Deformity - Degenerative Interbody Fusion Tumour - Trauma Cervical Emerging Technology

Surgical Technique
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**Introduction & Philosophy**

**Surgical Technique**

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**MONARCH™ SPINE SYSTEM**
Building upon decades of cumulative design history, clinical experience and biomechanical performance of the VSP™, Isola® and MOSS® Miami systems, the Monarch™ Spine System represents the combination of existing design principles with revolutionary new technology. Monarch’s technique simplifying designs, including a state of the art internal closure mechanism and a unique set of fixed or polyaxial implant options, maximise performance to meet the challenge of even the most difficult pathologies.

Developed for comprehensive, multi-pathology application, Monarch™ seamlessly integrates an unprecedented breadth of versatile and complementary components in a single implant system. The Monarch™ Spine System offers fine-tuned solutions derived from the ultimate union of simplicity and sophistication.

**Primary Indications Include:**

- Use of pedicle screws, hooks, plates and rods in situations of deformity or spinal instability such as:
  - Degenerative disc disease (discogenic back pain with degeneration of the disc)
  - Idiopathic scoliosis
  - Neuromuscular scoliosis/kyphoscoliosis
  - Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele
  - Spondylolisthesis
  - Instability following a previously failed fusion
  - Spinal fractures (acute reduction or late deformity)
  - Neoplastic disease

**Contraindications Include:**

- History of infection
- Bony abnormalities preventing safe screw fixation (dysplastic pedicles)
- Patients who can be safely and predictably managed without internal fixation
- Morbid obesity
- Severe osteopenia
- Open wounds
Monarch™ Bolts with Spine Plates
Pedicle Bolt Insertion

Pedicle preparation is performed using a selection of awls, pedicle probes, ball tip feelers and bone taps. Probes and bone taps are marked to help bolt selection.

Bolts are inserted into the pedicle using the Pedicle Bolt Driver.

Note: All bolts are self-tapping. Taps are provided for surgeon preference.

Note: See Pedicle Bolt Driver Assembly on Page 4.
Pedicle Bolt Driver Assembly:
The Pedicle Bolt Driver is placed over the threaded post until seated firmly into the integral nut drive feature.

Washer Rules

Polyaxial ‘Dome Down’
Polyaxial ‘Dome Down’ is used beneath either a Spine Plate or Slotted Connector. A single Polyaxial Washer must be placed ‘dome down’ into the integral nut of a Pedicle or Reduction Bolt, or the receiving portion of a Spacer Washer.

Polyaxial ‘Dome Up’
Polyaxial ‘Dome Up’ issued where a Polyaxial Washer has been placed beneath a Spine Plate or Slotted Connector. One must be placed above in the opposite orientation, i.e. ‘dome up’ to mate with the bottom of the Domed Nut.

Spacer
Spacer Washers may only be placed beneath a Spine Plate or Slotted Connector, directly into the integral nut of a Pedicle or Reduction Bolt. Spacer Washers must not be placed on top of Polyaxial Washers.

Note: A total of two washers (two Spacer, or one Spacer and one Polyaxial) is permitted below a Spine Plate or Slotted Connector on a Pedicle Bolt. If additional Washers are required, a Reduction Bolt must be used.
Appropriate selection and insertion of Pedicle & Reduction Bolts is completed.

Where necessary, Polyaxial and/or Spacer Washers are applied to Bolts. Polyaxial Washers must be placed ‘dome down’ under the Spine Plate.

Note: See Polyaxial/Spacer Washer Application on Page 6.
Instrument Selection
Select the appropriate Washer Inserter instrument.

Washer Loading
Rotate handle *anti-clockwise* until the counter shows the number of washers you want to apply to the bolts.

Select Washers ‘dome down’ or ‘dome up’ from appropriate columns of the caddy. Press tip of Washer Inserter into each Washer until the selected number of Washers have been retained.
Washer Unloading

Washers are released onto Bolts with a single clockwise rotation of the handle.

Polyaxial Washer Insertion – ‘Dome Up’

Select appropriate Spine Plates to place over selected Bolts and Washers. Contour Spine Plates if necessary and place over machine thread of Bolts.
Where Polyaxial Washers were placed on Bolts below the Spine Plate, a second Washer must be placed ‘dome up’ on each Bolt on top of the Spine Plate. **Spacer Washers must not be placed above Spine Plates.**

**Domed Nut Loading**

Domed nuts are easily removed from the Washer/Nut Caddy using either the Domed Nut Torque Shaft or the Domed Nut Driver.

*Note:* See Polyaxial/Spacer Washer Application on pages 6-7.
Apply Domed Nuts using a Domed Nut Driver or Domed Nut Torque Shaft. Where reduction is necessary, first apply the Domed Nuts to the Stabilising Bolts (i.e. L4 and S1 Pedicle Bolts as shown above). Then apply the nuts to the Bolts that will perform the reduction (i.e. the Reduction Bolts in the L5 pedicle as shown above).

Provisionally tighten the Stabilising Bolts prior to reduction.
Prior to tightening the Domed Nut to reduce the vertebral body, the Hexlobe Driver must be placed into the hexlobe feature on the top of the Reduction Bolt to prevent the Bolt from advancing into the pedicle.

The reduction manoeuvre is performed accordingly.

Note: See Reduction Technique on Page 11.
Bolt Compression/Distraction Option:
Compression or Distraction with Bolts may be accomplished using the Bolt Style Compressors or Distractors with associated instruments in the set.
Domed Nut Final Tightening

Nut Torque Shaft inserted into the T-Handle Torque Wrench, which is set to 100 in-lb (11.3Nm). The Hexlobe Driver is placed through the cannula of the T-Handle Torque Wrench to prevent the Bolt advancing into the pedicle. The T-Handle is then rotated clock-wise until it clicks and resistance is no longer evident.

Note: See Domed Nut Final Tightening (below).

Domed Nut Final Tightening

The T-Handle Torque Wrench is always set to 100 in-lb (11.3Nm) for Domed Nut tightening.
Pedicles are prepared as shown previously for Spine Plates. Appropriate selection and insertion of Pedicle and Reduction Bolts is completed.

Where necessary, Polyaxial and/or Spacer Washers are applied to Bolts. Polyaxial Washers must be placed ‘dome down’ under the Slotted Connectors.

**Note:** See Polyaxial/Spacer Washer Application shown previously for Spine Plates (see Page 6-7).
VHG stands for V-Groove Hollow Ground. The V-Groove is formed by two distinct radiuses producing an uneven oval. The rod is forced into a smaller groove for superior fixation.

In addition, there are two raised shelves that produce a Hollow Ground area in the center that allows for multiple fixation points with a curved rod.

Appropriate style Slotted Connectors are chosen for optimal connection to each Bolt. The Slotted Connectors are loosely loaded onto the selected length rod and placed over the threaded posts of the Bolts.

Where Polyaxial Washers were placed on Bolts below the Slotted Connectors, a second Washer must be placed ‘dome up’ on each Bolt on top of the Slotted Connector.

*Note:* See Polyaxial/Spacer Washer Application shown previously for Spine Plates (page 6).
Final tightening is first performed on the body of the Slotted Connector to ensure proper seating of the rod into the VHG groove. The X25 Torque Shaft is inserted into the T-Handle Torque Wrench, which is set to 80 in-lb (9Nm).

The shaft is inserted through the Closed Connection Stabiliser and then into the Set Screw of the Slotted Connector body.

Appropriate style Slotted Connectors are chosen. Apply Domed Nuts and gently tighten using a self-retaining Domed Nut Driver or Domed Nut Torque Shaft.

Note: See Domed Nut Application shown previously for Spine Plates (see Page 9).
The Stabiliser is passed down over the body of the Slotted Connector and onto the rod. The T-Handle is then rotated clockwise until it clicks and resistance is no longer evident.

Slotted Connector Final Tightening – Step 2

*Note:* See Domed Nut Final Tightening shown previously for Spine Plates (page 12).

Final tightening is then performed on the Domed Nuts.
The T-Handle Torque Wrench is always set to 80 in-lb (9Nm) for Set Screw tightening (Figure 2).

The Closed Connection Stabiliser is used to prevent torsion of the construct during final tightening (Figure 1).
Monarch™ Bolts with Polyaxial Band Clamps

Polyaxial Band Clamp

The Band Clamp’s integrated polyaxial washers eliminate assembly.

The Band Clamps are easily pre-loaded onto the spinal rod.

Pedicles are prepared as shown previously for Spine Plates. Appropriate selection and insertion of Pedicle and Reduction bolts are completed.
Final tightening is then performed on the Domed Nuts.

Utilising a Rod Holder, position the Band Clamps and rod over the Pedicle Bolts.

Note: See Domed Nut Final Tightening shown previously for Spine Plates (page 12).
Probes and Bone Taps are marked to indicate appropriate length Polyaxial Screw selection. Polyaxial Screws are inserted utilising the Polyaxial Screw Driver.

Polyaxial Screw heads are remobilised with the Polyaxial Head Positioner if necessary.

Note: See Polyaxial Screw Driver Application (page 21).

Pedicle preparation is performed utilising a selection of Awls, Pedicle Probes, Ball Tip Feelers and Bone Taps. All Screws are self-tapping. Taps are provided for surgeon preference.

Monoaxial Screws
Monoaxial Screws may be used according to surgeon preference.
Monarch™ Polyaxial Screws
Polyaxial Screw Driver Application

Step 1

Polyaxial Screw Driver Loading/ Unloading

Step 1 – “Off”
Assembly mechanism must be in the “Off” position. Place onto head of screw as shown with Tightener tip withdrawn from shoulder of head.

Step 2

Step 2 – “On”
Hold screw onto shaft while holding shaft steady. Twist knurled knob from “Off” indicator until etch line on knob reaches “on.”

Step 3

Step 3 – “Alignment Guide Loading”
Insert the screw (on the driver) into the appropriate diameter hole in the Alignment Guide. Push the screw down until it is seated.
Step 4 – “Screw Shank Locking”
Hold shaft and rotate driver handle **clockwise** until tight.
The Loading Block will ensure that the screw shank is straight (in line with head). Remove the Screwdriver and screw from the Loading Block.

Step 5 – “Removal”
Hold shaft and rotate driver handle **anti-clockwise** (one turn). Continue to hold shaft and rotate knurled knob to “off” position to release.
Choose the appropriate length rod with desired lordosis. Place the rod into implant heads.

Capture rod into implant by inserting the Typhoon Cap.

Note: See Typhoon Cap Pick and Insertion (page 24).
Typhoon Cap Application

1. Place **Guide** Block over Typhoon Caps.

2. **Align** vertical etched line on Inserter with line on Guide Block and push into caddy until the horizontal etched line mates with top of Guide Block.

3. **Remove** Typhoon Cap. 
   *Ensure Set Screw does not protrude below bottom of Typhoon Cap prior to insertion.*

---

Option 1

1. Insert
2. Twist
3. Retract

**Typhoon Cap Insertion**

Select the appropriate length Cap Guide and hold firmly over the Polyaxial Screw head and rod as shown. Select the matching length Cap Inserter.

If resistance is felt when twisting the Inserter, do not continue. The rod may not be seated adequately and rod reduction must be performed.
1. Hold Inserter in Guide in "Retract" position. Place assembly over Polyaxial Screw head so that the Guide contacts the rod.

2. While holding Guide firmly onto rod, press Inserter straight down to bottom of J-slot.

3. Twist the Inserter anti-clockwise.

4. Remove Inserter and Guide.

Typhoon Cap Removal
Ensure Typhoon Cap set screw is loosened.

Rod Reduction – Typhoon Approximator

Prep
T-Handle pin should be located at its lowest point in the slot.
Outer sleeve should be in the retracted (up) position.

With thumb over the T-Handle as shown, the Typhoon Cap is picked from the caddy and retracted into the Approximator.
Connect
With the Barrel and T-Handle at their highest positions, and the sleeve retracted, the springs are connected to the open implant head holding features. The sleeve is then slid down over the springs to lock the instrument to the implant.

Reduce
The rod is reduced by turning the outer barrel clockwise until the pin in the slot meets the appropriate etch mark:

- **5.50 mm System – Green**
  - Single etch line for all implants.
- **6.35 mm System – Blue**
  - Polyaxial Screws: top etch line.
  - Monoaxial Screws/Open Hooks: bottom etch line.
Capture
The rod is captured into the open implant head by turning the T-Handle clockwise until the pin hits the opposite side of the slot.

If resistance is felt when twisting the T-Handle, further reduction may be required.

Typhoon Cap Set Screw position should be verified prior to additional reduction attempts.

Remove
Turn the Barrel anti-clockwise at least three turns. Pull up on the T-Handle until the pin hits the top of the slot.

Retract the outer sleeve. Twist the Approximator off of the screw with the T-Handle.
Attach the Rocker tips to the holding feature on the sides of the implant head. Lever the Rocker to fully seat the rod.

Cap Insertion
Align the vertical etch line on the Cap Inserter with the etch line on the implant head. Insert the Typhoon Cap so that the tabs on the cap clear the bottom of the locking tabs on the implant head. Twist 1/8 turn clockwise and remove the Inserter.

If resistance is felt when twisting the Inserter, further reduction may be required.

Typhoon Cap Set Screw position should be verified prior to additional reduction attempts.
Attach the tips of the **Camlok** to the holding feature on the sides of the implant head using the lever. Turn the reduction handle of the Camlok *clockwise* until the rod is fully seated.

**Cap Insertion**

Align etch line of Inserter with etch line on Camlok guide slot. Place the Inserter through the guide slot. Insert the Typhoon Cap so that the tabs on the cap clear the bottom of the locking tabs on the implant head. Twist 1/8 turn *clockwise* and remove the Inserter.

If resistance is felt when twisting the Inserter, further reduction may be required.

**Typhoon Cap Set Screw position** should be verified prior to additional reduction attempts.
Once the rod has been captured into all of the Polyaxial Screw heads, Compression and Distraction manoeuvres can be easily accomplished by simply loosening and tightening the pre-loaded Set Screw within the Typhoon Cap.
Final tightening is performed with the Hexlobe Shaft inserted into the T-Handle Torque Wrench, which is set to 80 in-lb (9Nm). The shaft is then inserted through the Open Connection Stabiliser and into the Set Screw in the Typhoon Cap.

The Stabiliser is then slid down over the head of the Polyaxial Screw and onto the rod.

The T-Handle is rotated clockwise until it clicks and resistance is no longer evident.
The Open Connection Stabiliser is used to prevent torsion of the construct during final tightening.

Typhoon Cap Set Screw Loosening

The Typhoon Cap Stabiliser should cover the portion of implant head above the rod but not rest directly on top of rod.

The Torque setting handle is always set to 80 in-lb for Set Screw tightening.
The Hexlobe Shaft of the Torque Wrench Assembly is inserted through the Typhoon Cap Stabiliser and into the Typhoon Cap Set Screw.

The Torque Wrench Handle is set to 80 in-lb.

The Typhoon Cap Stabiliser is then slid down over the head of the implant until snug. The Torque Handle is rotated anti-clockwise until the Set Screw is loosened.

Remove Typhoon Cap Stabiliser and Torque Wrench Assembly. Check to ensure Typhoon Cap has remained in proper “captured” orientation.
The Hook Driver can be used in conjunction with the Open Hook Holder to position the Pedicle Hook. The rod is captured into the Pedicle Hook by inserting the Typhoon Cap.
Hook Site Preparation
Hook sites are chosen pre-operatively or intra-operatively by the surgeon. The appropriate Hook Starter is used to prepare each selected hook site.

Open Hook Rules

Closure Mechanism
See Typhoon Cap Application (page 21).

Compression/Distraction
See Typhoon Cap Compression/Distraction (page 30).

Final Tightening and Loosening
See Typhoon Cap Final Set Screw Tightening and Loosening (page 31-32).

Rod Reduction
See Rod Reduction (page 25-27).

Closed Hook Rules

Closure Mechanism
Pre-loaded Set Screw

Compression/Distraction
Compression/Distraction maneuvers are facilitated through interim tightening and loosening of Set Screw.

Final Tightening and Loosening
See Slotted Connector Final Tightening – Step 1 (page 11).

Note: Short Cap Inserter and Short Cap Guide are typically recommended for Typhoon Cap application in the Thoracic spine.
The Hook Driver can be used in conjunction with Open and Closed Hook Holder to position an Open or Closed Hook on the Transverse Process. 

*Open or Closed Hooks may be used according to surgeon preference.*

Closed

Ensure Closed Hook body is clear of the Set Screw prior to insertion of the rod.

Open

The rod is captured into the Open Hook by inserting the Typhoon Cap. Final tightening is performed.
The Hook Driver can be used in conjunction with the Open or Closed Hook Holder to position an Open or Closed Hook on the Lamina.

Closed
Ensure Closed Hook body is clear of the Set Screw prior to insertion of the rod.

Open
The rod is captured into the Open Hook by inserting the Typhoon Cap. Final tightening is performed.

Open or Closed Hooks may be used according to surgeon preference.
The Offset Hook Holder may be used to manipulate an Open Hook, reduce the rod (with the Corkscrew) and insert the Typhoon Cap.
Cephalad/Caudal Hook Holder (5.50 mm only)

The Cephalad/Caudal Hook Holder is connected to the C/C holding features on the implant head to avoid medial/ lateral obstruction. A Typhoon Cap may be inserted with the C/C Hook Holder engaged.