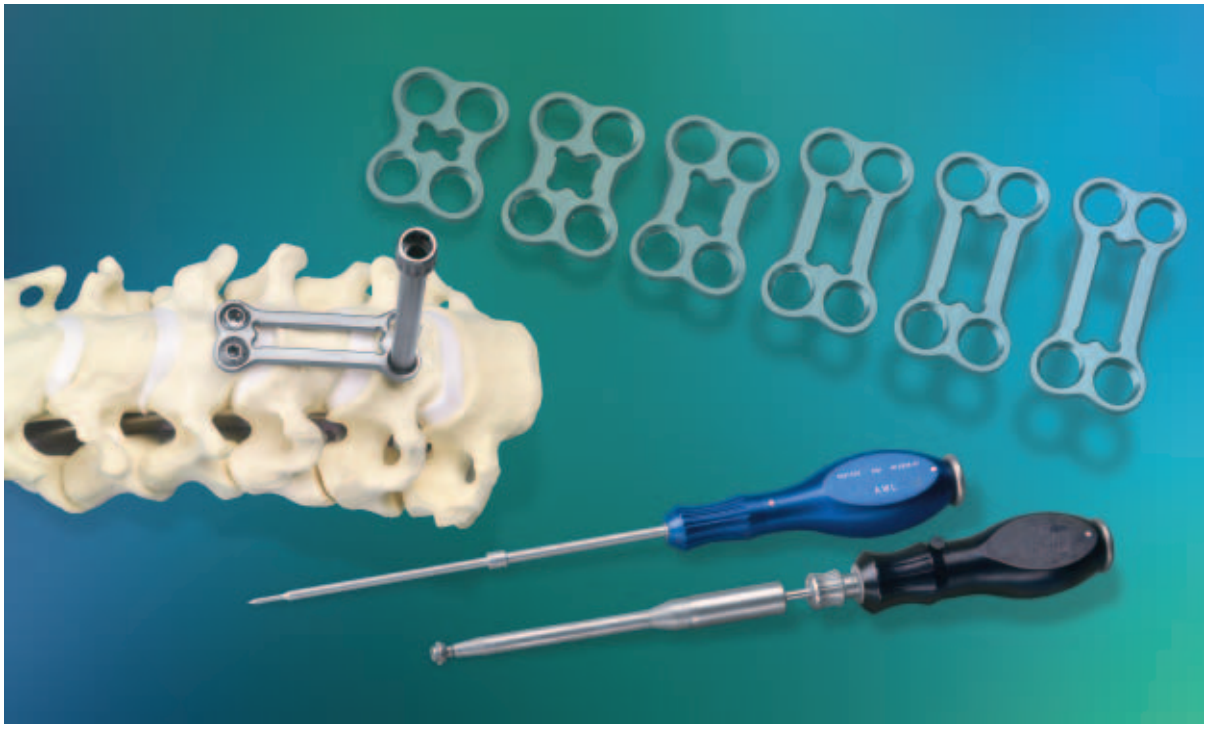
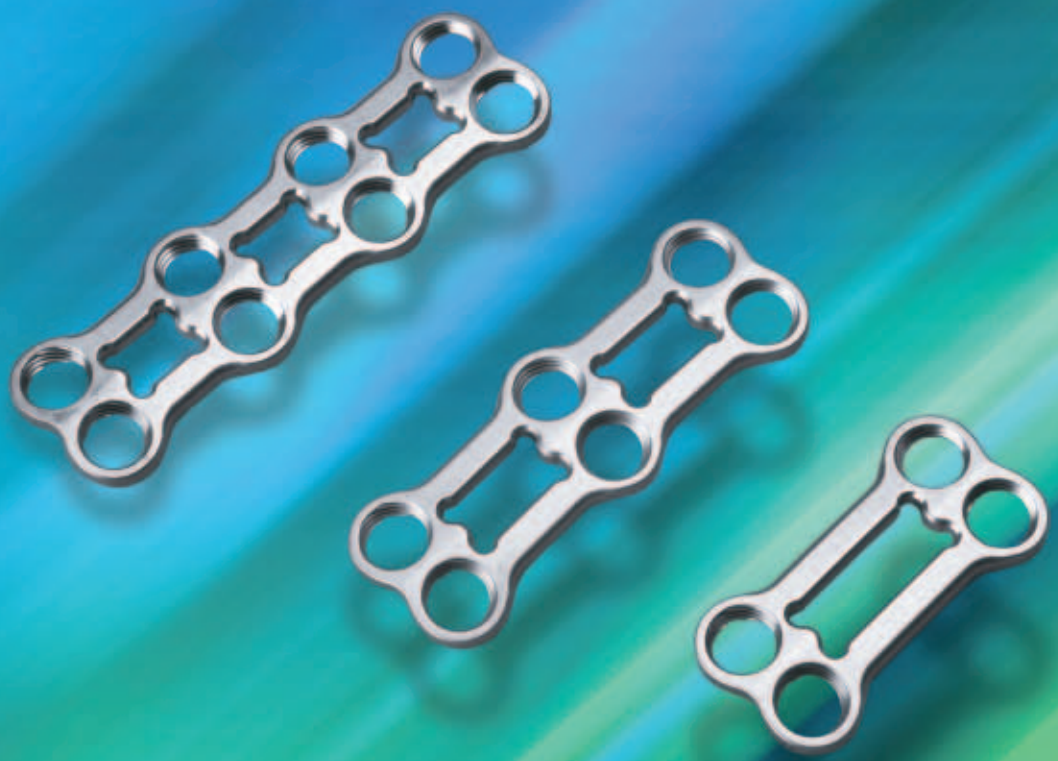
BIOMET SPINE

Cyprus® Anterior Cervical Plate System

Surgical Technique



Contents



BIOMET SPINE

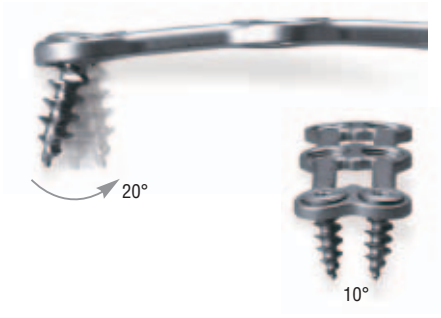
Introduction

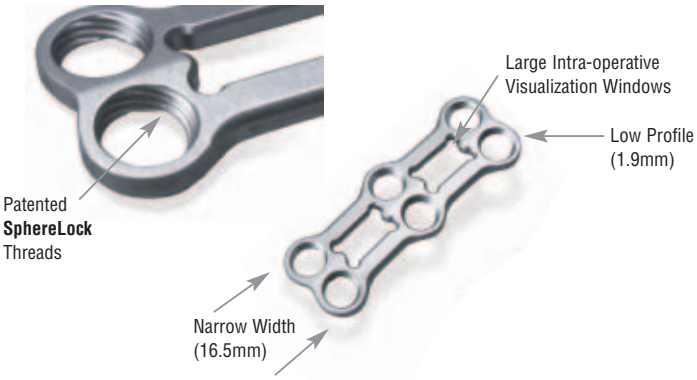
The **Cyprus** Anterior Cervical Plate System offers surgeons simplicity, efficiency and versatility. This anterior cervical plate system is a low profile system that offers surgeons the option of a constrained or semi-constrained construct. The system composed of Titanium Alloy (Ti 6Al-4V ELI) features a simple one step locking mechanism and large visualization windows for great intra-operative and post-operative views of the graft site.

Description

The **Cyprus** Anterior Cervical Plate System is intended for anterior interbody bone screw fixation during the development of cervical spine fusion. The spinal fixation device includes Self-Drilling/Self-Tapping and Variable/Fixed Bone Screws, patented spherical thread design and pre-contoured 1-3 level plates. Various instruments are also available as part of the **Cyprus** Anterior Cervical Plate System for use by the surgeon to facilitate implantation of the device.

Design Features





Features	**Benefits**
SphereLock Technology	Encourages alignment between the plate and bone screw interface Self-seats bone screw into the recess of the plate Ease of use for surgeon
Locking Mechanism	10in-lb torque
Type of Fixation	Constrained: Restrict motion; provide additional stability Semi-Constrained: Micro-motion; promotes graft settling through “load sharing”
Open Design	Intraoperative visualization of the bone graft and the end plate Post-operative visualization and consolidation of the bone graft in the vertebral disc space
Titanium Alloy (Ti 6Al-4V ELI)	Excellent imaging compatibility and enhanced biomechanical performance
Low Profile	Height: 1.9mm Width: 16.5mm Minimal interference with anatomical structures (i.e. soft tissue)
Pre-Contoured Plates	Conforms to the lordotic curvature of the spine Lordosis increases with plate length
Plate Selection	1-3 level fusion 1 Level: 12-24mm 2 Level: 24-44mm 3 Level: 44-66mm Plates increase in 2mm increments
Bone Screw Options	Self-Tapping/Self-Drilling Fixed/Variable
Bone Screw Dimensions	Major: 4mm Rescue/Salvage Major: 4.75mm Minor: 2mm Rescue/Salvage Minor: 2.75mm Lengths: 12/14/16mm
Fixed Screw Angulation	10° Fixed trajectory cephalad and caudal Saggital plane is neutral (0°)
Variable Screw Angulation	20° Cone of angulation 10° screw placement in any plane (i.e. cephalad, caudal, midline, away from midline)
Screw Convergence	10° in the axial plane

System Components

Self-Drilling/Self-Tapping

Bone Screws

There are Self-Tapping and Self-Drilling Bone Screws with the system. All bone screws are color-coded by length and are available in 4mm (primary application) and 4.75mm (salvage application). Bone screw lengths are 12mm to 16mm in 2mm increments.


Bone Screw Lengths

Variable Bone Screw

The Variable Bone Screw features a unique Poly-Axial Bone Screw head that is independent of the bone screw shaft. This feature creates a 20° cone of angulation; allotting for 10° in any direction.

Fixed Bone Screw

The bone screw threads interlock with the threads of the plate at a preset 10° trajectory cephalad/caudal.

Spherical Thread Design

Both the threads of the plate and the threads of the bone screw resemble a sphere, which provides optimal plate/screw alignment. The spherical thread design allows the bone screws to self center; thereby facilitating surgeon ease of use.

Plate Selection

Plates are available for 1, 2, or 3 level cervical spine fusion. Plates range from 12-66mm in increments of 2mm. Plates are pre-contoured to conform to the natural lordosis of the cervical spine. Lordosis varies, gradually increasing with the size of the plate.

System Components (Continued)

Cyprus Anterior Cervical Plate System Instruments

Caliper

Plate Tack

Plate Bender

Quick Connect Handle

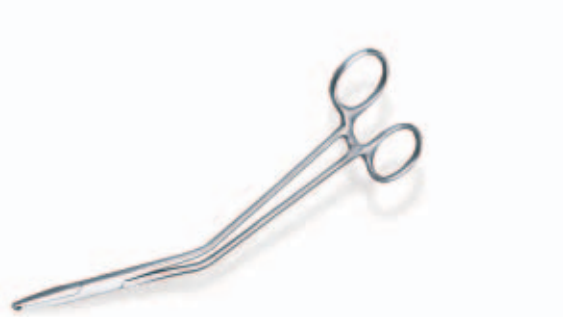


Plate Holder

Drill Bits (Disposable)

Tack Inserter

Variable Adjustable Awl

System Components (Continued)

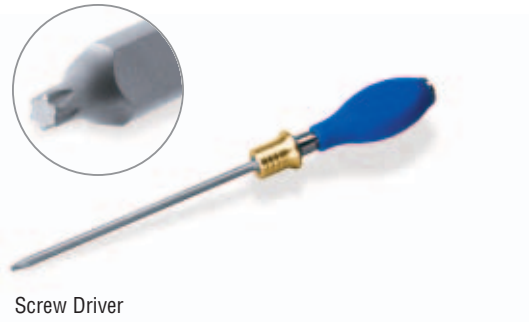
Awl

Variable Drill
Guide Tube

Fixed Drill
Guide Tube

Torque Limiting Quick Connect Handle

Soft Tissue Sleeve



Screw Driver

Revision Screw
Remover

Surgical Technique

Surgical Approach And Preparation

The patient is positioned supine on the operative table with a folded towel beneath the intrascapular region to maintain the head in slight extension. The use of a head halter attached to an outrigger for traction may be helpful. If fluoroscopy is used, it can be utilized at this point to confirm positioning and check that desired vertebral levels can be adequately visualized. (See Figure 1)

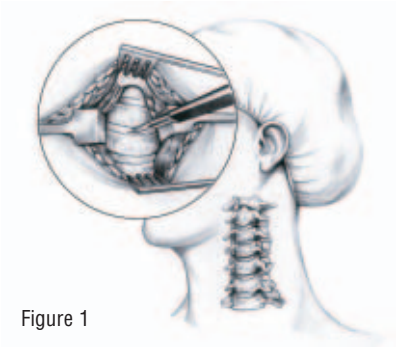


Figure 1

The standard anterior approach to the cervical spine is utilized. This can be through one of several incisions with the exposure typically medial to the carotid sheath and lateral to the trachea and esophagus. Adequate fascial plane release is important for optimal exposure. After identification of the disc space is confirmed with x-ray, preparation for anterior interbody fusion is commenced. (See Figure 2)

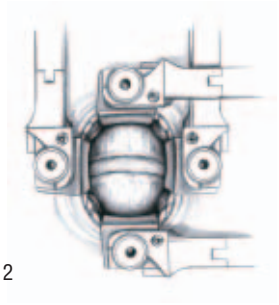


Figure 2

The discectomy and resection of osteophytes is performed. Further preparation of the interbody fusion bed is performed. (See Figure 3)

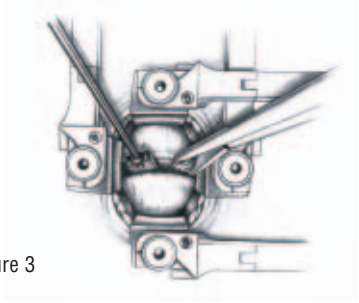


Figure 3

The OsteoStim® Cervical Allograft Spacer System may be used to restore the disc height. (See Figure 4)

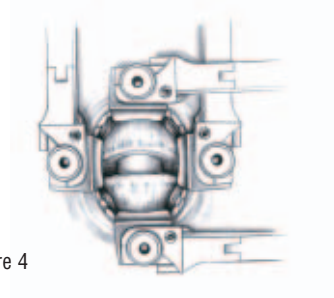


Figure 4

Surgical Technique (Continued)

Plate Positioning

The Caliper estimates the appropriate length of the plate. Seat the prongs of the Caliper in line with the desired bone screw trajectory and read the measurement. Please note that the plate length is measured from the center hole of the inferior to superior bone screw holes.

Plate Size Selection

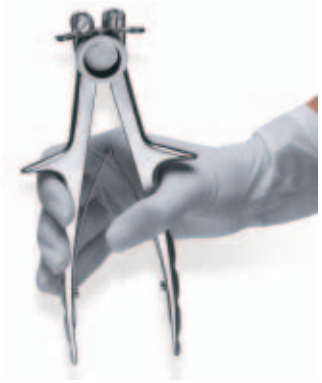
Select the appropriate plate length and place the Plate Holder on the lateral edge of the plate. Press the Plate Holder handles together to engage the locking mechanism and place the plate on the anterior surface of the spine. Review landmarks to ensure that the plate is centered appropriately on the vertebrae. Depress the handles to release the plate.

Plate Insertion Option

Alternatively, the Plate Clip may be used to insert the plate. Select the appropriate plate length and attach the Plate Clip over the lateral edges of the plate. Retract the sleeve of the Tack Inserter and load the hex portion of the Plate Clip. Release the sleeve and insert the plate. Once the plate has been positioned, re-attach the Tack Inserter on the Plate Clip and remove it from the plate.

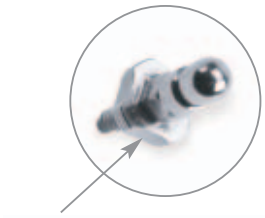
Adjust Curvature

If additional lordosis is desired, moderate changes can be made to adjust the pre-contoured curvature of the plate. You have the option to increase or decrease your plate lordosis (reference Plate Bender etching). Seat the plate inside the Plate Bender and gradually depress the handle until the desired curvature has been achieved. Be careful not to bend the plate too much to avoid compromising the locking mechanism.



Tack Insertion (Optional)

Retract the sleeve of the Tack Inserter and load the hex portion of the Tack. Release the sleeve and insert the Tack into the distal plate indentation or threaded hole of the plate.



TIP: Tack placement will maintain plate in the proper position and aid in correct Bone Screw placement

Load Drill Bits

4mm and 4.75mm Drill Bits are available with the standard set. Each Drill Bit is color-coded to the corresponding bone screw length. Load the selected Drill Bit into the Quick Connect Handle and select the appropriate Drill Guide.

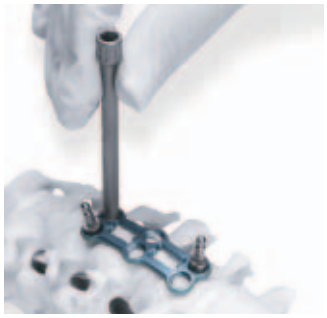
Positioning Drill Guide(s)

The Drill Guide and Awl options with the system are: Fixed and Variable Drill Guide Tubes, Awl and Variable Adjustable Awl.

Surgical Technique (Continued)

Fixed Drill Guide Tube

The Fixed Drill Guide Tube is preset to a 10° angle cephalad and caudal. Turn the tube clockwise to lock by hand or drive assembly. Drill until the Drill Bit stop engages with the Drill Guide Tube. Rotate the drill in the opposite direction to remove the Drill Bit. To unlock, turn the tube counterclockwise.



Variable Drill Guide Tube

The Variable Drill Guide Tube permits a 20° cone of angulation, allotting for 10° in any plane. Turn the tube clockwise to lock by hand or drive assembly. Drill until the Drill Bit stop engages with the Drill Guide Tube. Rotate the drill in the opposite direction to remove the Drill Bit. To unlock, turn the tube counterclockwise.

Awl Selection

As an alternative to drilling, a Variable Adjustable Awl or Awl can be used to pierce the anterior cortex of the vertebral body. The awls pierce the anterior cortex to the minor diameter of a 4mm Bone Screw. The Awl penetrates to a 9mm depth with a Fixed or Variable Drill Guide. To use the Variable Adjustable Awl, depress the button on the handle and turn the sleeve clockwise to the desired depth marking (range 8-16mm).

Bone Screw Insertion

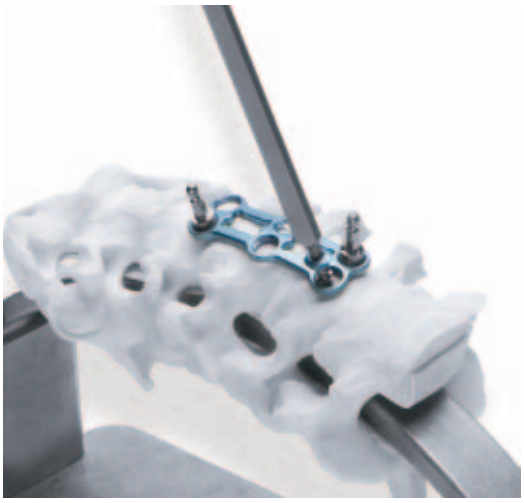
The appropriate length and diameter of the bone screw can be verified using the Bone Screw Gauge on the Bone Screw Caddy.

Select the appropriate length bone screw and diameter. Insert the distal tip of the Screw Driver into the bone screw head. The Screw Driver is designed so that the bone screw head will adhere to the tip geometry of the instrument.

Insert the bone screw into the recess of the plate and turn the Screw Driver clockwise. Continue advancing the bone screw until the spherical threads interlock with the plate and an audible click is heard. Tilt the Screw Driver medially to release the bone screw. Fluoroscopy may be used to confirm the bone screw trajectory.

OPTIONAL: The Soft Tissue Sleeve may be attached to the Screw Driver to move anatomical tissue out of the way during bone screw insertion.

NOTE: The Torque Limiting Quick Connect Handle has a gold collar to distinguish between the Quick Connect Handle. The Torque Limiting Quick Connect Handle applies the appropriate torque to securely lock the bone screw in place.

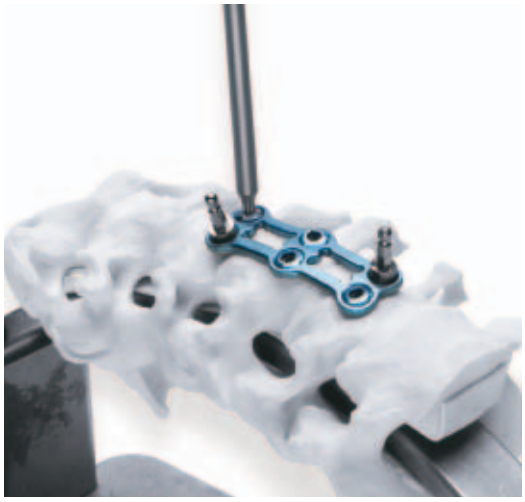


Surgical Technique (Continued)

Bone Screw Removal

If a bone screw has been locked in place but needs to be removed, the Screw Driver is utilized. Assemble the Screw Driver Shaft to the Quick Connect Handle. Insert the distal tip of the Screw Driver into the hex shaped portion of the bone screw. Turn the bone screw counterclockwise to disengage the bone screw threads. A Plate Holder may be used to stabilize the plate during removal.

OPTIONAL: If the bone screw head hex will not engage with the Screw Driver, use the Revision Screw Remover to disengage the bone screw. Assemble the Revision Screw Remover to the Quick Connect Handle. Insert the distal tip and turn counterclockwise until the spherical threads disengage.



Additional Surgical Options

1. Use caution when bending the plate near the threaded hole locations.

2. Be sure that all drill guides are fully seated into the plate bone screw hole to commence drilling.

3. If the drill guide is not positioned properly, the bone screw may be beyond the acceptable angle (which is defined by the Guide), and may crossthread into the plate.

4. As a reminder, after a bone screw is inserted through the plate, the bone purchase is 1mm less than the indicated length (i.e. 12mm Bone Screw is 11mm in bone).

5. The depth of drilling is controlled by an individual pre-set drill stop for each length bone screw. The Drill Bit is designed to create a pilot hole equivalent to the minor diameter of the bone screw.

6. Please note that the Drill Bits are color coded to match the bone screw length.

Closure And Postoperative Care

Closure

After implantation of the **Cyprus** Anterior Cervical Plate System is complete, closure is performed in layers according to standard protocol. Radiographs should be taken during surgery to confirm appropriate placement of the cervical plate and bone screws prior to closing.

Postoperative Care

Collar (soft or hard) immobilization may be used for comfort but also may be indicated given individual bone density and quality of fixation. This should be determined on an individual basis. Postoperative radiographs should be taken.

Implant Removal

Removal of the **Cyprus** Anterior Cervical Plate is performed by reversing the order of the implant procedure. The Screw Driver is used first to remove the bone screws from the plate. If the screw driver cannot engage with the bone screw head, use the Revision Screw Remover to disengage bone screws.

Regulatory Status

CE
0086

Indications For Use

The **Cyprus** Anterior Cervical Plate System implants are intended for temporary anterior interbody bone screw fixation of the cervical spine during the development of cervical spine fusion. The system is indicated for use in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses and/or failed previous fusion.

Contraindications

1. Spinal infection or inflammation
2. Morbid obesity
3. Mental illness, alcoholism, or drug abuse
4. Pregnancy
5. Metal Sensitivity/foreign body sensitivity
6. Open wounds local to the operative area
7. Rapid joint disease, bone absorption, osteopenia and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and or intolerance
8. Patients with inadequate tissue over the operative site

Warnings

1. This device is not approved for bone screw attachments to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

2. Selection of Implants: Selection of proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants.

3. Implant Strength and Loading: These devices are not designed to withstand the unsupported stress of full weight bearing and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight bearing and activity levels will dictate the longevity of the implant.

4. Corrosion: Contact of dissimilar metals accelerates the corrosion process, which could enhance fatigue fracture of the implants. Therefore, only use like or compatible metals with implants that are in contact with each other.

See the Warnings, Precautions, and Possible Adverse Effects section of the package insert for a complete list of potential risks.

Sterilization Recommendations

The **Cyprus** Anterior Cervical Plate System is provided nonsterile, and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended:

Cycle:	High Vacuum
Temperature:	270°F/132°C
Time:	Eight minutes
Note:	Allow for Cooling

Individuals or hospitals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

Ordering Information

Implant Tray (88800)

Plates

Catalog #	Description	Qty.
1-Level		
5001112	12mm Plate	2
5001114	14mm Plate	2
5001116	16mm Plate	2
5001118	18mm Plate	2
5001120	20mm Plate	2
5001122	22mm Plate	2
5001124	24mm Plate	2
2-Level		
5001224	24mm Plate	2
5001226	26mm Plate	2
5001228	28mm Plate	2
5001230	30mm Plate	2
5001232	32mm Plate	2
5001234	34mm Plate	2
5001236	36mm Plate	2
5001238	38mm Plate	2
5001240	40mm Plate	2
5001242	42mm Plate	2
5001244	44mm Plate	2
3-Level		
5001344	44mm Plate	2
5001346	46mm Plate	2
5001348	48mm Plate	2
5001350	50mm Plate	2
5001352	52mm Plate	2
5001354	54mm Plate	2
5001356	56mm Plate	2
5001358	58mm Plate	2
5001360	60mm Plate	2
5001362	62mm Plate	2
5001364	64mm Plate	2
5001366	66mm Plate	2

Instrument Tray (88820)

Instruments

Catalog #	Description	Qty.
5001501	Quick Connect Handle	2
5001519	Torque Limiting Quick Connect Handle	2
55001605	Screw Driver	2
5001528	Plate Holder	1
5001527	Caliper	1
5001524	Tack Inserter	1
5001530	Awl	1
5001531	Variable Adjustable Awl	1
5001523	Revision Screw Remover Shaft	1
5001504	Soft Tissue Sleeve	2
5001508	Plate Bender	1
5001600	Fixed Drill Guide Tube	2
5001601	Variable Drill Guide Tube	2
5001512	Drill Guide Drill 4mm x 12mm	2
5001513	Drill Guide Drill 4.75mm x 12mm	1
5001514	Drill Guide Drill 4mm x 14mm	2
5001515	Drill Guide Drill 4.75mm x 14mm	1
5001516	Drill Guide Drill 4mm x 16mm	2
5001517	Drill Guide Drill 4.75mm x 16mm	1
5001604	Tack	2
5001529	Plate Clip	2

Ordering Information (Continued)

Implant Tray (88800)

Self-Tapping Variable Bone Screws

Catalog #	Description	Qty.	Diameter	Length	Head Color	Shaft Color
5000912	Self-Tapping Variable Bone Screw	8	4mm	12mm	Light Green	Light Green
5000914	Self-Tapping Variable Bone Screw	16	4mm	14mm	Gold	Gold
5000916	Self-Tapping Variable Bone Screw	8	4mm	16mm	Dark Blue	Dark Blue
5000962	Self-Tapping Variable Bone Screw	6	4.75mm	12mm	Light Green	Light Green
5000964	Self-Tapping Variable Bone Screw	6	4.75mm	14mm	Gold	Gold
5000966	Self-Tapping Variable Bone Screw	6	4.75mm	16mm	Dark Blue	Dark Blue
Self-Tapping Fixed Bone Screws						
5001012	Self-Tapping Fixed Bone Screw	8	4mm	12mm	Light Green	Light Green
5001014	Self-Tapping Fixed Bone Screw	16	4mm	14mm	Gold	Gold
5001016	Self-Tapping Fixed Bone Screw	8	4mm	16mm	Dark Blue	Dark Blue
5001062	Self-Tapping Fixed Bone Screw	6	4.75mm	12mm	Light Green	Light Green
5001064	Self-Tapping Fixed Bone Screw	6	4.75mm	14mm	Gold	Gold
5001066	Self-Tapping Fixed Bone Screw	6	4.75mm	16mm	Dark Blue	Dark Blue
Self-Drilling Variable Bone Screws						
5000913	Self-Drilling Variable Bone Screw	8	4mm	12mm	Light Green	Silver
5000915	Self-Drilling Variable Bone Screw	16	4mm	14mm	Gold	Silver
5000917	Self-Drilling Variable Bone Screw	8	4mm	16mm	Dark Blue	Silver
5000963	Self-Drilling Variable Bone Screw	6	4.75mm	12mm	Light Green	Silver
5000965	Self-Drilling Variable Bone Screw	6	4.75mm	14mm	Gold	Silver
5000967	Self-Drilling Variable Bone Screw	6	4.75mm	16mm	Dark Blue	Silver
Self-Drilling Fixed Bone Screws						
5001013	Self-Drilling Fixed Bone Screw	8	4mm	12mm	Light Green	Silver
5001015	Self-Drilling Fixed Bone Screw	16	4mm	14mm	Gold	Silver
5001017	Self-Drilling Fixed Bone Screw	8	4mm	16mm	Dark Blue	Silver
5001063	Self-Drilling Fixed Bone Screw	6	4.75mm	12mm	Light Green	Silver
5001065	Self-Drilling Fixed Bone Screw	6	4.75mm	14mm	Gold	Silver
5001067	Self-Drilling Fixed Bone Screw	6	4.75mm	16mm	Dark Blue	Silver

Additional Information

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

The **Cyprus** Anterior Cervical Plate System Surgical Technique is presented to demonstrate the surgical techniques utilized by Gary Dix, M.D., Maryland Brain and Spine, Annapolis, MD; John Finkenberg, M.D., Alvarado Orthopedic Medical Group, Inc., San Diego, CA; Scot Miller, D.O., Crystal Clinic, Akron, OH; Douglas Wong, M.D., Panorama Orthopedics, Golden, CO; Philip Schneider, M.D., Director, Holy Cross Hospital Spine Center, Assistant Professor of Orthopedic Surgery, Howard University Medical School, Washington, DC. Biomet Spine, as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

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Notes:

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