# VIP®

## Anterior Cervical Plate system

SURGICAL TECHNIQUE GUIDE

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# SURGICAL TECHNIQUE GUIDE

# VIP®

# VIP® *(Vertical In-line Plate)*

## Anterior Cervical Plate System

The VIP® plate system is the low impact ACDF solution. The plates' narrow width allows for a small incision and less retraction compared to standard ACDF plating solutions. A larger diameter screw and single continuous bone interface ridge provides secure stabilization while securing the bone graft or interbody fusion.

### Low Impact ACDF

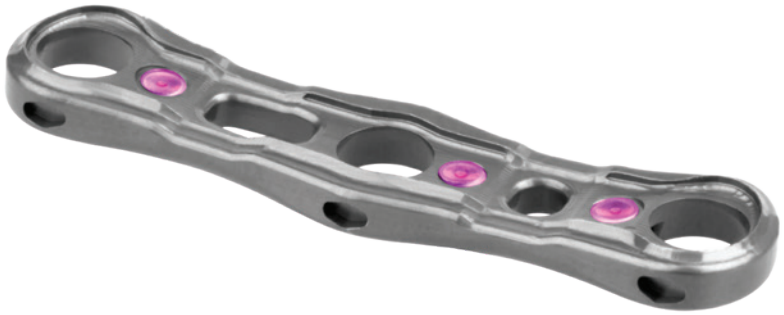
Narrow, 10mm width plate may be inserted through a small incision and require less retraction.

### Less Time Spent in the Operating Room

One screw per level and easy-to-use instrumentation

### Construct stability

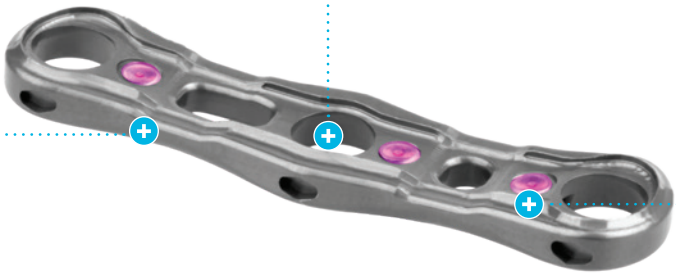
A single continuous bone interface ridge and larger diameter screws (4.6mm and 5.1mm)



Single continuous bone interface ridge enhances plate-to-bone contact and provides comparable stability to a standard two screw per level plate*

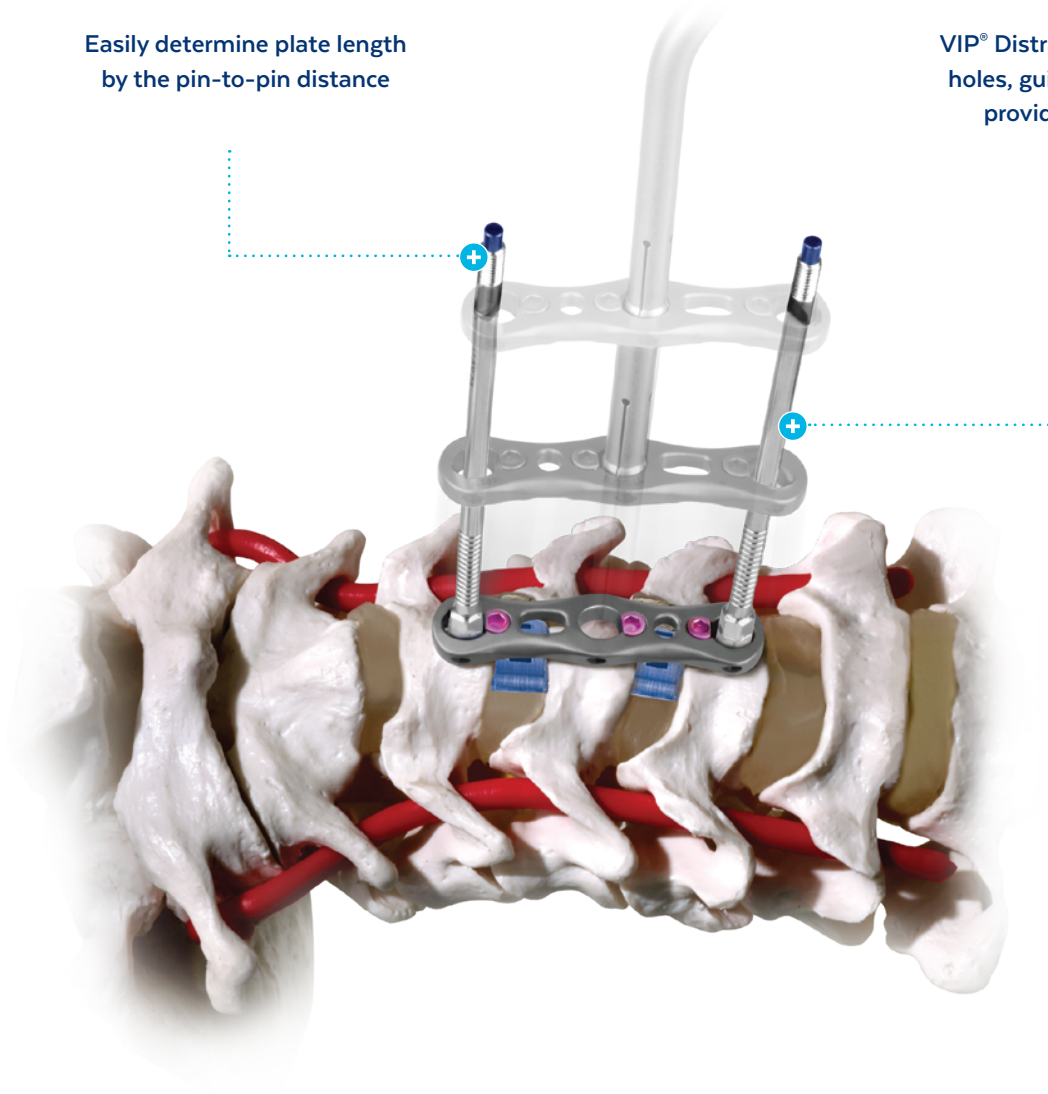
One screw per level may reduce the need for a large incision which may minimize surgical access, retraction and tissue disruption

Integrated blocking set screws provide audible, tactile and visual confirmation and prevent screw back-out



Easily determine plate length by the pin-to-pin distance

VIP® Distraction Pins initiate screw holes, guide plate placement and provide temporary fixation



*Data on file at Globus Medical

# **IMPLANT** OVERVIEW

## Plates

- One screw per level may minimize surgical access, retraction and tissue disruption
- 2.3mm low-profile is designed to reduce esophageal irritation
- Narrow 10mm width may help reduce scarring
- Windows and a narrow cross-section allow graft visualization
- A single continuous bone interface ridge enhances bone contact
- Ability to lag to the bone aids in maintaining the low profile
- Lordotic and extra lordotic to match patient anatomy
- Lengths from 13mm–46mm in 2mm increments
- 1 and 2 level plates available

## Blocking Set Screw

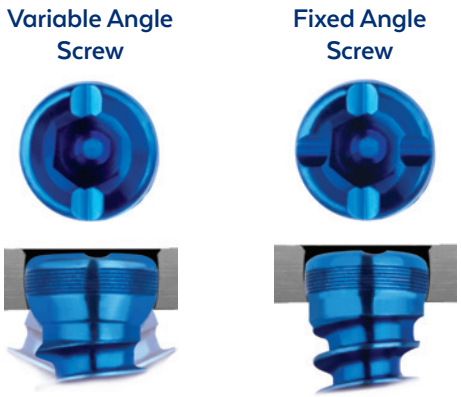
- Provides audible, tactile and visual confirmation of set screw engagement
- Preassembled into the plate
- Prevents screw back-out


## Screws

- 4.6mm and 5.1mm diameters
- Self-Drilling and Self-Tapping
- Variable Angle and Fixed Angle
- Lengths from 12mm–26mm in 2mm increments

## Screw Angle

- Variable Screws provide ±20° angulation
- 10° pre-set cephalad/caudal angulation with drill guides




*Additionally Available

# **INSTRUMENT** OVERVIEW

## SCREW PREPARATION INSTRUMENTS

Cervical Awl, with Sleeve 650.100

*Awl Sleeve Retracted*


Cervical Awl, for Drill Guide 650.102

Drill Bits

| | |
|---|---|
|  | Drill Bit, 12mm 650.112 |
|  | Drill Bit, 14mm 650.114 |
|  | Drill Bit, 16mm 650.116 |
|  | Drill Bit, 18mm 650.118 |
|  | Drill Bit, 20mm 650.120 |

Quick Connect Handle, Swivel 636.450

Cervical Tap 650.160

## PLATE INSTRUMENTS

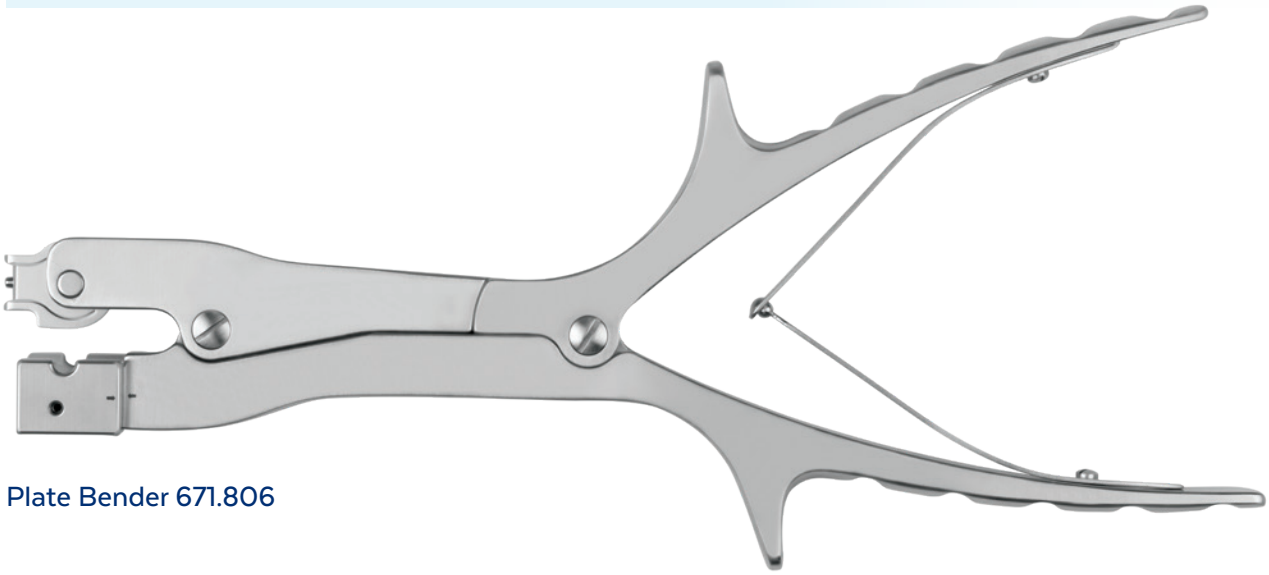


Plate Bender 671.806

Simple Plate Holder 671.201

Temporary Screw 650.012

## BLOCKING SET SCREW INSTRUMENTS

Set Screw Positioner, 2.0mm Hex, Torque Limiting 650.312

Screwdriver, 2.1mm Hex, QC 671.313

## SCREW INSTRUMENTS

Screwdriver, 2.5mm Hex, Self-Retaining, with Cap 671.301

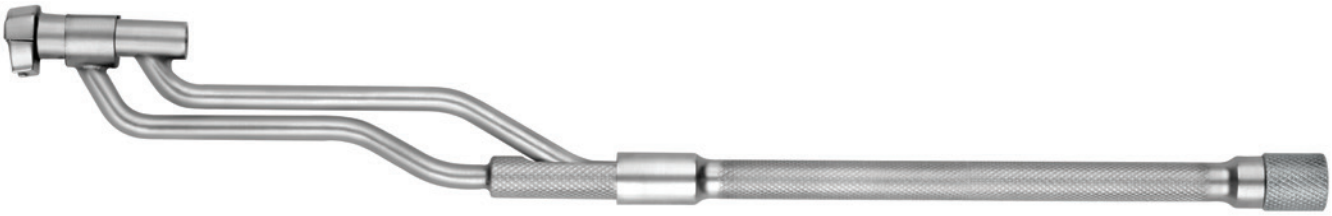
### Drill Guides

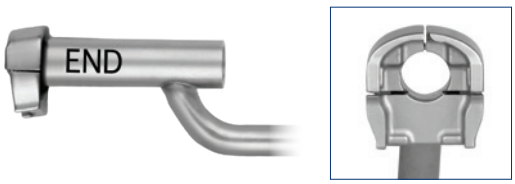


Variable Angle 671.208

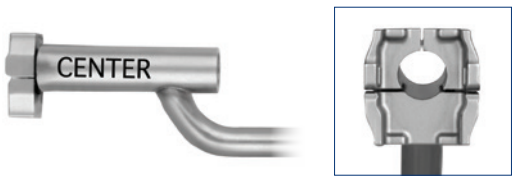

Pre-set Angle 671.209

### DTS Guides






End holes 671.203




Center hole 671.206

# SURGICAL TECHNIQUE

# VIP®

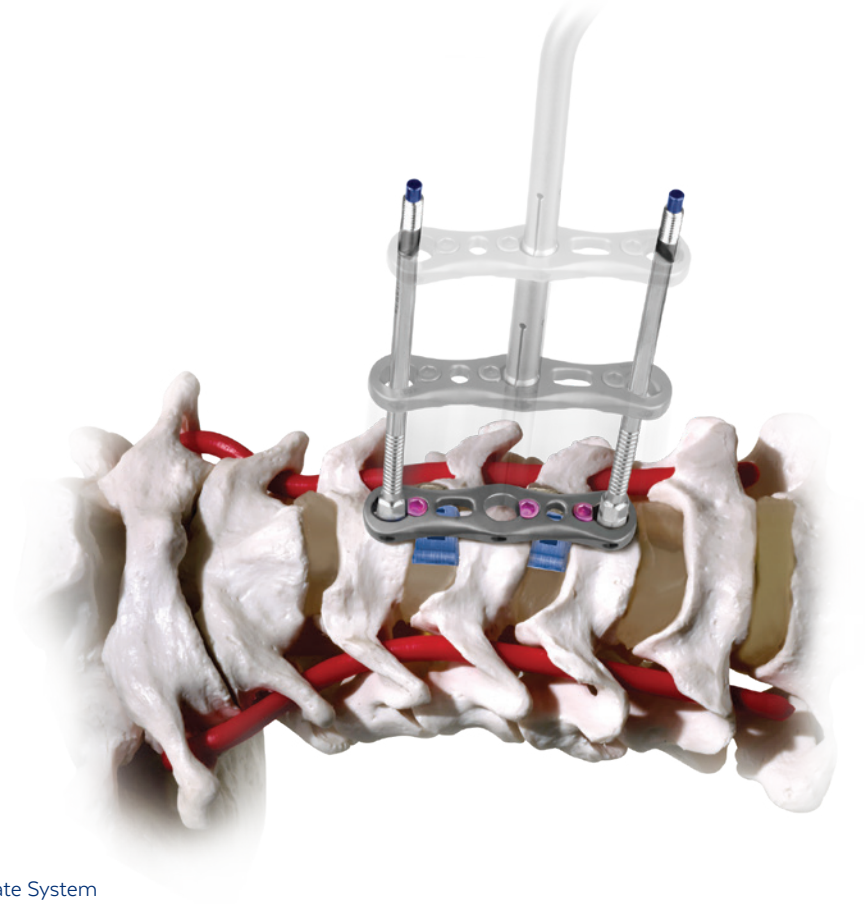
## STEP 1 APPROACH AND PREPARATION

The patient is placed under anesthesia and positioned supine. The operative area is cleaned and an incision is made at the appropriate fusion level(s). VIP® fixation may be used in the cervical spine from C2 to C7. Please refer to the product insert for complete description, indications, contraindications and warnings.

Distraction may be accomplished using a standard distractor or other standard methods. Refer to the COLONIAL® ACDF Surgical Technique Guide for recommended techniques.

If distracting midline, insert pins at the desired trajectory for screw placement. Prepare the disc space and insert bone graft or an interbody fusion device. Remove anterior osteophytes to allow the plate to sit flush on the vertebral body.

VIP® **Distraction Pins** slide through the screws holes of the plate, allowing the pin to initiate the screw hole and to be used for temporary fixation. When the distraction pins are parallel to each other, the distance from pin to pin can be measured for plate size. Once a plate has been selected, slide the plate over the pins. Leave one pin in place as temporary fixation and insert a screw into the opposite screw hole. This technique is applicable only with VIP® Distraction Pins.



# STEP 2 PLATE PLACEMENT

Choose the appropriate plate size. Plate length is measured from the center of the cephalad hole to the center of the caudal hole.

All plates are pre-contoured in the sagittal plane to provide lordosis, however, additional contouring may be accomplished using the **Plate Bender**.

To add lordosis, insert the graft window into the Plate Bender prongs as shown below. Rotate the top anvil down. Using a slow, controlled movement, compress the handles to achieve the desired curvature.

*Notes: Do not bend the plate at the bone screw hole and adjacent set screw interface. This is avoided by placing the plate on the bender in the correct position, as described.*

*Plates with graft windows may be bent to increase lordosis only. Plates may not be bent to decrease lordosis. If additional lordosis is required on a plate without a graft window, an extra lordotic plate should be used.*

## PLATE LENGTH

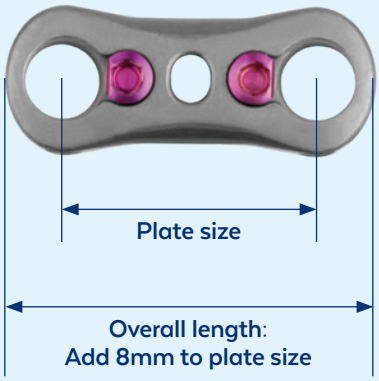


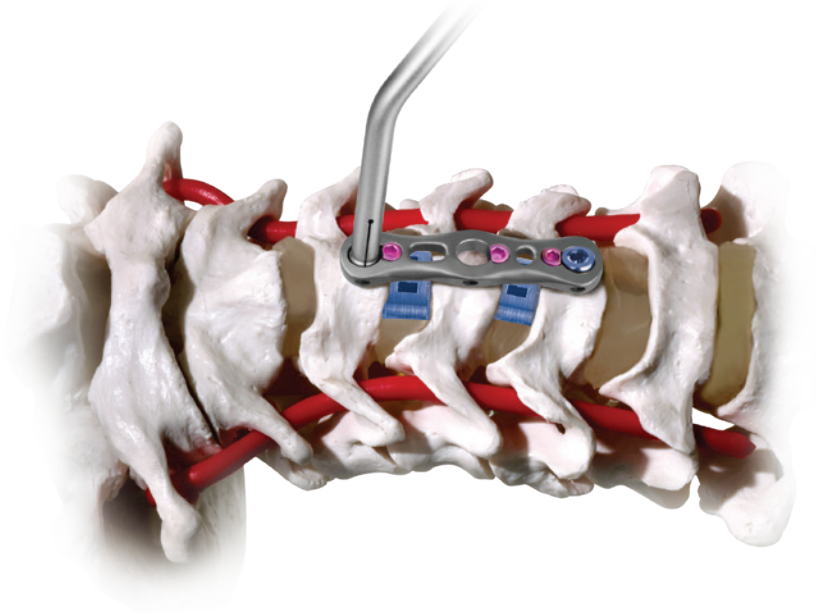

Plate properly inserted

Anvil rotated to final position

# PLATE PLACEMENT (CONT'D)

Use the **Simple Plate Holder** to place the plate. Press the plate holder into a bone screw hole and lift firmly to remove.

Alternately, the **DTS Guide (End or Center Hole)** may be used to place the plate.



## STEP 3 SCREW HOLE PREPARATION

The plate may be temporarily secured by using a **Temporary Fixation Screw**. Use the **Screwdriver, 2.5mm Hex, Self-Retaining, with Cap** to insert the temporary screw through the screw hole.

### OPTION A - *Pre-Set Angulation Using the Pre-Set Angle Drill Guide*

Place the **Pre-Set Angle Drill Guide** into the desired screw hole. Start each pilot screw hole by inserting the Cervical Awl, for Drill Guide through the Pre-Set Angle Drill Guide.

Determine the desired drill depth and select the appropriate fixed length Drill Bit. The Drill Bits are color coded by screw length. Assemble the Drill Bit to the Quick Connect Handle, Swivel and insert into the drill guide. Drill to the stop.

Screw holes may be tapped using the Cervical Tap once the drill guide is removed.

**PRE-SET ANGLE DTS AND DRILL GUIDES**

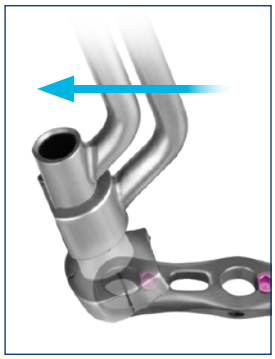
These instruments provide the pre-set screw angulation shown below for awling, drilling, tapping, and inserting screws.

## OPTION A - *Pre-Set Angulation Using the DTS Guides*

Ensure that the knurled cap is rotated counterclockwise until the stop. Align the DTS guide over the appropriate screw hole and apply pressure to attach the guide to the plate. Rotate the knurled cap clockwise to establish a rigid connection.

Align with plate

Attach to plate



Remove from plate

Start each pilot screw hole by inserting the **Cervical Awl, for Drill Guide** into the DTS guide.

Determine the desired drill depth and select the appropriate fixed length Drill Bit. The Drill Bits are color-coded by screw length. Assemble the **Drill Bit** to the **Quick Connect Handle, Swivel** and insert into the drill guide. Drill to the stop.

*Note: Drill bits are not intended for connection to power drill sources.*

Screw holes may be tapped through the DTS guides using the **Cervical Tap**. Screws may also be inserted through the DTS guides (see Step 4, page 15 for screw insertion).

Release the DTS guide by rotating the knurled cap counterclockwise and rocking away from the plate.

*Note: DTS Guides cannot be used with extra lordotic plates.*

Using the DTS Guide on an end hole to prepare screw pilot hole

# SCREW HOLE PREPARATION (CONT'D)

## **OPTION B** - *Variable Angulation Using the Variable Angle Drill Guide*

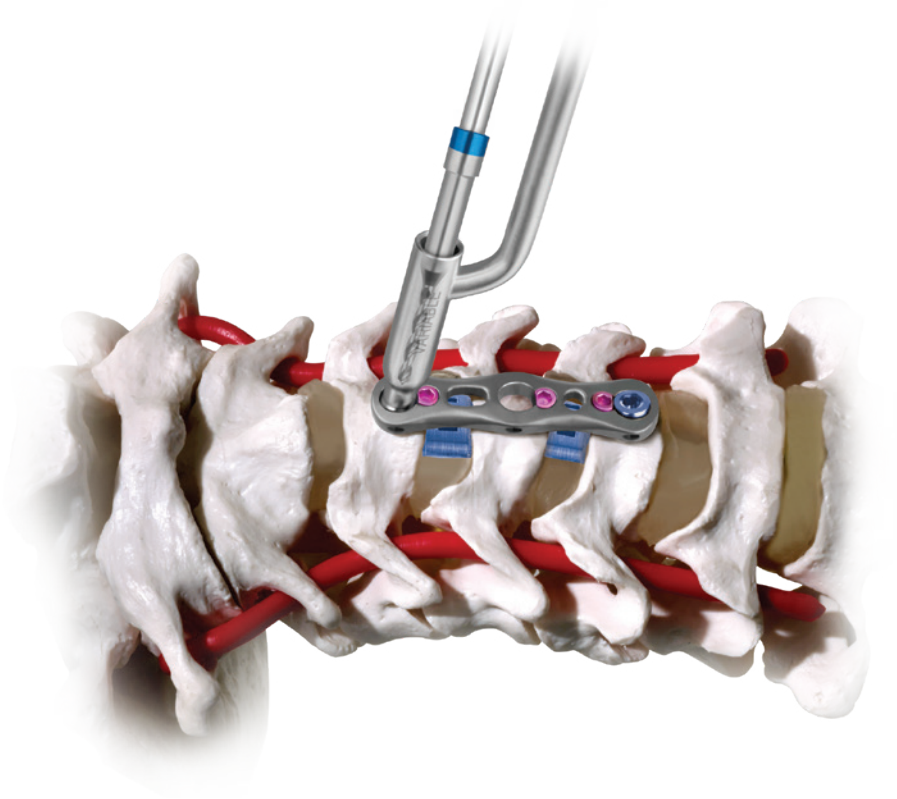
Start each pilot screw hole by inserting the Cervical Awl, with Sleeve into the screw hole within the plate. Alternately, the Cervical Awl, for Drill Guide may be inserted through the **Variable Angle Drill Guide**.

Place the Variable Angle Drill Guide into the desired screw hole. This guide permits full angulation of the drill bit through the plate.

Determine the desired drill depth and select the appropriate fixed length Drill Bit. The Drill Bits are color coded by screw length. Assemble the Drill Bit to the Quick Connect Handle, Swivel and insert into the drill guide. Drill to the stop.

Screw holes may be tapped using the Cervical Tap once the drill guide is removed.

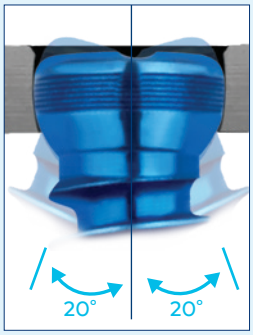
*Note: The variable angle guide should not be used to prepare screw holes for Fixed Angle Screws.*



**Using the Variable Angle Drill Guide to prepare screw pilot hole**

### VARIABLE ANGLE DRILL GUIDE

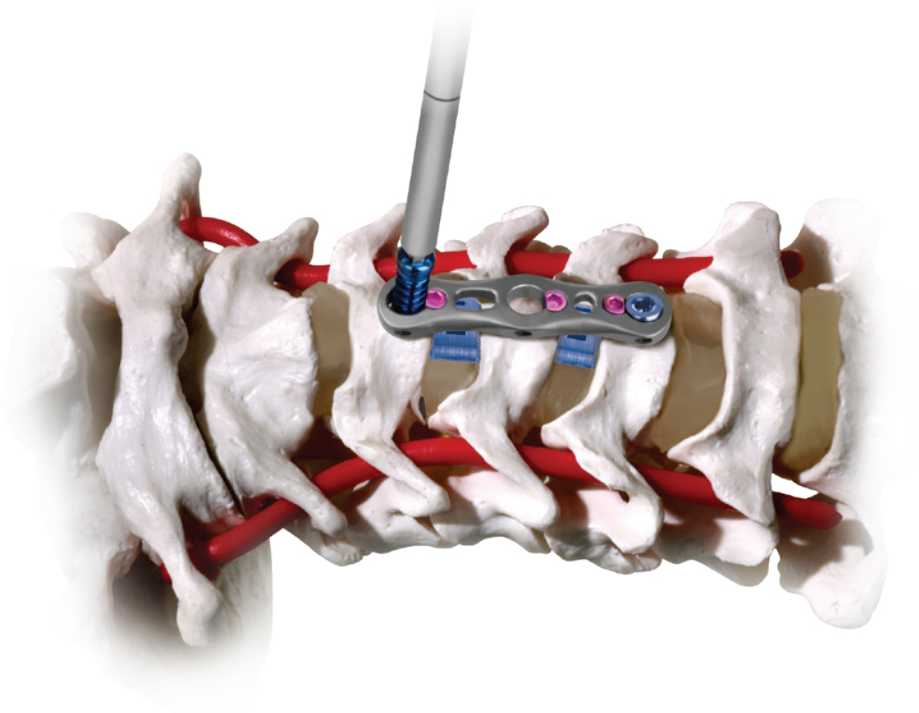
This guide allows screw angulation of 20° in any direction for drilling screw pilot holes.



## STEP 4 SCREW INSERTION

Load the desired screw from the module using the Screwdriver, 2.5mm Hex, Self-Retaining, with cap. Verify screw length and diameter using the gauges within the screw module. Insert the screw through the screw hole. As the screw is inserted, the plate will lag to the bone.

*Note: All screw lengths are measured by bone engagement, not overall length.*



## STEP 5 SCREW BLOCKING

Once the screws are fully seated within the plate, insert the **Set Screw Positioner, 2.0mm Hex, Torque Limiting** into the blocking set screw and turn clockwise approximately 180°. The set screw positioner will provide audible and tactile confirmation that the screw is blocked from backing out. As a final check, visually confirm that the blocking set screw is correctly rotated approximately 180°, as shown below.

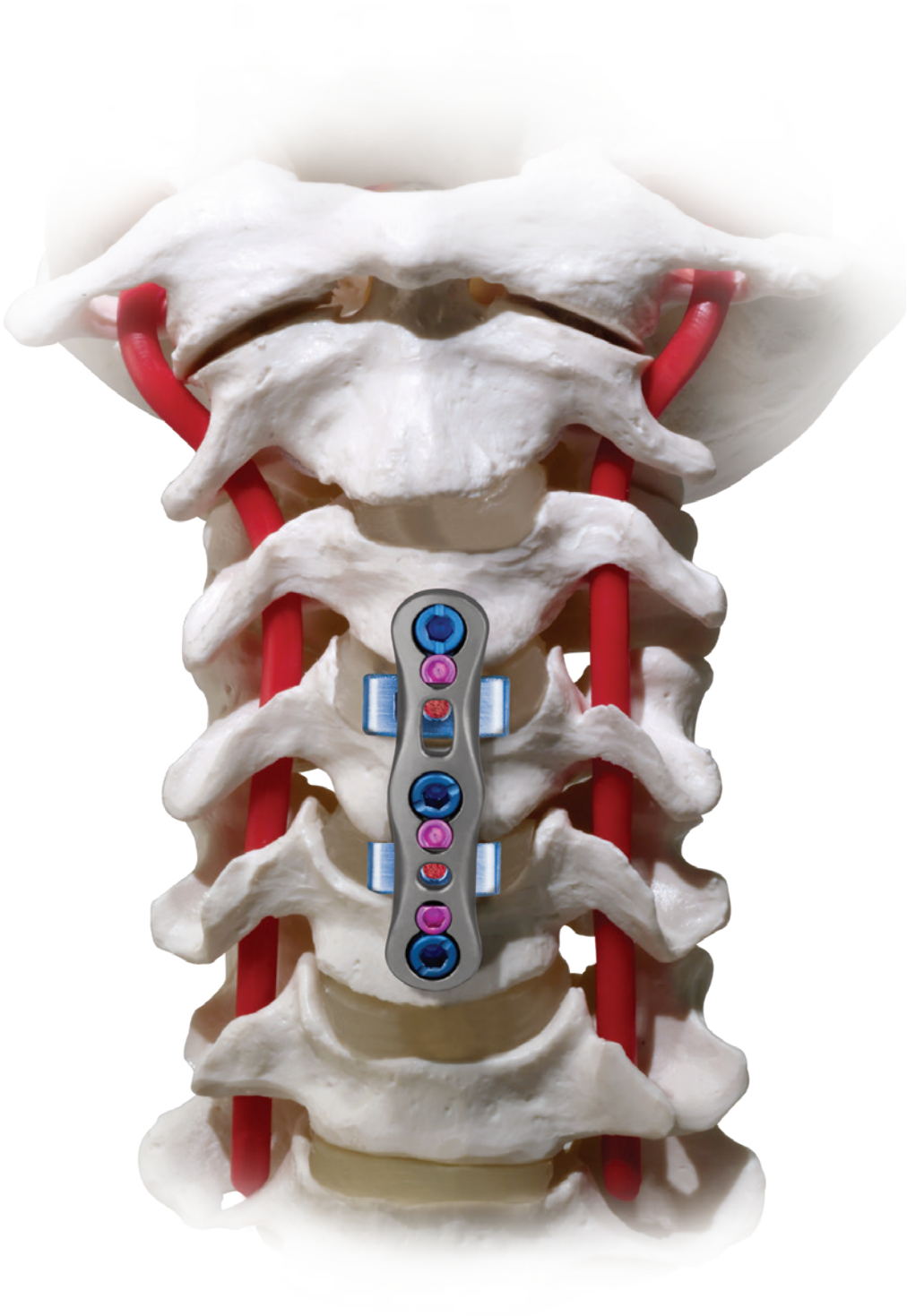
**Initial Position**

**Flat of blocking set screw *facing* bone screw**

**Final Position**

**Flat of blocking set screw *facing away* from bone screw**

# FINAL CONSTRUCT – AP VIEW



# FINAL CONSTRUCT - LATERAL VIEW

# SCREW REMOVAL

For screw removal, simply reverse the steps for insertion. Use the Set Screw Positioner, 2.0mm Hex, Torque Limiting to turn the blocking set screws counter-clockwise 180°. Remove the screws from the plate using the Screwdriver, 2.5mm Hex, Self-Retaining, with cap.

In the event the blocking set screw hex is stripped, use the **Screwdriver, 2.1mm Hex, QC**.

# VIP® CERVICAL PLATE IMPLANT SETS

## VIP® Cervical Plate Set 971.902 (Qty 1 each)

### 1-Level

| Part No. | Length |
|---|---|
| 171.113 | 13mm |
| 171.115 | 15mm |
| 171.117 | 17mm |
| 171.119 | 19mm |
| 171.121 | 21mm |
| 171.123 | 23mm |
| 171.125 | 25mm |

### 2-Level

| Part No. | Length |
|---|---|
| 171.226 | 26mm |
| 171.228 | 28mm |
| 171.230 | 30mm |
| 171.232 | 32mm |
| 171.234 | 34mm |
| 171.236 | 36mm |
| 171.238 | 38mm |
| 171.240 | 40mm |
| 171.242 | 42mm |
| 171.244 | 44mm |
| 171.246 | 46mm |

## Extra-Lordotic (Qty 1 each)

### 1-Level

| Part No. | Length |
|---|---|
| 171.163 | 13mm |
| 171.165 | 15mm |
| 171.167 | 17mm |
| 171.169 | 19mm |

### 2-Level

| Part No. | Length |
|---|---|
| 171.276 | 26mm |
| 171.278 | 28mm |
| 171.280 | 30mm |
| 171.282 | 32mm |

### Modules

971.002 VIP® Plate Module

971.006 VIP® Screw Module

## VIP® Screw Set 971.906

### Variable Angle Screws

| Self-Drilling | 12mm | Qty | 14mm | Qty | 16mm | Qty | 18mm | Qty | 20mm | Qty |
|---|---|---|---|---|---|---|---|---|---|---|
| 4.6mm | 171.012 | 6 | 171.014 | 6 | 171.016 | 6 | - | - | - | - |
| 5.1mm | 171.412 | 6 | 171.414 | 6 | 171.416 | 6 | - | - | - | - |

| Self-Tapping | 12mm | Qty | 14mm | Qty | 16mm | Qty | 18mm | Qty | 20mm | Qty |
|---|---|---|---|---|---|---|---|---|---|---|
| 4.6mm | 171.312 | 6 | 171.314 | 6 | 171.316 | 6 | 171.318 | 3 | 171.320 | 3 |
| 5.1mm | 171.512 | 6 | 171.514 | 6 | 171.516 | 6 | 171.518 | 3 | 171.520 | 3 |

### Fixed Angle Screws

| Self-drilling | 12mm | Qty | 14mm | Qty | 16mm | Qty | 18mm | Qty | 20mm | Qty |
|---|---|---|---|---|---|---|---|---|---|---|
| 4.6mm | 171.612 | 6 | 171.614 | 6 | 171.616 | 6 | - | - | - | - |
| 5.1mm | 171.812 | 6 | 171.814 | 6 | 171.816 | 6 | - | - | - | - |

| Self-Tapping | 12mm | Qty | 14mm | Qty | 16mm | Qty | 18mm | Qty | 20mm | Qty |
|---|---|---|---|---|---|---|---|---|---|---|
| 4.6mm | 171.712 | 6 | 171.714 | 6 | 171.716 | 6 | 171.718 | 3 | 171.720 | 3 |
| 5.1mm | 171.912 | 6 | 171.914 | 6 | 171.916 | 6 | 171.918 | 3 | 171.920 | 3 |

### Additionally Available - Variable Angle Screws

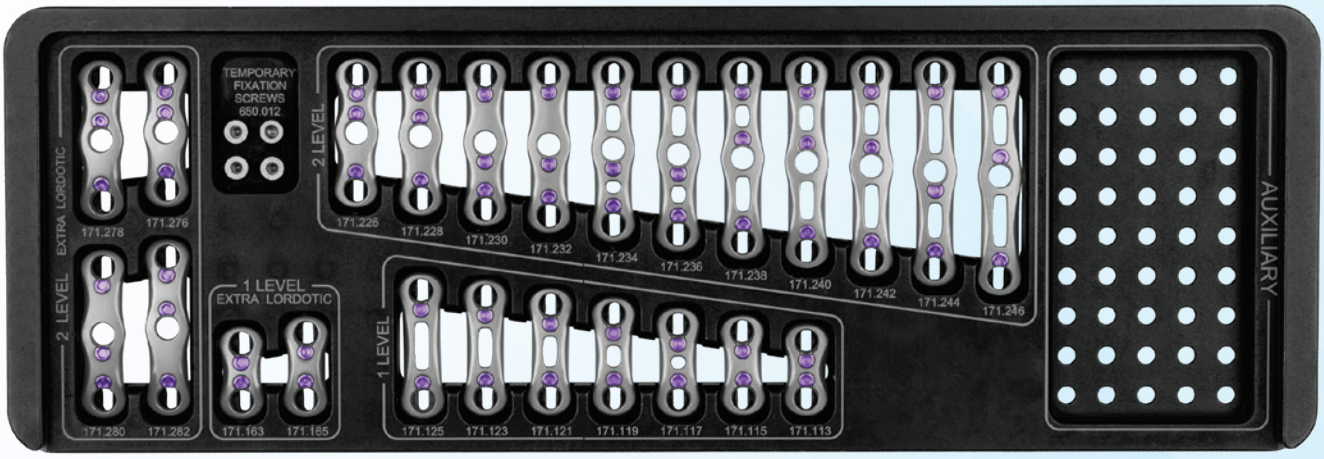
| Self-Tapping | 22mm | 24mm | 26mm |
|---|---|---|---|
| 4.6mm | 171.322 | 171.324 | 171.326 |
| 5.1mm | 171.522 | 171.524 | 171.526 |

### Additionally Available - Fixed Angle Screws

| Self-Tapping | 22mm | 24mm | 26mm |
|---|---|---|---|
| 4.6mm | 171.722 | 171.724 | 171.726 |
| 5.1mm | 171.922 | 171.924 | 171.926 |



*Items in gray are additionally available


2 LEVEL EXTRA LORDOTIC
171.278
171.276
171.280
171.282
TEMPORARY FIXATION SCREWS 650.012
1 LEVEL EXTRA LORDOTIC
171.163
171.165
2 LEVEL
171.226
171.228
171.230
171.232
171.234
171.236
171.238
171.240
171.242
171.244
171.246
1 LEVEL
171.125
171.123
171.121
171.119
171.117
171.115
171.113
AUXILIARY


SELF-DRILLING
GAUGES
SELF-TAPPING
Ø4.6
Ø5.1
12mm
14mm
16mm
18mm
20mm
171.012
171.014
171.016
171.412
171.414
171.416
171.612
171.614
171.616
171.812
171.814
171.816
SCREW LENGTH
171.312
171.314
171.316
171.318
171.320
171.512
171.514
171.516
171.518
171.520
171.712
171.714
171.716
171.718
171.720
171.912
171.914
171.916
171.918
171.920
VARIABLE
FIXED

# VIP® CERVICAL PLATE
# INSTRUMENT SET 971.901

| | | Drilling and Tapping Instruments | Qty |
|---|---|---|---|
| 1 | 650.100 | Cervical Awl, with Sleeve | 1 |
| 2 | 650.102 | Cervical Awl, for Drill Guide | 1 |
| 3 | 636.450 | Quick Connect Handle, Swivel | 2 |
| 4 | 650.112 | Drill Bit, 12mm | 1 |
| 5 | 650.114 | Drill Bit, 14mm | 1 |
| 6 | 650.116 | Drill Bit, 16mm | 1 |
| 7 | 650.118 | Drill Bit, 18mm | 1 |
| 8 | 650.120 | Drill Bit, 20mm | 1 |
| 9 | 650.160 | Cervical Tap | 1 |

| | | Plate and Screw Instruments | |
|---|---|---|---|
| 10 | 671.201 | Simple Plate Holder | 1 |
| 11 | 671.203 | DTS Guide, End holes | 1 |
| 12 | 671.206 | DTS Guide, Center Hole | 1 |
| 13 | 671.208 | Variable Angle Drill Guide | 1 |
| 14 | 671.209 | Pre-Set Angle Drill Guide | 1 |
| 15 | 671.301 | Screwdriver, 2.5mm Hex, Self-Retaining, with Cap | 1 |
| 16 | 650.312 | Set Screw Positioner, 2.0mm Hex, Torque Limiting | 1 |
| 17 | 671.313 | Screwdriver, 2.1mm Hex, QC | 1 |
| 18 | 671.806 | Plate Bender | 1 |

### Graphic Case

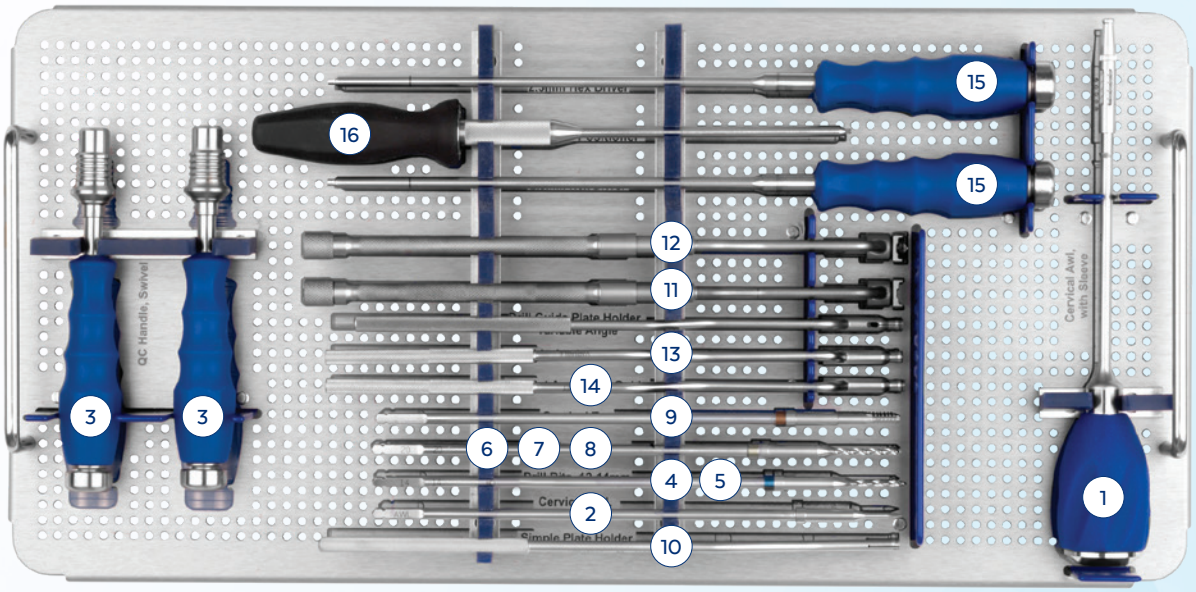
| | |
|---|---|
| 971.100 | VIP® Graphic Case |

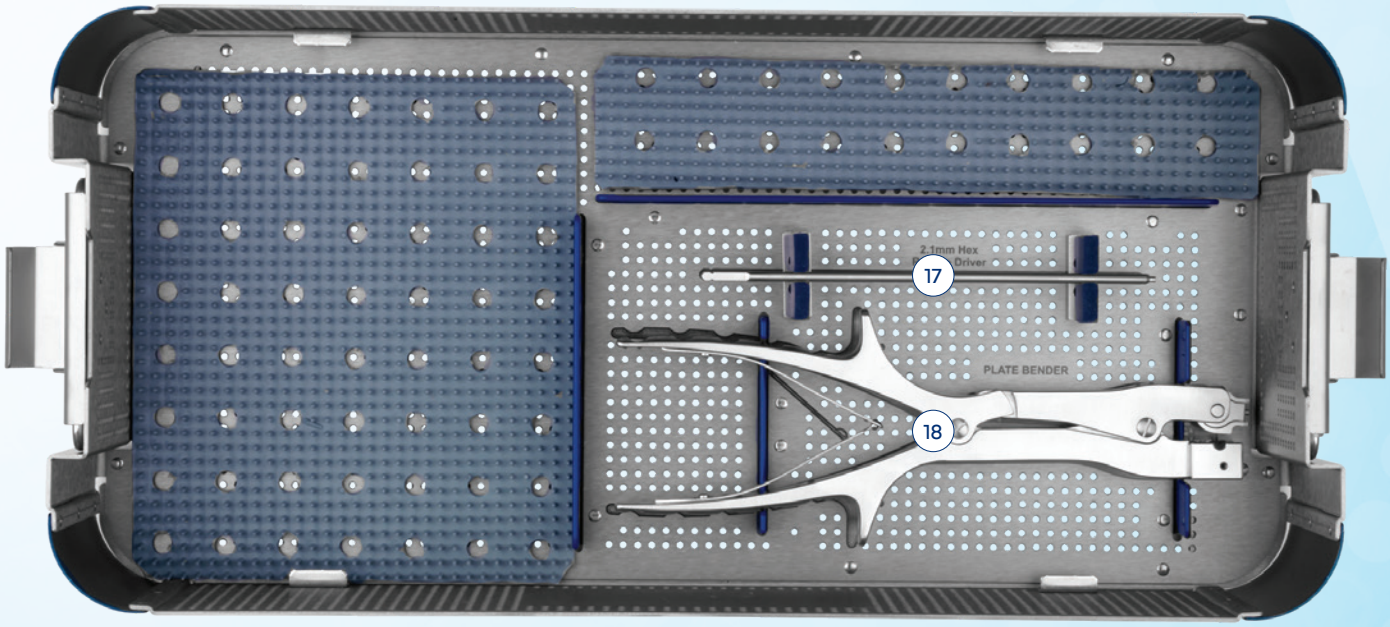
### Additionallly Available

| | |
|---|---|
| 671.010 | Distraction Pin, 10mm |
| 671.012 | Distraction Pin, 12mm |
| 671.014 | Distraction Pin, 14mm |
| 671.016 | Distraction Pin, 16mm |
| 671.018 | Distraction Pin, 18mm |
| 671.303 | Screwdriver Sleeve |
| 636.451 | Quick Connect Handle |
| 665.608 | Distractor Pin Driver |
| 610.801 | Caliper |
| 610.811 | Cervical Depth Gauge |
| 650.105 | Quick Connect Handle, Small, with Cap |
| 650.301 | Screwdriver, 2.5mm Hex, Self-Retaining, with Cap |



**Items in gray are additionally available*


15
16
15
12
11
13
14
9
6
7
8
4
5
2
10
3
3
1
QC Handle, Swivel
Plate Holder
Cervical Awl, with Sleeve


17
18
PLATE BENDER

# IMPORTANT INFORMATION ON VIP® ANTERIOR CERVICAL PLATE SYSTEM

**DESCRIPTION**

The VIP® Anterior Cervical Plate System consists of plates of various lengths to be used with either variable angle screws or fixed angle screws. Each VIP® plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2-C7).

VIP® implants are composed of titanium alloy, as specified in ASTM F136, F1295.

**INDICATIONS**

The VIP® Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

**WARNINGS**

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

The components of this system are manufactured from titanium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical, and functional reasons.

Possible adverse effects which may occur include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction

to implant materials; device fracture or failure; device migration or loosening; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

**PRECAUTIONS**

The implantation of screw and plate systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative planning and patient anatomy should be considered when selecting screw diameter and length.

Surgical implants must never be reused. An explanted metal implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

**ATTENTION**

See Warnings, Precautions and Potential Adverse Events sections of the insert entitled “Suggestions Concerning Orthopaedic Metallic Internal Fixation Devices” for a complete list of potential risks.

**MRI SAFETY INFORMATION**

MR

VIP® Anterior Cervical Plate Systems are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Quadrature Body Coil only

Under the scan conditions defined above, the VIP® Anterior Cervical Plate Systems are expected to produce a maximum temperature rise of less than or equal to 3.5°C after 15 minutes of continuous scanning.

The image artifact is not expected to extend beyond 55mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

**CONTRAINDICATIONS**

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient’s ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient’s weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

**PACKAGING**

These implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

**HANDLING AND USE**

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

**CLEANING**

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer’s recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.

# IMPORTANT INFORMATION ON VIP® ANTERIOR CERVICAL PLATE SYSTEM

7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

**CONTACT INFORMATION**

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

**STERILIZATION**

These implants may be available sterile or nonsterile. Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of $10^{-6}$. Sterile products are packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of $10^{-6}$. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. 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) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 $in^2$ total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows::

| Method | Cycle Type | Temperature | Exposure Time | Drying Time |
|---|---|---|---|---|
| Steam | Pre-vacuum | 132°C (270°F) | 4 Minutes | 30 Minutes |

*These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

**CAUTION:** Federal (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

| | | | |
|---|---|---|---|
| REF | CATALOGUE NUMBER | STERILE R | STERILIZED BY IRRADIATION |
| LOT | LOT NUMBER | EC REP | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
| ⚠ | CAUTION | | MANUFACTURER |
| | SINGLE USE ONLY | | USE BY (YYYY-MM-DD) |
| QTY | QUANTITY | | |

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