



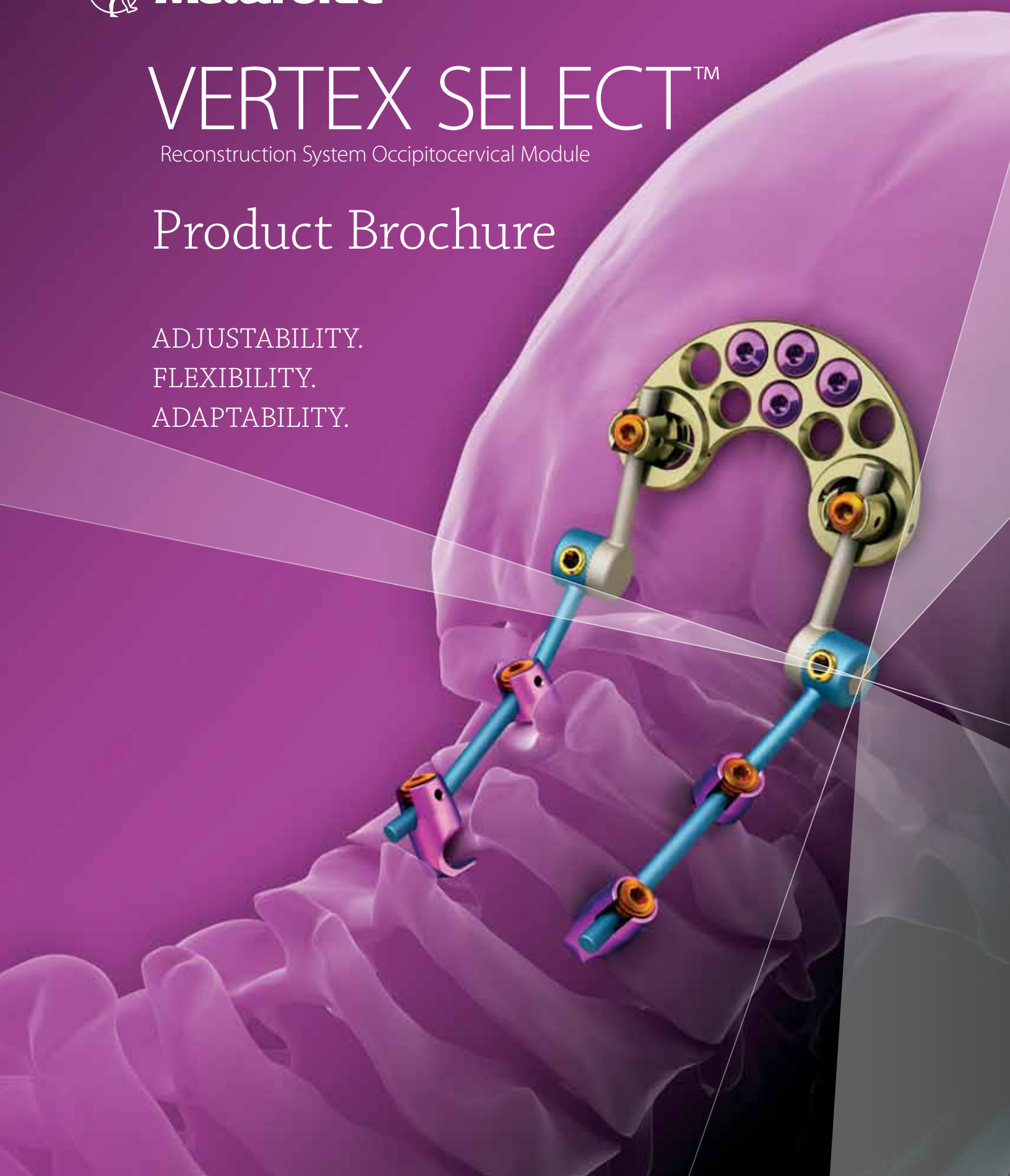
Medtronic

VERTEX SELECT™

Reconstruction System Occipitocervical Module

Product Brochure

ADJUSTABILITY.
FLEXIBILITY.
ADAPTABILITY.



“Three-in-One” System of Options

The VERTEX SELECT™ Reconstruction System Occipitocervical Module is a “Three-in-One” system of options that provides adjustability, flexibility, and adaptability to meet the anatomical challenges within the occipitocervical spine.



Offering more occipitocervical options than any other commercially available system.

VERTEX SELECT™ Reconstruction System is being brought to you in three phases of continuous improvement. With the addition of the Adjustable OC Plate to the VERTEX SELECT™ Occipitocervical Module, the first two phases of the comprehensive VERTEX SELECT™ Reconstruction System are complete.

☐ 3. Advancing for the Future

VERTEX SELECT™ Reconstruction System Launch

☑ 2. Elevating for Tomorrow

VERTEX SELECT™ Reconstruction System Adjustable OC Plate Launch

☑ 1. Optimizing for Today

VERTEX SELECT™ Reconstruction System Occipitocervical Module Launch

System Features and Benefits

- » Adjustable OC Plate with rotating and translating saddles for flexibility in rod placement.
- » Low profile occipitocervical fixation options.
- » Versatile connection options from occiput to cervical spine.
- » Adjustable rods to account for variations in patient anatomy.
- » Flexible shaft and alternate angle instruments to address anatomical challenges that are particular to occipitocervical junction.
- » One 3.2mm drill bit for both occipitocervical screw diameters.
- » Adaptable with the current VERTEX MAX® Reconstruction System cervical-upper thoracic components.

What's New?

Fixation

Occipitocervical Bone Screws

- » *Increased diameters — 4.5mm and 5.0mm
- » Slightly tapered tip for easier insertion
- » *Increased thread pitch



Adjustable OC Plate

- » Rotating and translating saddles allow for flexibility in rod placement
- » Multiple screw holes for choice of screw placement (must place at least four screws)
- » Arched design for increased bone graft volume on occiput
- » Low profile design
- » Lateral screw placement options to allow for torsional stability



Occipitocervical Midline “M” Plate

- » M-shape of plate provides space for bone grafting in the midline of the occiput for increased bone graft volume
- » Lateral screw placement allows for torsional stability
- » Multiple sizes available to match patient anatomy



Occipitocervical Midline Keel Plate

- » Lower profile version of the original VERTEX MAX® Reconstruction System midline plate
- » Lateral screw placement allows for torsional stability
- » Multiple sizes available to match patient anatomy



Occipitocervical Screw Connectors

- » Allows for six points of midline fixation
- » Low profile implant option
- » Flexibility in placement on the occiput in the cephalad/caudal directions
- » Longer offset (additional 5mm) connector options for medial/lateral adjustment
- » Dorsal height adjustment to accommodate uneven bone surfaces
- » Accepts 3.5mm portion of occipitocervical adjustable rod and occipitocervical precurved rod.



Rods

Occipitocervical Adjustable Rod

- » “Hinge” portion of rod adjusts to accommodate various angles at occipitocervical junction
- » Requires less bending to fit difficult anatomy
- » 360° of rotation for medial/lateral adjustment
- » Angulation can be adjusted intraoperatively
- » 3.5mm superior rod segment, 3.2mm inferior rod segment for compatibility with the VERTEX MAX® Reconstruction System cervical-upper thoracic components



*Versus the VERTEX MAX® Reconstruction System occipitocervical screws

Instruments

Fixed Occipital Drill-Tap Guides and Screwdriver Guide

- » Rotational stop to prevent “over-tapping” (spinning of the tap in bone after desired depth has been achieved).



Flexible Drill Bit, Tap and Screwdriver Options

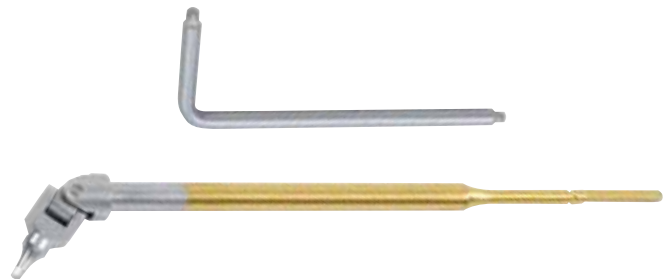
- » Flexible shaft instruments reserved as an alternative to the straight shaft drill, tap, and screwdriver for anatomical challenges.
- » One 3.2mm drill bit for both 4.5mm and 5.0mm occipitocervical bone screws.



Alternate Angle Screwdriver Options

Screwdrivers reserved as an alternative to the straight hex screwdriver for anatomical challenges.

- » Universal Joint Driver
 - Final tightening, straight hex
- » Right Angled Driver
 - Final tightening, straight hex
 - 90° to screw
 - 2.5mm hex on both ends



Bending Instruments

- » Occipital Midline Plate Bender
 - Creates a gradual bend along the occipital plate
 - One instrument to contour both the occipital rods and midline plates
- » Left and Right Bending Irons
 - Additional tool for contouring both the occipital rods and midline plates
 - Accepts the 3.6mm portion of the precurved rod

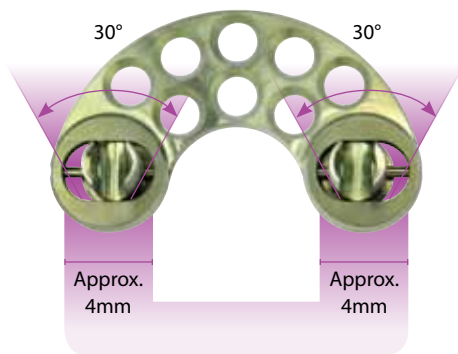


Helpful Information

- » The adjustable rod can be rotated in the medial/lateral orientation for better alignment between the occipital points of fixation and the cervical subaxial components. In order to do so, the set screw can be removed and placed on the opposite side of the hinge.
- » The adjustable rod has a slight offset from the 3.2mm rod portion to the 3.5mm rod portion. When selecting a plate, use the size that fits 4-5mm medial or lateral to the subaxial components.
- » The left and right bending irons may be utilized to bend the adjustable rods in the region close to the hinge.
- » Avoid repeated bending motions to the implants, as excessive bending will decrease the integrity of the implant.
- » The set screws located on the adjustable rods and screw connectors are to be hand tightened. Use a tactile feel to determine the final locked position.
- » The universal joint and right angle occipitocervical screwdrivers are a straight 2.5mm hex, therefore, should only be used for final tightening. They are not intended to hold the occipitocervical screws or set screws.
- » The Adjustable OC Plate allows approximately 4mm translation per saddle and 30° rotation per saddle.

Biomechanical Data

The implants in the VERTEX SELECT™ Reconstruction System Occipitocervical Module (midline plates, screw connectors, and occipitocervical adjustable rods) were tested in dynamic axial compression (i.e., construct fatigue) and dynamic torsion. All implants demonstrated equivalency to the predicate VERTEX® Reconstruction System Occipitocervical Plate/Rod.



Frequently Asked Questions

Compatibilities:

Q: Is the VERTEX SELECT™ Reconstruction System Occipitocervical Module compatible with the VERTEX MAX® System?

A: It was designed to be used in conjunction with the VERTEX MAX® Reconstruction System when connecting down to the cervical and/or thoracic spine. However, please note:

The VERTEX MAX® Reconstruction System and the VERTEX SELECT™ Reconstruction System occipitocervical implants are different in profile and diameter; therefore, the occipitocervical components (implants and instruments) between the two systems are NOT compatible.

Reasons:

1. The fixed occipitocervical guides take into account the profile of the VERTEX SELECT™ Reconstruction System implant profile. The VERTEX SELECT™ Reconstruction System implants are up to 1mm thinner than the original VERTEX MAX® Reconstruction System occipitocervical plates and screw connectors.
2. The occipitocervical drill bits match the specific minor diameter of the occipitocervical screws. The VERTEX SELECT™ Reconstruction System occipitocervical screws have a minor diameter of 3.2mm and the VERTEX MAX® Reconstruction System occipitocervical screws have a minor diameter of 3.0mm for the 4.0mm occipitocervical screws and 3.5mm for the 4.5mm occipitocervical screws.
3. The occipitocervical taps match the specific diameter and thread pitch of the occipitocervical screws. The occipitocervical screw diameters are 4.5mm and 5.0mm in the VERTEX SELECT™ Reconstruction System, but the occipitocervical screw diameters are 4.0mm and 4.5mm in the VERTEX MAX® Reconstruction System. The thread pitch for the VERTEX SELECT™ Reconstruction System occipitocervical screws are 1.25mm, but the thread pitch on VERTEX MAX® Reconstruction System occipitocervical screws is 1.0mm.

Therefore, due to the differences between the two systems, the surgeon will either over- or under-drill/tap if using the VERTEX SELECT™ Reconstruction System and

VERTEX MAX® Reconstruction System Occipitocervical Module components interchangeably.

Remember the rule regarding occipitocervical components

“New With the New, Old With the Old”

Q: Are there occipitocervical components that are exceptions to the rule?

A: All rods (straight, precurved, and adjustable) and screwdrivers (self-holding, straight hex, flexible, universal joint, and right angle) can be used interchangeably between the two systems. The screwdrivers are compatible because they all have a 2.5mm hex.

Q: Are the bending irons and occipital plate bender/rod bender found in the VERTEX SELECT™ Reconstruction System Occipitocervical Module compatible with the VERTEX MAX® Reconstruction System midline plates and occipitocervical rods?

A: Because of the difference in profiles of the occipital midline plates, they are NOT compatible. However, they are compatible with the rods (straight, precurved, and adjustable), and are the exception to the previously mentioned rule.

Q: Does it matter which direction the adjustable rod segments are positioned?

A: Yes. For compatibility to the VERTEX MAX® Reconstruction System subaxial components, the 3.2mm portion must be placed caudal (down). The 3.5mm rod portion should be placed cephalad (up) to connect to the occipital components.

Frequently Asked Questions *continued*

Design Features:

Q: What is the profile difference between the VERTEX SELECT™ Reconstruction System implants and the VERTEX MAX® Reconstruction System implants?

A: The VERTEX SELECT™ Reconstruction System Adjustable OC Plate, fixed midline plate, and screw connectors are 2.0mm in profile (height). The VERTEX MAX® Reconstruction System midline keel plate is 2.75mm in profile and the screw connectors are 3.0mm in profile.

Q: Can the occipitocervical midline plates be contoured?

A: Yes, the Occipitocervical Midline Plate Bender/Rod Bender creates a gradual bend along the midline plates. The Bending Irons can be used as an additional tool for contouring.

Note: Due to the geometry of the Midline Keel Plate, the Occipitocervical Plate Bender/Rod Bender cannot be utilized. Please use the Bending Irons for contouring the Midline Keel Plates.

Q: What is the distance from the rod to the occipital screw connectors?

A: The standard screw connector is 7.35mm and the offset screw connector is 12.35mm (additional 5mm offset).

Q: What is the diameter of the drill bit?

A: The VERTEX SELECT™ Reconstruction System drill bit is 3.2mm in diameter and drills up to 18mm, used in conjunction with the occipitocervical guides.

Q: What is the diameter of the taps?

A: The taps match the diameter of the occipitocervical screws; therefore, use the 4.5mm tap for the 4.5mm

occipitocervical screws and the 5.0mm tap for the 5.0mm occipitocervical screws.

Q: What occipitocervical screw sizes are available?

A: The VERTEX SELECT™ Reconstruction System occipitocervical screws are 4.5mm and 5.0mm in diameter and 6mm – 18mm in length. Sizes 6mm – 14mm are included in the standard loaner set configuration.

Q: Can I drill and tap through the occipitocervical fixed guides?

A: Yes, the VERTEX SELECT™ Reconstruction System fixed occipitocervical guides were designed for the straight and flexible drills and taps in the new Occipitocervical Module.

Q: Can I insert the occipitocervical screws through the occipitocervical fixed guides?

A: The occipitocervical screws can be inserted through the screw guide on the opposite end of the 18mm occipitocervical fixed guide.

Q: Which holes are used for screw placement? Do I put screws in every hole?

A: Typically, you insert the two midline screws as that is where the thickest part of bone is, the additional 2 screws can be placed in any holes that best suit the patient's anatomy. We recommend using a total of four screws for your placement.

Q: What is the function of the pin in the Adjustable OC Plate?

A: The pin's only function is to keep the head assembled during shipping. Once the rods are locked onto the plate, the heads are locked down.

Frequently Asked Questions *continued*

Ordering Information:

Q: What is the loaner set type for the VERTEX SELECT™ Occipitocervical Module?

| A: Set Type | Description |
|--|---|
| SPS02168 | VERTEX SELECT™ System Occipitocervical Module Implants and Instrument Set |
| SPS02177 | VERTEX SELECT™ System Occipitocervical Module Sterile Drill Bits |
| **The Occipitocervical Module is not a stand-alone set, and must be used in conjunction with the VERTEX MAX® Reconstruction System: | |
| SPS02074 | VERTEX MAX® System Implants |
| SPS00696 | VERTEX MAX® System Instrument Set |
| SPS00697 | VERTEX MAX® System Sterile Drill Bits |

Q: What is not in the VERTEX SELECT™ Reconstruction System Occipitocervical Module that I will need out of the VERTEX MAX® Reconstruction System sets for an occipitocervical case?

A: You will need the set screws (#6950315) to lock the occipitocervical plates to the rod, any or all of the straight shaft hex screwdrivers for initial and final tightening, the universal handles (#6956016) and any implants and instruments used when connecting past the occipitocervical junction.

Q: Are the occipitocervical plate/rods found in the VERTEX SELECT™ Reconstruction System Occipitocervical Module?

A: No, they are ordered as “extras” through Customer Service. The part numbers are #6900270 (100mm) and #6900280 (200mm). The plate/rods must be used with the instruments and implants found in the VERTEX MAX® Reconstruction System set.

Product Ordering Information

Set Ordering Information

| Set Type | Description |
|--|---|
| SPS02168 | VERTEX SELECT™ System Occipitocervical Module Implants and Instrument Set |
| SPS02177 | VERTEX SELECT™ System Occipitocervical Module Sterile Drill Bits |
| **The Occipitocervical Module is not a stand-alone set, and must be used in conjunction with the VERTEX MAX® Reconstruction System: | |
| SPS02074 | VERTEX MAX® System Implants |
| SPS00696 | VERTEX MAX® System Instrument Set |
| SPS00697 | VERTEX MAX® System Sterile Drill Bits |

Occipital Midline Plates

| Item # | Description | Qty In Standard Set | Loose Goods |
|---------|---------------------------------|---------------------|-------------|
| 7755278 | Adjustable OC Plate | 2 | |
| 7759970 | Occipital Midline Plate, S | 1 | |
| 7759971 | Occipital Midline Plate, M | 1 | |
| 7759972 | Occipital Midline Plate, L | 1 | |
| 6959970 | Occipital Midline Keel Plate, S | 1 | |
| 6959971 | Occipital Midline Keel Plate, M | 1 | |
| 6959972 | Occipital Midline Keel Plate, L | 1 | |

Occipital Screw Connectors

| Item # | Description | Qty In Standard Set | Loose Goods |
|---------|-----------------------------------|---------------------|-------------|
| 7755325 | Occipital Screw Connector | 8 | |
| 7755327 | Occipital Screw Connector, Offset | 4 | |

Occipitocervical Rods

| Item # | Description | Qty In Standard Set | Loose Goods |
|---------|---|---------------------|-------------|
| 7755122 | 3.2/3.5mm × 120mm Occipitocervical Adjustable Rod | | × |
| 7755123 | 3.2/3.5mm × 220mm Occipitocervical Adjustable Rod | 3 | |
| 6955270 | 3.2mm × 200 Precurved Occipitocervical Rod | 3 | |

Occipital Bone Screws

| Item # | Description | Qty In Standard Set | Loose Goods |
|---------|---------------------------------|---------------------|-------------|
| 7750506 | 4.5 × 6mm Occipital Bone Screw | 6 | |
| 7750508 | 4.5 × 8mm Occipital Bone Screw | 6 | |
| 7750510 | 4.5 × 10mm Occipital Bone Screw | 6 | |
| 7750512 | 4.5 × 12mm Occipital Bone Screw | 6 | |
| 7750514 | 4.5 × 14mm Occipital Bone Screw | 4 | |
| 7750516 | 4.5 × 16mm Occipital Bone Screw | | × |
| 7750518 | 4.5 × 18mm Occipital Bone Screw | | × |
| 7750606 | 5.0 × 6mm Occipital Bone Screw | 4 | |
| 7750608 | 5.0 × 8mm Occipital Bone Screw | 4 | |
| 7750610 | 5.0 × 10mm Occipital Bone Screw | 4 | |
| 7750612 | 5.0 × 12mm Occipital Bone Screw | 4 | |
| 7750614 | 5.0 × 14mm Occipital Bone Screw | 2 | |
| 7750616 | 5.0 × 16mm Occipital Bone Screw | | × |
| 7750618 | 5.0 × 18mm Occipital Bone Screw | | × |

Occipitocervical Instruments

| Item # | Description | Qty In Standard Set | Loose Goods |
|---------|--|---------------------|-------------|
| 7756334 | 4.5mm Occipital Tap | 1 | |
| 7756383 | 4.5mm Occipital Flexible Tap | 1 | |
| 7756337 | 5.0mm Occipital Tap | 1 | |
| 7756384 | 5.0mm Occipital Flexible Tap | 1 | |
| 7759978 | Fixed Occipital DT Guide, 6mm/8mm | 1 | |
| 7759979 | Fixed Occipital DT Guide, 10mm/12mm | 1 | |
| 7759980 | Fixed Occipital DT Guide, 14mm/16mm | 1 | |
| 7759982 | Fixed Occipital DT Guide, 18mm / Screwdriver Guide | 1 | |
| 7756286 | Flexible Screwdriver, Self Holding, 2.5mm Hex | 1 | |
| 7756187 | Universal Joint Screwdriver, Straight 2.5mm Hex | 1 | |
| 7756188 | Screwdriver, Right Angle 2.5 Hex | 1 | |
| 7756290 | Bending Iron, Left | 1 | |
| 7756291 | Bending Iron, Right | 1 | |
| 7756230 | Occipital Midline Plate Bender/ Rod Bender | 1 | |

Disposable Drill Bits

| Item # | Description | Qty In Standard Set | Loose Goods |
|----------|--|---------------------|-------------|
| 7756131 | 3.2mm Occipital Drill Bit, Sterile | 1 | |
| 7756281S | 3.2mm Occipitocervical Flexible Drill Bit, Sterile | 1 | |

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See package insert for labeling limitations.

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



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