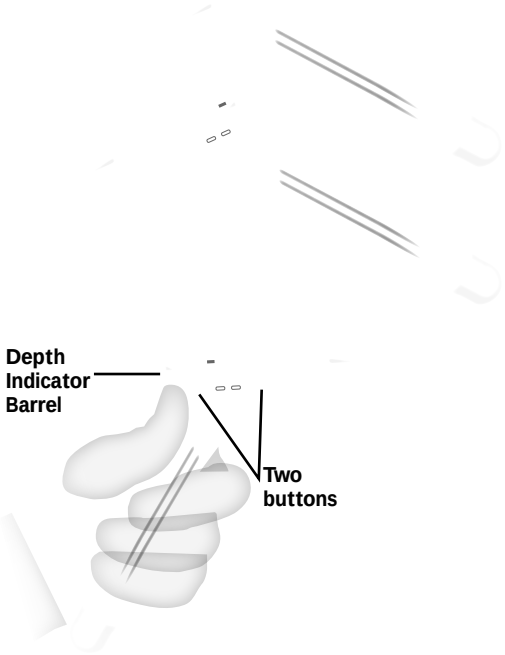


Figure 2

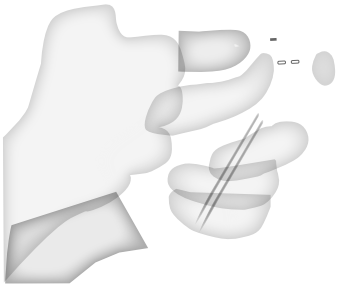


Figure 3

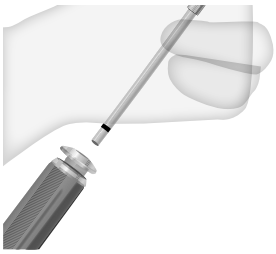


Figure 4

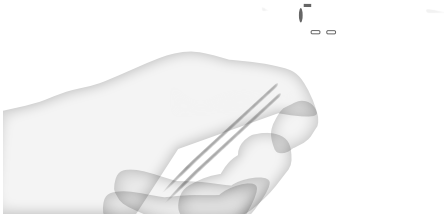


Figure 5

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 57. 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).

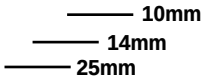


Figure 6

Figure 7

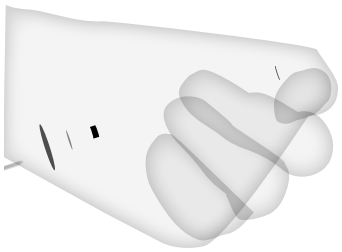


Figure 8

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 is comprised of 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) (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.

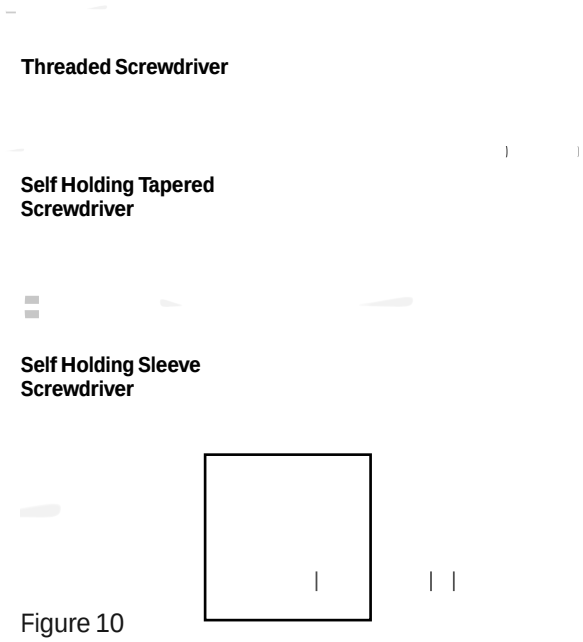


Figure 10

Figure 11

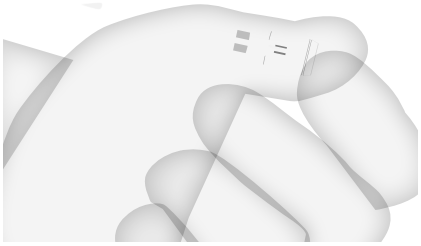


Figure 12

Figure 13

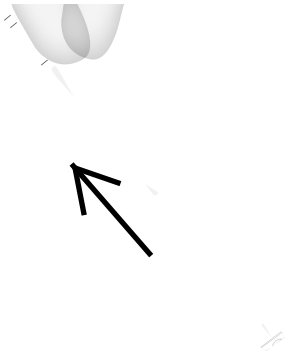


Figure 14

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.

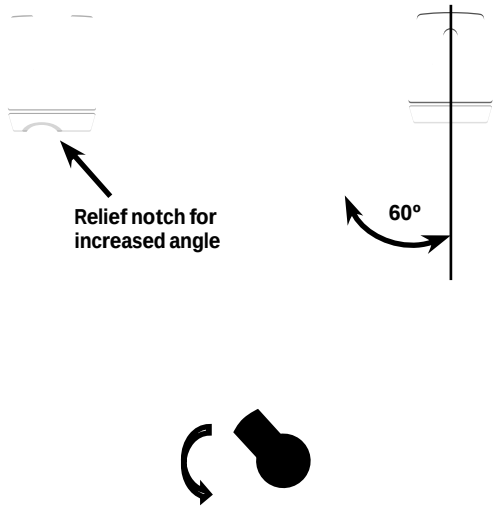
Note
Friction within the saddle will maintain position after adjustments have been made.

Figure 15

2) Increased Angled Positioner / Alignment Tool (IAP) (3605786)

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°of rotation.

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



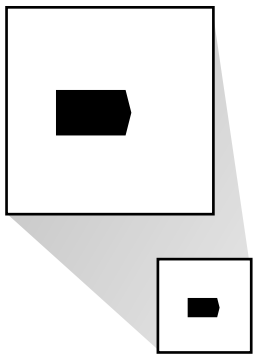


Figure 16

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 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

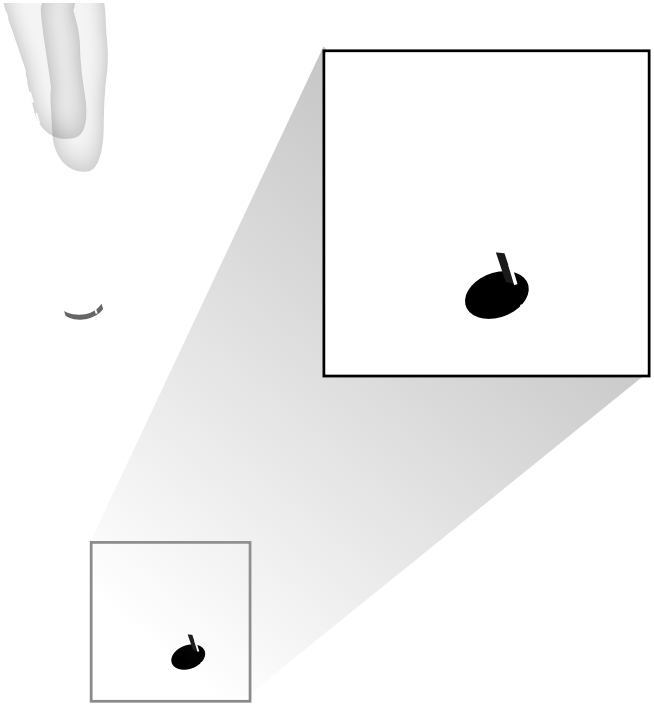


Figure 18

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 towards 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 max angulation.

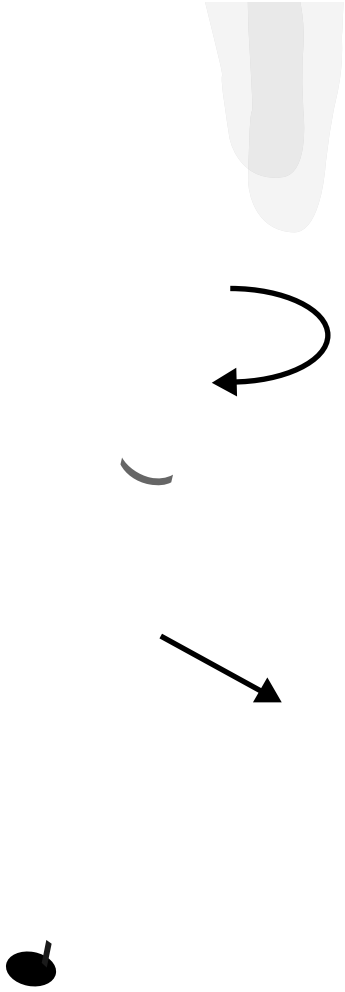


Figure 19

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.

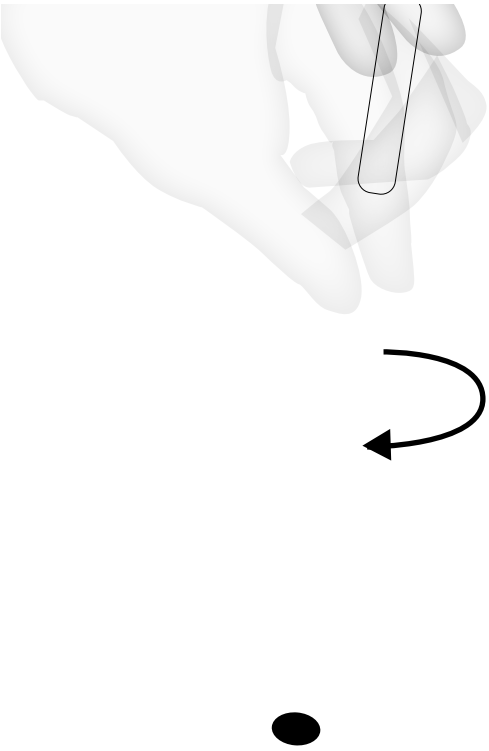


Figure 20

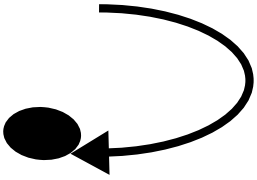


Figure 21

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 22

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.

3.5mm Pre-Cut/ Bent option

3.5mm option

3.2mm option

Figure 24

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 25

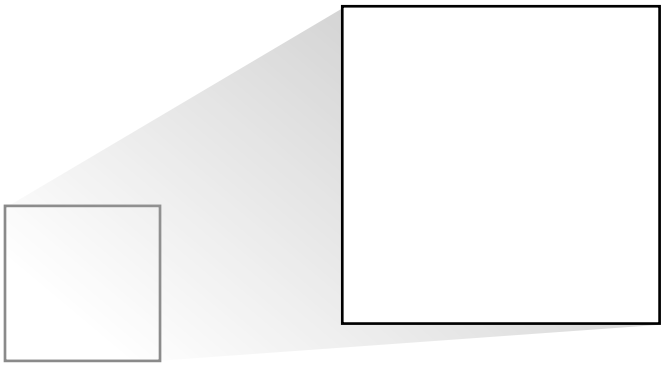


Figure 26

ROD **CUTTING**

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

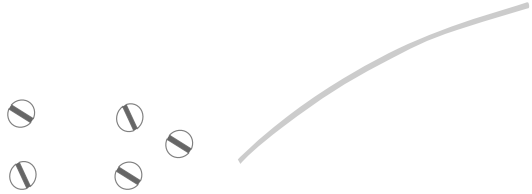


Figure 27

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) .

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).

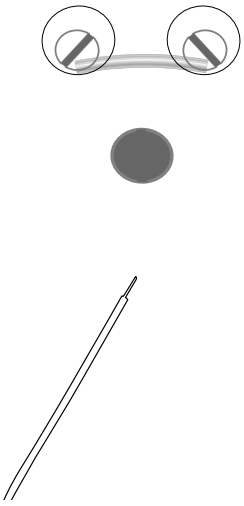


Figure 28

Figure 29

Figure 30

USING LATERAL **OFFSET CONNECTORS**

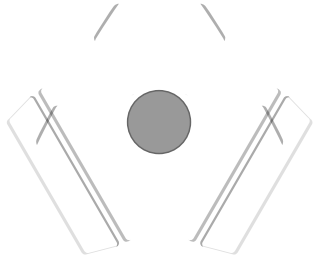
If additional medial/lateral offset is required, beyond the 60 degrees of angulated, Lateral Connectors can facilitate rod attachment of the non-linear screws patterns and can adjust for screw height differences.

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.



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™ 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™ Connector and MAS Extension Connector section for more information.

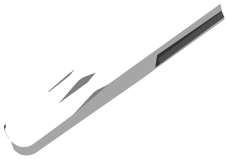


Figure 34

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. (Figure 36a, 36b, and 36c)

Figure 35a

Figure 35b

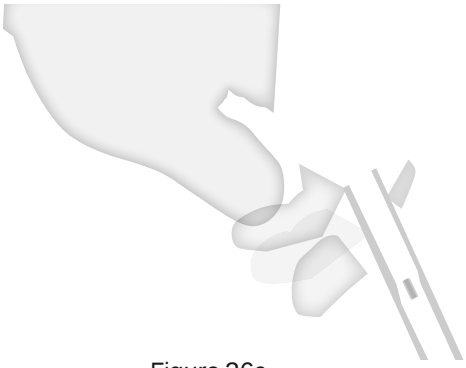


Figure 36a

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. (Fig 37)

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

Figure 37

Figure 38

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) 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.

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

Torque Limiting T-Handle

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
- 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)

Tapered Rod

Offset Dominos

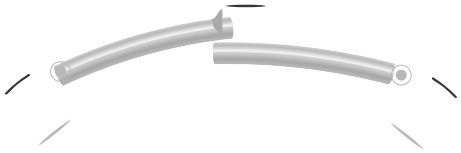
Open to Open Offset Domino

Axial Domino

Multi-Axial Screw (MAS) Extension Connector

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

ROD CROSSLINK™ CONNECTOR **PLACEMENT**

The Rod CROSSLINK™ 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) .

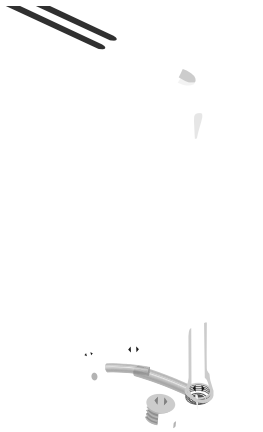


Figure 44

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™, 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).

Note
Applying tension will minimize motion of the crosslilnk 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
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.

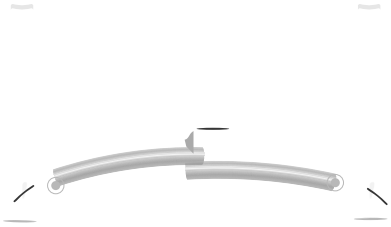


Figure 46

Figure 47

Figure 48

Figure 49

Insert a MAS Crosslink Locking Screw into the crosslink and provisionally tighten using the Self Holding Screw Driver (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) 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

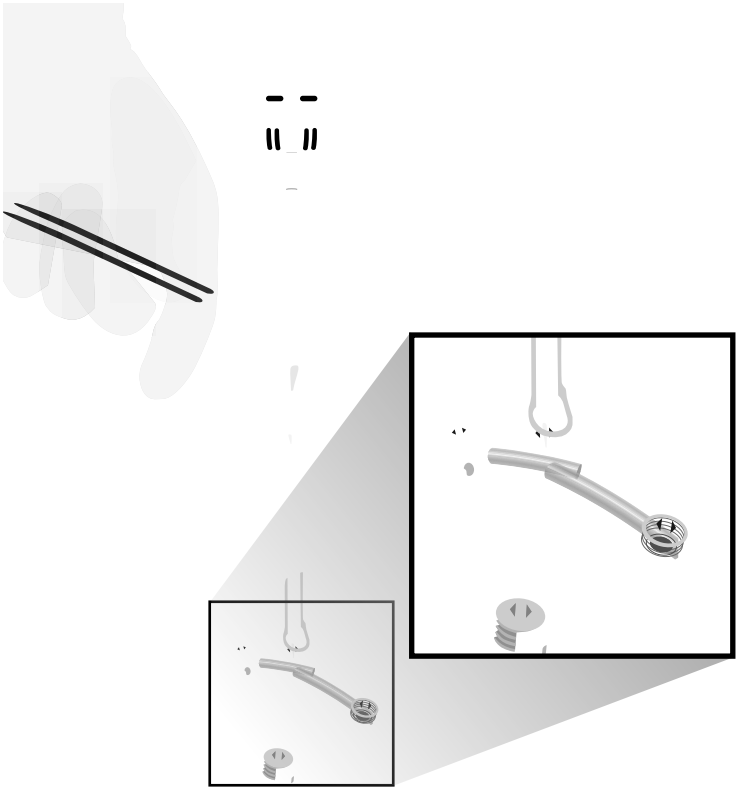


Figure 52

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:

Grafton™ DBM Putty

Mastergraft™ Putty

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 homogeonous 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 Grafton™ Matrix Strips, Grafton™ DBM Putty, or Mastergraft™ Putty Instructions for Use Manuals for further production 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).

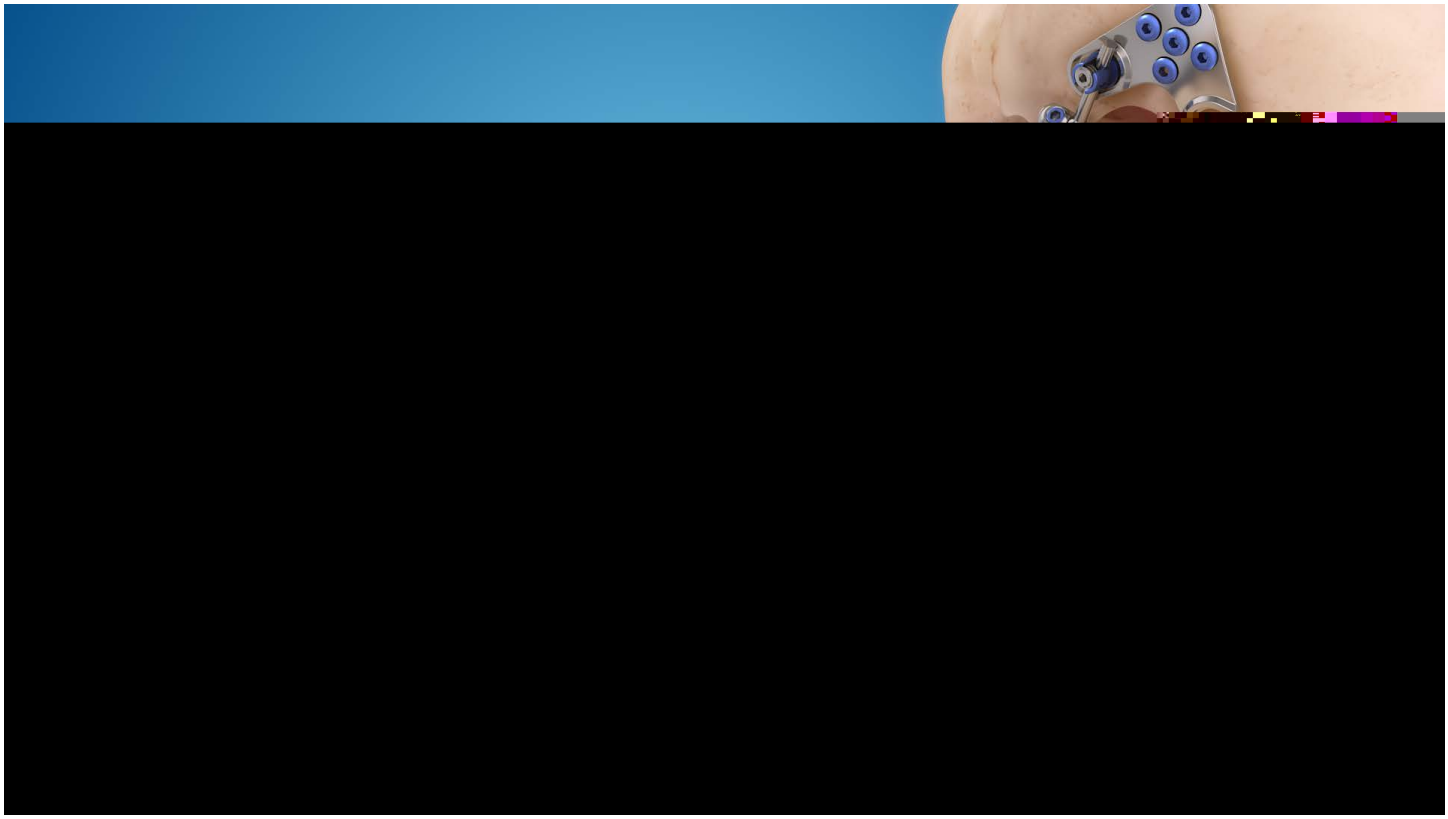


Figure 53

Explantation

To remove any of the Infinity™ 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.[1,2]

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

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˚ 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.

C1 Lateral Mass Screw Fixation

Figure 58

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[3], and C2 pars interarticularis screw fixation as described by Mummaneni[4] and Foley.[5]

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˚ 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˚ cephalad (Figure 62).

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

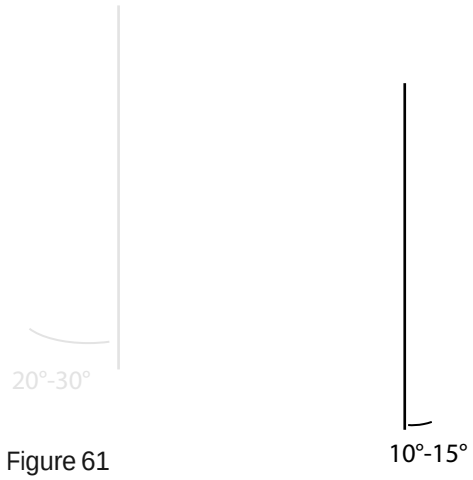


Figure 61

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 Pedicle and Pars Interarticularis Screw Fixation

Figure 63

C2 Pedicle Screw

C2 Pars Interarticularis Screw

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.[6]

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

Figure 67

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˚ 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.[3]

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.

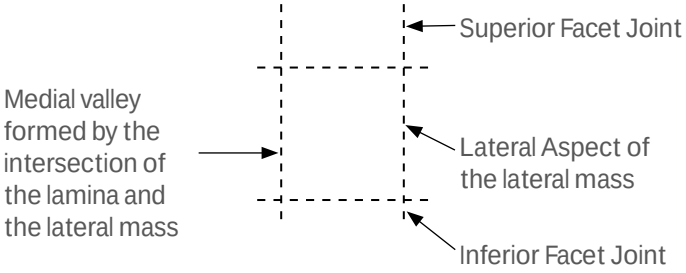


Figure 74

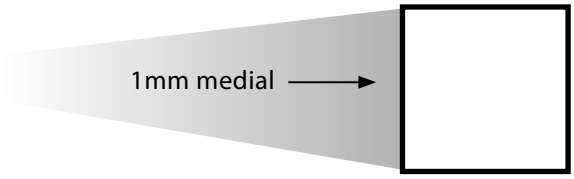


Figure 75

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 the entry point has been established, the drill should be placed perpendicular to the lateral mass and then angled 20˚– 30˚ laterally (Figure 76) and approximately 20˚– 30 ˚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

Figure 79

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˚ medial to the midline (Figure 80).

For pedicle screw placement in T1-T3, the drill bit should be angled 10-15° medially and 5° caudally. (Figure 81)

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

Figure 80

Figure 81

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

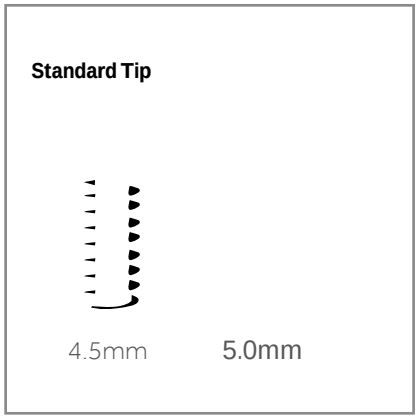
Two different designs of OC bone screws are available:

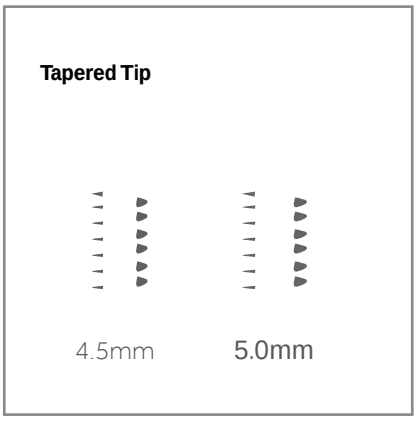
Standard Tip:

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

Tapered Tip:

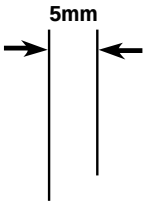
- 4.5mm × 6-14mm
- 5.0mm × 6-14mm





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



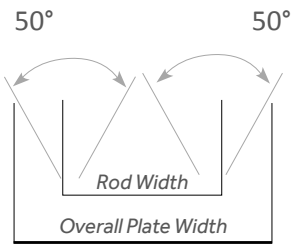
Standard

Offset

Occipital Adjustable Plates

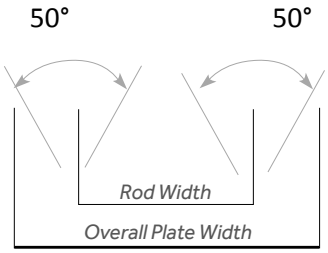
- Three hole midline fixation to the occiput to maximize bone purchase in the midline
- Rotating and translating saddles allow for flexibility in rod placement
- Space between saddles of the plate for bone grafting on the occiput
- Pre-machined radius of curvature for proper fit onto the occipital anatomy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

Small OC Adjustable Plate Dimensions

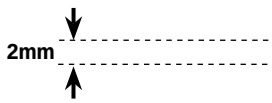


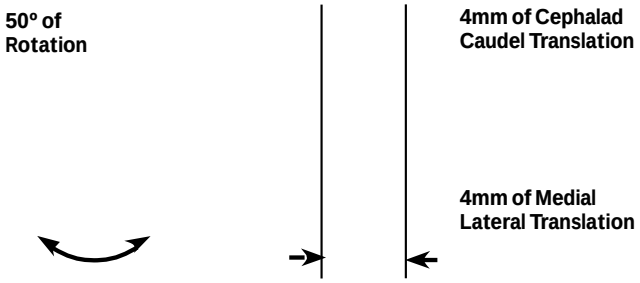
Min Rod Width	Max Rod Width	Overall Plate Width
24mm	32mm	46.9mm

Standard OC Adjustable Plate Dimensions



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



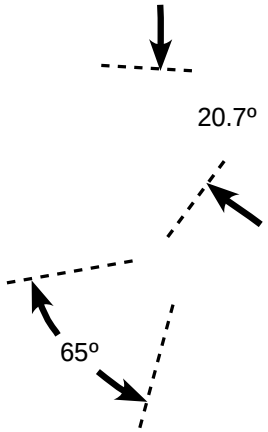


Occipitocervical Adjustable Rods

- 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° 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 200mm lengths
- Available in Titanium and Chromaloy Plus



OC INSTRUMENT **SET**

Drill-Tap (DT) Screw Guides

Fixed Occipital Drill Tap Guide,
6mm/8mm

Fixed Occipital Drill Tap Guide,
10mm/12mm

Fixed Occipital Drill Tap Guide,
14mm / Screwdriver Guide

Drill Bits

OC 3.2mm Flexible Drill Bit (for both standard and tapered tip OC bone screws)

Taps

OC 4.5mm Flexible Tap

Standard OC Bone Screw or Tapered OC Bone Screw

OC 4.5mm Straight Tap

Standard OC Bone Screw or Tapered OC Bone Screw

OC 5.0mm Flexible Tap

Standard OC Bone Screw or Tapered OC Bone Screw

OC 5.0mm Straight Tap

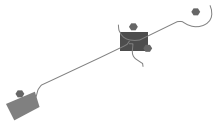
Standard OC Bone Screw or Tapered OC Bone Screw

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

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) .

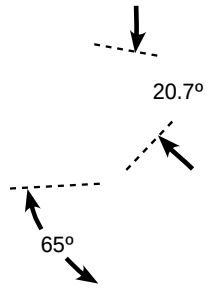
There are multiple rod options to choose from depending on patient anatomy and surgeon preference:

1.) OC Adjustable Rod

- Available in Titanium and Chromaloy 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.

Figure 84

Figure 85



2.) OC Precurved Rods

- Available in Titanium and Chromaloy Plus
- Available in 3.5mm diameter

3.) Straight Rods

- Available in Titanium and Chromaloy 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.

ROD **CONTOURING**

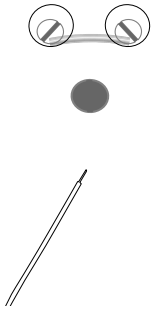
For additional contouring to any of the rods, the French Bender (3605782), Left and Right Sagittal Benders (3606290 and 3606291) , or Tube Benders (3606292) may be used.

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).

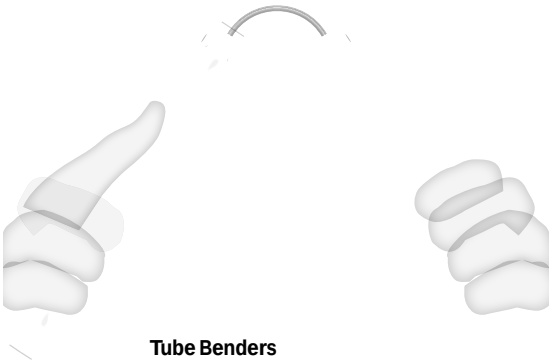
Note
Avoid repeated bending motions or reverse bending motions to the implants, as excessive bending will decrease the integrity of the implant (Figure 51).



French Bender

Sagittal Benders

Figure 86



Tube Benders

Figure 87

ROD **CUTTING**

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

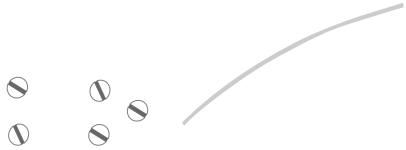


Figure 88

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.

Figure 89

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 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)	Tap
Infinity™ 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	Silver	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 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

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).

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).

Figure 96

Figure 97

Figure 98

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 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.

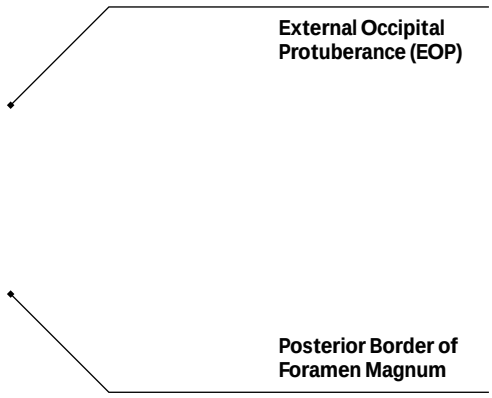
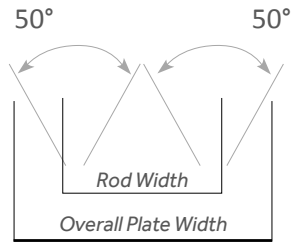


Figure 101

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.

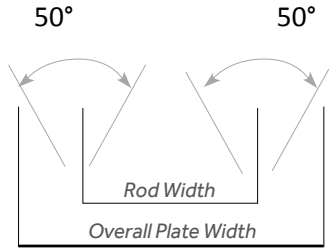
There are two sizes of the Occipital Adjustable Plate to accommodate varying anatomies., Small and Standard.

Small OC Adjustable Plate Dimensions



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

Standard OC Adjustable Plate Dimensions



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

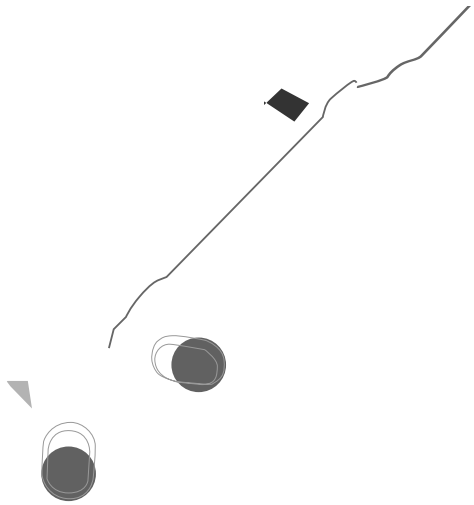
Figure 102

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 / caudel planes and the medial / lateral planes (Figure 103a and 103b)

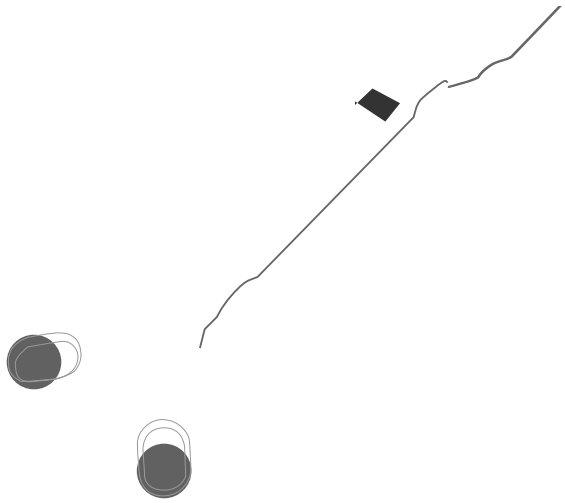
It also may be necessary to contour a small portion of uneven occipital bone with a high-speed drill to allow the plate to lie flush.

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



Bending in the Cephalad / Caudel 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)	Tap
Infinity™ 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	Silver	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

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) 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.

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) 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 RodPusher/Counter Torque (3606170).

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

Figure 111

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

Figure 112

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™ System implants described throughout this technique, engage the set screws and the occipital bone screw s 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

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
Multi Axial Screws																
G3603008	Multi Axial X-Small Screw, G3603008 3.0 X 8MM									4						
G3603010	Multi Axial X-Small Screw, G3603010 3.0 X 10MM									4						
G3603012	Multi Axial X-Small Screw, G3603012 3.0 X 12MM									4						
G3603014	Multi Axial X-Small Screw, G3603014 3.0 X 14MM									4						
G3603016	Multi Axial X-Small Screw, G3603016 3.0 X 16MM									4						
G3603018	Multi Axial X-Small Screw, G3603018 3.0 X 18MM									4						
G3603020	Multi Axial X-Small Screw, G3603020 3.0 X 20MM															x
G3603022	Multi Axial X-Small Screw, G3603022 3.0 X 22MM															x
G3603024	Multi Axial X-Small Screw, G3603024 3.0 X 24MM															x
G3603026	Multi Axial X-Small Screw, G3603026 3.0 X 26MM															x
G3603028	Multi Axial X-Small Screw, G3603028 3.0 X 28MM															x
G3603030	Multi Axial X-Small Screw, G3603030 3.0 X 30MM															x
G3603032	Multi Axial X-Small Screw, G3603032 3.0 X 32MM															x
G3603034	Multi Axial X-Small Screw, G3603034 3.0 X 34MM															x
G3603508	MULTI AXIAL SCREW 3603508 3.5 X 8MM															x
G3603510	MULTI AXIAL SCREW 3603510 3.5 X 10MM															x
3603512	MULTI AXIAL SCREW 3603512 3.5 X 12MM	8														
3603514	MULTI AXIAL SCREW 3603514 3.5 X 14MM	14														
3603516	MULTI AXIAL SCREW 3603516 3.5 X 16MM	8														
3603518	MULTI AXIAL SCREW 3603518 3.5 X 18MM	6														
3603520	MULTI AXIAL SCREW 3603520 3.5 X 20MM	4														
3603522	MULTI AXIAL SCREW 3603520 3.5 X 22MM	2			2		2									

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
3603524	MULTI AXIAL SCREW 3603520 3.5 X 24MM	2			2		2									
3603526	MULTI AXIAL SCREW 3603520 3.5 X 26MM	2			2		2									
3603528	MULTI AXIAL SCREW 3603520 3.5 X 28MM	2			2		2									
3603530	MULTI AXIAL SCREW 3603530 3.5 X 30MM				2		2									
3603532	MULTI AXIAL SCREW 3603532 3.5 X 32MM				2		2									
3603534	MULTI AXIAL SCREW 3603534 3.5 X 34MM				2		2									
G3603536	MULTI AXIAL SCREW 3603536 3.5 X 36MM															x
G3603538	MULTI AXIAL SCREW 3603538 3.5 X 38MM															x
G3603540	MULTI AXIAL SCREW 3603540 3.5 X 40MM															x
G3603542	MULTI AXIAL SCREW 3603542 3.5 X 42MM															x
G3604008	MULTI AXIAL SCREW 3604008 4.0 X 8MM															x
G3604010	MULTI AXIAL SCREW 3604010 4.0 X 10MM															x
3604012	MULTI AXIAL SCREW 3604012 4.0 X 12MM	4														
3604014	MULTI AXIAL SCREW 3604014 4.0 X 14MM	4														
3604016	MULTI AXIAL SCREW 3604016 4.0 X 16MM	4														
3604018	MULTI AXIAL SCREW 3604018 4.0 X 18MM	4														
3604020	MULTI AXIAL SCREW 3604020 4.0 X 20MM	4														
3604022	MULTI AXIAL SCREW 3604020 4.0 X 22MM	2			2		2									
3604024	MULTI AXIAL SCREW 3604020 4.0 X 24MM	2			2		2									
3604026	MULTI AXIAL SCREW 3604020 4.0 X 26MM	2			2		2									
3604028	MULTI AXIAL SCREW 3604020 4.0 X 28MM	2			2		2									
3604030	MULTI AXIAL SCREW 3604030 4.0 X 30MM				2		4									
3604032	MULTI AXIAL SCREW 3604032 4.0 X 32MM				2		4									

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
3604034	MULTI AXIAL SCREW 3604034 4.0 X 34MM				2		4									
G3604036	MULTI AXIAL SCREW 3604036 4.0 X 36MM															x
G3604038	MULTI AXIAL SCREW 3604038 4.0 X 38MM															x
G3604040	MULTI AXIAL SCREW 3604040 4.0 X 40MM															x
G3604042	MULTI AXIAL SCREW 3604042 4.0 X 42MM															x
G3604508	MULTI AXIAL SCREW 3604508 4.5 X 8MM															x
G3604510	MULTI AXIAL SCREW 3604510 4.5 X 10MM															x
G3604512	MULTI AXIAL SCREW 3604512 4.5 X 12MM															x
G3604514	MULTI AXIAL SCREW 3604514 4.5 X 14MM															x
G3604516	MULTI AXIAL SCREW 3604516 4.5 X 16MM															x
G3604518	MULTI AXIAL SCREW 3604518 4.5 X 18MM															x
G3604520	MULTI AXIAL SCREW 3604520 4.5 X 20MM															x
3604522	MULTI AXIAL SCREW 3604522 4.5 X 22MM						2									
3604524	MULTI AXIAL SCREW 3604524 4.5 X 24MM						2									
3604526	MULTI AXIAL SCREW 3604526 4.5 X 26MM						2									
3604528	MULTI AXIAL SCREW 3604528 4.5 X 28MM						2									
3604530	MULTI AXIAL SCREW 3604530 4.5 X 30MM						4									
3604532	MULTI AXIAL SCREW 3604532 4.5 X 32MM						4									
3604534	MULTI AXIAL SCREW 3604534 4.5 X 34MM						4									
G3604536	MULTI AXIAL SCREW 3604536 4.5 X 36MM															x
G3604538	MULTI AXIAL SCREW 3604538 4.5 X 38MM															x
G3604540	MULTI AXIAL SCREW 3604540 4.5 X 40MM															x
G3604542	MULTI AXIAL SCREW 3604542 4.5 X 42MM															x

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
G3605515	Multi Axial Transition Screw G3605515 5.5 X 15MM															x
G3605520	Multi Axial Transition Screw G3605520 5.5 X 20MM															x
G3605525	Multi Axial Transition Screw G3605525 5.5 X 25MM										4					
G3605530	Multi Axial Transition Screw G3605530 5.5 X 30MM										4					
G3605535	Multi Axial Transition Screw G3605535 5.5 X 35MM										4					
G3605540	Multi Axial Transition Screw G3605540 5.5 X 40MM										4					
Partially Threaded Multi Axial Screws																
G360PT3518	MULTI AXIAL SCREW G360PT3518 3.5 X 18MM															x
G360PT3520	MULTI AXIAL SCREW G360PT3520 3.5 X 20MM															x
360PT3522	MULTI AXIAL SCREW 360PT3522 3.5 X 22MM				2											
360PT3524	MULTI AXIAL SCREW 360PT3524 3.5 X 24MM				2											
360PT3526	MULTI AXIAL SCREW 360PT3526 3.5 X 26MM				2											
360PT3528	MULTI AXIAL SCREW 360PT3528 3.5 X 28MM				2											
360PT3530	MULTI AXIAL SCREW 360PT3530 3.5 X 30MM				2											
G360PT3532	MULTI AXIAL SCREW G360PT3532 3.5 X 32MM															x
G360PT3534	MULTI AXIAL SCREW G360PT3534 3.5 X 34MM															x
G360PT3536	MULTI AXIAL SCREW G360PT3536 3.5 X 36MM															x
G360PT3538	MULTI AXIAL SCREW G360PT3538 3.5 X 38MM															x
G360PT3540	MULTI AXIAL SCREW G360PT3540 3.5 X 40MM															x
G360PT4018	MULTI AXIAL SCREW 360PT4018 4.0 X 18MM															x
G360PT4020	MULTI AXIAL SCREW 360PT4020 4.0 X 20MM															x
360PT4022	MULTI AXIAL SCREW 360PT4022 4.0 X 22MM				2											-
360PT4024	MULTI AXIAL SCREW 360PT4024 4.0 X 24MM				2											

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
360PT4026	MULTI AXIAL SCREW 360PT4026 4.0 X 26MM				2											
360PT4028	MULTI AXIAL SCREW 360PT4028 4.0 X 28MM				2											
360PT4030	MULTI AXIAL SCREW 360PT4030 4.0 X 30MM				2											
G360PT4032	MULTI AXIAL SCREW G360PT4032 4.0 X 32MM															x
G360PT4034	MULTI AXIAL SCREW G360PT4034 4.0 X 34MM															x
G360PT4036	MULTI AXIAL SCREW G360PT4036 4.0 X 36MM															x
G360PT4038	MULTI AXIAL SCREW G360PT4038 4.0 X 38MM															x
G360PT4040	MULTI AXIAL SCREW G360PT4040 4.0 X 40MM															x
Laminar Hooks																
G3606073	HOOK LAMINAR 4.5MM											2				
G3606073L	HOOK LAMINAR 4.5MM OFFSET L											2				
G3606073R	HOOK LAMINAR 4.5MM OFFSET R											2				
G3606074	HOOK LAMINAR 6.0MM											2				
G3606074L	HOOK LAMINAR 6.0MM OFFSET L											2				
G3606074R	HOOK LAMINAR 6.0MM OFFSET R											2				
Pre-Cut Rods																
3603725	ROD PRE-CUT 3.5MM X 25MM	2														
3603730	ROD PRE-CUT 3.5MM X 30MM	2														
3603740	ROD PRE-CUT 3.5MM X 40MM	2														
3603750	ROD PRE-CUT 3.5MM X 50MM	2														
3603760	ROD PRE-CUT 3.5MM X 60MM	2														
3603770	ROD PRE-CUT 3.5MM X 70MM	2														
3603780	ROD PRE-CUT 3.5MM X 80MM	2														
G7753870	ROD PRE-CUT 3.5MM X 70MM CCM								2							
G7753880	ROD PRE-CUT 3.5MM X 80MM CCM								2							

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Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
G7753890	ROD PRE-CUT 3.5MM X 90MM CCM								2							
G7753900	ROD PRE-CUT 3.5MM X 100MM CCM								2							
Straight Rods																
3602240	ROD 3.2X240MM TI	2														
3605240	ROD 3.5MM X 240MM	2														
G7750088	ROD 3.5MM CHROMALOY PLUS 300MM								2							
CROSSLINK™ Connectors and Lateral Connectors																
3602510	CONNECTOR 3602510 LATERAL OPEN 10MM	2														
G3602513	CONNECTOR LATERAL OPEN 13MM								2							
G3602519	CONNECTOR 3602519 LATERAL OPEN 19MM															x
3602519A	CONNECTOR 3602519A LTRL OPEN ANGLED 19MM				2											
3601510	CONNECTOR 3601510 LATERAL CLOSED 10MM	2														
G3601513	Connector Lateral Closed 13mm								2							
G3601519	Connector Lateral Closed 19mm															x
G3602525	CROSSLINK 3602525 MAS TO MAS S								1							
3602526	CROSSLINK 3602526 MAS TO MAS M	2														
G3602527	CROSSLINK G3602527 MAS TO MAS L								1							
G3602535	CROSSLINK G3602535 ROD TO ROD S								1							
3602536	CROSSLINK 3602536 ROD TO ROD M	2														
G3602537	CROSSLINK G3602537 ROD TO ROD L								1							
Set Screws																
3600315	SET SCREW 3600315 STANDARD	26														
3602615	SET SCREW CLOSED CONNECTOR FLAT	6														
Cervical to Thoracic Transition Options																
3601350	DOMINO 3601350 OFFSET 3.5 TO 3.5MM						3									

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Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
3601475	DOMINO 3601475 OFFSET 3.5 TO 4.75MM						3									
3601550	DOMINO 3601550 OFFSET 3.5 TO 5.5/6.0MM						3									
3603350	DOMINO 3603350 OFFSET O/O 3.5 TO 3.5						3									
3603475	DOMINO 3603475 OFFSET O/O 3.5 TO 4.75						3									
3603635	DOMINO OFFSET O/O 3.5 - 5.5/6.0/6.35						3									
G3602350	DOMINO G3602350 AXIAL 3.5 TO 3.5MM								3							
G3602475	DOMINO G3602475 AXIAL 3.5 TO 4.75MM								3							
G3602550	DOMINO G3602550 AXIAL 3.5 TO 5.5/6.0MM								3							
G3606069	DOMINO G3606069 MAS EXT 3.2/3.5MM								3							
G3606071	DOMINO G3606071 MAS EXT 4.75								3							
G3606072	DOMINO G3606072 MAS EXT 5.5/6.0								3							
3603706	ROD 3603706 TAPERED 3.5/4.75MM X 420MM						3									
3603707	ROD 3603707 TAPERED 3.5/5.5MM X 420MM						3									
3603806	ROD 3603806 TAPERED 3.5/4.75 X 420MM CCM						3									
3603807	ROD 3603807 TAPERED 3.5/5.5 X 420MM CCM						3									
G3603709	TAPERED ROD 3.5/6.0 X 420MM Ti															X
G3603809	TAPERED ROD 3.5/6.0 X 420MM CCM+															X
G3603708	TAPERED ROD 3.5/6.0 X 600MM Ti															X
G3603808	TAPERED ROD 3.5/6.0 X 600MM CCM+															X
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

*For a listing of indications, contraindications, precautions, warnings, and portential adverse events, please refer to the Vertex Reconstruciton System Instructions for Use.

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
7753805*	TAPERED ROD 3.5MM/5.5MM CCM+ 600MM															Vertex Shelf Item
Occipital Screw Connectors																
3600300	CONNECTOR 3600300 OC EYELET STANDARD				4											
3600301	CONNECTOR 3600301 OC EYELET OFFSET				4											
Occipital Adjustable Plate																
3600600	PLATE 3600600 OC ADJUSTABLE SMALL				1											
3600601	PLATE 3600601 OC ADJUSTABLE				1											
Occipital Bone Screws																
3600406	SCREW 3600406 OC 4.5 X 6MM				5											
3600408	SCREW 3600408 OC 4.5 X 8MM				5											
3600410	SCREW 3600410 OC 4.5 X 10MM				5											
3600412	SCREW 3600412 OC 4.5 X 12MM				5											
3600414	SCREW 3600414 OC 4.5 X 14MM				4											
3600506	SCREW 3600506 OC 5.0 X 6MM				4											
3600508	SCREW 3600508 OC 5.0 X 8MM				4											
3600510	SCREW 3600510 OC 5.0 X 10MM				4											
3600512	SCREW 3600512 OC 5.0 X 12MM				4											
3600514	SCREW 3600514 OC 5.0 X 14MM				2											
G360T0406	OC Bone Screw Tapered 4.5 X 6mm													5		
G360T0408	OC Bone Screw Tapered 4.5 X 8mm													5		
G360T0410	OC Bone Screw Tapered 4.5 X 10mm													5		
G360T0412	OC Bone Screw Tapered 4.5 X 12mm													5		
G360T0414	OC Bone Screw Tapered 4.5 X 14mm													4		
G360T0506	OC Bone Screw Tapered 5.0 X 6mm													4		

*For a listing of indications, contraindications, precautions, warnings, and portential adverse events, please refer to the Vertex Reconstruciton System Instructions for Use.

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
G360T0508	OC Bone Screw Tapered 5.0 X 8mm													4		
G360T0510	OC Bone Screw Tapered 5.0 X 10mm													4		
G360T0512	OC Bone Screw Tapered 5.0 X 12mm													4		
G360T0514	OC Bone Screw Tapered 5.0 X 14mm													2		
Occipital Rods																
G3600100	OC Adjustable Rod, Ti 3.5 x 100mm															x
G3600110	OC Adjustable Rod, 3.5 x 100 CCM															x
3600200	ROD 3600200 OC ADJUSTABLE TI 3.5 X 200				3											
3600210	ROD 3600210 OC ADJUSTABLE CCM 3.5 X 200				3											
3600201	ROD 3.5 X 200MM PRE CURVED ROD				3											
3600211	ROD 3.5 PRECURV CHROMALOY PL 200				3											
Instruments																
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													
G851100	Torque Limiting Handle, T-Handle		1													
3606170	Rod Pusher / Counter Torque, MAS		1													
3606172	Rod Pusher / Counter Torque, Universal		1													

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
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 Fixation Instruments																
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-Screwguide				1											
3600250	OC Self Holding Screwdriver				1											
3600251	OC Self Holding Screwdriver, Flexible				1											
G700251	OC Torque Limiting Ratchet Wrench				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											
G360T0320	OC 3.3mm Drill Bit, Tapered													1		
G360T0321	OC 3.3mm Drill Bit, Tapered, Flexible													1		
3600334	OC Tap 4.5mm, Tapered														1	
3600383	OC Tap 4.5mm, Tapered, Flexible														1	
3600337	OC Tap 5.0mm, Tapered														1	

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
3600384	OC Tap 5.0mm, Tapered, Flexible														1	
Cases and Trays																
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														
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														

Part Number	Description	C3-C7 Implant Module (Nonsterile)	C3-C7 Instrument Module (Nonsterile)	2.4mm Drill Bit Module (Sterile)	OC-C2 Implant & Instrument Module (Nonsterile)	OC Drill Bit Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Outlier Implant Module (Sterile)	3.0mm X-Small MAS Module	5.5mm Transition MAS Module	Laminar Hook Module (Sterile)	Laminar Hook Instrument Module (NonSterile)	OC Tapered Bone Screw and Drill Bit Module (Sterile)	OC Tapered Bone Screw Instrument Module (Nonsterile)	Loose Good (Sterile)
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 **ON THE INFINITY™ OCT SYSTEM**

PURPOSE
The Infinity™ 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™ 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™ 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™ 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™ OCT System components should never be reused under any circumstances.

INDICATIONS
The Infinity™ 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™ 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.

In order to achieve additional levels of fixation, the Infinity™ OCT System may be connected to the CD Horizon™ Spinal System and VERTEX™ Reconstruction System rods with the Infinity™ OCT System rod connectors. Transition rods with differing diameters may also be used to connect the Infinity™ OCT System to the CD Horizon™ Spinal System. Refer to the CD Horizon™ Spinal System package insert and VERTEX™ Reconstruction 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™ 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.
- 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.

For US Audiences Only

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

IMPLANT SELECTION

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure.

Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. The devices should be protected during storage, especially from corrosive environments.
- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify all parts and necessary instruments are present before the surgery begins.
- Unless sterile packaged, all implants should be sterilized before use.

INTRAOPERATIVE

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of device components may cause injury to the patient or operative personnel.
- Rods should not be repeatedly or excessively bent. Rods should not be reverse bent in the same location. Ensure implant surfaces are not scratched or notched, since such deformations may reduce the functional strength of the construct. If rods are cut to length, they should be cut to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
- Whenever possible or necessary, use an imaging system to facilitate surgery.
- To insert a screw properly, drill a pilot hole corresponding to selected screw size and prepare screw site.
- Caution: do not overtap or use a screw that is either too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or other possible adverse events listed elsewhere in this package insert.
- Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
- Before closing the soft tissues, all screws and set screws should be tightened firmly. Recheck the tightness of all screws and/or set screws after finishing to ensure none loosened during the tightening of the other screws or set screws. Failure to do so may cause loosening of the other implant components.

POSTOPERATIVE
The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, debilitated, or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, patients or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco, use nicotine products, or consume alcohol or non-steroidal anti-inflammatory medications such as aspirin during the bone graft healing process.
- Patients should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the implant(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
- Infinity™ OCT System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. While the final decision on implant removal is up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant position, possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening, and breakage, which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) possible increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING
Devices may be supplied in a sterile or non-sterile form. Packages for each of the implant components should be intact upon receipt. Once the seal of the sterile package has been broken, the product should not be re-sterilized. If a loaner or consignment system is used, all sets should be carefully checked for completeness, and all device components should be carefully checked to ensure there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Medtronic.

STERILIZATION
Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants used in surgery must be sterilized prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters in Table 1.

Table 1: Sterilization cycle parameters for the US and its territories

Method	Cycle	Temperature	Exposure time	Minimum dry time[1]
Steam	Dynamic-air-removal	270°F (132°C)	4 Minutes	30 Minutes
Steam	Dynamic-air-removal	275°F (135°C)	3 Minutes	30 Minutes

Note: because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) cleared by the Food and Drug Administration (FDA) for the selected sterilization cycle specifications (time and temperature). The sterilization cycles listed in Table 2 are not considered by the FDA to be standard sterilization cycles.

For medical facilities located outside the US and its territories, some non-US health care authorities recommend sterilization according to these process parameters to minimize the risk of transmission of Creutzfeldt-Jakob disease.

Table 2: Sterilization cycle parameters for medical facilities outside the US and its territories

Method	Cycle	Temperature	Exposure time	Minimum dry time[1]
Steam	Dynamic-air-removal	273°F (134°C)	4 Minutes	30 Minutes
Steam	Dynamic-air-removal	273°F (134°C)	20 Minutes	30 Minutes

1The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.

PRODUCT COMPLAINTS
To report product problems, contact Medtronic.

MRI INFORMATION
MR Conditional

The Infinity™ OCT System was determined to be MR Conditional based on comparison to previously evaluated Medtronic products. A patient with this device can be safely scanned immediately after device placement under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Maximum spatial gradient magnetic field of 3000 gauss/cm (30 T/m).
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of <2W/kg (Normal Operating Mode) for a continuous 6 minutes of scanning per pulse sequence within a quadrature whole-body radiofrequency transmit coil.

Under the scan conditions defined, a worst case posterior occipitocervical-upper thoracic system representative of the Infinity™ OCT System produced a maximum temperature rise of less than 6.8°C after 6 minutes of continuous scanning.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Infinity™ OCT System. The image artifact extends approximately 25mm from the device when imaged with a gradient echo pulse sequence in a 3.0 T MRI system.

The presence of other implants or the health state of the patient may require a modification of the MR conditions.

MRI Patient Counseling Information

Physicians should communicate with the patient the following information about MRI with respect to the Infinity™ OCT System:

- Infinity™ OCT System performance has been established for MRI systems at field strengths of 1.5 Tesla and 3.0 Tesla.
- During an MRI, the patient may notice a warming sensation around the implant or feel a tingling sensation. If the warming or tingling sensation is uncomfortable, the patient should communicate this to the MR technologist, the MRI should be stopped, and the settings adjusted to reduce or eliminate the sensation. The highest temperature change observed in nonclinical testing was 6.8ºC (associated with specific conditions previously listed).
- Additionally, the metal in the implant may cause the MRI image to be distorted in the area around the implant. The MRI can be adjusted to minimize the image distortion.
- Physicians should instruct patients to:
- Inform any healthcare personnel (e.g. doctor or MR technologist) they have an implanted posterior cervical-thorasic fusion device prior to receiving an MRI.
- The patient's doctor will recommend whether or not an MRI is appropriate.

If the Infinity™ OCT System is used in connection with any other device which is not MR Conditional, be advised this combination has not been evaluated in the MR environment and, therefore, higher heating and possible injury to the patient may occur.

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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Note: The 3.0mm multi axial screw (MAS) requires the use of MAS Crosslink™ 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.

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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.

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