ZION

ANTERIOR CERVICAL FIXATION SYSTEM

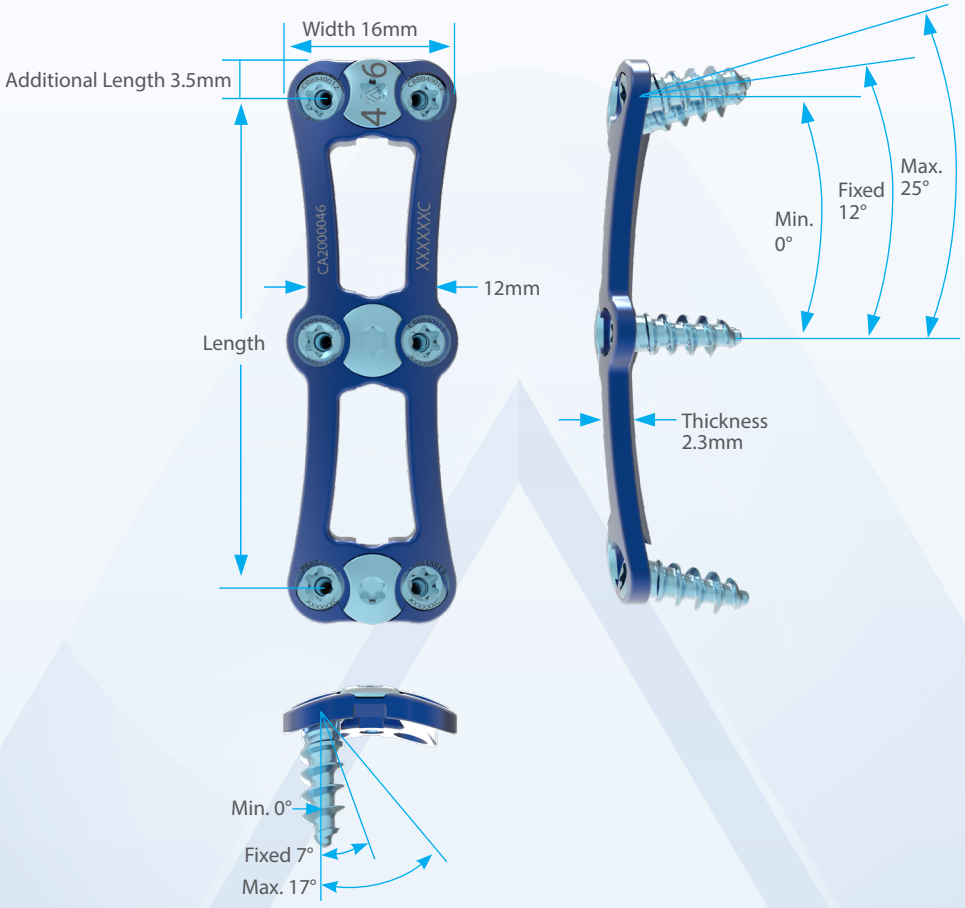
ASTURA MEDICAL

DESIGN RATIONALE

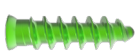
The Zion Anterior Cervical Plating System is an elegant system that provides the ability to achieve a maximum screw angulation of up to 25°, while maintaining a low-profile plate design with a robust and repeatable locking mechanism that allows for tactile and visual confirmation of the screws locking. The intuitive design and comprehensive offering of instruments, screw options, and plates ranging from 1-5 levels ensures an efficient and streamlined procedural sequence.

ANTERIOR CERVICAL FIXATION OVERVIEW

FIXED & VARIABLE SCREW ANGLES

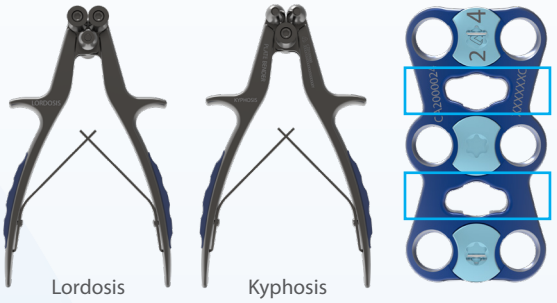


SCREWS SPECIFICATIONS

Tip Option	Constraint	Diameter (mm)	Image	Length (mm)
Self-Drilling	Fixed	4.0		10-24
	Variable	4.0		
Self-Tapping	Fixed	4.0		10-24
		4.5		
	Variable	4.0		
		4.5		

1.0 EXPOSURE

1.1 Identify the affected level using a combination of palpation and fluoroscopy. Using a right or left-sided approach, incise the skin, then use standard exposure techniques to expose the segments being fused.

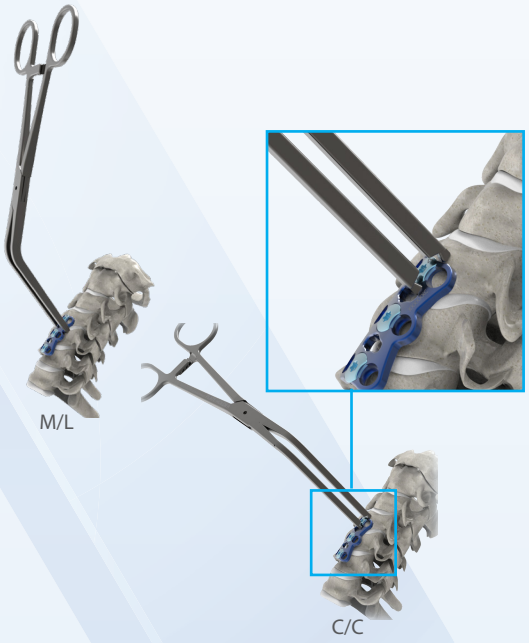


2.0 PLATE SELECTION AND CONTOURING

2.1 Select the plate required based on levels being fused and patient anatomy.

2.2 Plates are pre-contoured to match the patient's anatomy. If additional contouring is required, use the ACFS Bender (CZ0100000). The Bender allows for both Lordotic and Kyphotic bends.

2.3 CAUTION: Plates must only be bent within the zones identified.



3.0 PLATE PLACEMENT AND FIXATION

3.1 Attach the Plate Holder (CZ0200000) to the plate in either A/P or M/L orientation. Place in the desired location on the vertebra.

3.2 Attach either the Threaded Temporary Fixation Pin (CZ030001) or Smooth Fixation Pin (CZ0300002) to the Temporary Fixation Pin Driver (CZ0400000) by pulling back the locking sleeve, then inserting the pin.

3.3 Use the Pin Driver to insert the Temporary Fixation Pin through the desired screw hole in the plate. Once inserted, pull back the locking sleeve to remove the Temporary Fixation Pin Driver from the Temporary Fixation Pin. Remove the pin from the plate once the screws have been placed and the plate is secured.

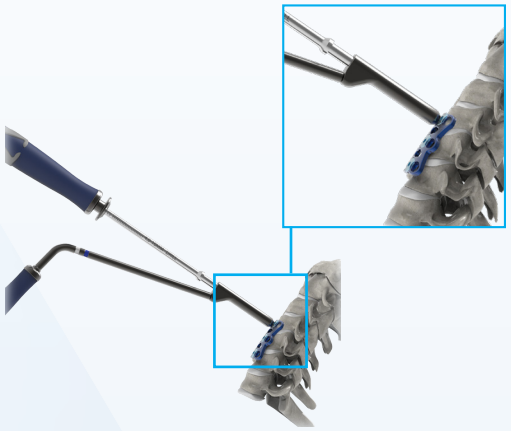
4.0 SCREW SELECTION

4.1 Select the desired bone screw from the options on page 3.

5.0 DRILLING OPTIONS

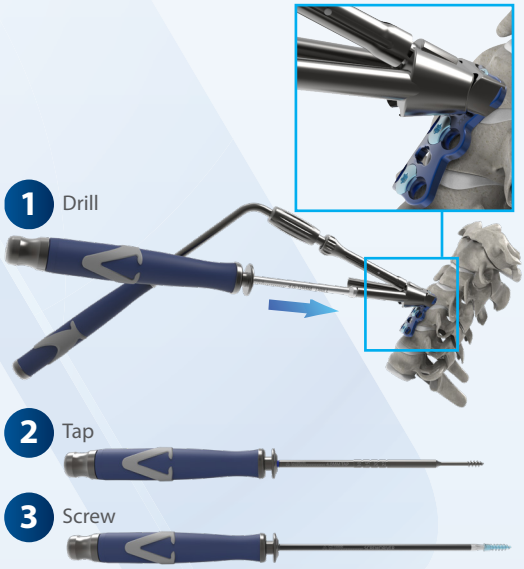
5.1 Manual Drill Guide

5.1.1. Select the Drill Guide (CZ0700140, CZ0700240) that corresponds to the screw that was selected (Fixed or Variable). Select the Drill (CZ0940XX) that corresponds to the screw length selected, then attach it to the Modular Axial Handle (EABEASADZ) or power driver. Place the Drill Guide into the plate, then pass the Drill through the Drill Guide and Drill at the desired trajectory. The Awl (CZ0600000) can also be used in a similar manner to the drill to create the pilot hole.



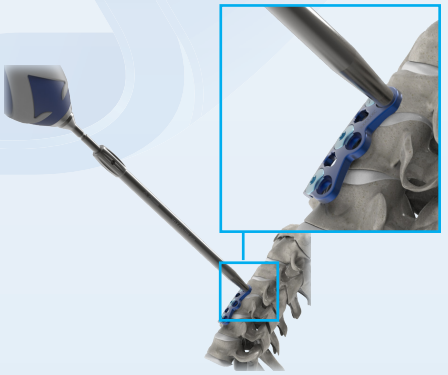
5.2 Drill Tap Screw Guide (DTS)

5.2.1. Select the desired DTS (Double: CZ0800010 or Single: CZ0800020 or Double Variable: CZ0800030) and place onto the plate at the desired level. Select the Drill (CZ0940XX) that corresponds to the screw length that was selected, then attach to the Modular Axial Handle (EABEASADZ) or power driver. Place the Drill Guide onto plate, then pass the drill through the drill guide and drill tothe desired trajectory.



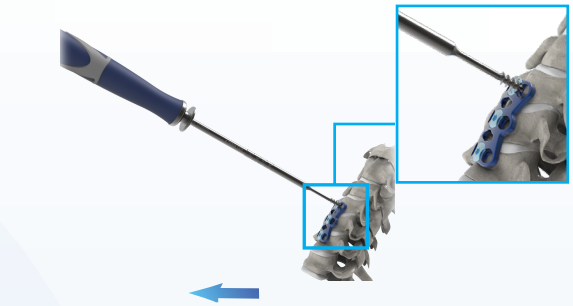
5.3 Self-Centering Awl

5.3.1. To use the Self-Centering Awl (CZ050000), place the tip of the device into the desired plate hole. Orientate in the desired trajectory, then place downward force on the handle while twisting. The tip is limited to 10mm in length.



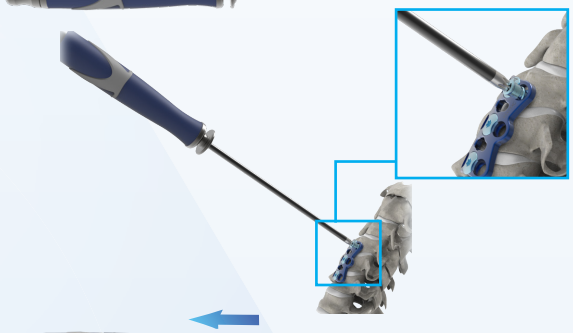
6.0 TAPPING

6.1 If tapping is desired, attach the Tap (CZ1000040) to the Modular Axial Handle (EABEASADZ), then place the Tap into the desired screw plate hole and advance to the desired depth. When the Tap is used with either DTS Guide (CZ0800010, CZ0800020), the depth markings on the Tap can be used to approximate the depth that has been tapped. Repeat for all plate holes.



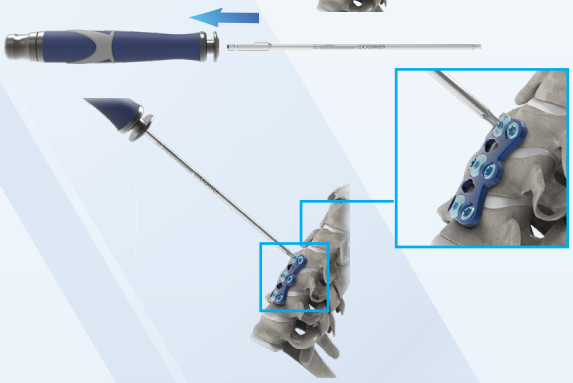
7.0 SCREW INSERTION

7.1 Attach the Screwdriver Shaft (CZ1100000) to the Modular Axial Handle (EABEASADZ), then press the tip of the Screwdriver into the drive portion of the screw. Once assembled, place the tip of the screw into the desired plate hole and advance until the screw is completely seated in the plate. Repeat for all plate holes.



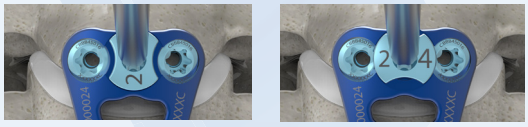
8.0 PLATE LOCKING

8.1 Attach the Lockdriver Shaft (CZ1200000) to the Modular Axial Handle (EABEASADZ). Insert the tip of the Lockdriver Shaft into the mating feature within the plate locking mechanism and rotate 90^0. Visually verify that both screws are covered by the locking mechanism. Repeat for all remaining locking mechanisms.



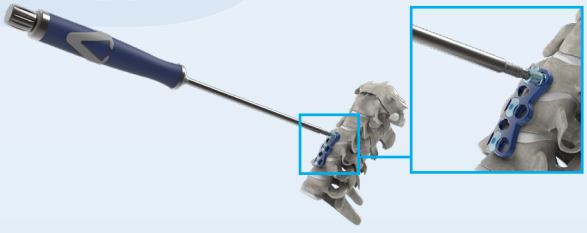
9.0 REVISION/REMOVAL

9.1 Attach the Lockdriver Shaft (CZ1200000) to the Modular Axial Handle (EABEASADZ). Insert the tip of the Lockdriver Shaft into the mating feature within the plate locking mechanism and rotate 90^0 so the locking mechanism is in the unlocked position.



9.2 Obtain the Screw Remover (CZ1300000) and insert the tip of the shaft into the desired screw. Once coupled to the screw, rotate the knob on the proximal portion of the Screw Remover threading clockwise until resistance is achieved. Rotate the Screw Remover counter-clockwise until the screw is removed from the plate. Repeat for all remaining screws.

9.3 Once all the screws have been removed, attach the Plate Holder (CZ0200000) to the plate and remove from the patient.



ZION IMPLANT OFFERING

CERVICAL PLATES

Part Number	Description	Qty
CA1000010	ACP, 1-Level, 10mm	2
CA1000012	ACP, 1-Level, 12mm	2
CA1000014	ACP, 1-Level, 14mm	2
CA1000016	ACP, 1-Level, 16mm	2
CA1000018	ACP, 1-Level, 18mm	1
CA1000020	ACP, 1-Level, 20mm	1
CA1000022	ACP, 1-Level, 22mm	1
CA1000024	ACP, 1-Level, 24mm	1
CA1000026	ACP, 1-Level, 26mm	1

CA2000024	ACP, 2-Level, 24mm	2
CA2000026	ACP, 2-Level, 26mm	2
CA2000028	ACP, 2-Level, 28mm	2
CA2000030	ACP, 2-Level, 30mm	2
CA2000032	ACP, 2-Level, 32mm	2
CA2000034	ACP, 2-Level, 34mm	1
CA2000036	ACP, 2-Level, 36mm	1
CA2000038	ACP, 2-Level, 38mm	1
CA2000040	ACP, 2-Level, 40mm	1
CA2000042	ACP, 2-Level, 42mm	1
CA2000044	ACP, 2-Level, 44mm	1
CA2000046	ACP, 2-Level, 46mm	1

CA3000039	ACP, 3-Level, 39mm	2
CA3000042	ACP, 3-Level, 42mm	2
CA3000045	ACP, 3-Level, 45mm	2
CA3000048	ACP, 3-Level, 48mm	2
CA3000051	ACP, 3-Level, 51mm	1
CA3000054	ACP, 3-Level, 54mm	1
CA3000057	ACP, 3-Level, 57mm	1
CA3000060	ACP, 3-Level, 60mm	1
CA3000063	ACP, 3-Level, 63mm	1
CA3000066	ACP, 3-Level, 66mm	1
CA3000069	ACP, 3-Level, 69mm	1

ZION IMPLANT OFFERING

CERVICAL PLATES

Part Number	Description	Qty
CA4000056	ACP, 4-Level, 56mm	1
CA4000060	ACP, 4-Level, 60mm	1
CA4000064	ACP, 4-Level, 64mm	1
CA4000068	ACP, 4-Level, 68mm	1
CA4000072	ACP, 4-Level, 72mm	1
CA4000076	ACP, 4-Level, 76mm	1
CA4000080	ACP, 4-Level, 80mm	1

CA5000085	ACP, 5-Level, 85mm	1 / OPT
CA5000090	ACP, 5-Level, 90mm	1 / OPT
CA5000095	ACP, 5-Level, 95mm	1 / OPT
CA5000100	ACP, 5-Level, 100mm	1 / OPT

ZION IMPLANT OFFERING

CERVICAL SCREWS

Part Number	Description	Qty
CBAA40010	ACS, Self-Drilling, Fixed 4.0mm x 10mm	8 / OPT
CBAA40011	ACS, Self-Drilling, Fixed 4.0mm x 11mm	8 / OPT
CBAA40012	ACS, Self-Drilling, Fixed 4.0mm x 12mm	8 / OPT
CBAA40013	ACS, Self-Drilling, Fixed 4.0mm x 13mm	8 / OPT
CBAA40014	ACS, Self-Drilling, Fixed 4.0mm x 14mm	8 / OPT
CBAA40015	ACS, Self-Drilling, Fixed 4.0mm x 15mm	8 / OPT
CBAA40016	ACS, Self-Drilling, Fixed 4.0mm x 16mm	8 / OPT
CBAA40017	ACS, Self-Drilling, Fixed 4.0mm x 17mm	8 / OPT
CBAA40018	ACS, Self-Drilling, Fixed 4.0mm x 18mm	8 / OPT
CBAA40019	ACS, Self-Drilling, Fixed 4.0mm x 19mm	OPT
CBAA40020	ACS, Self-Drilling, Fixed 4.0mm x 20mm	OPT
CBAB40010	ACS, Self-Drilling, Variable 4.0mm x 10mm	8
CBAB40011	ACS, Self-Drilling, Variable 4.0mm x 11mm	8
CBAB40012	ACS, Self-Drilling, Variable 4.0mm x 12mm	12
CBAB40013	ACS, Self-Drilling, Variable 4.0mm x 13mm	12
CBAB40014	ACS, Self-Drilling, Variable 4.0mm x 14mm	12
CBAB40015	ACS, Self-Drilling, Variable 4.0mm x 15mm	12
CBAB40016	ACS, Self-Drilling, Variable 4.0mm x 16mm	12
CBAB40017	ACS, Self-Drilling, Variable 4.0mm x 17mm	8
CBAB40018	ACS, Self-Drilling, Variable 4.0mm x 18mm	8
CBAB40019	ACS, Self-Drilling, Variable 4.0mm x 19mm	OPT
CBAB40020	ACS, Self-Drilling, Variable 4.0mm x 20mm	OPT

ZION IMPLANT OFFERING

CERVICAL SCREWS

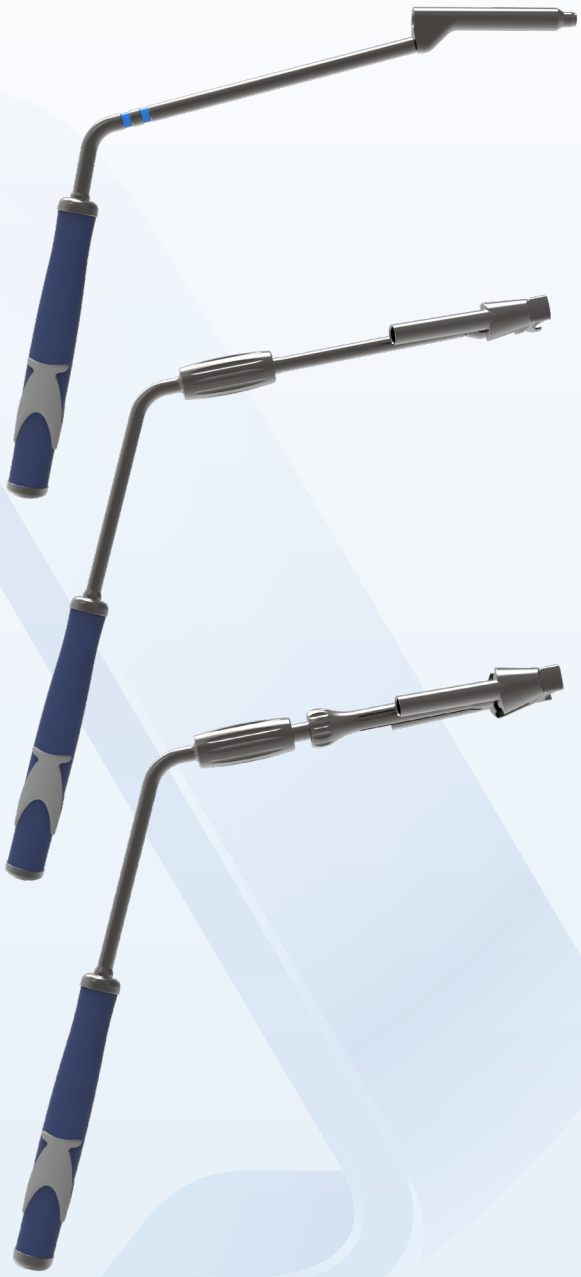
Part Number	Description	Qty
CBBA40010	ACS, Self-Tapping, Fixed 4.0mm x 10mm	6
CBBA40011	ACS, Self-Tapping, Fixed 4.0mm x 11mm	6
CBBA40012	ACS, Self-Tapping, Fixed 4.0mm x 12mm	6
CBBA40013	ACS, Self-Tapping, Fixed 4.0mm x 13mm	6
CBBA40014	ACS, Self-Tapping, Fixed 4.0mm x 14mm	6
CBBA40015	ACS, Self-Tapping, Fixed 4.0mm x 15mm	6
CBBA40016	ACS, Self-Tapping, Fixed 4.0mm x 16mm	6
CBBA40017	ACS, Self-Tapping, Fixed 4.0mm x 17mm	6
CBBA40018	ACS, Self-Tapping, Fixed 4.0mm x 18mm	6
CBBA45010	ACS, Self-Tapping, Fixed 4.5mm x 10mm	4
CBBA45012	ACS, Self-Tapping, Fixed 4.5mm x 12mm	4
CBBA45014	ACS, Self-Tapping, Fixed 4.5mm x 14mm	4
CBBA45016	ACS, Self-Tapping, Fixed 4.5mm x 16mm	4
CBBA45018	ACS, Self-Tapping, Fixed 4.5mm x 18mm	OPT
CBBB40010	ACS, Self-Tapping, Variable 4.0mm x 10mm	8
CBBB40011	ACS, Self-Tapping, Variable 4.0mm x 11mm	8
CBBB40012	ACS, Self-Tapping, Variable 4.0mm x 12mm	12
CBBB40013	ACS, Self-Tapping, Variable 4.0mm x 13mm	12
CBBB40014	ACS, Self-Tapping, Variable 4.0mm x 14mm	12
CBBB40015	ACS, Self-Tapping, Variable 4.0mm x 15mm	12
CBBB40016	ACS, Self-Tapping, Variable 4.0mm x 16mm	12
CBBB40017	ACS, Self-Tapping, Variable 4.0mm x 17mm	8
CBBB40018	ACS, Self-Tapping, Variable 4.0mm x 18mm	8
CBBB40019	ACS, Self-Tapping, Variable 4.0mm x 19mm	OPT
CBBB40020	ACS, Self-Tapping, Variable 4.0mm x 20mm	OPT
CBBB45010	ACS, Self-Tapping, Variable 4.5mm x 10mm	6
CBBB45011	ACS, Self-Tapping, Variable 4.5mm x 11mm	OPT
CBBB45012	ACS, Self-Tapping, Variable 4.5mm x 12mm	6
CBBB45013	ACS, Self-Tapping, Variable 4.5mm x 13mm	OPT
CBBB45014	ACS, Self-Tapping, Variable 4.5mm x 14mm	6
CBBB45015	ACS, Self-Tapping, Variable 4.5mm x 15mm	OPT
CBBB45016	ACS, Self-Tapping, Variable 4.5mm x 16mm	6
CBBB45017	ACS, Self-Tapping, Variable 4.5mm x 17mm	OPT
CBBB45018	ACS, Self-Tapping, Variable 4.5mm x 18mm	6
CBBB45019	ACS, Self-Tapping, Variable 4.5mm x 19mm	OPT
CBBB45020	ACS, Self-Tapping, Variable 4.5mm x 20mm	OPT
CBBB45021	ACS, Self-Tapping, Variable 4.5mm x 21mm	OPT
CBBB45022	ACS, Self-Tapping, Variable 4.5mm x 22mm	OPT
CBBB45023	ACS, Self-Tapping, Variable 4.5mm x 23mm	OPT
CBBB45024	ACS, Self-Tapping, Variable 4.5mm x 24mm	OPT

ZION INSTRUMENT OFFERING

Part Number	Description	Qty
EABEASADZ	Modular Axial Handle, AO, Spin Top	2
EDDEATAAZ	Modular Egg Handle	1
CZ0100000	Plate Bender	1
CZ0200000	Plate Holder	1
CZ0300001	Temporary Fixation Pin, Threaded	4
CZ0300002	Temporary Fixation Pin, Smooth	4
CZ0400000	Temporary Fixation Pin Driver	1
CZ0500000	Self-Centering Awl	1
CZ0600000	Awl	1
CZ0700140	Drill Guide, Variable, 4.0mm	1

ZION INSTRUMENT OFFERING

Part Number	Description	Qty
CZ0700240	Drill Guide, Fixed, 4.0mm	1
CZ0800010	DTS Guide, Single	1 / OPT
CZ0800030	DTS Guide, Double, Variable	1 / OPT



ZION INSTRUMENT OFFERING

Part Number	Description	Qty
CZ0940010	Drill 4.0mm x 10mm	2
CZ0940012	Drill 4.0mm x 12mm	2
CZ0940014	Drill 4.0mm x 14mm	OPT
CZ0940016	Drill 4.0mm x 16mm	OPT
CZ0940018	Drill 4.0mm x 18mm	OPT
CZ1000040	Tap, 4.0mm	1
CZ1100000	Screwdriver, T13	2
CZ1200000	Lockdriver, T9	2
CZ1300000	Screw Remover, T13	1
CZ9900000	Sterilization Container	1

ZION
ANTERIOR CERVICAL FIXATION SYSTEM

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

1.0 IMPORTANT NOTE TO OPERATING SURGEON: ZION Anterior Cervical Fixation System (ACFS) spinal implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed. Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves. The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

2.0 DESCRIPTION: The ZION ACFS is a screw and plate fixation system designed to provide fixation during the fusion process. The system is composed of pre-contoured plates and bone screws. The system is supported by a comprehensive set of instruments to install the implants within the system. All implant components are manufactured from the materials listed in the table below.

Material	Conforming Standard
Ti-6Al-4V ELI	ASTM F136
Nitinol	ASTM F2063

3.0 CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician. All implants are intended for single use only. The ZION ACFS must not be reused under any circumstances. These instructions for use are designed to assist in use of the ZION ACFS and are not a reference for surgical techniques.

4.0 INDICATIONS: The ZION Anterior Cervical Fixation System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) trauma (including fractures), 4) tumors, 5) deformity (defined as kyphosis, lordosis, or scoliosis), 6) pseudarthrosis 7) failed previous fusions, and/or 8) spinal stenosis.

5.0 CONTRAINDICATIONS: Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection, or infection localized to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

6.0 POSSIBLE ADVERSE EVENTS

6.1 Bending or fracture of implant.
6.2 Loosening of the implant.
6.3 Metal sensitivity, or allergic reaction to a foreign body.
6.4 Infection, early or late.
6.5 Nonunion, delayed union.
6.6 Decrease in bone density due to stress shielding.
6.7 Pain, discomfort, or abnormal sensations due to the presence of the device.
6.8 Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
6.9 Bursitis.
6.10 Paralysis.
6.11 Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
6.12 Death.
6.13 Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malposition implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
6.14 Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
6.15 Damage to lymphatic vessels and/or lymphatic fluid exudation.
6.16 Spinal cord impingement or damage.
6.17 Fracture of bony structures.
6.18 Degenerative changes or instability in segments adjacent to fused vertebral levels.

7.0 WARNINGS AND PRECAUTIONS: The following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

7.1 **Warnings**

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

7.1.2 The safety and effectiveness of anterior cervical fixation systems have been established only for spinal conditions with significant mechanical instability requiring fusion with instrumentation. These conditions are significant mechanical instability of the cervical spine, objective evidence of neurologic impairment, 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, and/or failed previous fusions. The safety and effectiveness of these devices for any other conditions are unknown.

7.1.3 Correct Selection of The Implant Is Extremely Important: The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing

7.1.4 Implants Can Break When Subjected to The Increased Loading Associated with Delayed Union or Nonunion: Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure

7.1.5 PATIENT SELECTION: In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

7.1.5.1 The patient's weight: An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

7.1.5.2 The patient's occupation or activity: If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

7.1.5.3 A condition of senility, mental illness, alcoholism, or drug abuse: These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

7.1.5.4 Foreign body sensitivity: The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

7.1.5.5 Smoking: Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

The ZION ACFS has not been evaluated for safety and compatibility in the MR environment. The ZION ACFS has not been tested for heating, migration, or image artifact in the MR environment. The safety of ZION ACFS in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

7.2 **Precautions**

7.2.1 The implantation of anterior cervical fixation systems should be performed only by experienced spinal surgeons with specific training in the use of this anterior cervical fixation system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device. Refer to the individual system surgical technique manuals for additional important information. A surgical technique can be obtained from the local representative.

7.2.2 After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

7.2.3 These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

7.2.4 Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

7.2.5 Surgical Implants Must Never Be Reused: An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

INSTRUCTIONS FOR USE

7.2.6 Correct Handling Of The Implant Is Extremely Important: Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

7.2.7 Considerations For Removal Of The Implant After Healing: If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

7.2.8 Adequately Instruct The Patient: Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

8.0 PREOPERATIVE

8.1 Only patients that meet the criteria described in the indications should be selected.

8.2 Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

8.3 Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

8.4 The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

8.5 The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.

8.6 Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The ZION ACFS components are not to be combined with the components from another manufacturer

8.7 All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

8.8 All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.

8.9 A surgical technique manual may be obtained from ASTURA MEDICAL from any of its representatives.

9.0 INTRAOPERATIVE

9.1 Any instruction manuals should be carefully followed.

9.2 Extreme caution should be used around the spinal cord and nerve roots at all times. Damage to nerves will cause loss of neurological functions.

9.3 The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.

9.4 Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.

9.5 Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.

9.6 Before closing the soft tissues, all of the devices should be securely seated.

9.7 Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

10.0 POSTOPERATIVE:

10.1 Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

10.2 Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

10.3 To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

10.4 The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

10.5 If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

10.6 Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.

10.7 Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved ZION ACFS components should ever be reused under any circumstances.

11.0 PACKAGING: Packages for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to ASTURA MEDICAL.

12.0 CLEANING AND DECONTAMINATION: Instruments are supplied clean and NOT STERILE, and must be sterilized prior to use.

13.0 CLEANING: All instruments must first be cleaned before sterilization and introduction into a sterile surgical field. Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. An enzymatic cleaner bath (soak) or a solution of water and neutral pH detergent are effective in removing organic material from instruments. Use distilled water if possible. Instruments should be fully submerged for at least ten (10) minutes. Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Confirm that all cannulated and modular instruments are fully disassembled. Ensure that all cannulas are flushed until cleaning solution runs clear and that all instruments are completely immersed. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Once instruments are cleaned and disassembled, place instruments in an ultrasonic cleaner with warm enzymatic detergent for a minimum of fifteen (15) minutes. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Rinse instruments under running water for at least one (1) minute to remove solutions. Instruments should never be exposed to cleaning agents containing any peroxides. Users should periodically inspect instruments for corrosion, discoloration, etc., and properly dispose of instruments that show signs of wear and tear. Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

14.0 STERILIZATION: Moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2006 according to the following validated cycle parameters for both implants and instruments:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270°F(132°C)	4 minutes	30 minutes

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods. No claims of pyrogenicity are made. Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to ASTURA MEDICAL.It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

15.0 PRODUCT COMPLAINTS: Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify ASTURA MEDICAL or its representative. Further, if any of the implanted ZION ACFS component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately. If any ZION ACFS product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or ASTURA MEDICAL must be notified immediately by telephone, fax or in writing. For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help ASTURA MEDICAL understand the cause of the complaint. If further information is needed or required, please contact using the company information listed below.

16.0 COMPANY INFORMATION

Astura Medical
4949 W Royal Lane
Irving, TX 75063
Phone: (469) 501-5530
Email: info@asturamedical.com


ASTURA
MEDICAL