

AlectaTM

Anterior Cervical Plate System (**ACP**)

SURGICAL TECHNIQUE & SET INFORMATION

The ALECTA ACP System Description

The ALECTA Anterior Cervical Plate System is designed for use in a variable, constrained, or hybrid screw configuration.

Implant & Instrument Versatility

Anterior Cervical system consists of mobile and fixed safety screws, plate which provides high strength with low thickness, screws of mobile and fixed bone anchorage.

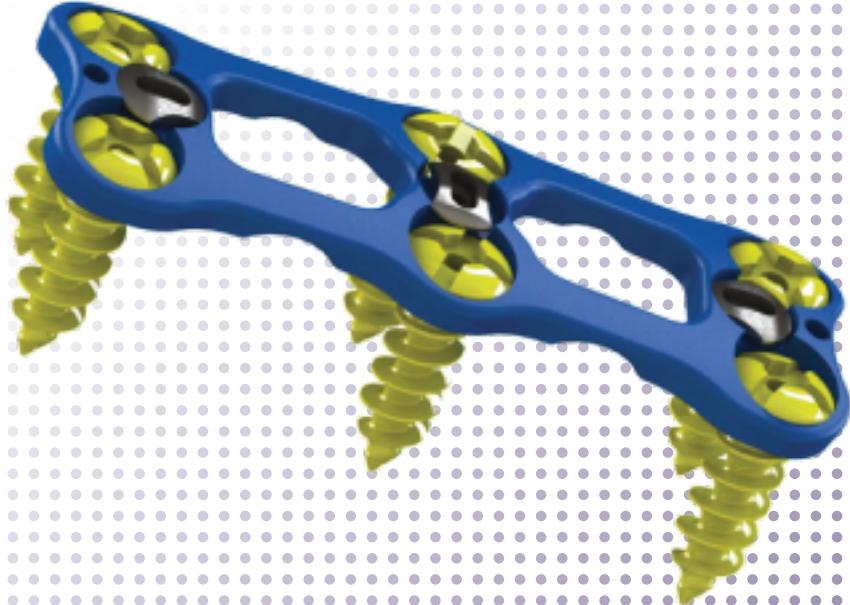
Blocking system that avoids the anteropulsion of screws, is friendly and effective with the plate.

The mobile safety screws allow polyaxial angulation of 15°. The fixed safety screws are placed perpendicularly to the plate in order to obtain more solid fixings.

The ionically anodized surface avoids friction wearing out and boosts resistance to fatigue.

The rounded peripheral rim lowers the aggressiveness of the implant over soft tissues.

It provides effective and simple use.



The ALECTA ACP System Indications & Contraindications

Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2–C7) for the following indications:

- Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Fracture
- Spinal stenosis
- Deformity (i.e kyphosis, lordosis and/or scoliosis)
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudarthrosis

Contraindications:

- The ALECTA Anterior Cervical System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies.
- Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.



The ALECTA ACP System Surgical Technique

STEP 1 - PLATE SIZING

- After placing the interbody spacer, insert the caliper into the surgical opening. Adjust the length until the ends of the caliper rest directly on the corner of the most cephalad and caudal endplates in the construct.
- The corresponding measurement reading provides the suggested plate length for which the graft window will align directly with the most cephalad and caudal endplates in the construct.

STEP 2 - PLATE HOLDER

- The plate holder can be used alone or in conjunction with the modular A-O handle. Insert the tip of the holder into the locking cap until it is seated snugly. Place the plate onto the cervical spine in the preferred location.

Note: Distraction pins should be removed, and spacer(s) should be in place prior to plate measurement. This reading places the middle of each screw hole 4.25 mm away from the superior edge of the window, and the edge of the plate 8.25 mm from the superior edge of the window. A properly sized plate will bridge the affected segment(s) without overhanging into adjacent disc.

Note: The caliper reading is a suggested plate length only. Each surgeon should consider their patient's indications and unique anatomy when determining a final plate length.



The ALECTA ACP System Surgical Technique

STEP 3 - PLATE BENDING OPTION

STEP 3A

Option 1: Increase Lordosis

- To increase the bend of the plate, insert the plate in the plate bender with the anterior surface resting against the anvil. Turn the plate bender's hammer so that the convex portion is facing the plate. Once positioned, squeeze the pliers-style handle to obtain the desired plate curvature.

STEP 3B

Option 2: Decrease Lordosis

- To decrease the bend of the plate, insert the plate in the plate bender with the posterior surface resting against the anvil. Turn the plate bender's hammer so that the concave portion is facing the plate. Once positioned, squeeze the pliers-style handle to obtain the desired plate curvature.
- Caution: Plate bending can significantly weaken the plate. Never bend the plate over the locking cap. Do not reverse bend the plate (i.e., bending in the opposite direction).



The ALECTA ACP System Surgical Technique

STEP - 4 TEMPORARY FIXATION (Optional)

Temporary fixation pins can be used during initial plate placement and are seated using the screw driver.

STEP 4A

Retaining the Pin on the Driver

- Press the driver down into the head of the pin until it holds the pin securely.

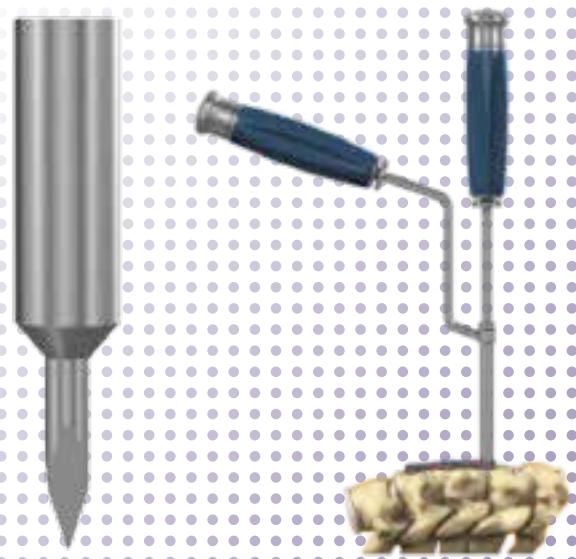
STEP 4B

Temporary Fixation Pin Placement

- Place the tip of the pin into the preferred screw hole, then turn the pin clockwise until it is firmly seated into the plate. The pin can travel to a depth of 14 mm. The pin must be removed by re-engaging the driver and rotating it counterclockwise.

All temporary fixation pins must be removed. Do not implant temporary fixation pins.

Note: The temporary fixation pins are intended for single-use only and should be discarded after one use.



The ALECTA ACP System Surgical Technique

STEP 5 - SCREW HOLE PREPARATION

The ALECTA ACP system provides several options for screw hole preparation, including: fixed and adjustable drill guides, awl and taps.

Option 1: Fixed and Adjustable Drill Guides

Fixed and adjustable drill guides are used in conjunction with the drill/modular handle assembly.

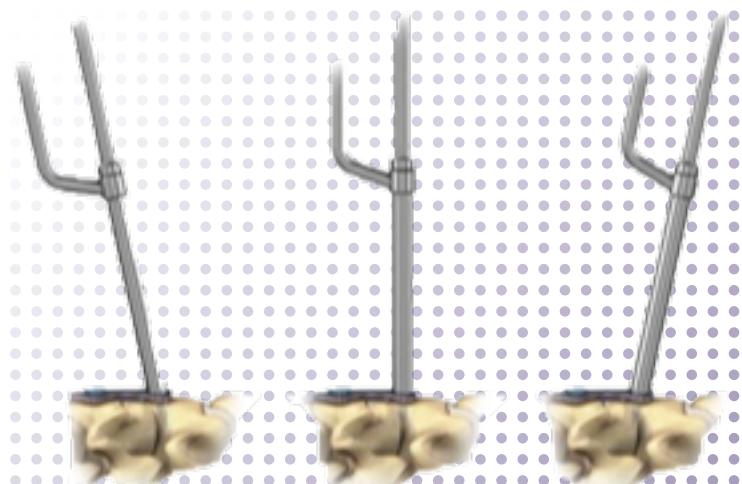
The fixed drill guide will prepare a screw hole at a 6/0 (medial/cephalad) angle, while the adjustable drill guide will allow screw placement within a +/- 11 degree range of motion.

Drilling/Hole Preparation

- Insert the tip of the fixed or adjustable drill guide into the desired screw hole.

Once firmly engaged, insert the drill into the drill guide and advance it by rotating the handle clockwise until the drill's positive stop contacts the drill guide.

Remove the drill from the drill guide.



The ALECTA ACP System Surgical Technique

STEP 5 - SCREW HOLE PREPARATION Option 1 (Continued)

Tapping Option

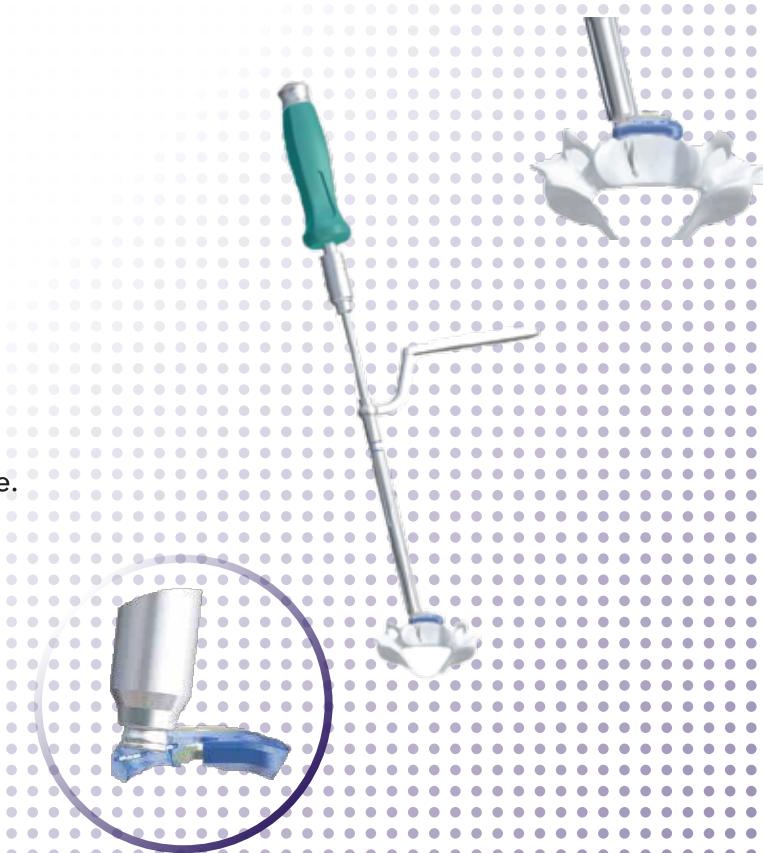
Tapping is an optional step when using the fixed or adjustable drill guides. The modular bone tap is used in conjunction with the drill guide/modular AO handle assembly.

- Position the fixed or adjustable drill guide over the previously drilled hole. Insert the bone tap into the drill guide and advance it by rotating it clockwise until the positive stop reaches the top of the drill guide. To remove the tap, rotate it counterclockwise until it is free of bone, and then remove it from the drill guide.

Caution: Continued clockwise rotation of the tap after reaching the positive stop will strip the bone.

Screw Placement — Fixed and Adjustable Drill Guides

- Once screw hole preparation is complete, select the desired screw type and length. Insert the tip of the screw driver/modular assembly into the socket of the screw using downward pressure on the driver to secure the screw to the driver tip. Insert the screw and driver assembly into the previously prepared screw hole. Rotate the driver clockwise to advance the screw until it is firmly seated. Final adjustments may be needed once the drill guide has been removed.
- Repeat these steps until a screw has been placed into every hole.



The ALECTA ACP System Surgical Technique

STEP 6 – SCREW INSERTION

- The self retaining screw driver may be used to remove the desired screw from the screw caddy.
- Insert the screw into the screw bore and advance it into the vertebral body. Use fluoroscopic imaging to confirm the final trajectory of the screw and plate position before screws are fully tightened and secured.

STEP 7 – LOCKING THE PLATE

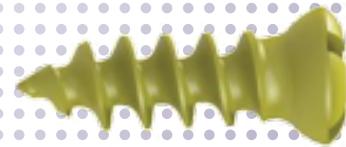
- All screws should be secured to the vertebral bodies before beginning the plate locking procedure.
- Assemble the plate tightener shaft to the handle.
- Locking mechanism locking caps are preinstalled and positioned on the plate to allow insertion of the bone screws. Each cap will retain the bone screws within the plate when the cap is rotated to a secure position.
- Once all bone screws have been placed, use the locking cap driver to rotate the cap clockwise approximately 45° to secure it properly. The cap will tighten and you will be able to visually confirm the cap covering the screws.



The ALECTA ACP System Implants

Variable Self Tapping Screws (4.0mm – 4.5mm)

Ref. Number	Size	Ref. Number	Size
AT1010.0004012	12mm	AT1010.0004512	12mm
AT1010.0004014	14mm	AT1010.0004514	14mm
AT1010.0004016	16mm	AT1010.0004516	16mm
AT1010.0004018	18mm	AT1010.0004518	18mm
AT1010.0004020	20 mm	AT1010.0004520	20mm



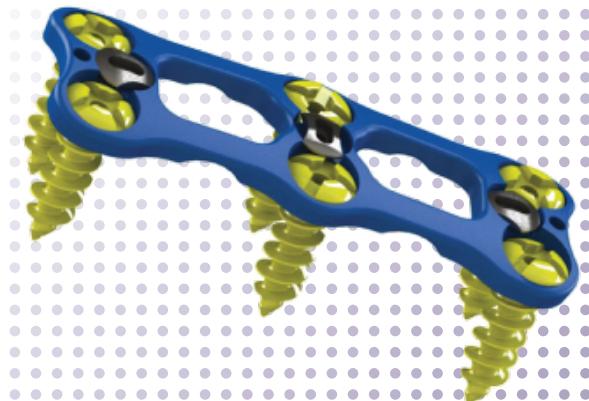
The ALECTA ACP System Implants

One Level Plates

Ref. Number	Size
AT1009.0000014	14mm
AT1009.0000016	16mm
AT1009.0000018	18mm
AT1009.0000020	20mm
AT1009.0000024	24 mm

Two Level Plates

Ref. Number	Size
AT1009.0000028	28mm
AT1009.0000030	30mm
AT1009.0000032	32mm
AT1009.0000034	34mm
AT1009.0000036	36 mm
AT1009.0000040	40mm
AT1009.0000044	44mm



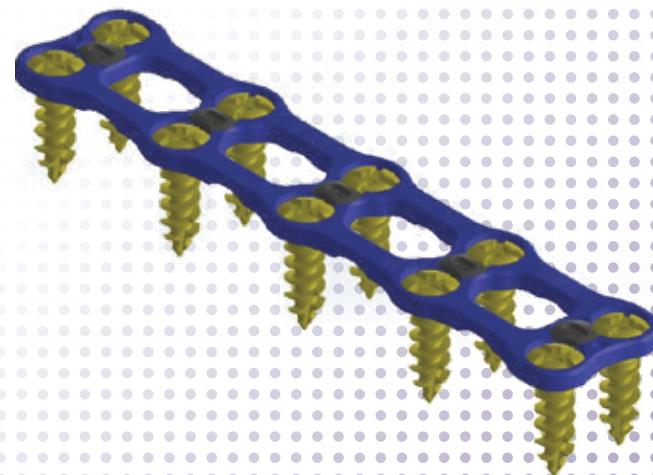
The ALECTA ACP System Implants

Three Levels Plate

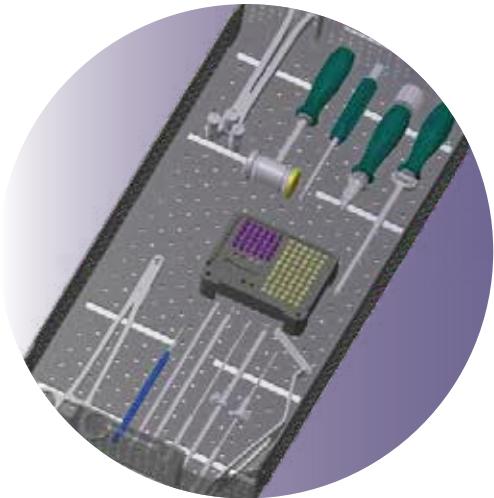
Ref. Number	Size
AT1009.0000048	48mm
AT1009.0000051	51mm
AT1009.0000054	54mm
AT1009.0000057	57mm
AT1009.0000060	60 mm
AT1009.0000063	63mm
AT1009.0000066	66mm
AT1009.0000068	68mm
AT1009.0000069	69mm

Four Levels Plate

Ref. Number	Size
AT1009.0000072	72mm
AT1009.0000076	76mm
AT1009.0000080	80mm
AT1009.0000084	84mm
AT1009.0000088	88 mm
AT1009.0000092	92mm
AT1009.0000094	94mm
AT1009.0000100	100mm



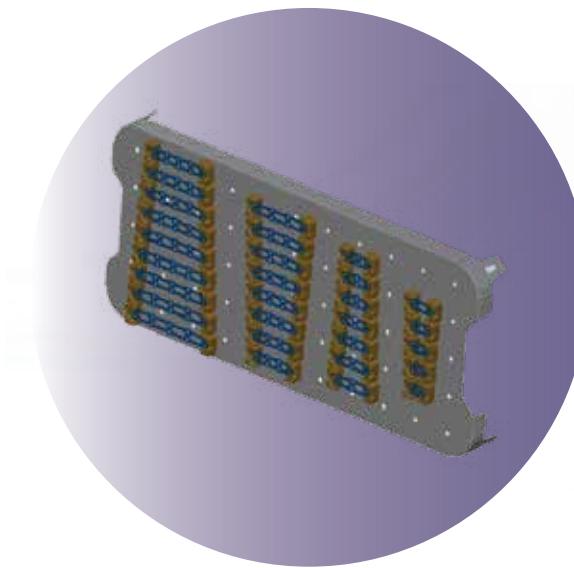
The ALECTA ACP System Instruments



Ref. Number	Description	Ref. Number	Description
15000.INS0101	Plate Bender	15006.INS0107	Plate Locker
15001.INS0102	Drill Guide	15007.INS0108	Awl
15002.INS0103	Handle A-O	15008.INS0109-01	Tap (for 4 mm)
15003.INS0104-01	Adjustable Drill (for 4 mm)	15008.INS0109-02	Tap (for 4.5 mm)
15003.INS0104-02	Adjustable Drill (for 4.5 mm)	15010.INS0111	Screw Box
15004.INS0105	Plate Holder	15014.INS0115	Screw Diameter Control
15005.INS0106	Screw Driver	15016.INS0117	Mallet

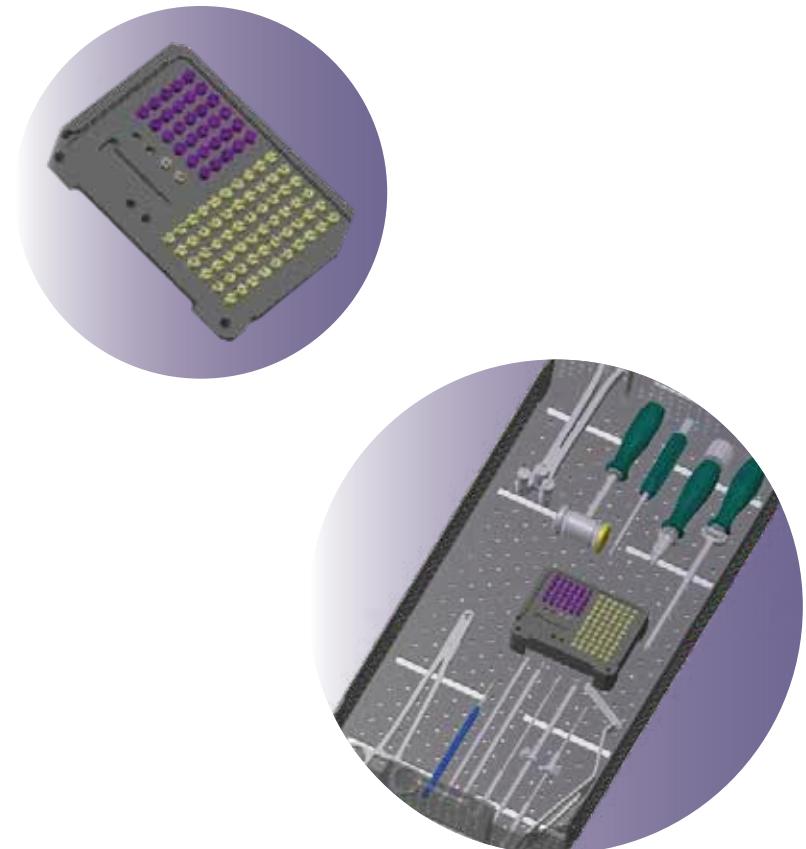
The ALECTA ACP System Kit Contents

Description of Goods	Ref. Number	Quantity (PC)
ALECTA ANTERIOR CERVICAL PLATE 14 MM	AT1009.0000014	1
ALECTA ANTERIOR CERVICAL PLATE 16 MM	AT1009.0000016	1
ALECTA ANTERIOR CERVICAL PLATE 18 MM	AT1009.0000018	1
ALECTA ANTERIOR CERVICAL PLATE 20 MM	AT1009.0000020	1
ALECTA ANTERIOR CERVICAL PLATE 24 MM	AT1009.0000024	1
ALECTA ANTERIOR CERVICAL PLATE 28 MM	AT1009.0000028	1
ALECTA ANTERIOR CERVICAL PLATE 30 MM	AT1009.0000030	1
ALECTA ANTERIOR CERVICAL PLATE 32 MM	AT1009.0000032	1
ALECTA ANTERIOR CERVICAL PLATE 34 MM	AT1009.0000034	1
ALECTA ANTERIOR CERVICAL PLATE 36MM	AT1009.0000036	1
ALECTA ANTERIOR CERVICAL PLATE 40 MM	AT1009.0000040	1
ALECTA ANTERIOR CERVICAL PLATE 44 MM	AT1009.0000044	1
ALECTA ANTERIOR CERVICAL PLATE 48 MM	AT1009.0000048	1
ALECTA ANTERIOR CERVICAL PLATE 51 MM	AT1009.0000051	1
ALECTA ANTERIOR CERVICAL PLATE 54 MM	AT1009.0000054	1
ALECTA ANTERIOR CERVICAL PLATE 57 MM	AT1009.0000057	1
ALECTA ANTERIOR CERVICAL PLATE 60 MM	AT1009.0000060	1
ALECTA ANTERIOR CERVICAL PLATE 63 MM	AT1009.0000063	1
ALECTA ANTERIOR CERVICAL PLATE 66 MM	AT1009.0000066	1
ALECTA ANTERIOR CERVICAL PLATE 68 MM	AT1009.0000068	1
ALECTA ANTERIOR CERVICAL PLATE 69 MM	AT1009.0000069	1
ALECTA ANTERIOR CERVICAL PLATE 72 MM	AT1009.0000072	1
ALECTA ANTERIOR CERVICAL PLATE 76 MM	AT1009.0000076	1
ALECTA ANTERIOR CERVICAL PLATE 80 MM	AT1009.0000080	1
ALECTA ANTERIOR CERVICAL PLATE 84 MM	AT1009.0000084	1
ALECTA ANTERIOR CERVICAL PLATE 88 MM	AT1009.0000088	1
ALECTA ANTERIOR CERVICAL PLATE 92 MM	AT1009.0000092	1
ALECTA ANTERIOR CERVICAL PLATE 96 MM	AT1009.0000096	1
ALECTA ANTERIOR CERVICAL PLATE 100 MM	AT1009.0000100	1



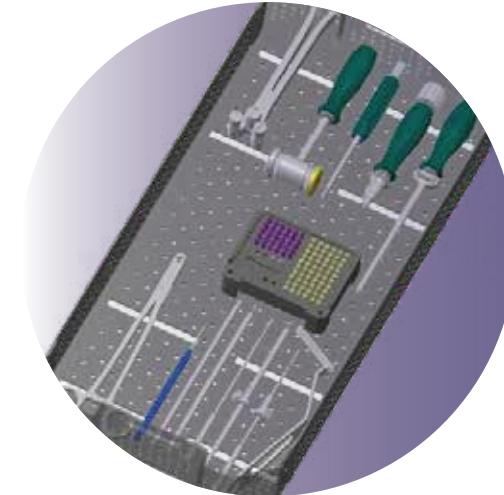
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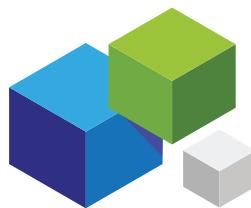
Description of Goods	Ref. Number	Quantity (PC)
ALECTA ANTERIOR CERVICAL SCREW Ø 4.0X12 MM	AT1010.0004012	12
ALECTA ANTERIOR CERVICAL SCREW Ø 4.0X14 MM	AT1010.0004014	12
ALECTA ANTERIOR CERVICAL SCREW Ø 4.0X16 MM	AT1010.0004016	12
ALECTA ANTERIOR CERVICAL SCREW Ø 4.0X18 MM	AT1010.0004018	12
ALECTA ANTERIOR CERVICAL SCREW Ø 4.0X20 MM	AT1010.0004020	12
ALECTA ANTERIOR CERVICAL SCREW Ø 4.5X12 MM	AT1010.0004512	6
ALECTA ANTERIOR CERVICAL SCREW Ø 4.5X14 MM	AT1010.0004514	6
ALECTA ANTERIOR CERVICAL SCREW Ø 4.5X16 MM	AT1010.0004516	6
ALECTA ANTERIOR CERVICAL SCREW Ø 4.5X18 MM	AT1010.0004518	6
ALECTA ANTERIOR CERVICAL SCREW Ø 4.5X20 MM	AT1010.0004520	6



The ALECTA ACP System Kit Contents

Description of Goods	Ref. Number	Quantity (PC)
Plate Bender	15000.INS0101	1
Drill Guide	15001.INS0102	1
Handle A-O	15002.INS0103	1
Adjustable Drill (for 4 mm)	15003.INS0104-01	1
Adjustable Drill (for 4.5 mm)	15003.INS0104-02	1
Plate Holder	15004.INS0105	1
Screw Driver	15005.INS0106	2
Plate Locker	15006.INS0107	1
Awl	15007.INS0108	1
Tap (for 4 mm)	15008.INS0109-01	1
Tap (for 4.5 mm)	15008.INS0109-02	1
Screw Box	15010.INS0111	1
Screw Diameter Control	15014.INS0115	1
Mallet	15016.INS0117	1





Produced Exclusively for
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MEDICAL SOLUTIONS

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