

APTITUDE[®]

STANDARD & MIDLINE
ANTERIOR CERVICAL PLATE SYSTEM



Surgical Technique Guide





APTITUDE® STANDARD & MIDLINE ANTERIOR CERVICAL PLATE SYSTEM

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Disclaimer

The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

APTITUDE® STANDARD ANTERIOR CERVICAL PLATES

The Aptitude® Cervical Plate features a slim profile design allowing for a smooth anterior surface. The plates are available in 1 to 5 levels with varying screw types and lengths to adapt to the surgeon's needs. The simple and intuitive one-step locking mechanism facilitates complete control by the surgeon during the procedure. All system components are manufactured from biocompatible titanium alloy.



Plates - Standard

- 17mm plate width
- 2.2mm thick, low profile design
- 13.5mm scalloped waist and large graft window allow for enhanced graft and endplate visualization
- Single Cam Lock per level
- Simple and effective, one-step locking mechanism
- Pre-Lordosed design reduces the need for contouring
- Dedicated bend zones
- Posterior ridges resist slippage and increase torsional stability

Part Number: C154-XX-YY

(XX - Levels, YY - Length)

Plate Lengths

One Level: 10, 12, 14, 16, 18, 20, 22, 24, & 26 mm

Two Level: 24, 27, 30, 33, 36, 39, 42, 45, 48 mm

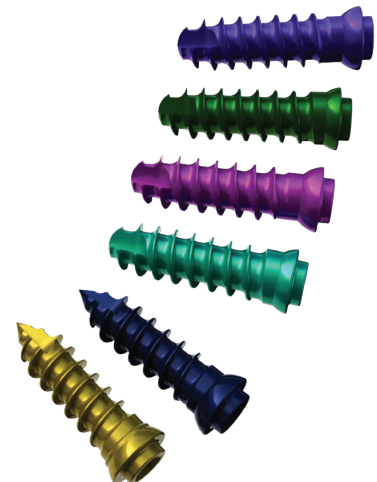
Three Level: 39, 42, 45, 48, 51, 54, 57, 60, 63 mm

Four Level: 60, 64, 68, 72, 76, 80, & 84 mm

Five Level: 76, 80, 84, 88, 92, 96, 100, & 104 mm

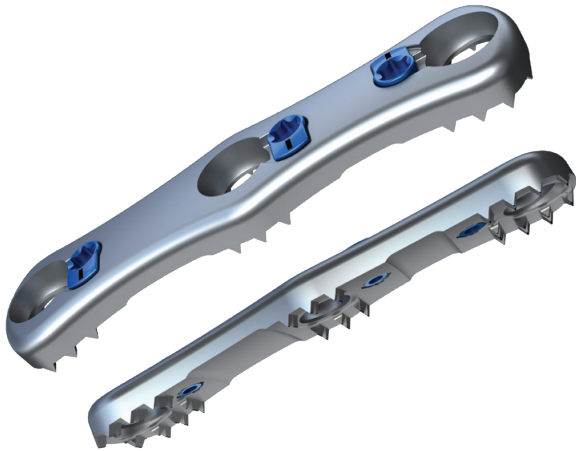
Screws

- Ø4.0 and Ø4.5 in 12-18mm lengths (in 2mm increments)
- Self-Drilling, Self-Tapping, Fixed and Variable Screws
- Increased screw angulation to enhance bone purchase
- 5° medial biased at all screw holes
- 5° cephalad/caudal biased at end screw holes
- 22° conical screw angulation at all screw holes, with 27° angulation at cephalad/caudal screw holes
- Color-coded screws allow for easy identification
- Same screws used for both Standard and Midline plates



APTITUDE® MIDLINE ANTERIOR CERVICAL PLATES

The Aptitude® Midline Cervical Plate offers a slim profile design that allows for less lateral retraction than a wider cervical plate. The Midline plate was designed to simplify ACDFs and possibly reduce operating room time using a narrow plate and one screw per vertebral body. The plates are available in 1 to 2 levels using the same screws and instruments as the Standard plate.



Plates - Midline

- 10.5mm plate width
- 2.2mm thick, low profile design
- 8.25mm scalloped waist
- Allows for a small incision, minimizing lateral retraction of soft tissue
- Narrow width optimizes post-operative visualization of the fusion site
- Posterior cleats resist slippage and increase torsional stability

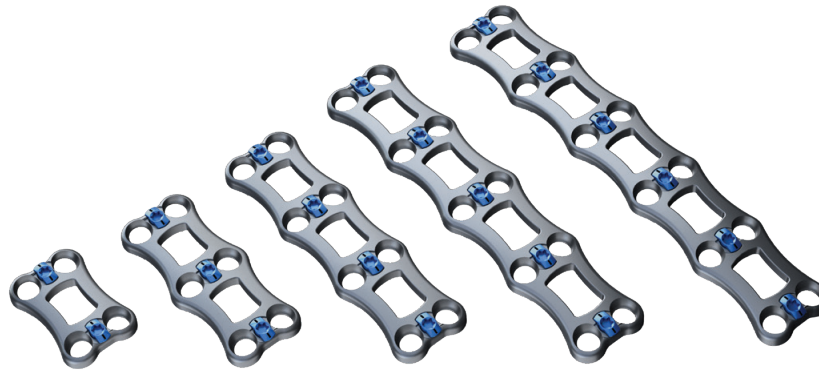
Part Number: C164-XX-YY
(XX - Levels, YY - Length)

Plate Lengths

One Level: 12, 14, 16, 18, 20, 22, 24, & 26 mm

Two Level: 26, 28, 30, 32, 34, 36, 38, 40, 42 mm

APTITUDE® STANDARD ANTERIOR CERVICAL PLATES



One-Level Anterior Cervical Plates

Catalog Number	Description	A	B
C154-01-10*	One-Level, 10mm ACP	10	17.5
C154-01-12	One-Level, 12mm ACP	12	19.5
C154-01-14	One-Level, 14mm ACP	14	21.5
C154-01-16	One-Level, 16mm ACP	16	23.5
C154-01-18	One-Level, 18mm ACP	18	25.5
C154-01-20	One-Level, 20mm ACP	20	27.5
C154-01-22	One-Level, 22mm ACP	22	29.5
C154-01-24*	One-Level, 24mm ACP	24	31.5
C154-01-26*	One-Level, 26mm ACP	26	33.5

Two-Level Anterior Cervical Plates

Catalog Number	Description	A	B
C154-02-24	Two-Level, 24mm ACP	24	31.5
C154-02-27	Two-Level, 27mm ACP	27	34.5
C154-02-30	Two-Level, 30mm ACP	30	37.5
C154-02-33	Two-Level, 33mm ACP	33	40.5
C154-02-35	Two-Level, 35mm ACP	35	42.5
C154-02-36	Two-Level, 36mm ACP	36	43.5
C154-02-39	Two-Level, 39mm ACP	39	46.5
C154-02-42	Two-Level, 42mm ACP	42	49.5
C154-02-45*	Two-Level, 45mm ACP	45	52.5
C154-02-48*	Two-Level, 48mm ACP	48	55.5

Three-Level Anterior Cervical Plates

Catalog Number	Description	A	B
C154-03-39	Three-Level, 39mm ACP	39	46.5
C154-03-42	Three-Level, 42mm ACP	42	49.5
C154-03-45	Three-Level, 45mm ACP	45	52.5
C154-03-48	Three-Level, 48mm ACP	48	55.5
C154-03-51	Three-Level, 51mm ACP	51	58.5
C154-03-54	Three-Level, 54mm ACP	54	61.5
C154-03-57	Three-Level, 57mm ACP	57	64.5
C154-03-60*	Three-Level, 60mm ACP	60	67.5
C154-03-63*	Three-Level, 63mm ACP	63	70.5

Four-Level Anterior Cervical Plates

Catalog Number	Description	A	B
C154-04-60*	Four-Level, 60mm ACP	60	67.5
C154-04-64*	Four-Level, 64mm ACP	64	71.5
C154-04-68*	Four-Level, 68mm ACP	68	75.5
C154-04-72*	Four-Level, 72mm ACP	72	79.5
C154-04-76*	Four-Level, 76mm ACP	76	83.5
C154-04-80*	Four-Level, 80mm ACP	80	87.5
C154-04-84*	Four-Level, 84mm ACP	84	91.5

Five-Level Anterior Cervical Plates

Catalog Number	Description	A	B
C154-05-76*	Five-Level, 76mm ACP	76	83.5
C154-05-80*	Five-Level, 80mm ACP	80	87.5
C154-05-84*	Five-Level, 84mm ACP	84	91.5
C154-05-88*	Five-Level, 88mm ACP	88	95.5
C154-05-92*	Five-Level, 92mm ACP	92	99.5
C154-05-96*	Five-Level, 96mm ACP	96	103.5
C154-05-100*	Five-Level, 100mm ACP	100	107.5
C154-05-104*	Five-Level, 104mm ACP	104	111.5

*Available by Request

APTITUDE® MIDLINE ANTERIOR CERVICAL PLATES



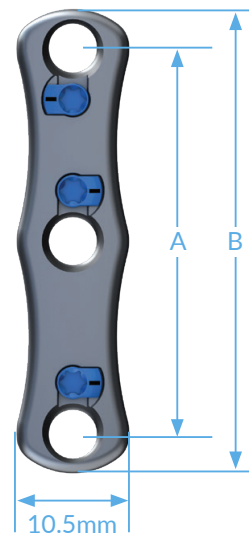
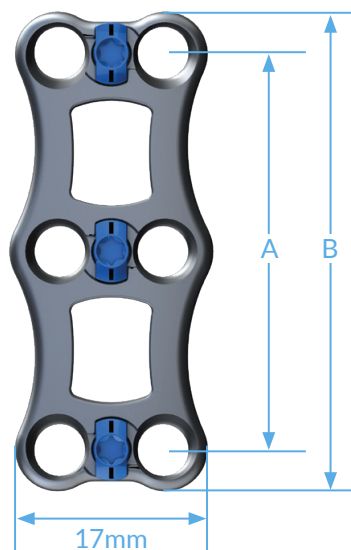
One-Level Midline Anterior Cervical Plates

Catalog Number	Description	A	B
C164-01-12*	One-Level, 12mm ACP	12	19.5
C164-01-14*	One-Level, 14mm ACP	14	21.5
C164-01-16*	One-Level, 16mm ACP	16	23.5
C164-01-18*	One-Level, 18mm ACP	18	25.5
C164-01-20*	One-Level, 20mm ACP	20	27.5
C164-01-22*	One-Level, 22mm ACP	22	29.5
C164-01-24*	One-Level, 24mm ACP	24	31.5
C164-01-26*	One-Level, 26mm ACP	26	33.5

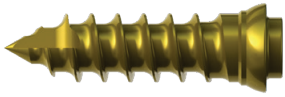
Two-Level Midline Anterior Cervical Plates

Catalog Number	Description	A	B
C164-02-26*	Two-Level, 26mm ACP	26	33.5
C164-02-28*	Two-Level, 28mm ACP	28	35.5
C164-02-30*	Two-Level, 30mm ACP	30	37.5
C164-02-32*	Two-Level, 32mm ACP	32	39.5
C164-02-34*	Two-Level, 34mm ACP	34	41.5
C164-02-36*	Two-Level, 36mm ACP	36	43.5
C164-02-38*	Two-Level, 38mm ACP	38	45.5
C164-02-40*	Two-Level, 40mm ACP	40	47.5
C164-02-42*	Two-Level, 42mm ACP	42	49.5

*Available by Request



APTITUDE® SCREWS



Self-Drilling Fixed Screws

Catalog Number	Dimensions	Color
C154-4012-FSD	4.0 x 12mm	Gold
C154-4014-FSD	4.0 x 14mm	Gold
C154-4016-FSD	4.0 x 16mm	Gold
C154-4018-FSD	4.0 x 18mm	Gold



Self-Drilling Variable Screws

Catalog Number	Dimensions	Color
C154-4012-VSD	4.0 x 12mm	Dark Blue
C154-4014-VSD	4.0 x 14mm	Dark Blue
C154-4016-VSD	4.0 x 16mm	Dark Blue
C154-4018-VSD	4.0 x 18mm	Dark Blue



Self-Tapping Fixed Screws

Catalog Number	Dimensions	Color
C154-4012-FST*	4.0 x 12mm	Green
C154-4014-FST*	4.0 x 14mm	Green
C154-4016-FST*	4.0 x 16mm	Green
C154-4018-FST*	4.0 x 18mm	Green



Self-Tapping Variable Screws

Catalog Number	Dimensions	Color
C154-4012-VST*	4.0 x 12mm	Purple
C154-4014-VST*	4.0 x 14mm	Purple
C154-4016-VST*	4.0 x 16mm	Purple
C154-4018-VST*	4.0 x 18mm	Purple



Self-Tapping Fixed Rescue Screws

Catalog Number	Dimensions	Color
C154-4512-FST	4.5 x 12mm	Aqua
C154-4514-FST	4.5 x 14mm	Aqua
C154-4516-FST	4.5 x 16mm	Aqua
C154-4518-FST	4.5 x 18mm	Aqua



Self-Tapping Variable Rescue Screws

Catalog Number	Dimensions	Color
C154-4512-VST	4.5 x 12mm	Magenta
C154-4514-VST	4.5 x 14mm	Magenta
C154-4516-VST	4.5 x 16mm	Magenta
C154-4518-VST	4.5 x 18mm	Magenta

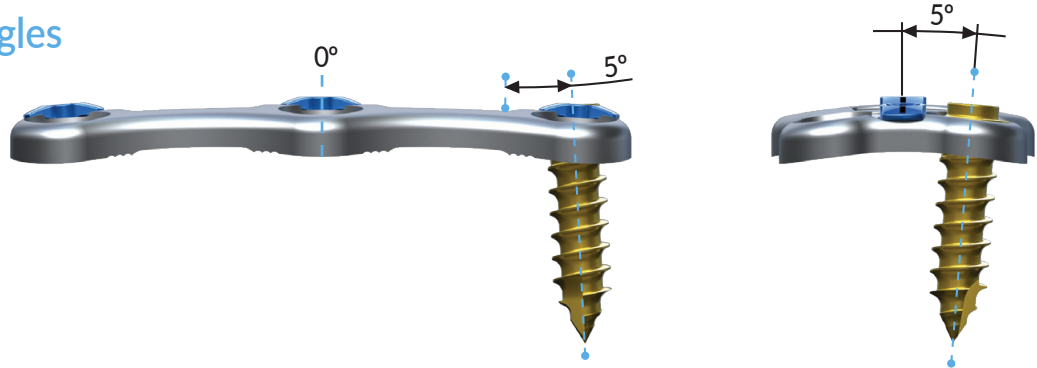
*Available by Request

APTITUDE[®] SCREW INTERFACE GEOMETRY

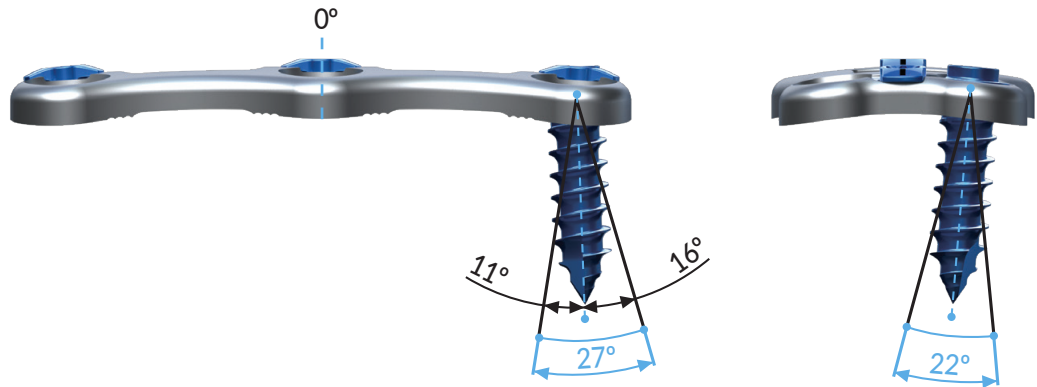
Cephalad-Caudal
Screw Angulation

Medial-Lateral
Screw Angulation

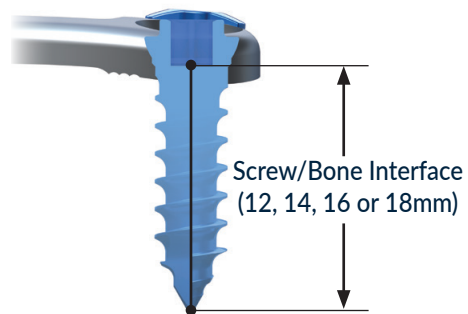
Fixed / Biased Angles



Variable



Screw Lengths



Instrument Features and Benefits

- Self-retaining, tapered Screwdriver provides “Stab and Grab” fit with screw
- Same Screwdriver is used to drive bone screws and engage cam locks
- Streamlined, intuitive instrumentation
- Multiple drill guide and hole preparation options
- Strategically designed instrument set to minimize operating time



C155-700

Screwdriver



Cervical Drills

C155-500-12	Drill, 2.5 x 12mm
C155-500-14	Drill, 2.5 x 14mm
C155-500-16	Drill, 2.5 x 16mm
C155-500-18	Drill, 2.5 x 18mm



C155-600

3.5mm Tap



C155-400

Awl, 2.5 x 10mm



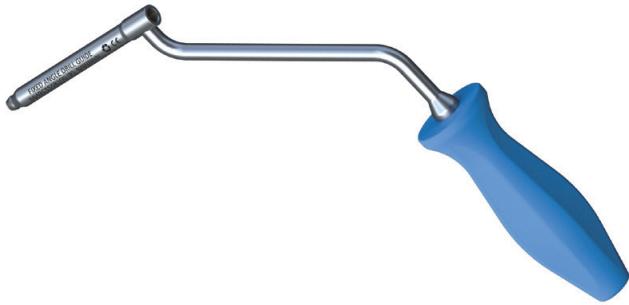
C155-1000

Streamline Spin Handle

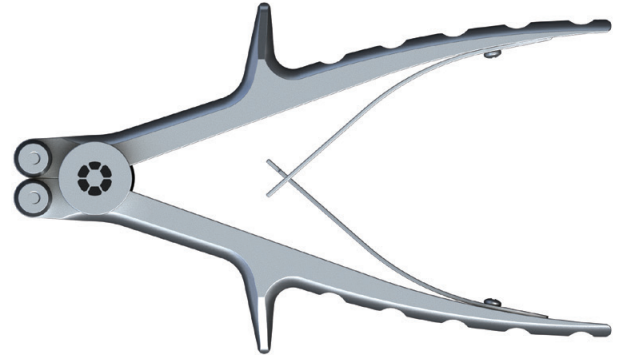


C155-300-10 Temporary Fixation Screw, 2.5 x 10mm

Instrument Guide



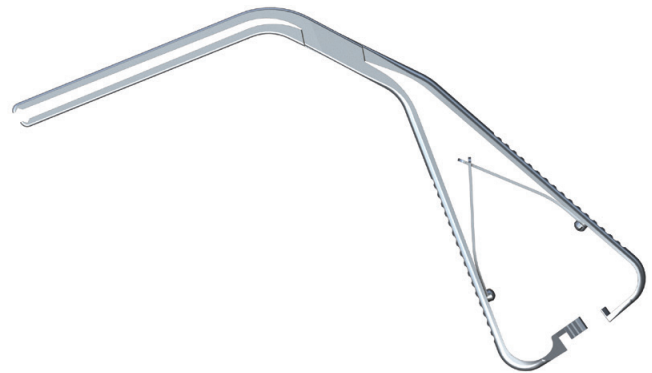
C155-800 Variable Angle Drill Guide



C155-200 Plate Bender



C155-810 Fixed Angle Drill Guide



C155-100 Plate Holder



C155-900 Dual Barrel Drill/Tap/Screw (DTS) Guide



APTITUDE[®]
Surgical Technique

Each surgical step applies to the Midline plate but the illustrations only show the Standard plate.

Step 1: Site Preparation

The patient should be placed in a supine position with the head in slight extension. The cervical spine should be supported to maintain cervical lordosis. Following decompression and interbody grafting procedures, all osteophytes should be removed to create a smooth surface for optimal surface exposure and plate positioning.

Step 2: Plate Selection

Choose the appropriate plate length. The length indicated on the plate corresponds to the distance between the most cephalad and caudal screw holes. Ensure that the plate length provides sufficient area for cephalad and caudal screw angulation without endplate penetration. Please also refer to the Implant Guide. **(Figure 2)**

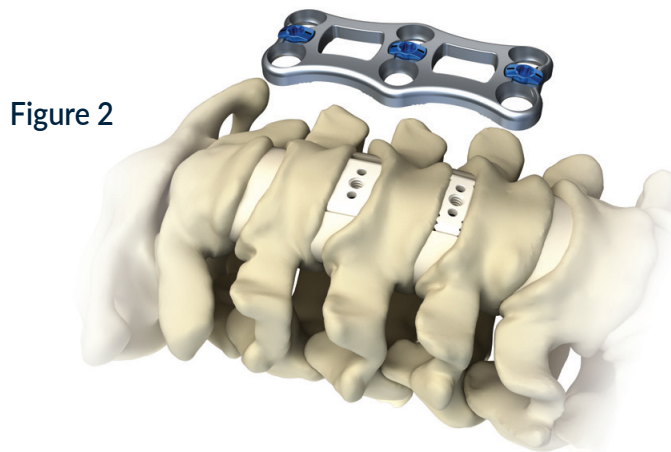


Figure 2

Step 3: Plate Bending

All plates are pre-contoured to match the curvature of the cervical spine. The Plate Bender (C155-200) can be used if additional contouring is required. The plates should only be bent within the specified bending zones. **(Figure 3a, 3b)**

CAUTION: Once bent, avoid reverse bending the plate in the same location. This may result in plate weakening and premature fatigue fracture. Do not bend the plate in the proximity of the screw holes or cam locking mechanisms as this may result in screw locking mechanism malfunction.

Figure 3a

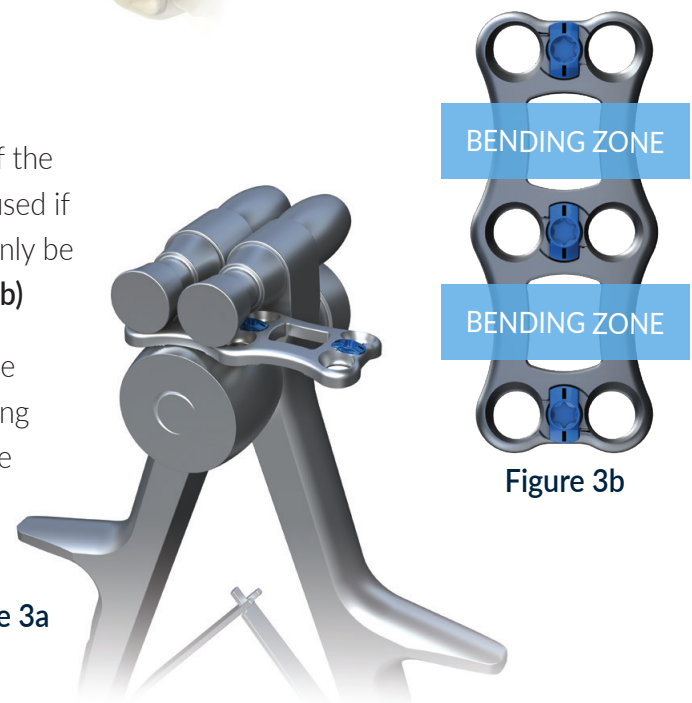


Figure 3b

Step 4: Plate Placement

Place the plate into position using the provided Plate Holder (C155-100). (Figure 4a)

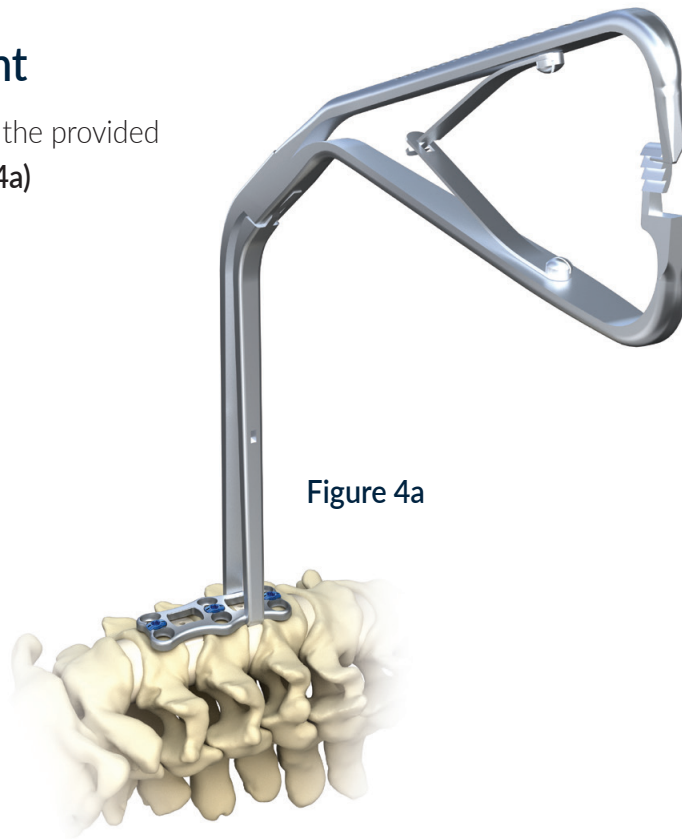


Figure 4a

Temporary Fixation Screws (C155-300-10) may be placed in any of the screw holes to provide short-term stability during screw placement. The Temporary Fixation Screws can be inserted and extracted with the Screwdriver (C155-700). Ensure that the Temporary Fixation Screws are removed before completing the procedure. (Figure 4b)

Note: Temporary Fixation Screws seat 10mm into the bone.

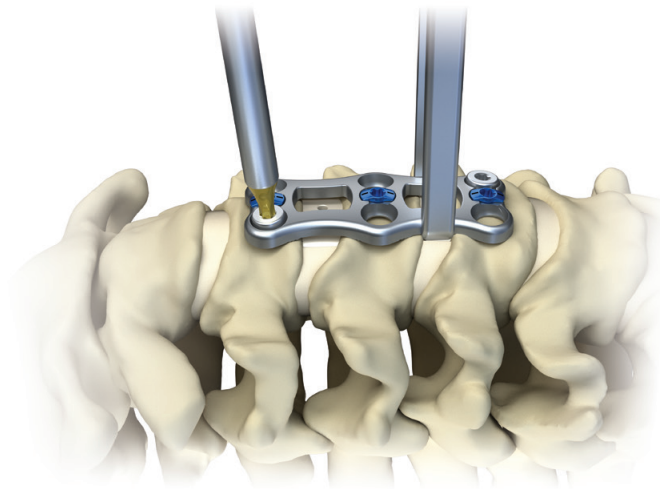


Figure 4b

Step 5: Hole Preparation

Option 1: The Fixed Angle Drill Guide (C155-810) provides a fixed angle of introduction for the Awl, Drills and Tap. This single barrel instrument should be fully seated in the screw socket with the small pilot diameter on the distal tip of the Drill Guide engaging the screw hole to ensure proper angulation. (Figure 5a, 5b)

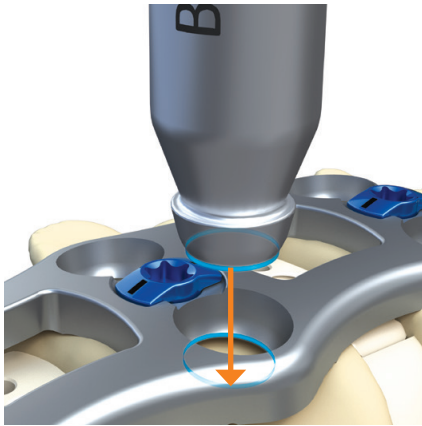


Figure 5a

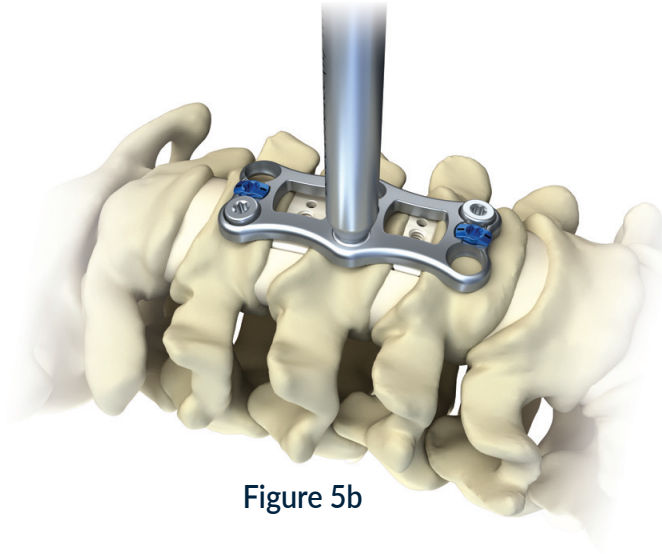


Figure 5b

Option 2: The Variable Angle Drill Guide (C155-800) allows for freehand angle selection within the conical limitations of the screw sockets (22° for central holes and 27° for cephalad/caudal screw holes) for the Awl, Drills, and Tap. This single barrel instrument should be fully seated in the screw socket to ensure proper angulation. (Figure 5c)

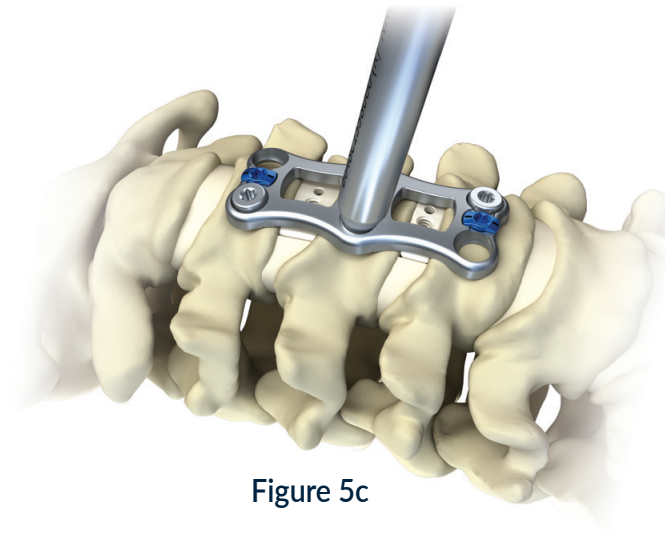


Figure 5c

Surgical Technique

Option 3: The Dual Barrel Drill/Tap/Screw (DTS) Guide (C155-900) provides a fixed angle of introduction for the Awl, Drills, Tap, and Screws. This instrument should be fully seated in the graft window and cam lock to ensure proper angulation. (Figure 5d, 5e)

Note: This option is not available with the Midline plate.

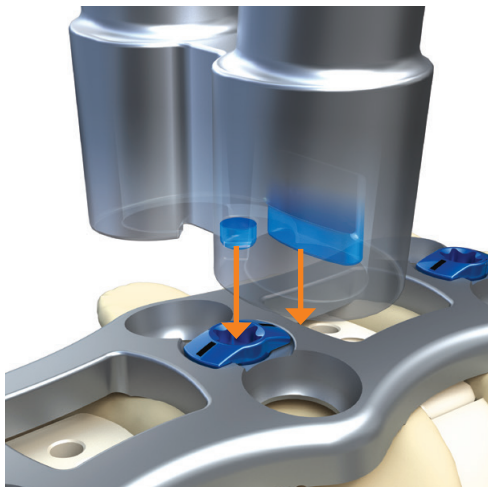


Figure 5d

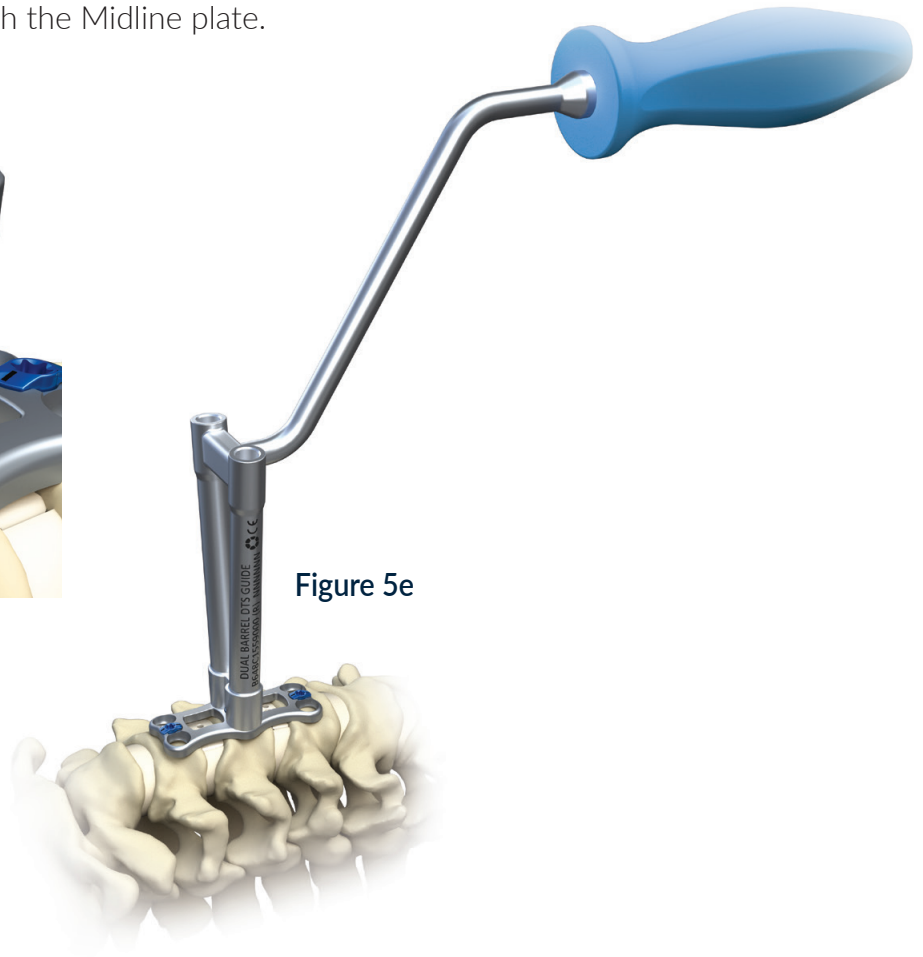


Figure 5e

A 2.5mm diameter pilot hole can be created using the Awl or Drills. The Awl generates a 10mm deep pilot hole and the Drills generate 12-18mm deep pilot holes. The Awl and Drills should be advanced until they stop on the Drill Guide to achieve the specified depth.

A 3.5mm Tap is also provided and can be used with each of the guide options. The shaft of the tap is depth marked to the top of the Dual Barrel DTS Guide.

Note: Please refer to the Implant and Instrument Guide.

CAUTION: Over-angulation of the drilled hole beyond the prescribed insertion angles may result in failure of the screw to engage the plate and/or locking mechanism.

Step 6: Screw Insertion

The cervical bone screws are offered in various diameters, lengths and styles. Please refer to the Implant Guide for more details.

Once the desired screws have been selected, the Screwdriver is used to properly insert them into vertebra. The Screwdriver has a self-retaining tapered tip to hold the screw during insertion. Load the screw onto the Screwdriver and prior to inserting the screw, confirm that the Screwdriver is fully engaged with the hexalobular screw socket. Screws should be advanced until they are firmly seated inside the screw socket in the plate. Screws must be fully seated to allow the cam locks to be properly engaged. **(Figure 6)**

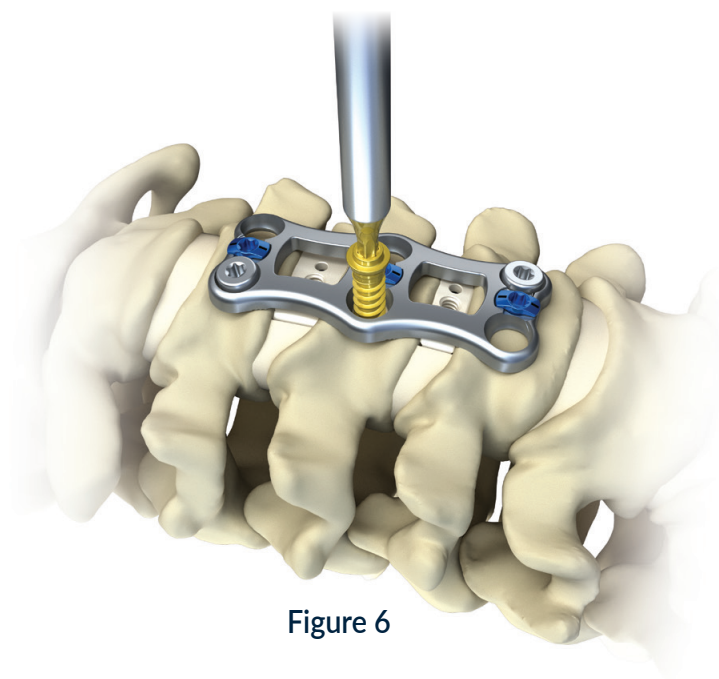


Figure 6

Note: The screws may also be inserted using the Dual Barrel DTS Guide.

CAUTION: Over-torquing the screws during insertion may result in plate damage, stripping of bone, or compromise of the screw/plate interface.

CAUTION: Following plate and screw placement, confirm appropriate construct positioning fluoroscopically prior to final screw locking.

CAUTION: Failure to fully seat the screw in the screw socket may inhibit the cam lock from functioning properly by not rotating to the locked position, or by causing damage to the cam lock due to direct interference with the screw.

Step 7: Screw Locking

Each screw is locked by rotating the adjacent cam lock clockwise one-quarter turn using the same Screwdriver that is used to insert the screws. It is not recommended to rotate the cam lock more than two times.

(Figure 7a, 7b)

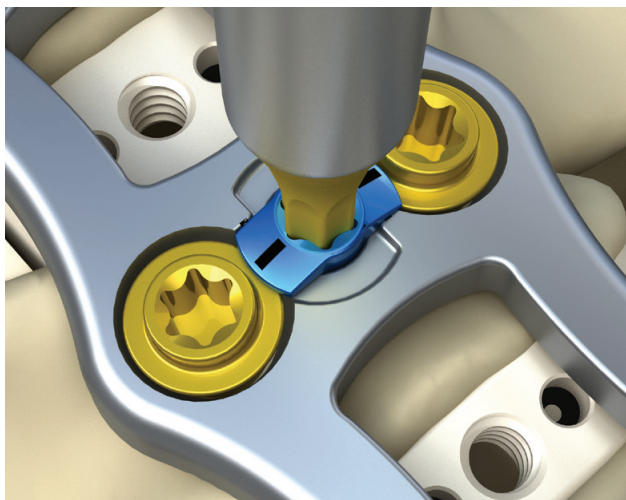


Figure 7a - Standard Plate

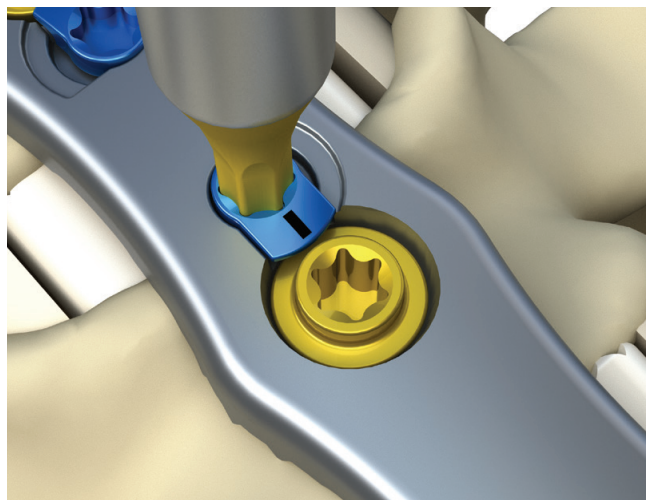


Figure 7b - Midline Plate

Step 8: Implant Removal (optional)

Use the Screwdriver to unlock each cam lock by rotating counterclockwise one-quarter turn to uncover the screw socket. After cam locks have been rotated, each screw can be removed using the Screwdriver.

(Figure 8a, 8b)

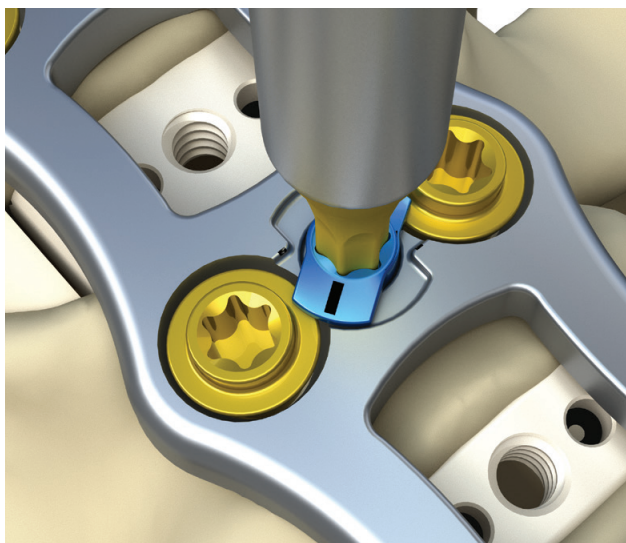


Figure 8a

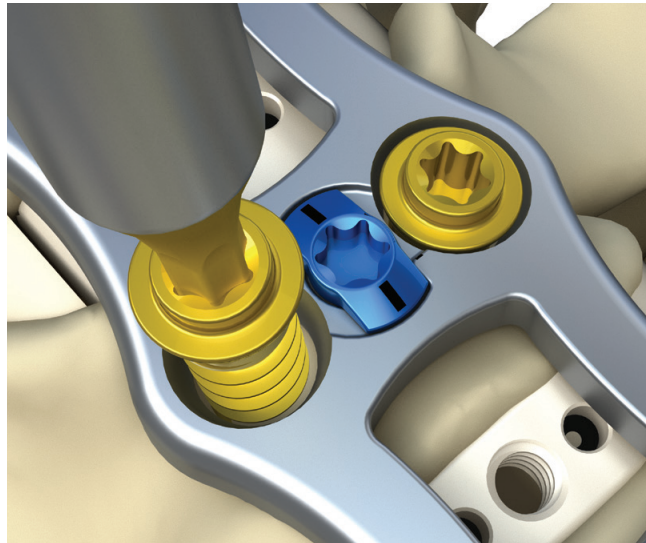


Figure 8b

Indications for Use:

The APTITUDE® Anterior Cervical Plate System is intended for anterior fixation of the cervical spine (C2-T1) as an adjunct to fusion. The system is intended to provide temporary stabilization during the development of cervical spinal fusion in patients with the following: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformity (e.g., kyphosis, lordosis, scoliosis), tumors, pseudarthrosis, and/or failed previous fusion.

Contraindications:

Contraindications for the APTITUDE® Anterior Cervical Plate System are comparable to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.

Cautions, Precautions and Warnings:

Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.

Do not use components of the APTITUDE® Anterior Cervical Plate System with components from any other manufacturer.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the APTITUDE® Anterior Cervical Plate System components should ever be reused under any circumstances.

Precautions:

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

Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The APTITUDE® Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the APTITUDE® Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results. The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

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