CervAlign®

Anterior Cervical Plate System

SURGICAL TECHNIQUE

DEVICE DESCRIPTION

The CervAlign Anterior Cervical Plate System is designed to promote cervical fusion by providing temporary resistance to flexion, extension, lateral bending, and axial rotation with strength and stiffness in the cervical spine (C2-C7). The system includes implants of various sizes of screws and plates to accommodate varying patient anatomies. The plates have integrated cover-style locking mechanisms that actuate to cover each screw. Implants are manufactured from titanium alloy, Ti-6Al-4V ELI (ASTM F136). The implants are supplied with instrumentation necessary to facilitate the insertion and removal. The implants and instruments are provided non-sterile and must be sterilized before use. Sterilization cases and trays are provided to facilitate proper sterilization and storage.

INDICATIONS FOR USE

The CervAlign Anterior Cervical Plate System is intended for anterior cervical fixation (C2-C7) for the following conditions: degenerative disc disease (DDD) defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion

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INTRODUCTION

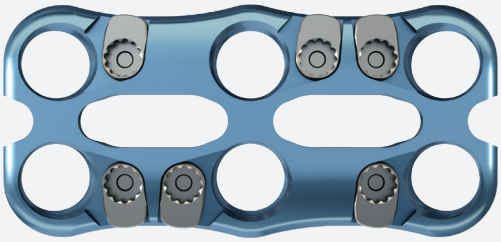
System Overview

The CervAlign® Anterior Cervical Plate (ACP) System is simple, adaptable and designed to optimize anterior cervical fusion (ACF) procedures while addressing the clinical needs of anterior cervical discectomy and fusion (ACDF) surgery.

The CervAlign ACP System accommodates semi-constrained, constrained and hybrid constructs, all in one set.
A CervAlign ACP System construct consists of the following components: plate with integrated locking mechanisms and screws.

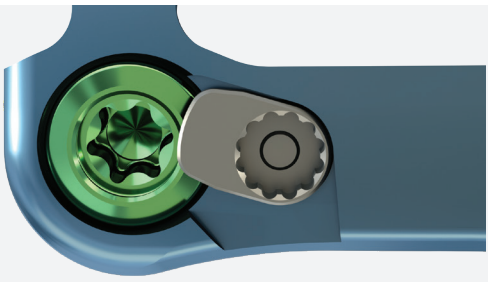
Plates

- Large graft window
- One to five level plates
- Accommodates semi-constrained, constrained and hybrid constructs
- Ti-6Al-4V (Titanium Alloy)



Locking Mechanism

- Integrated, cover-style locking mechanism
- One lock per screw
- Ti-6Al-4V (Titanium Alloy)

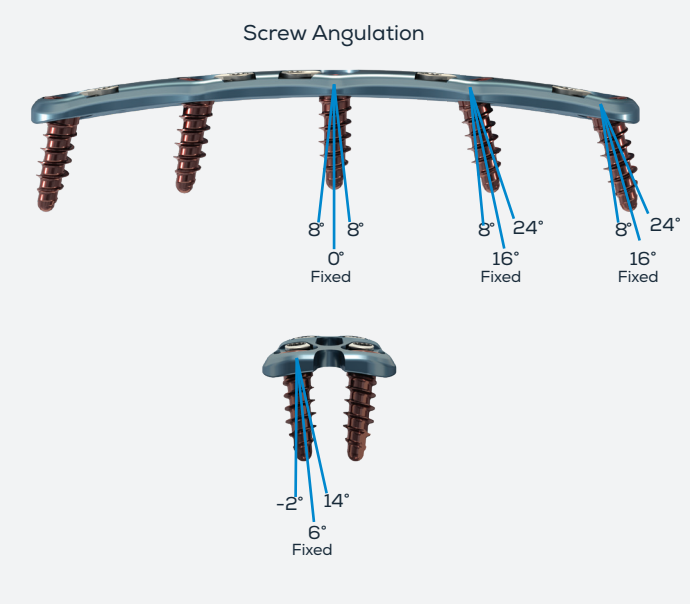


Screws

- Self-drilling, and self-tapping designs available in fixed and variable options
- Diameters:
  - 4.0mm (self-drilling and self-tapping)
  - 4.5mm (self-tapping rescue only)
- Lengths:
  - 12 - 16mm, 2mm increments (self-drilling)
  - 12 - 20mm, 2mm increments (self-tapping and self-tapping rescue)
- Optimal thread form for enhanced bone purchase and tactile feedback from insertion to final seating
- Aggressive tip designs provide for rapid bone purchase
- Ti-6Al-4V (Titanium Alloy)

Screw Angulation

- Fixed screw angulation
  - Cephalad/caudal:
    - 16° at the intermediate and end holes
    - 0° at the middle holes (two level only)
  - Medial/lateral:
    - 6° medial
- Variable screw angulation
  - Cephalad/caudal:
    - Up to 24° (+/-8° from the fixed angle)
  - Medial/lateral:
    - -2° to 14° (+/- 8° from the fixed angle)



Driver/Locking Driver

- T-10 hexalobe drive mechanism with retention tip feature
  - Stab-and-grab
  - Tapered

SURGICAL TECHNIQUE

Surgical Exposure

Perform the appropriate surgical exposure. Confirm radiographically that the desired surgical level(s) are localized. Retract the trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs. Remove anterior osteophytes using bone cutting instruments and/or high-speed burrs to allow optimal plate/vertebral body apposition.

Note: *Removal of osteophytes before discectomy facilitates complete discectomy and restoration of sagittal contour.*

Graft Placement

Perform a complete discectomy and prepare the endplates prior to inserting the anterior support implant and bone graft material.

If necessary, remove the anterior lip of the superior vertebra to maximize fit and fill of the anterior support implant and to facilitate placement of the screws near the endplate.

Note: *The Fortilink®-C IBF System with TETRAfuse® 3D Technology†, C-Plus™ PEEK* IBF System† or cervical allograft spacers† offered by Xtant Medical may be used as the anterior support implant.*

**PEEK-OPTIMA™ polymer from INVIBIO™*

† Please refer to the product specific package insert and Surgical Technique for instructions on proper use of these products.

Plate Selection

Optimal Screw Placement

Insertion of screws near the endplate may allow for greater pull-out strength and may minimize the chance of adjacent segment impingement of the plate. Gauge the plate length such that the cephalad screws are placed in the lower one-third of the vertebral body and the caudal screws are placed in the upper one-third of the vertebral body (Figure 1).

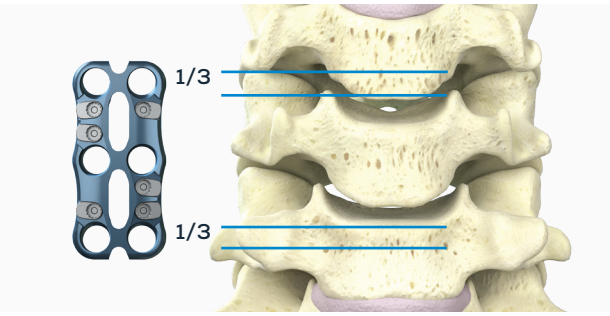


Figure 1

Plate Sizing

Proper plate sizing is important to achieve optimal screw placement. The caliper provided is designed for plate sizing guidance.

Identify optimal screw placement. Next, insert the caliper into the surgical site and rotate the dial counterclockwise to extend the inside tips of the caliper arms to the identified screw locations (Figure 2). Select the plate size closest to the value on the scale (Figure 3).

Figure 2

Figure 3

Note: *Once the caliper is dialed to the desired screw locations, the plate size can also be determined by aligning the inside tips of the caliper to the center of the cephalad and caudal plate screw holes.*

Note: *The caliper is a spring-loaded memory instrument that returns the caliper arms to the plate length that was established in the wound site.*

Plate Size Confirmation

Attach the selected plate to the plate holder.

To attach, position the tips of the plate holder within the midline of the plate between the screw holes (Figure 4). Squeeze the handle of the plate holder to grasp the plate. Check for proper length, alignment and apposition to the vertebral bodies.

Figure 4

Note: *The one-level 10 and 12mm plates attach to the plate holder within the midline of the plate at the cephalad-most and caudal-most edges. The two-level 24 and 26mm plates attach to the plate holder at the middle screw holes only.*

Plate Contouring (Optional)

Plates are pre-contoured with a lordotic curvature (184mm radius). If an increase in lordosis is required (Figure 5), the plate bender provided may be used.

Select the appropriate side of the bender labeled, "INCREASE LORDOSIS." Align the desired bend zone of the plate, located between the screw holes (Figure 6), over the center fulcrum of the bender (Figure 7) and insert the plate, from either the front or side, through the center fulcrum and rollers (Figure 8).

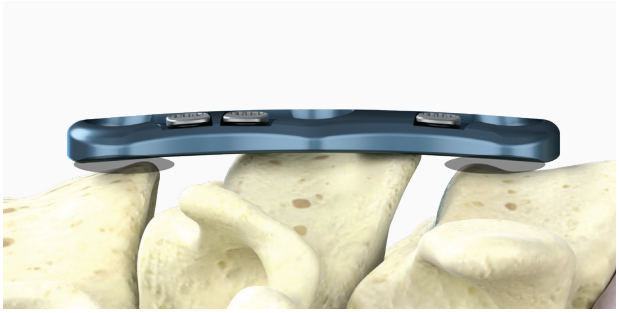


Figure 5

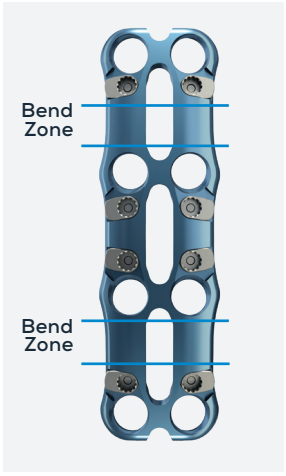


Figure 6

Figure 7

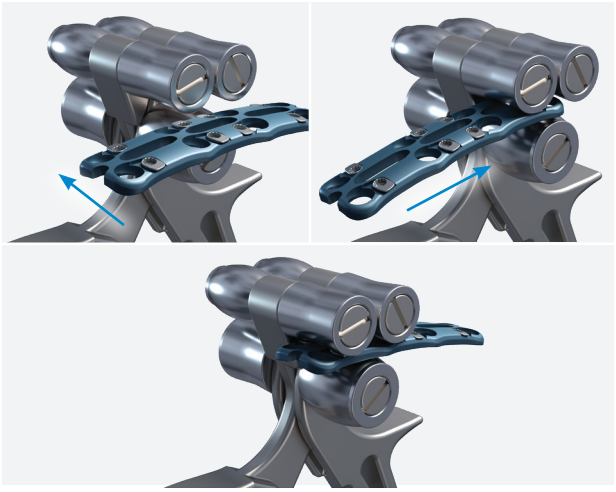


Figure 8

Ensure the plate is properly aligned and fully inserted into the bender. Next, bend the plate to the appropriate contour as needed for the desired lordosis (Figure 9). Repeat for the remaining bend zones as required. Distribute bending evenly along the plate at each bend zone.

One Level One Bend Zone

Two Level Two Bend Zones

Three Level Three Bend Zones

Four Level Four Bend Zones

Five Level Five Bend Zones

Note: *Cannot bend 10 and 12mm plates as they will not fit within the plate bender.*

Warning: *Do not contour the plate over the screw holes or locking mechanism as it may hinder the ability of the locking mechanism to function properly.*

Contouring titanium plates can weaken the mechanical integrity of the device; plates should not be contoured repeatedly, excessively, or in a kyphotic direction. Once the plate bender has been used to alter the contour of the plate, do not bend in the reverse direction as this may introduce micro fractures within the titanium plate that can compromise its strength.

If reverse plate bending or excessive bending has occurred, the bent plate must be discarded. Please contact Xtant Medical at (844) 894-7752 with any questions regarding plate contouring prior to surgery.

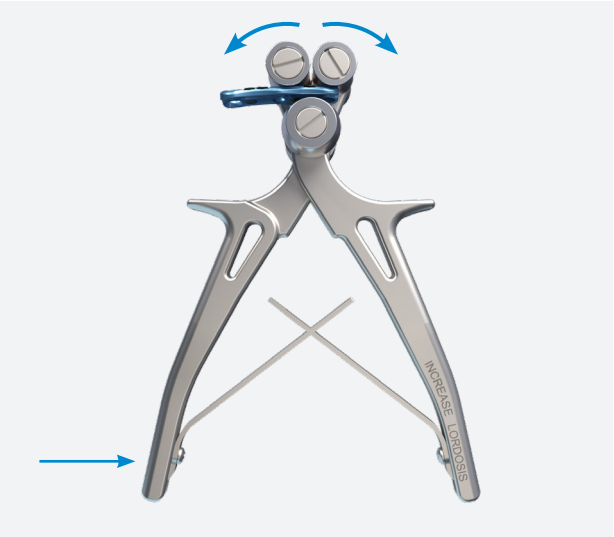


Figure 9

Plate Insertion and Fixation

Plate Insertion

Attach the selected plate to the plate holder. To attach, connect the plate holder to the plate as described in Step 3, "PLATE SELECTION."

***Important Technique**: Position the one-level 10 and 12mm plates onto the prepared vertebral bodies so that the midline plate holder features are in a cephalad-caudal orientation (Figure 10).*

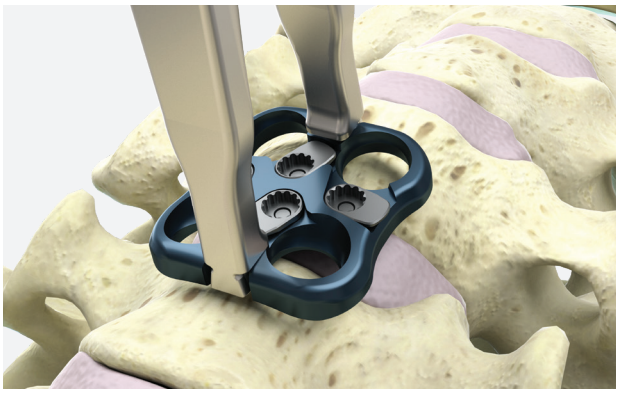


Figure 10

Temporary Fixation

If temporary fixation is desired, pins are provided (Figure 11).

Figure 11

Temporary Fixation Pins

Temporary fixation pins are designed for placement through the plate's screw holes and can be threaded into the vertebral body. Pins measure 10mm below the undersurface of the plate when fully seated (Figure 12).

***Note:** The pin hole angles are designed to match the cephalad/caudal angle of the variable screws at each level. Refer to the System Overview for the variable screw angles..*

***Note:** Threaded pins are available upon special request.*

Figure 12

Push Pin Technique

Connect the push pin to the preferred screw driver. To connect, place the tip of the driver into the drive pocket of the push pin within the screw caddy.

Apply firm downward pressure until the driver is fully seated. Check to ensure the connection between the push pin and driver is secure.

Insert the push pin through the selected screw hole (Figure 13). The push pins can be tapped or pushed into the vertebral body (Figure 14). Pull the driver straight up to release the driver from the pin. Repeat the steps above for the second pin, if desired.

Check for proper plate position and alignment. If necessary, remove the pins to reposition the plate.

To remove, connect the driver to the pin as described in the steps above. Once connected, rotate the pin counterclockwise to remove the pin. Do not pull or use other instrumentation to remove the pin.

Figure 13

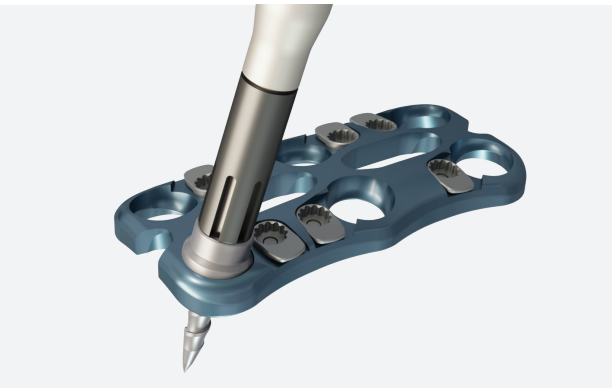


Figure 14

Screw Hole Preparation (Awl, Drill, Tap)

Bone Preparation

After the desired plate position is achieved, prepare the pilot holes for screw insertion with either the bone awl or drill, followed by a tap, if desired.

Bone Awl

The bone awl is designed to be used with a guide or with the awl sleeve variable guide to create a screw pilot hole. The bone awl tip protrudes 10mm below the undersurface of the plate when fully advanced (Figure 15).

Drill

The drills are designed to be used with a guide to create a screw pilot hole. When fully advanced, the drill tip protrudes below the undersurface of the plate by the length identified on the drill. The standard drill lengths are 12, 14 and 16mm (Figure 16).

Tap

The tap is designed to be used with a guide to tap a screw pilot hole prior to screw insertion. The tap tip protrudes 12mm below the undersurface of the plate when fully advanced (Figure 17).

Important Technique: The pilot hole should be centered within the screw hole. The awl sleeve or guides should be used to ensure a concentric pilot hole.

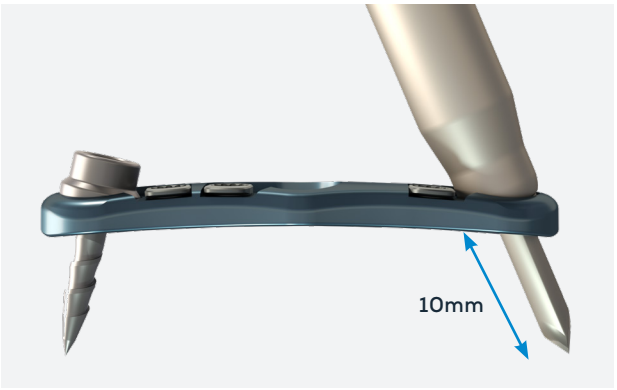


Figure 15

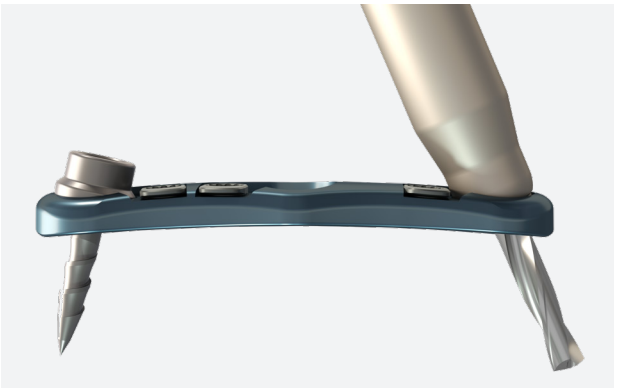


Figure 16

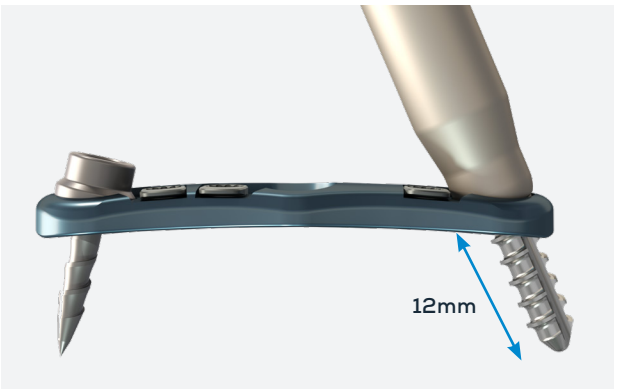


Figure 17

Screw Hole Preparation (Awl Sleeve)

Awl Sleeve Guide

The awl sleeve variable guide is a spring loaded, self-centering outer sleeve designed to maintain a single-entry point for the bone awl.

The awl sleeve locates into the screw holes for secure controlled handling and allows for angled trajectories within the variable screw angulation range.

Note: *The awl sleeve does not control for fixed screw angulations. Do not use the awl sleeve variable guide for fixed screws.*

Note: *Spring loaded awl sleeve has a "punch awl" function when used with the bone awl.*

Awl Sleeve Guide Technique

Assemble the bone awl and awl sleeve variable guide. Insert the bone awl through the awl sleeve until a hard stop is reached (Figure 18).

Engage the awl sleeve to the plate. Align awl sleeve variable guide over the screw hole (Figure 19). Fully seat the tip of the awl sleeve into the screw hole. Once fully seated, the awl sleeve will self-center in the screw hole.

Adjust the bone awl to the desired trajectory, within the variable screw angulation range (Figure 20). Refer to the System Overview for the variable screw angulations.

Note: *The distal tip of the awl sleeve does not provide resistance to over-angulation within each screw hole. Ensure that the pilot hole does not exceed the screw angulation range. Excess angulation may result in the screw head not fully seating within the screw hole. Refer to the System Overview for the fixed and variable screw angulations.*

Advance the bone awl tip through the anterior cortex of the vertebral body. Twist and push, or tap on the handle of the bone awl until the positive stop is reached (Figure 21). The positive stop is located internally within the awl sleeve.

After the pilot hole is created, carefully extract the bone awl and awl sleeve.

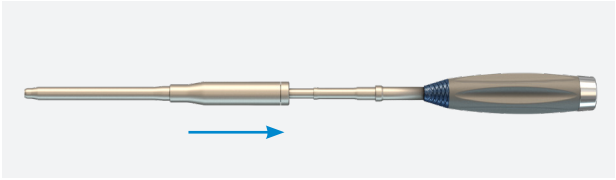


Figure 18

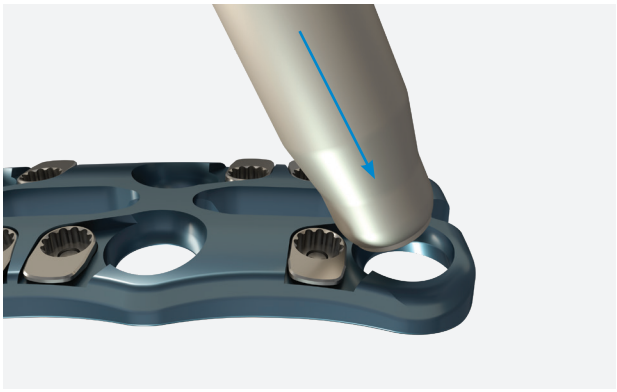


Figure 19

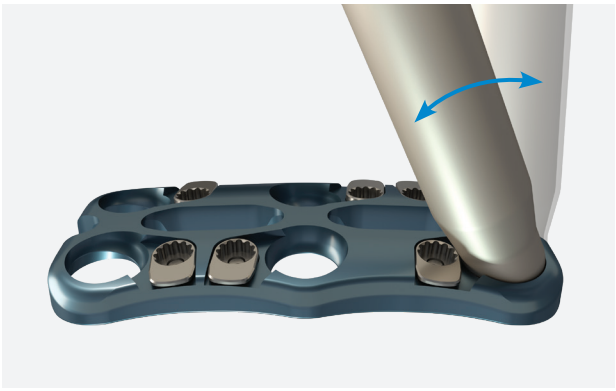


Figure 20

Figure 21

Screw Hole Preparations (Guides)

Two styles of guides are provided:

1. Variable guide (Figure 22)

2. Fixed guide (Figure 23)

Variable and Fixed Guides

The variable and fixed guides are designed to maintain a single entry point for the bone awl, drills and tap.

The guides locate into the screw holes for secure controlled handling. The variable guide allows for variable angle screw trajectories within the allowable range of variable screw angulation. The fixed guide provides control for the fixed screw insertion angles.

Refer to the System Overview for the screw insertion angles and allowable range of screw angulation.

Note: *Screws will not pass through the variable and fixed guides.*

Variable and Fixed Guide Technique

Engage the variable or fixed guide to the plate.

To engage, align the variable or fixed guide over the screw hole (Figure 24). Fully seat the tip of the selected guide into the screw hole and maintain downward pressure to ensure a fully seated position.

Once the guide is fully seated, the guide will self-center in the screw hole and can be adjusted to the desired trajectory within the allowable range (Figure 25).

Note: *The distal tip of the variable guide does not provide resistance to over-angulation within each screw hole. Ensure that the pilot hole does not exceed the screw angulation range. Excess angulation may result in the screw head not fully seating within the screw hole. Refer to the System Overview for the fixed and variable screw angulations.*

Figure 22

Figure 23

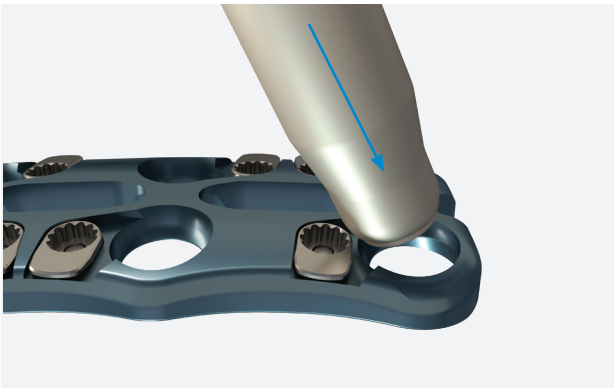


Figure 24

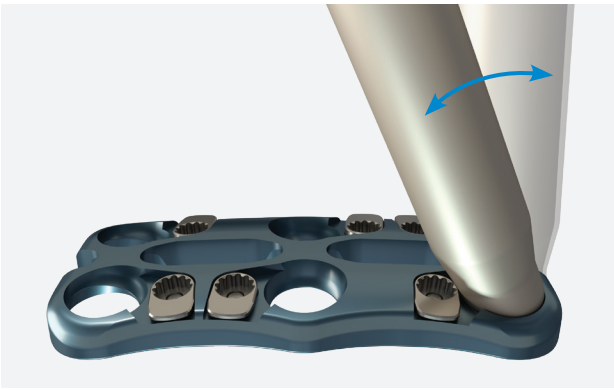


Figure 25

Insert the bone awl or drill through the guide. Next, penetrate the anterior cortex of the vertebral body (Figure 26). Continue to advance the awl or drill until the instrument fully seats and contacts the guide (Figure 27).

To advance the bone awl, push and twist or tap the handle.

To advance the drill, utilize the modular handle to rotate the drill clockwise.

If desired, place the tap through the guide once the pilot hole is created. To advance the tap, utilize the modular handle to rotate the tap clockwise. Advance the tap until the instrument fully seats and contacts the guide.

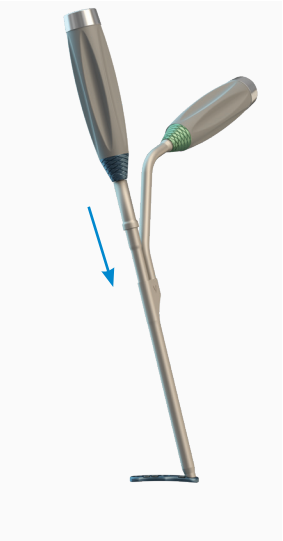


Figure 26

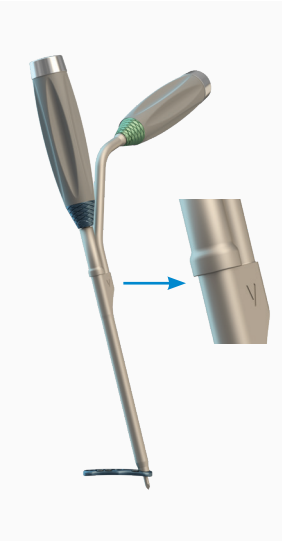


Figure 27

Screw Insertion

Two styles of screw drivers are provided:

1. Stab-and-grab (Figure 28)

2. Tapered (Figure 29)

Select the desired screw length and style and insert the preferred driver tip into the head of the screw until the driver is fully seated.

Stab-and-Grab Screw Driver

Fully insert the tip of the stab-and-grab driver into the drive pocket of the screw. There may be tactile/audible feedback once the screw is secured to the stab-and-grab driver.

Note: *Confirm screw is securely connected to driver by gently pulling on the screw once extracted from the caddy. Push screw back on so it is fully seated and co-axial with the screw driver.*

Tapered Driver

Fully insert the tip of the tapered driver into the drive pocket of the screw while it is positioned in the screw caddy.

Note: *Ensure a friction fit by firmly pressing the driver tip into the drive pocket of the screw while it is positioned within the screw caddy.*

After the pilot hole is created through either a guide or the awl sleeve, place the screw through the center of the screw hole until the tip contacts the pilot hole (Figure 30). Turn the driver clockwise to advance the screw along the path of the pilot hole. Continue to advance the screw until the head is seated just below the locking mechanism, but plate is not lagged to the bone (Figure 31).

Figure 28

Figure 29

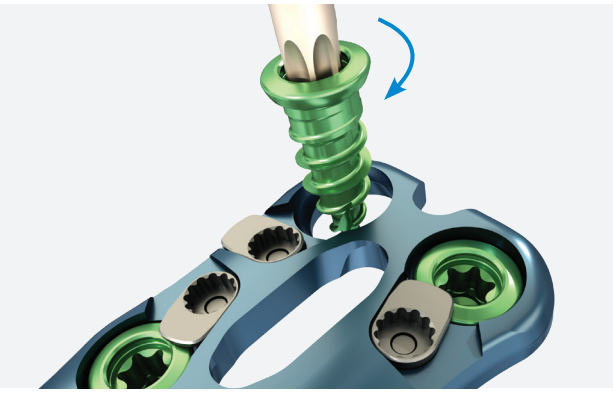


Figure 30

Figure 31

Release the driver from the screw by pulling the driver straight up and away from the screw drive pocket.

In the next preferred screw hole, repeat the screw hole preparation steps as described in Step 6, "SCREW HOLE PREPARATION." After the pilot hole is created, repeat the screw insertion steps above (Figure 32). Repeat the screw hole preparation and insertion steps for the remaining screw holes in the suggested order (Figure 33).

Once each screw is inserted, advance each screw in the order of insertion until each screw is fully seated and the plate is lagged to the bone.

Note: *After the screws are fully advanced, a "three-finger technique" can help verify the screws are securely tightened.*

Important Technique: *Remove push pins if used. To remove, connect the driver to the pin as described in Step 5, "PLATE INSERTION AND FIXATION." Once connected, rotate the pin counterclockwise to remove the pin. Do not pull or use other instrumentation to remove the pin.*

Figure 32

Figure 33

Final Locking

When the screws are fully seated, engage the tip of the preferred driver into the hexalobe of the screw hole's locking mechanism (Figure 34). Tactile feedback may occur once the screw driver is completely engaged.

Using a "three-finger technique" and while maintaining axial downward pressure, rotate the preferred driver until the locking mechanism rotates over the screw head and contacts the stop within the midline of the plate (Figure 35).

Warning: *Do not rotate locking mechanism beyond positive stop as this may damage the locking mechanism. If you do, remove the screws and plate from the patient as described in "SCREW REMOVAL (OPTIONAL) and "REMOVAL (IF NECESSARY)," and discard. Replace with a new plate and screws as described in Step 5, "PLATE INSERTION AND FIXATION" and Step 9, "SCREW INSERTION."*

Visually confirm that all screws are covered by the locking mechanisms (Figure 36).

Note: *All locking mechanisms for the two shortest one-level plates (10-12mm) and the two shortest two-level plates (24-26mm) actuate in a counterclockwise rotation.*

Figure 34

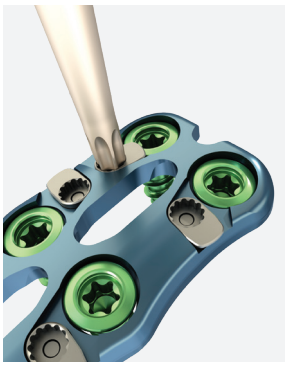


Figure 35

Figure 36

Screw Removal (Optional)

If it is necessary to remove a screw, engage the tip of the preferred driver into the hexalobe of the screw hole's locking mechanism (Figure 37). Tactile feedback may occur once the screw driver is completely engaged.

Using a "three-finger technique" and while maintaining axial downward pressure, rotate the preferred screw driver until the locking mechanism is no longer covering the screw.

Warning: *Do NOT rotate locking mechanism beyond positive stop as this may damage the locking mechanism.*

Remove the screw driver from the locking mechanism and reengage it into the screw drive pocket. Once the screw driver is fully engaged with the screw, rotate the handle counterclockwise and remove the screw (Figure 38). Replace the screw with the larger diameter rescue screw following the procedure described in Step 9, "SCREW INSERTION."

Repeat for remaining screw(s) if necessary.

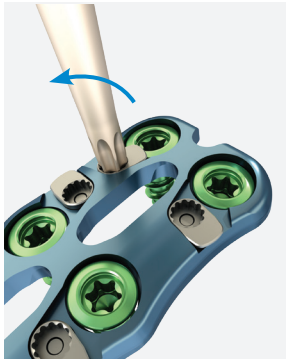


Figure 37

Figure 38

Closure

After the plate and screws are secured in their final location, confirm final implant position via intraoperative fluoroscopy. Once implant position is confirmed, perform wound closure.

Important Technique: *Ensure all instruments, including pins, have been removed.*

Removal (if necessary)

If removal is necessary, remove the screws as described in "SCREW REMOVAL (OPTIONAL)," then remove the plate.

DTS Guide Technique (Optional)

The fixed DTS (drill, tap, screw) guides are designed to maintain a single-entry point for the bone awl, drills, tap and screws.

The fixed DTS guides are offered in 0-, 8-, 16- and 24-degree options (Figure 39).

Each guide provides a fixed insertion angle as identified on the guide. Refer to Figure 40 for the fixed and variable screw angulation.

Note: *Ensure the fixed DTS guide tube corresponds to the desired screw hole level as shown in Figure 40.*

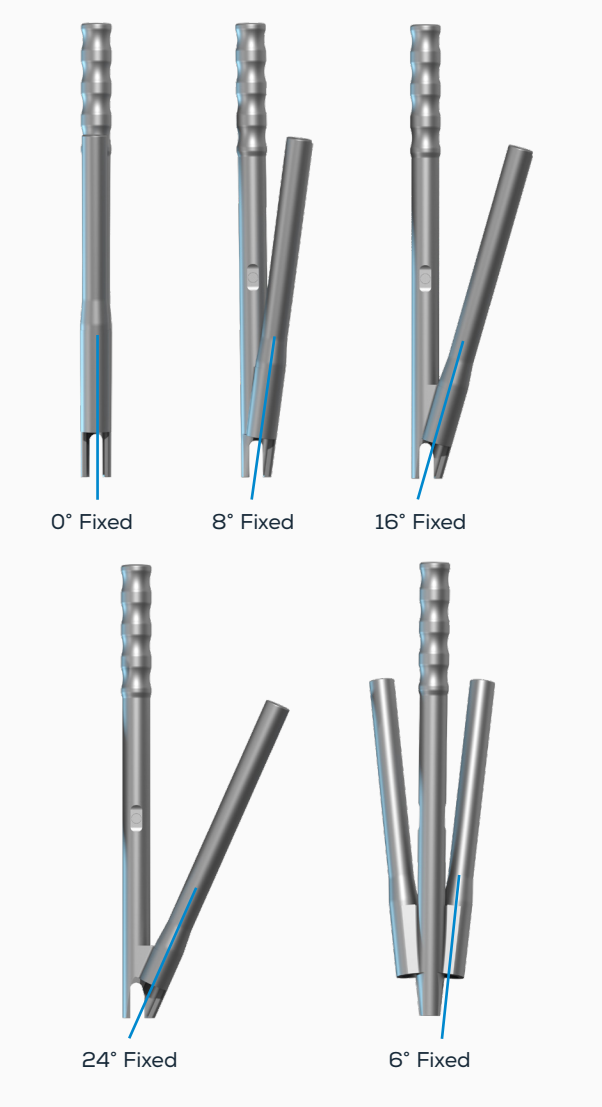


Figure 39

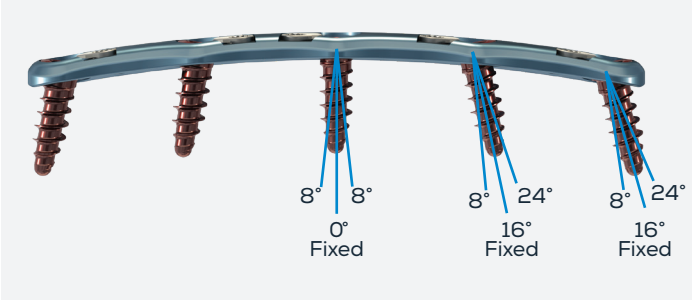


Figure 40

SURGICAL TECHNIQUE

Assembly

To assemble the DTS guide, select your desired fixed DTS guide tube (0-, 8-, 16- or 24-degree). Place the proximal tip of the DTS fork through the central shaft of the selected fixed DTS guide tube until the fork's proximal tip reaches the proximal tip of the fixed DTS guide's central shaft (Figure 41).

Important Technique: *Prior to plate attachment, do NOT fully seat the DTS fork into the fixed DTS guide tube as it will prevent plate attachment.*

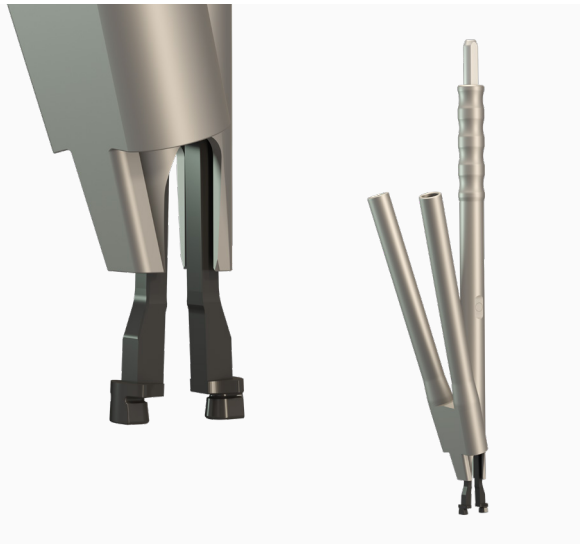


Figure 41

Connecting to Plate

The DTS guide mates within the midline of the plate between the screws holes at the desired level for a secure fit (Figure 42). Holding the DTS guide by the central shaft, align the distal tip of the DTS guide and apply downward pressure to slide it towards the plate until it is fully seated. Ensure the DTS guide is firmly attached to the plate.

Note: *DTS guides do not work with 1-level 10mm and 12mm plates or the 2-level 24mm and 26mm plates.*

Important Technique: *Do NOT pull anteriorly on the DTS guide prior to temporary fixation, screw hole preparation and/or screw placement as it will detach from the plate.*

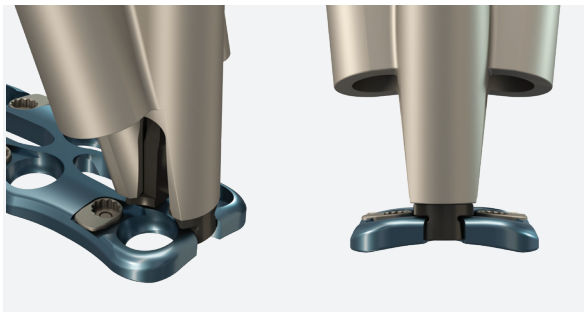


Figure 42

Note: *Position the DTS guide tubes so that they are in the correct orientation. The guide tubes for 8-, 16- and 24-degree fixed guide options will be positioned away from the nearest cephalad or caudal edge of the plate (Figure 43).*

Figure 43

Screw Hole Preparation (Awl, Drill, Tap)

Connect the selected fixed DTS guide to the plate at the desired level as described above. Fully seat the guide onto the plate.

Important Technique: *Ensure push pin is removed prior to using DTS Guide at that level.*

Holding the DTS guide by the central shaft, insert the bone awl or drill through one of the tubes of the fixed DTS guide (Figure 44). Next, penetrate the anterior cortex of the vertebral body. Advance the awl or drill until the positive stop contacts the guide (Figure 45). To advance the awl, push and twist or tap the handle. To advance the drill, turn the handle clockwise.

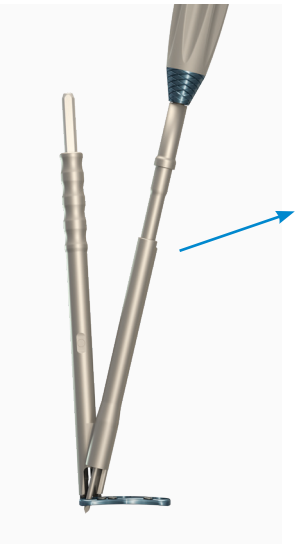


Figure 44

Figure 45

If desired, place a tap through the fixed DTS guide once the pilot hole is created. Advance the tap until the instrument fully seats and contacts the DTS guide. To advance the tap, turn the handle clockwise.

Screw Insertion

Connect the driver to the desired screw type and length. Place the screw through the tube of the fixed DTS guide until the tip contacts the anterior cortex or pilot hole (Figure 46).

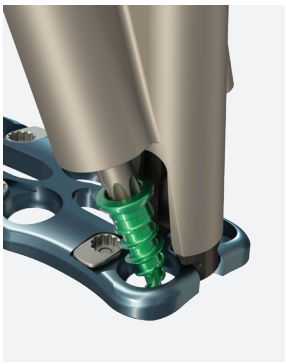


Figure 46

Advance the screw by turning the driver clockwise until the etch line of the driver reaches the sleeve of the fixed DTS guide (Figure 47), indicating that the screw is fully seated into the plate. Release the driver from the screw by pulling straight back.

Once the screw is fully seated, repeat the above steps for the contralateral screw hole.

Note: *The locking mechanisms cannot be actuated at the level where the DTS guide is attached to the plate.*

Release the DTS guide once both screws have been placed at the desired level. To release, pull the central shaft of the DTS guide anteriorly.

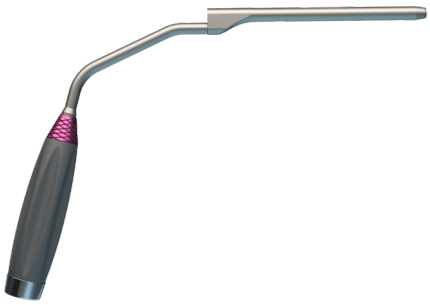
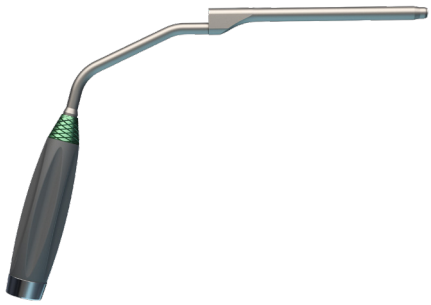
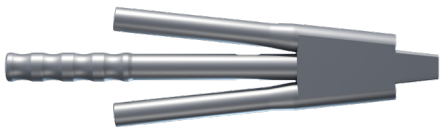
Figure 47

Repeat steps for the remaining levels utilizing the appropriate fixed DTS guide for each level. Visually confirm that all screws are fully seated and activate the locking mechanisms as described in Step 10, "FINAL LOCKING."

ORDERING GUIDE

Instrument Guide

Part Number	Instrument	Description	
66-CALIPER	Plate Sizing Caliper	Used for plate sizing guidance	
66-PLATE-HOLDER	Plate Holder	Used to insert and position the plate	
66-BENDER	Plate Bender	Used to contour the plates in a lordotic direction	
66-AWL-10	Awl, 10mm	Used to create a screw pilot hole; designed to be used with a variable or fixed guide or awl sleeve variable guide	
66-AWLSLEEVE	Awl Sleeve Variable Guide	Self-centering outer sleeve designed to maintain a single entry point for the bone awl; the awl sleeve is an alternative to a variable guide	
66-DRIVER-SG	Driver, Stab-and-Grab	Used to insert and/or remove screws and temporary fixation pins; also used to lock and/or unlock the locking mechanism	
66-DRIVER-T	Driver, Tapered	Used to insert and/or remove screws and temporary fixation pins; also used to lock and/or unlock the locking mechanism	
66-MODHANDLE	Modular AO Handle	Used with the modular drills and tap	

Part Number	Instrument	Description	
66-FIXED-GUIDE	Fixed Guide	Used to maintain a fixed angle entry point for an awl, drill and/ or tap	
66-VAR-GUIDE	Variable Guide	Used to provide a variable angle entry point for an awl, drill and/ or tap	
66-MODDRILL-X	Modular AO Drill, 12, 14, or 16mm (X)	Used to create a screw pilot hole; may also be used with a guide	
66-MODTAP-12	Modular AO Tap, 12mm	Used to tap a screw pilot hole; may also be used with a guide	
66-PUSHPIN	Push Pin	Used for temporary plate fixation through placement in the plate's screw holes	
66-DTS-FORK	DTS Fork	Used with the fixed DTS guide tubes for screw hole preparation and screw insertion	
66-DTS-GUIDE-0 66-DTS-GUIDE-8 66-DTS-GUIDE-16 66-DTS-GUIDE-24	Fixed DTS Guide Tube, 0°, 8°, 16° and 24°	Used with the DTS fork for screw hole preparation and screw insertion	

ORDERING GUIDE

Standard Implant & Instrument Set (66-LS-CervAlign123)

Top Tray Implants

ONE LEVEL STANDARD PLATES

Part Number	Description	Length	Quantity Per Set
66-110	One Level Standard Plate	10mm	2
66-112	One Level Standard Plate	12mm	2
66-114	One Level Standard Plate	14mm	2
66-116	One Level Standard Plate	16mm	2
66-118	One Level Standard Plate	18mm	2
66-120	One Level Standard Plate	20mm	2
66-122	One Level Standard Plate	22mm	1
66-124	One Level Standard Plate	24mm	1

TWO LEVEL STANDARD PLATES

Part Number	Description	Length	Quantity Per Set
66-224	Two Level Standard Plate	24mm	2
66-226	Two Level Standard Plate	26mm	2
66-228	Two Level Standard Plate	28mm	2
66-230	Two Level Standard Plate	30mm	2
66-232	Two Level Standard Plate	32mm	2
66-234	Two Level Standard Plate	34mm	2
66-236	Two Level Standard Plate	36mm	1
66-238	Two Level Standard Plate	38mm	1
66-240	Two Level Standard Plate	40mm	1
66-242	Two Level Standard Plate	42mm	1

THREE LEVEL STANDARD PLATES

Part Number	Description	Length	Quantity Per Set
66-342	Three Level Standard Plate	42mm	2
66-345	Three Level Standard Plate	45mm	2
66-348	Three Level Standard Plate	48mm	2
66-351	Three Level Standard Plate	51mm	2
66-354	Three Level Standard Plate	54mm	2
66-357	Three Level Standard Plate	57mm	1
66-360	Three Level Standard Plate	60mm	1
66-363	Three Level Standard Plate	63mm	1

VARIABLE SELF-DRILLING SCREWS (4.0MM)

Part Number	Description	Length	Quantity Per Set
66-VSD-40-12	Variable Self-Drilling Screw	12mm	10
66-VSD-40-14	Variable Self-Drilling Screw	14mm	10
66-VSD-40-16	Variable Self-Drilling Screw	16mm	10

VARIABLE SELF-TAPPING SCREWS (4.0MM)

Part Number	Description	Length	Quantity Per Set
66-VST-40-12	Variable Self-Tapping Screws	12mm	10
66-VST-40-14	Variable Self-Tapping Screws	14mm	10
66-VST-40-16	Variable Self-Tapping Screws	16mm	10
66-VST-40-18	Variable Self-Tapping Screws	18mm	8

VARIABLE SELF-TAPPING RESCUE SCREWS (4.5MM)

Part Number	Description	Length	Quantity Per Set
66-VST-45-12	Variable Self-Tapping Rescue Screw	12mm	4
66-VST-45-14	Variable Self-Tapping Rescue Screw	14mm	4
66-VST-45-16	Variable Self-Tapping Rescue Screw	16mm	4

FIXED SELF-DRILLING SCREWS (4.0MM)

Part Number	Description	Length	Quantity Per Set
66-FSD-40-12	Fixed Self-Drilling Screw	12mm	10
66-FSD-40-14	Fixed Self-Drilling Screw	14mm	10
66-FSD-40-16	Fixed Self-Drilling Screw	16mm	6

FIXED SELF-TAPPING SCREWS (4.0MM)

Part Number	Description	Length	Quantity Per Set
66-FST-40-12	Fixed Self-Tapping Screws	12mm	10
66-FST-40-14	Fixed Self-Tapping Screws	14mm	10
66-FST-40-16	Fixed Self-Tapping Screws	16mm	6
66-FST-40-18	Fixed Self-Tapping Screws	18mm	6

FIXED SELF-TAPPING RESCUE SCREWS (4.5MM)

Part Number	Description	Length	Quantity Per Set
66-FST-45-12	Fixed Self-Tapping Rescue Screw	12mm	4
66-FST-45-14	Fixed Self-Tapping Rescue Screw	14mm	4
66-FST-45-16	Fixed Self-Tapping Rescue Screw	16mm	4

Standard Implant & Instrument Set (66-LS-CervAlign123) (continued)

Push Pins and Instrumentation

PUSH PINS

Part Number	Description	Quantity Per Set
66-PUSHPIN	Push Pin	3

TOP TRAY INSTRUMENTS

Part Number	Description	Quantity Per Set
66-DTS-FORK	DTS Fork	2
66-DTS-GUIDE-24	DTS Guide Tube, 24°	1
66-DTS-GUIDE-16	DTS Guide Tube, 16°	1
66-DTS-GUIDE-8	DTS Guide Tube, 8°	1
66-DTS-GUIDE-0	DTS Guide Tube, 0°	1

BOTTOM TRAY INSTRUMENTS

Part Number	Description	Quantity Per Set
66-CALIPER	Caliper	1
66-PLATE-HOLDER	Plate Holder	1
66-BENDER	Plate Bender	1
66-AWL-10	Awl, 10mm	1
66-AWLSLEEVE	Awl Sleeve Variable Guide	1
66-DRIVER-SG	Driver, Stab and Grab	2
66-DRIVER-T	Driver, Tapered	2
66-FIXED-GUIDE	Fixed Guide	1
66-VAR-GUIDE	Variable Guide	1
66-MODHANDLE	Modular AO Handle	1
66-MODDRILL-12	Modular AO Drill, 12mm	2
66-MODDRILL-14	Modular AO Drill, 14mm	2
66-MODDRILL-16	Modular AO Drill, 16mm	1
66-MODTAP-12	Modular AO Tap, 12mm	1

ORDERING GUIDE

Optional Implants and Instruments

OPTIONAL INSTRUMENTS

Part Number	Description
66-MODDRILL-18	Modular Drill, 18mm
66-MODTAP-14	Modular Tap, 14mm
66-MODTAP-16	Modular Tap, 16mm
66-THREADPIN	Threaded Pin

OPTIONAL SCREWS

Part Number	Description	Length
66-FST-45-18	Fixed Self-Tapping Rescue Screw	18mm
66-VST-45-18	Variable Self-Tapping Rescue Screw	18mm
66-FST-40-20	Fixed Self-Tapping Screw	20mm
66-FST-45-20	Fixed Self-Tapping Rescue Screw	20mm
66-VST-40-20	Variable Self-Tapping Screw	20mm
66-VST-45-20	Variable Self-Tapping Rescue Screw	20mm

SET PART NUMBERS

Part Number	Description
66-LS-CERVALIGN123	Standard set: instruments, screws, 1, 2 and 3 level plates
66-LS-CERVALIGN-4	4 level plates
66-LS-CERVALIGN-5	5 level plates

OPTIONAL FOUR LEVEL PLATES

Part Number	Description	Length	Quantity Per Set
66-460	Four Level Standard Plate	60mm	1
66-464	Four Level Standard Plate	64mm	1
66-468	Four Level Standard Plate	68mm	1
66-472	Four Level Standard Plate	72mm	1
66-476	Four Level Standard Plate	76mm	1
66-480	Four Level Standard Plate	80mm	1
66-484	Four Level Standard Plate	84mm	1
66-488	Four Level Standard Plate	88mm	1

OPTIONAL FIVE LEVEL PLATES

Part Number	Description	Length	Quantity Per Set
66-575	Five Level Standard Plate	75mm	1
66-580	Five Level Standard Plate	80mm	1
66-585	Five Level Standard Plate	85mm	1
66-590	Five Level Standard Plate	90mm	1
66-595	Five Level Standard Plate	95mm	1
66-5100	Five Level Standard Plate	100mm	1
66-5105	Five Level Standard Plate	105mm	1

DRIVER INFORMATION

Part Number	Description	Tip	For Usage With
66-DRIVER-SG	Driver, Stab-and-Grab	T-10 Hexalobe	All Standard and Rescue Screws; Locking Mechanisms
66-DRIVER-T	Driver, Tapered	T-10 Hexalobe	All Standard and Rescue Screws; Locking Mechanisms

Due to regulatory conditions, implant and instrument availability differ from country to country. Therefore, we kindly ask you to consult the distributor in your region regarding the availability of specific implants and instruments in your country.

CLEANING AND STERILIZATION

- Implants are provided non-sterile.
- Reusable instruments are provided non-sterile.

For specific cleaning and sterilization instructions, refer to the instructions for use provided with the device.

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