The following occipito-cervico-thoracic technique guide describes the correct use and application of the instrumentation of the Summit™ SI OCT posterior fixation system.

The Summit™ SI OCT posterior fixation system is a versatile modular system, which delivers unparalleled flexibility by combining innovative technology with well established internal fixation techniques. The range of implants within the Summit™ SI System have been designed to give maximum intra-operative freedom, by allowing the surgeon the choice of bone anchor point at each level, independent of the implant system.
Pre-Operative Planning

It is a prerequisite that, due to the anatomic variability of each patient, the surgeon has available the range of necessary images in order to be equipped to plan the operation appropriately.

Patient Positioning

The patient is placed on the operating table in the prone position with head and neck held securely in proper alignment. Whenever it is safe to do so, position the spine in physiological alignment and use a pinion head holder or halo with Mayfield attachment to secure the skull to the table. Confirm proper alignment with an image intensifier or radiograph prior to draping.

Exposure

A standard mid-line sub-periosteal exposure of the portion of the cervical and thoracic spine to be fused is carried out. A wide exposure extending to the lateral aspect of the facet joints in the cervical spine and the transverse processes in the thoracic spine is achieved. Extend the exposure to the external occipital protuberance (EOP) (Figure 1). Care must be taken to avoid injury to the spinal cord, vertebral arteries, C2 nerve roots in the upper cervical spine and the facet capsules and interspinous ligaments at levels that will not be fused.

Intra-Operative Planning

Begin by planning the entire construct. Identify all system components required for the final construct.

General

It is recommended to insert the bone anchors with the greatest anatomical constraints first. The appropriate occipital plate size can then be selected once the distance between the longitudinal rods is determined.

Selection and placement of the Occipital Plate

By offering two types of plate (T-plate and inverted Y-plate) in three different sizes, the surgeon will have versatility at the operating table to choose the optimal plate type and size that best fit the individual patient anatomic variations, ensuring that the plate is fixed into the thickest and best quality bone in the optimum position.

Distance between rods (mm)

<table>
<thead>
<tr>
<th>Plate and/or</th>
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<th>Medium</th>
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<tr>
<td>T-Plate</td>
<td>31 mm</td>
<td>37 mm</td>
<td>45 mm</td>
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<tr>
<td>Inverted Y-Plate</td>
<td>(2 mm)</td>
<td>(4 mm)</td>
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Selecting and placing the Occipital Plate

Note: The sliding rod connectors should allow near parallel alignment of the rods with minimal, if any, contouring required in the coronal plane. The plate will accommodate a construct width between 29 mm - 49 mm (see chart for M/L width adjustment dimensions).

Note: Dual Diameter Rods are available for fixation of the cervico-thoracic junction. Depending on the degree of instability and patient size, the surgeon may choose to cross the cervico-thoracic junction with the Dual Diameter Rod System, placing the 3.5 mm or 4.0 mm Minipolyaxial Screws in the upper thoracic vertebrae. Alternatively, the Dual Diameter Rod will allow standard fixation in the cervical spine and pedicle screw fixation in the thoracic spine using a 5.5 mm or 6.75 mm rod system. Lastly, if the surgical goal is primary fixation in the thoracic spine, the Dual Diameter Rod System, when used in conjunction with a system that offers potential for pedicle screw fixation into the thoracic vertebrae, will provide an option for linkage to other systems such as Isola®, MOSS® Miami, or Monarch™. See System to System Components, page 26, for further details.
Identify the External Occipital Protuberance (EOP) and the posterior border of the foramen magnum. Position the occipital plate in the mid-line between the EOP and the foramen magnum. The T-Plate is intended to be oriented in an upright position. The single limb of the occipital plate should be secured to the occiput in the mid-line between the EOP and the foramen magnum allowing for a generous bone graft caudal to the implant. The plate is positioned where the bone is thickest (see bone thickness image). Use diathermy or a drill guide to mark the position.

The plate should be smoothly against the occiput. It may be necessary to smooth irregular bony protruberances slightly to optimise the bone to plate interface, but avoid removing significant portions of cortical bone especially in the vicinity of planned screw holes. To contour the plate place it securely in the border and gently bend to desired radius. The contouring should be performed only in the bend zones to avoid damage to the sliding connectors. Both plate designs can be bent by closing the bend zone to a maximum of 15°. Although the above illustration of the inverted Y-Plate and T-Plate shows correct placement position of the plate there may be occasions where due to the variation of individual anatomy either plate may be best placed and turned upside down.

Note: To maintain the integrity of the occipital implant care must be taken to bend the plate in one direction only. The inverted Y-Plate is intended to be oriented with the single limb of the implant cephalad in the mid-line and below the EOP. The two limbs of the occipital plate should be placed above the foramen magnum allowing for a generous bone graft caudal to the implant. Plate templates are available and can be used to determine the optimal plate configuration.

The T-Plate is intended to be oriented in an upright position. The single limb of the occipital plate should be secured to the occiput in the mid-line between the EOP and the foramen magnum allowing for a generous bone graft caudal to the implant. The plate is positioned where the bone is thickest (see bone thickness image). Use diathermy or a drill guide to mark the position.

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Select the appropriate Occipital Fixed Depth Drill Guide. With the plate in position, insert the fixed depth Drill Guide into the superior mid-line hole of the plate. Utilising the 3.5 mm Drill Bit, drill the initial occipital pilot hole.

Individual anatomic patient variations may inhibit the use of the 'in-line' instruments (drill, tap, screw driver). In these cases an alternative 'minimal access' drill, tap and screw driver may be used.

Confirm depth of pilot hole with the Depth Gauge.

Note: Use the same Fixed Depth Guide as used to drill the pilot hole.

Place the 4.5 mm Tap into the Drill Guide and tap the initial pilot hole.

Note: The Depth Gauge reflects actual screw thread length. Therefore select the same screw length as indicated by the gauge (e.g. 8 mm depth gauge reading = 8 mm Occipital Bone Screw).

Surgical Technique

Note: A flexible drill device may be used in cases where access is restricted.

Note: The mid-line ridge of bone is shaped like a keel and it is possible to penetrate the inner cortex on one side of the ridge and still be unicortical in the mid-line. The occipital sinus is located in the mid-line and drains into the transverse sinus. The consequences, if any, of penetrating this sinus are unknown.
Placement of Minipolyaxial Screws

The technique for the placement of Summit™ SI Minipolyaxial Screws is the same for either standard or favoured angle screw types. Favourable Angle Screws can be used as an alternative to regular Minipolyaxial Screws. The relevant posterior spinal elements are prepared by removing all soft tissue and decorticating the facets and laminae. When screws are to be inserted into the pedicles, a small laminotomy may allow for an easier palpation of the cephalad and medial borders of the pedicle to determine the appropriate starting point for the pilot hole. To ensure easy rod insertion with minimal contouring, it is important to align screw holes as co-linear as possible. The entry point of all Minipolyaxial Screws is marked with a burr, awl or marking pen.

The following description of Minipolyaxial Screws is designed to demonstrate the correct use of the Summit™ SI Instrumentation. Since the range of implants within the system allows for maximum intra-operative freedom, surgeons have the choice of screw placement in the lateral mass using their own preferred surgical technique. With this system, pedicle screw fixation is also an option. The combination of the aforementioned technique is also possible. A pre-operatively performed CT scan may reveal important information about the dimensions and orientation of the structures necessary for secure screw placement.

Surgical Technique

Alternatively, use the minimal access tap for the initial pilot hole.

Utilising the 2.5 mm Self Retaining Screwdriver, insert the selected 4.5 mm Outer Diameter Occipital Bone Screw and tighten. Insert remaining Occipital Bone Screws in the same manner.

Alternatively, use the minimal access driver to tighten the outer bone screws in cases where access is restricted.

15˚ Angulation Bias

Note: The green head of the favoured angle screw is biased 15˚ cranially. This allows optimum screw trajectory into posterior bone whilst allowing the screw head itself to sit neutrally in the best position to accept the rod.

The relevant posterior spinal elements are prepared by removing all soft tissue and decorticating the facets and laminae. When screws are to be inserted into the pedicles, a small laminotomy may allow for an easier palpation of the cephalad and medial borders of the pedicle to determine the appropriate starting point for the pilot hole. To ensure easy rod insertion with minimal contouring, it is important to align screw holes as co-linear as possible. The entry point of all Minipolyaxial Screws is marked with a burr, awl or marking pen.

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Prior to drilling the pilot hole, determine the desired depth of drill penetration. Drill depth can be set in 2 mm increments and is defined by the position of the Sleeve relative to the scale on the Drill Guide. The Sleeve is easily inserted into the Drill Guide by depressing the locking button on the guide and advancing the Sleeve into the guide.

Different variations for lateral mass screw placement have been described and all of these work well. However, we strongly recommend further study of the literature for definitive details for these techniques (Xu R, Haman SP, Ebraheim NA, Yeasting RA. The Anatomic Relation of Lateral Mass Screws to the Spinal Nerves. A Comparison of the Magerl, Anderson, and An Techniques. Spine, 1999, 24(19), pp2057-2061). All techniques ensure that neither the vertebral artery nor the nerve root are compromised.

Confirm the depth and containment within the pilot hole using the Depth Gauge. Confirm the depth and containment within the pilot hole using the Depth Gauge.

Tap the superficial cortex using the 3 - 5 mm tap whilst maintaining the appropriate trajectory. In the same manner, drill and tap the remaining pilot holes.
Select the appropriate length screw and load onto the Minipolyaxial Screwdriver and insert the screw into the prepared pilot hole (although the illustration below demonstrates bi-cortical screw placement, the Minipolyaxial screws may be placed to achieve mono-cortical or bi-cortical fixation, as is the surgeon’s preference). In the same manner, insert and tighten all the remaining Favoured Angle Minipolyaxial Screws.

Note: Select the appropriate length screw and load onto the Minipolyaxial Screwdriver and insert the screw into the prepared pilot hole (although the illustration below demonstrates bi-cortical screw placement, the Minipolyaxial screws may be placed to achieve mono-cortical or bi-cortical fixation, as is the surgeon’s preference). In the same manner, insert and tighten all the remaining Favoured Angle Minipolyaxial Screws.

When C2 placement is considered, it is essential to be aware of the unique anatomy and the individual variations that can occur within this specific region.

The Summit™ SI System is a ‘top-loading’ system allowing for precise contouring of the rod in line with the individual anatomical situation presented. Cut and contour the rods so that they lie smoothly against the posterior surface of the occiput and insert easily into all Minipolyaxial Screw Heads. The final length of the rod should extend from the occiput (1 cm caudal to the EOP) to the lowest level to be fused while not interfering with adjacent anatomy. To contour the rods, secure the rod with the French Rod Bender and gently contour until the desired shape is achieved. Ensure you use the French Rod Bender properly; use the 3 mm side to bend the 3 mm rod portion and utilise the 4 mm side to bend the 4 mm rod portion.

Note: To avoid potential fatigue failure of the implant, do not make sharp bends or “unbend” the rod. Hand malleable rod templates are available and can be used to obtain optimal rod configuration and placement. The key is to bend the rod little and often.
Place the ends of the rod into the slots on the occipital plate. The sliding connectors in the plate should allow near parallel alignment of the rods with minimal, if any, additional contouring required in the coronal plane. The final length of the rod should extend from the occiput to the lowest level to be fused, while not interfering with any adjacent anatomy. If any additional contouring is required, secure the rod within the Rod Bender and gently contour it until the desired radius is achieved.

If fine tuning of the A/P height of the screws is necessary, adjust the height of the screws to allow a smoothly contoured rod to seat fully in each of the bone anchors.

Note: The orientation of the screw head can be changed with the Minipolyaxial Head Adjuster.

The Rod Approximator is used to reduce the rod and simplify closure. The Rod Approximator approaches the rod laterally or medially and aligns with the Polyaxial Screw head.

Gently closing the pistol grip of the rod approximator allows the rod to be seated down onto the screw head.

Use the Inner Nut Inserter to apply Inner Nuts to the Screws. Tighten provisionally by turning the nut inserter clockwise.

Note: Caution should be exercised when using the rod approximator in situations where bone quality is sub-optimal.
Apply outer nuts to the sliding connectors on the occipital plate.

If required, the minimal access nut applicator can be used to apply the outer nuts.

Perform final tightening of the nuts on the Occipital Plate by rotating the nut tightener clockwise. The nut is completely tight when you hear an audible click.

Before final tightening the construct may be tightened in situ or loaded in compression depending on the bio-mechanical needs of the patient and the pathological process.

To load the construct in compression it is necessary to tighten the inner nut on one end of the construct and sequentially compress and lock off each level at each side to the other end of the construct.

Perform final tightening of the screw nuts by rotating the Torque Driver clockwise, while providing counter torque on the rod with the Anti-Torque Device. The nut is completely tight when the Torque Driver is automatically released.

Note: The pathology of the individual patient will dictate whether compression is necessary.

Note: It is essential that the anti-torque device is used in final tightening.

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Surgical Technique
Placement of C1 Articular Mass

Long-Shank Minipolyaxial Screw

The description for this section of C1-C2 fixation using individual bi-lateral fixation of the C1 articular mass and the C2 pedicle with Minipolyaxial Screws is designed to demonstrate the correct use of the Summit™ SI OCT Spinal Fixation System instrumentation only. It is not intended to be a definitive guide to the correct surgical steps to achieve direct C1-C2 fixation. For a more detailed clinical description of this process, it is highly recommended that the reader accesses the following:

· 'Posterior C1-C2 Fusion with Polyaxial screw and Rod Fixation' Jürgen Harms, MD, Robert P. Melcher, MD, SPINE Vol 26, No. 22, pp. 2467-2471, 2001, Lippincott Williams and Wilkins, Inc.

(Ask your local DePuy Spine representative for a copy of this paper).

Exposure

The upper cervical spine is exposed sub-periosteally from the occiput to C3.

C1 Screw Positioning

The entry point for the C1 screw is above the C2 nerve root, at the junction of the posterior arch of C1 and the lateral mass of C1, and at the highest point of the C1 mass. The drilling angle is dictated by the arch of C1, and so cannot be angled any more superiorly. A dissector should be used to move the C2 nerve root away from the intended entry point.

Using a high speed burr with 1 or 2 mm diamond paste drill tip, perforate the cortex to allow access for drilling. Bi-cortical fixation provides secure screw placement.

Note: Measure the depth for the Long Shank Screw. (The length of the screw starts at the arch of C1 - not from the entry point). The shank of the screw has to start just above the arch of C1.
Inferior and lateral views of C1 screw placement demonstrating the smooth polyaxial screw shank sitting proud of the bone.

Delinate the medial border of the C2 pedicle and mark the entry point for placement of the C2 pedicle screw with a high speed bur. The pilot hole is prepared with the 2.4 mm drill bit and just perforating the opposing cortex. The direction of the drill is angled approximately 20-30° in a convergent and cephalad direction, guided directly by the superior and medial surface of the C2 isthmus, respecting individual anatomic variations. The hole is then tapped and a 3.5 mm polyaxial screw of the appropriate length is inserted bicortically.

Turn and align the screw heads using the minipolyaxial head adjuster. Take a section of 3 mm rod and cut to shape using the rod cutters. Place the rod into position with the rod holders.

If necessary, further reduction maneuvers should be performed at this stage (as shown on page 17).

Lateral radiograph showing placement of C1-C2 screws (courtesy of Prof. J. Harms).
Summit™ SI OCT Cross Connectors

Notes:
The short length of rod between the Cross Connectors should be bent so as not to interfere or impinge on the spinous process complex.

Two designs of cross connectors are offered as part of the Summit™ OCT fixation system. If the anatomy allows and extra stability is required, one or more pairs of Cross Connectors can be secured to the rods.

Transverse Connectors

Begin by taking a measurement between the two 3.0 mm longitudinal rods. Select the additional 3.0 mm rod to be used as the connection. This rod should be cut between 9 mm and 11 mm shorter than the previously mentioned measurement. The rod can then be assembled with the Cross Connectors, which will then be placed onto the longitudinal rods. Provocatively tighten the medial set screws with the 2.0 mm Hex Driver. The transverse rod can slide within the connectors to fit between the longitudinal rods and be properly positioned. Once the rod and connectors are positioned, the lateral set screws on both connectors can be tightened, clamping the connectors to the longitudinal rod. Ensure that a portion of the 3.0 mm centre rod can be viewed through the circular cut out on the topside of the connector. Final tightening with the Torque Limiting Driver should occur once all components are in a satisfactory position.

J Hook Connectors

Cut a length of 3 mm rod to the appropriate size required and long enough to insert through both the J hook connectors across the width of the construct. At the chosen point along the construct rod, place one of the hooks onto one side of the rod. Slide one end of the short cross-member rod through this J Hook. Place the other J hook onto the opposing rod and thread the other end of the shorter length 3 mm rod through the second J hook. Final tightening of both inner screws can then be performed.

Placement of Sub Laminar Cables

Should the patient anatomy present with such little or poor quality bone that it might be unsuitable for placement of mini polyaxial screws, the option of utilizing sub laminar wires to attach to the 3 mm rod may be considered by the surgeon. The Summit™ SI OCT Fixation System offers viable connectors to facilitate this surgical option.

A: Attach the Cable Connector to Cable Connector Holder.
B: Beginning with the most distal cable, pass the leadered end through the Cable Connector and then through the eyelet of the cable.
C: Continue to pull the leadered end and thread the eyelet while simultaneously guiding Cable Connector onto rod.
D: Loosely secure the connector by tightening the Cable Connector Set Screw with the 2.0 mm Hex Screwdriver.

Final tightening of Cable Connectors is performed once all cables are cramped.

Surgical Technique
Surgical Technique

Dual Diameter Rods
The Summit™ OCT Spinal Fixation System offers two Dual Diameter Rod configurations which can be linked to thoracic components including: 3.0 mm / 4.75 mm and 3.0 mm / 5.5 mm dual diameter rod options. Select the appropriate rod. Cut and contour the rod to meet individual anatomical requirements. Hand malleable templates are available to assist in determining optimal rod configuration. Contour the Dual Diameter Rod to precisely match the curve of the template.

Axial Connectors
The Summit™ OCT Spinal Fixation System offers three different size connectors to accommodate the Isola®, MOSS® Miami and Monarch™ Systems. Rods are measured, cut and contoured. Axial connectors are loaded onto the rods such that the joint between the two rods lies approximately in the centre of the connector. The chosen connector is placed on a Hook Holder and slid up the upper rod until it has passed the end of the lower rod. The set screws of the connector are tightened provisionally with the X20 Hex Lobe driver. Final tightening of the Set Screws occurs once all components are in their final position.

Dual Wedding Band Connectors
The Summit™ OCT Spinal Fixation System offers three different size connectors to accommodate the Isola®, MOSS® Miami and Monarch™ Systems, should sagittal profile not be favourable and the use of an Axial Connector is not possible. Rods are measured, cut and contoured where the rods overlap side by side and are joined by the connector. The chosen connector is placed on a Hook Holder and slid up the upper rod until it has passed the end of the lower rod. The set screws of the connector are tightened provisionally, with the X20 Hex Lobe driver. Final tightening of the set screw occurs once all components are in their final position.
Bone Graft Solutions

“Shape memory” is retained in hydrated Healos® Bone Graft Replacement, resulting in excellent porosity within the site.

Healos® Bone Graft Replacement, just prior to hydration with bone marrow aspirate.

Hydrated, compacted Healos® Bone Graft Replacement.

• 3-Dimensional, osteoconductive matrix constructed of cross-linked type 1 collagen fibres, coated with non-crystal hydroxyapatite.
• Strong affinity for osteoprogenitor cell attachment and an ideal environment for the cellular proliferation needed in the bone formation process.
• Structural integrity and 95% porosity: 3-D cross-linked structure provides excellent strength and a “shape-memory” effect, retaining its structural integrity and porosity, even when hydrated.
• Excellent graft handling characteristics: Flexible, sponge-like strip moulds into place for complete graft site coverage, even in irregular or uneven surfaces.

Conduit™ TCP Granules are made entirely of β-TriCalcium Phosphate, the porous, osteoconductive ceramic similar to the mineral constituents of natural bone (i.e. 70%).

The partially connected pore structure of Conduit™ TCP Granules is well-suited for cell-to-cell interaction, nutrition and vascularisation. Its high degree of surface area provides a generous field for cellular attachment.

6-9 months resorption rate.

Lateral Offset Connectors

The Summit™ OCT System offers a Lateral Offset Connector in order to facilitate challenging rod/screw alignment situations. Screws are placed in the usual manner. Should the surgeon determine that the offset between a given screw and rod precludes direct contact, the surgeon may elect to use a Lateral Offset Connector. Place a Lateral Offset Connector on the rod loosely at the level of the target screw. Finger tighten the Set Screw on the Lateral Offset Connector.

The Lateral Offset Connector must be secure enough to remain in contact with the rod but also able to rotate around the rod. Rotate the head of the Polyaxial Screw to align it to the bar of the Lateral Offset Connector. Then rotate the bar into the Polyaxial Screw. Apply the closure mechanism to the Polyaxial Screw in the usual manner. Revisit all Set Screws for the final tightening when appropriate.

Surgical Technique

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## Ordering Information

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## Notes