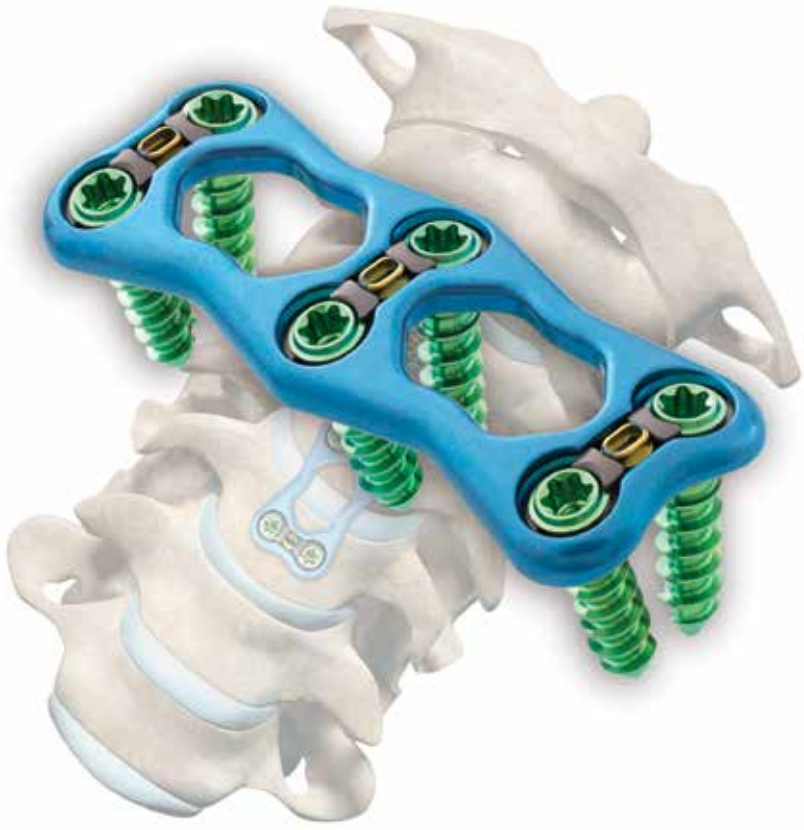
stryker

Tempus®

Anterior Cervical Plate System



Surgical technique

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Introduction

The Tempus Anterior Cervical Plate System offers a unique secondary locking mechanism, large graft windows, fixed and variable screws and simplified instrumentation.

The plates feature a blocking mechanism that covers the screw head automatically when the screw is fully seated within the correct range of angulation.

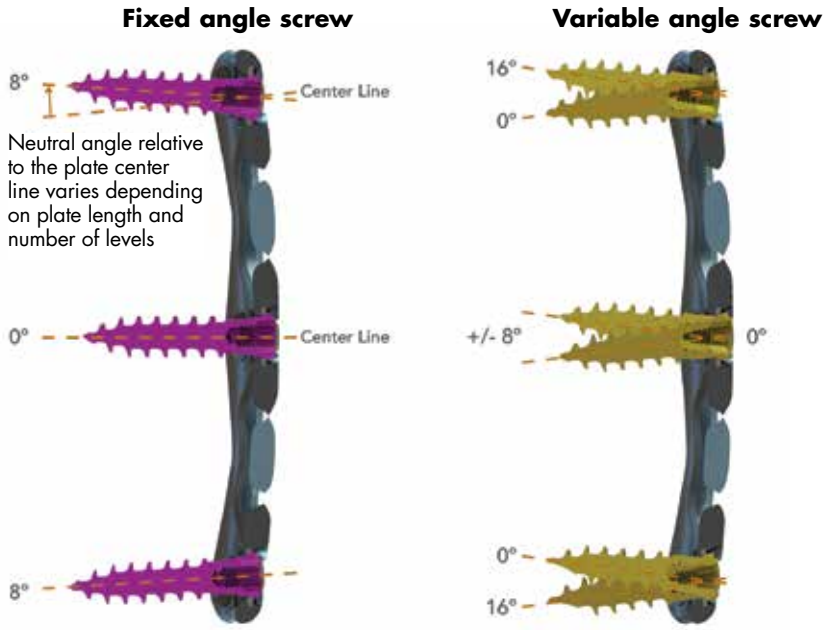
Additionally, the system offers a simple and robust one step locking mechanism at each level with visual lock verification.

The system features both fixed and variable angle screws to accommodate both rigid and semi-constrained bone screw fixation philosophies. Variable angle screws offer a 16° range of motion, and fixed screws are positioned at a fixed trajectory of 8° cephalad/ caudal. The neutral angle of medial convergence is 7° for the fixed screws. Variable screws have a range of +/- 8° from the neutral angle of medial convergence. Both screws are designed with a multi-lobe head feature to facilitate engagement with the instrumentation and to reduce the chance of stripping.

Instrument options further enhance surgical technique versatility by matching surgeon preference regarding approach and screw pathway preparation.

The Tempus plate is made of titanium alloy (TI-6AL-4V) with a titanium locking mechanism and is 2.2mm thick and 17.5mm wide.

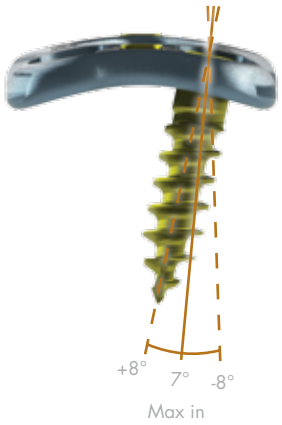
The Tempus Anterior Cervical Plate System offers plates that are pre-machined with lordosis. The large graft-viewing windows allow for visualization of the endplates to aid in plate and graft positioning.



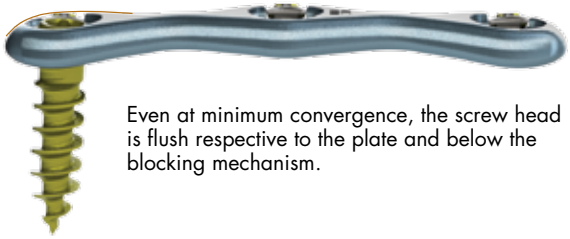
These images show the screw properly seated at maximum angles in and out.

Max angle horizontal - in

Front view



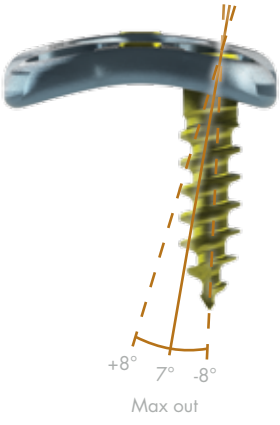
Side view



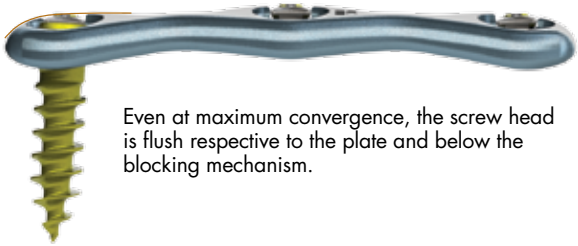
Even at minimum convergence, the screw head is flush respective to the plate and below the blocking mechanism.

Max angle horizontal - out

Front view



Side view



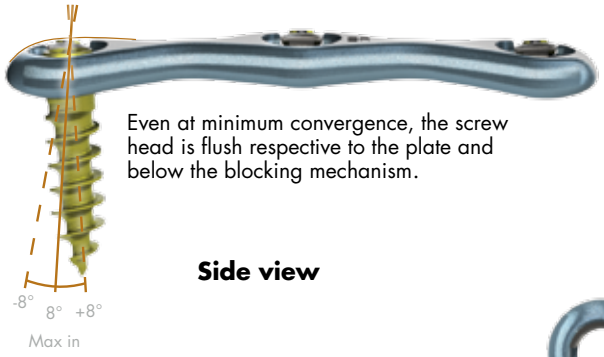
Even at maximum convergence, the screw head is flush respective to the plate and below the blocking mechanism.

Cross section view

Cross section view

These images show the screw properly seated at maximum angles in and out.

Max angle vertical - in

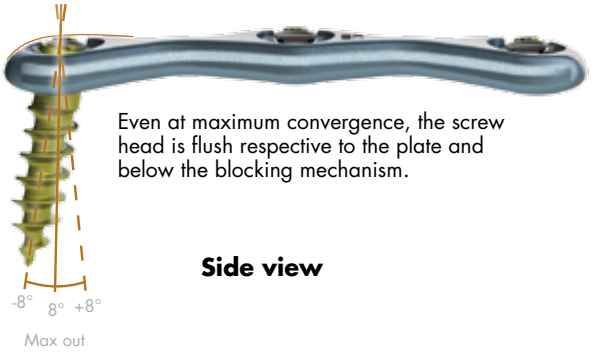


Even at minimum convergence, the screw head is flush respective to the plate and below the blocking mechanism.

Side view

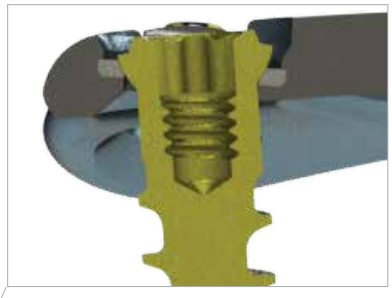
Cross section line

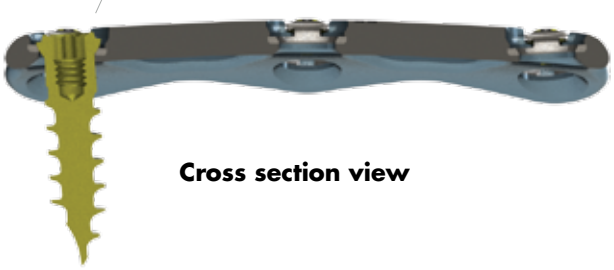
Max angle vertical - out



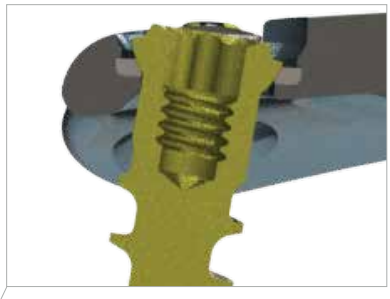
Even at maximum convergence, the screw head is flush respective to the plate and below the blocking mechanism.

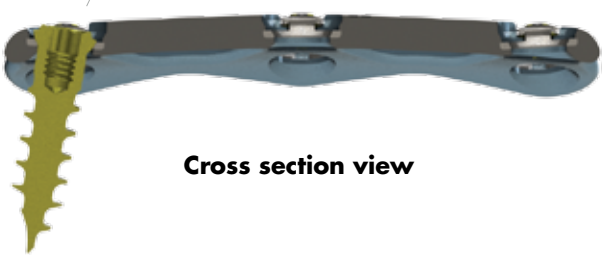
Side view





Cross section view





Cross section view

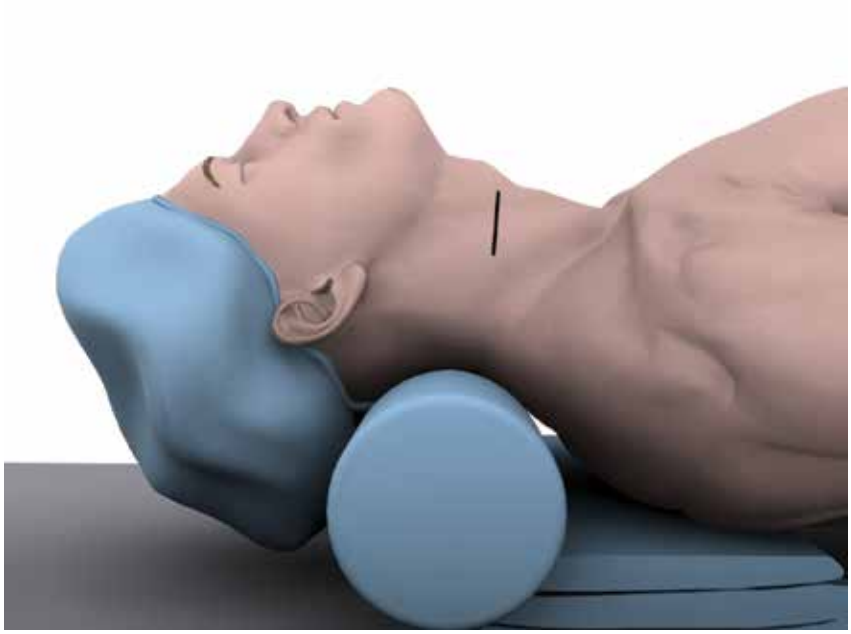
Surgical technique

Preoperative planning

Preoperative planning is essential to reduce the risk of intraoperative complications due to unrecognized anatomic aberrations. Measuring the vertebral body dimension in both A/P and lateral planes is recommended to determine the appropriate interbody device, cervical plate and bone screw sizes.

Patient positioning and exposure

Patient is placed in a supine position with the head turned slightly away from the side of the approach. For one- or two-level procedures, a transverse incision parallel to the skin creases of the neck is recommended. For longer level procedures, one can choose to do a transverse or oblique incision placed along the anterior border of the sternocleidomastoid. The left side is preferred, as the more constant course of the recurrent laryngeal nerve on this side potentially minimizes the risk of its injury. After blunt dissection through the various tissue layers, the anterior cervical spine is gently exposed.



The implantation of the anterior cervical plate follows a discectomy or a corpectomy, including an appropriate interbody/bone graft insertion.

Care should be taken to remove any bony anatomy or osteophytes which would inhibit the Tempus plate from sitting flat against the bone.

Implant selection and preparation

The sizing of Tempus plates is measured from the center of the cephalad hole to the center of the caudal hole. Using the **Plate Sizer** (Fig. 1), measure the distance between the center points of the appropriate vertebrae and select the corresponding plate. In cases in which the measured distance falls between two sizes, it is usually recommended that the smaller size be used. A plate that is too long may interfere with the adjacent disc space.

Regardless of the plate size selected, the screws must be inserted with the correct amount of screw angulation.

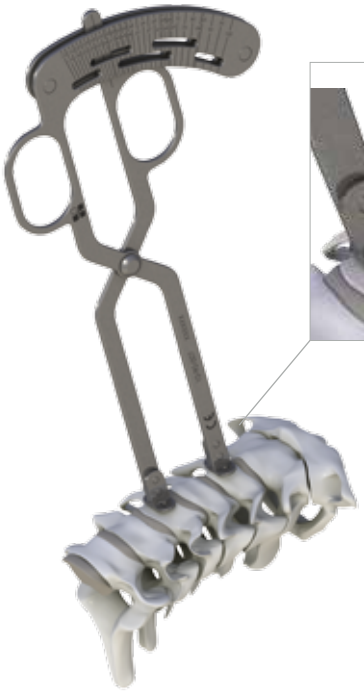


Figure 1
10-90-007 Plate Sizer

Figure 2

Note: Plate length is measured from most superior hole center to most inferior hole center.

A **Plate Holder** (Fig. 3) is available to hold the plate next to the vertebral column to confirm size selection.

Fluoroscopy can be used to confirm plate position.

Figure 3
10-90-006 Plate Holder

The Tempus plate is precontoured. Should additional lordosis be required, the plate can be contoured utilizing the **Plate Bender** (Fig. 4).

Note: Plate Bender does not remove lordosis.

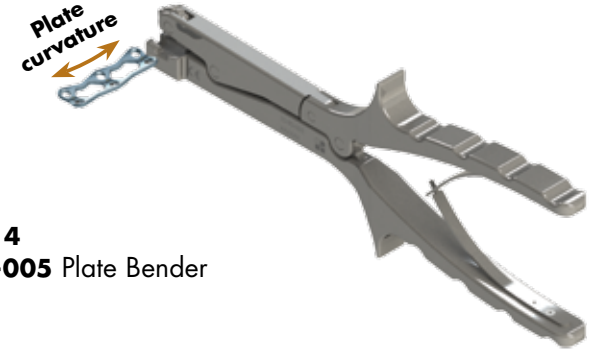


Figure 4
10-90-005 Plate Bender

Insert the Tempus plate into the Plate Bender as shown. Squeeze the handles of the Plate Bender together to contour the plate (Fig. 5).

Caution: Do not place the Plate Bender over the blocking and locking mechanisms as damage can occur and affect its function.

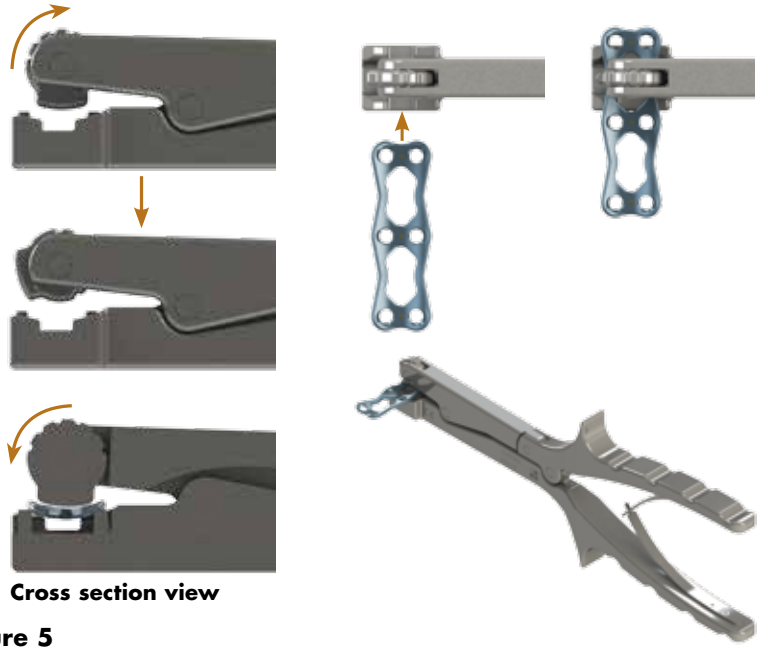


Figure 5

Contouring along the graft window, starting from outer edge working inward, helps ensure an even contour of the plate (Fig. 6).

Note: When contouring the plate, care should be taken not to scratch, notch or dent the surface of the plate or the blocking or locking mechanisms as the implant strength may be compromised. Plates 26mm or shorter should not be contoured.

Caution: Do not place the Plate Bender over the blocking mechanism as damage can occur and affect its function.

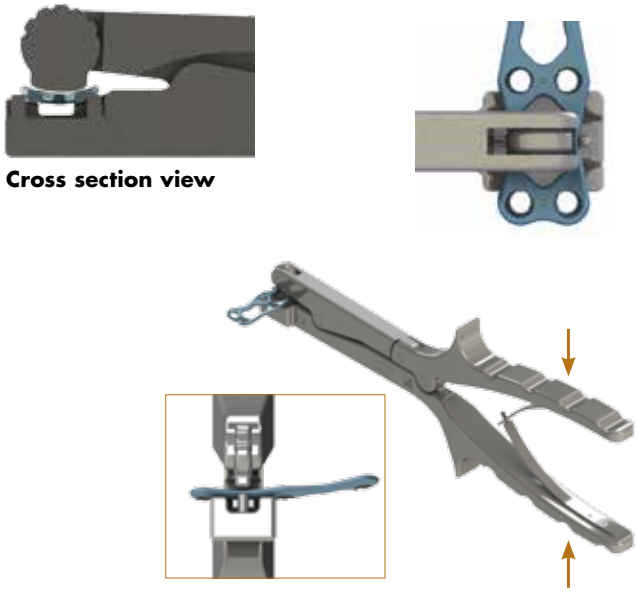
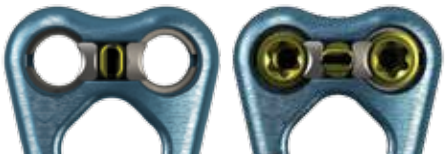


Figure 6

Note: Prior to placing the plate on the spine, ensure the locking mechanism is unlocked.



Unlocked **Locked**

Temporary Fixation Pins are available to hold the plate during screw hole preparation (Fig. 7). Ensure the plate is properly aligned with respect to the endplates. The Temporary Fixation Pin has a diameter of 2.1mm and penetrates 7.6mm in bone when fully inserted. Attach the **Temporary Pin Inserter** to a handle. A non-ratcheting handle is optimized for inserting Temporary Fixation Pins, but the **Ratch Axial Handle with A/O Connector** can also be used. Load the Temporary Fixation Pin onto the Temporary Fixation Pin Inserter handle assembly by rotating the sleeve on the Temporary Fixation Pin Inserter (Fig. 8). Ensure the plate is properly aligned with respect to the endplates, then position the pin in the center of the screw hole. Apply slight downward pressure while threading the pin into the screw hole. Advance the Temporary Fixation Pin until it is fully seated in the plate (Fig. 9).

10-90-017
Non-Ratch Palm Style Handle

10-90-018
Ratch Axial Handle with A/O Connector

Placement of two pins diagonally from each other is recommended for stabilization of the plate on the anterior vertebral column. Remove the Temporary Fixation Pins after the plate is sufficiently stabilized with screws.

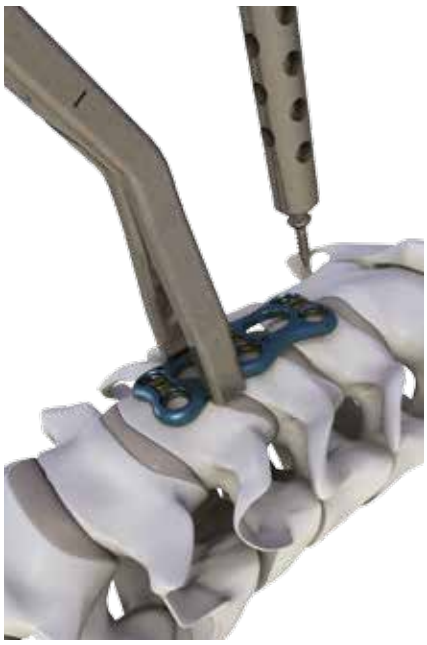


Figure 7

10-90-003
Temporary Fixation Pin

10-90-004
Temporary Fixation Pin Inserter

Figure 8

Figure 9

Screw hole preparation

There are a variety of techniques that can be used to create screw holes.

Awl technique

The **Fixed Angle Drill Guide** and **Variable Angle Drill Guide** are color coded to match the type screw to be used (Fig. 10, 11).

Insert the drill guide by pushing it into the desired screw hole of the plate (Fig. 12, 13).

Note: This technique is intended for use with self-drilling screws.

Figure 10. 10-90-008
Fixed Angle Drill Guide

Figure 11. 10-90-010
Variable Angle Drill Guide

Figure 12

Figure 13

Attach a handle to the **Awl For Use with Drill Guide** and place the assembly through the Drill Guide. Lightly tap awl handle until tip is through the cortical surface of the vertebral body to create a pilot hole (Fig. 14, 15).

Remove the awl by pulling straight up on the assembly.

10-90-013
8mm Awl For Use with Drill Guide

Note: Excessively converging hole patterns prohibit proper seating of the bone screws.

Figure 14

Figure 15

Drill technique

Select the appropriate length **Drill Bit** and attach it to a handle. Insert the Drill Bit handle assembly into the Drill Guide and rotate the handle in a clockwise direction to create the pilot hole for the screw. The depth stop will limit the drilling depth by contacting the Drill Guide (Fig. 16).

Drill Bits

10-90-015-010	Drill Bits 10mm
10-90-015-012	Drill Bits 12mm
10-90-015-014	Drill Bits 14mm
10-90-015-016	Drill Bits 16mm
10-90-015-018	Drill Bits 18mm

Once the hole has been created, back out the Drill Bit and remove the Drill Guide by gently rocking and pulling up to disengage it from the plate.

The **Stand Alone Tap** can be used once a hole has been created with an awl or drill bit.

10-90-016
Stand Alone Tap

Figure 16

Screw insertion

Prior to inserting the screws, ensure each locking mechanism is unlocked.

Attach the **Screwdriver** to a handle, then load the appropriate length screw. Screws should be inserted to the point where they are just above the blocking mechanism. Inserting the screws sequentially at opposite corners of the plate – and working toward the center of the plate – helps keep the plate flat against the bone.

Once all bone screws have been inserted, advance the screws until the head of the each screw is fully seated into the plate and is below the blocking mechanism (Fig. 17, 18).

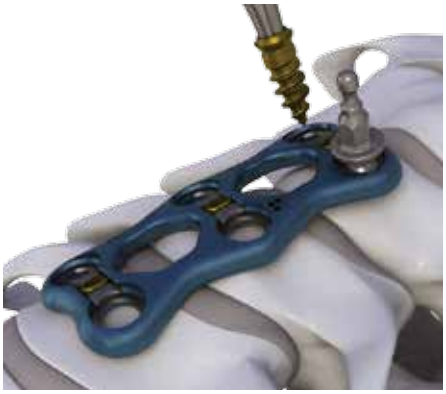


Figure 17

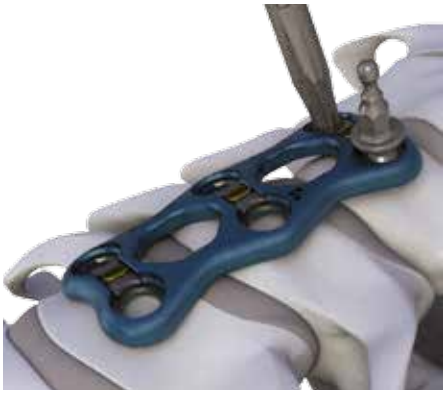


Figure 18

10-90-001
Screwdriver

The **Single Barrel Drill Tap Screw Guide** and **Double Barrel Drill Tap Screw Guide** allow awling with the 8mm Awl For Use with Drill Guide, drilling, tapping with the **All in One Tap** and variable screw insertion through the barrels of the guides as shown (Fig 19).

10-90-012
Single Barrel Drill Tap Screw Guide

10-90-009
Double Barrel Drill Tap Screw Guide

10-90-011
All in One Tap

Single Barrel Drill Tap Screw Guide

Double Barrel Drill Tap Screw Guide

Awl with Double Barrel Drill Tap Screw Guide

Drill with Drill Tap Screw Guide

Tap with Drill Tap Screw Guide

Screw with Drill Tap Screw Guide

Figure 19

Both instruments attach to the plate loosely and have barrels that move cephalad and caudal within the acceptable range of angulation. The angulation of the barrels can be locked in place by turning the knob on the shaft of the guide clockwise.

Note: The Drill Tap Screw Guides are optimized for use on the middle holes of a plate.

Locking the screws

Ensure that both screws are fully seated and underneath the blocking mechanism. Rotate the locking mechanism to the secured position using the **Flat Head Plate Locking Driver** or **Plate Locking Driver**. Verify that the line on the locking mechanism is in the horizontal position (Fig. 20, 21, 22).

10-90-020
Flat Head Plate Locking Driver

10-90-025
Plate Locking Driver

Note: There should be minimal resistance when rotating the locking mechanism.

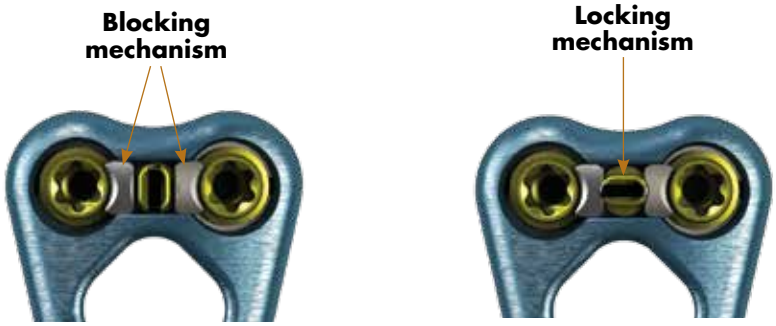


Figure 20

Top view

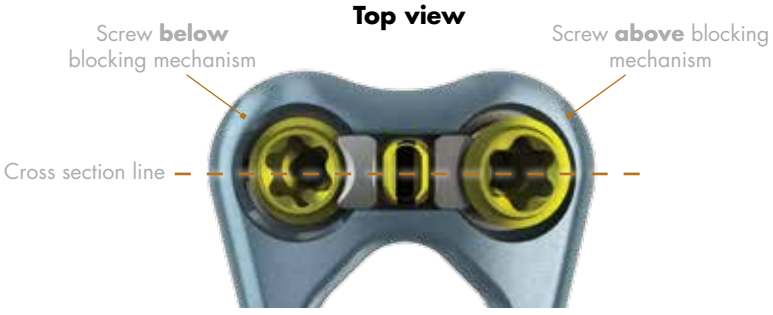
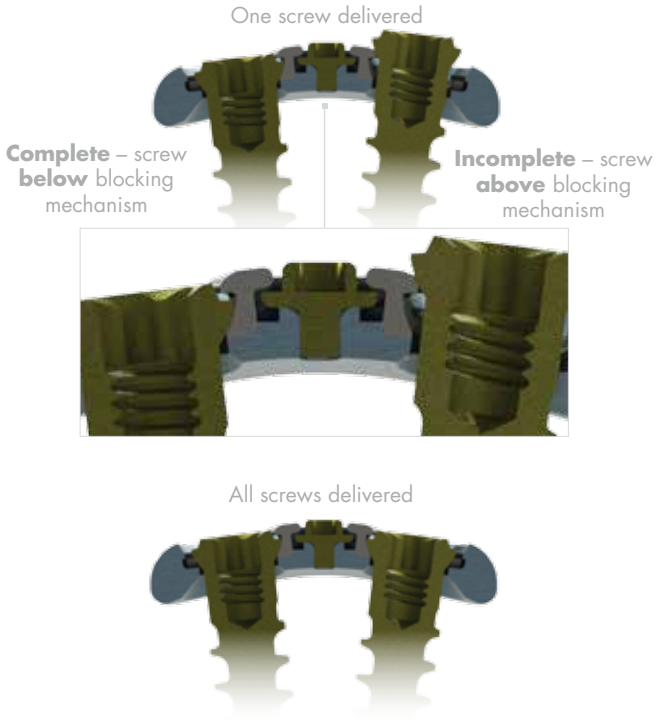


Figure 21

Top view

Figure 22

Cross section view

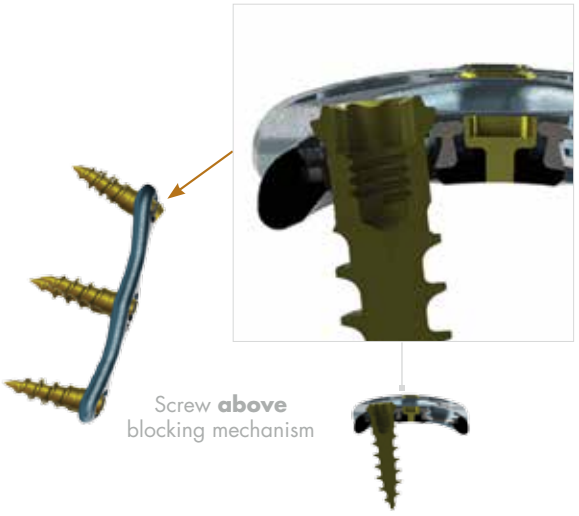


Final position

Check the final position of the plate and screws both visually and radiographically. Ensure that all screws are flush or recessed relative to the anterior surface of the plate, **covered by the blocking mechanism** and that the locking mechanism is in the horizontal position (Fig. 23).

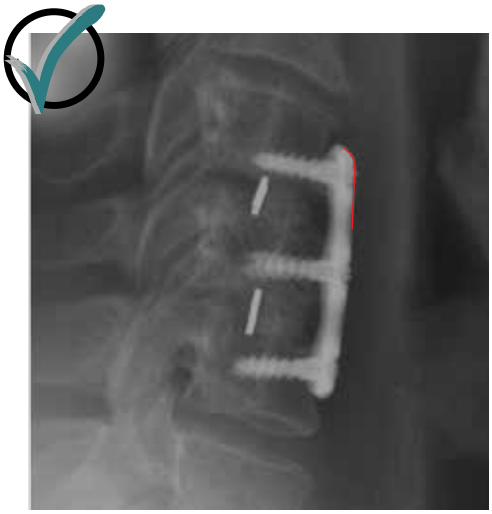
Figure 23

Incorrect: Screw should NOT be above blocking mechanism.



Cross section view

Correct: Screws should be flush or recessed relative to the anterior surface of the plate.



Screw removal

Return the locking mechanism to the unlocked position.

Insert the tip of the **Revision Driver** into the head of the desired screw (Fig. 24).

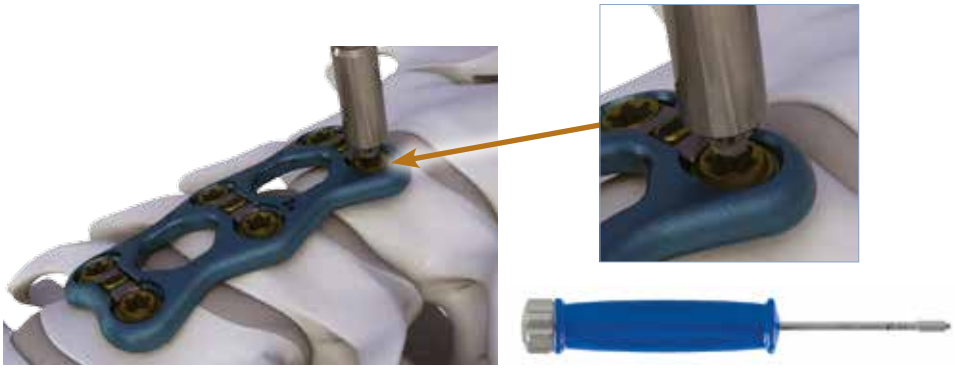


Figure 24

10-90-019
Revision Driver

Ensure the tip is fully seated within the screw head. (Fig. 25) Thread the inner shaft into the screw's internal threads. Tighten finger-tight to capture the screw. Ensure the distal tip of the instrument is fully seated. Use the knob at the end of the handle to engage screw by rotating the silver knob in a clockwise direction (Fig. 26 and 29).

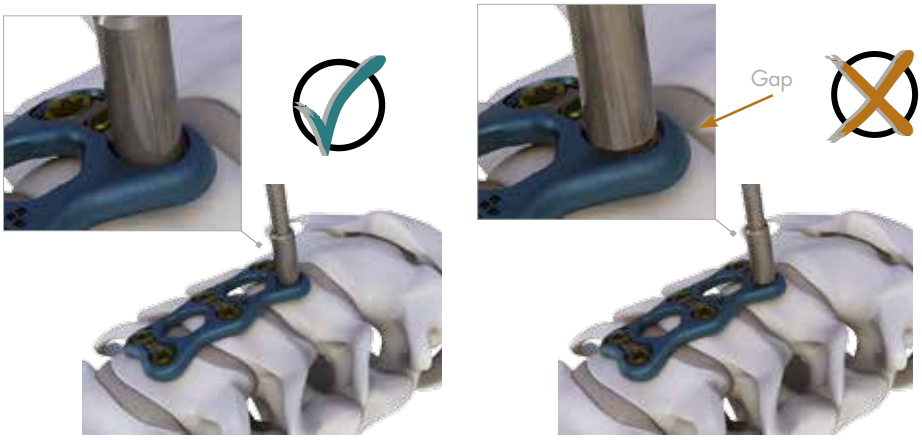


Figure 25

Figure 26

Note: The tip of the Revision Driver is designed to move the blocking mechanism to clear a pathway for screw removal.

Rotate the Revision Driver counterclockwise to disengage the blocking mechanism to allow for screw extraction (Fig. 27 and 30). Continue turning the removal tool counterclockwise until the screw is removed from the plate (Fig. 28).

Figure 27

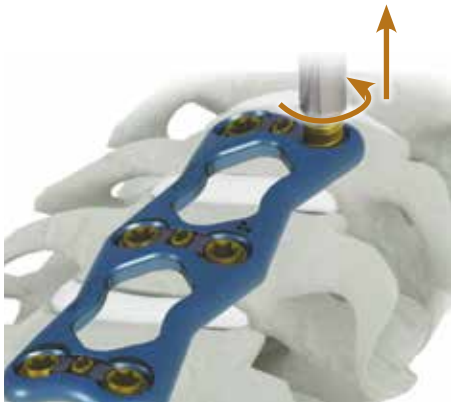


Figure 28

Screw removal

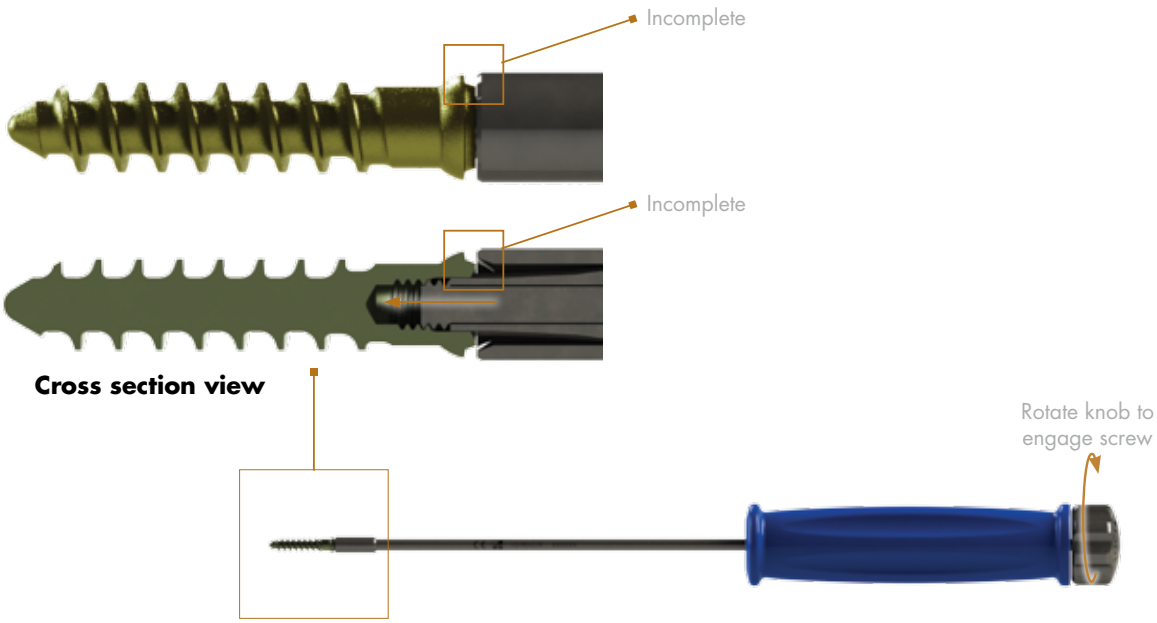


Figure 29

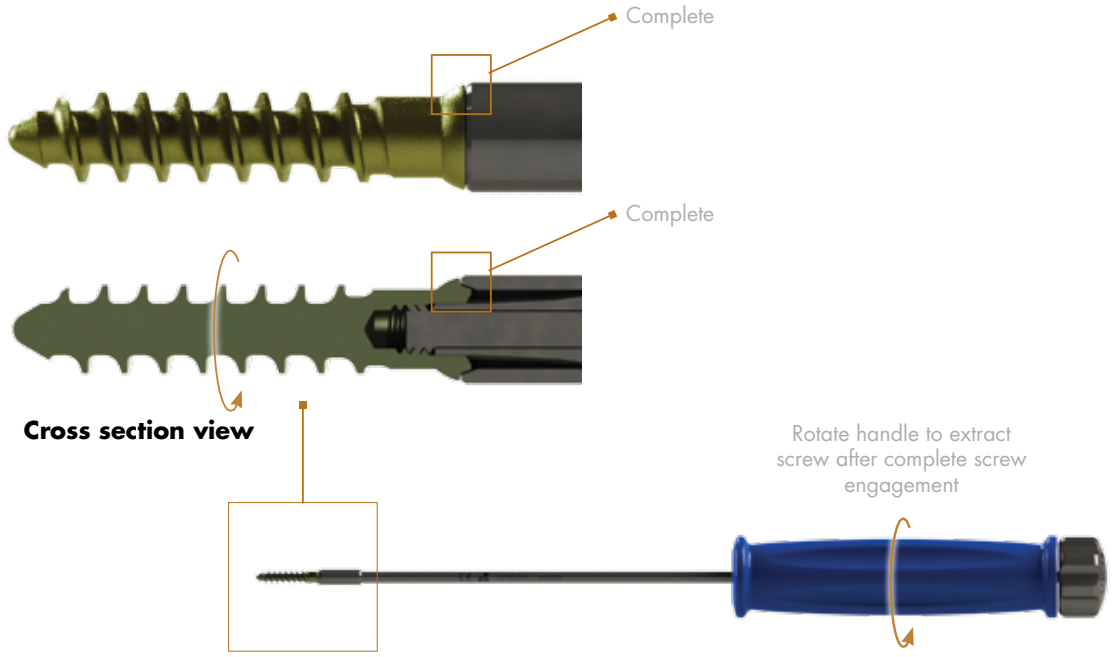


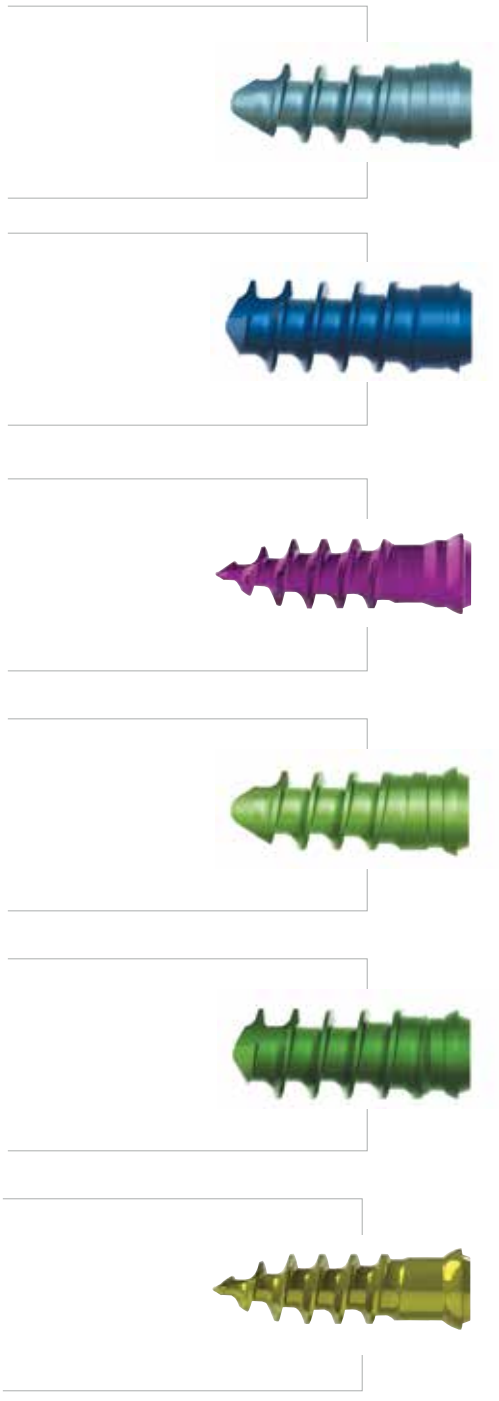
Figure 30

Plates

Reference number	Description
10-01-012	1 Level Plate 12mm
10-01-014	1 Level Plate 14mm
10-01-016	1 Level Plate 16mm
10-01-018	1 Level Plate 18mm
10-01-020	1 Level Plate 20mm
10-01-022	1 Level Plate 22mm
10-01-024	1 Level Plate 24mm
10-01-026	1 Level Plate 26mm
10-02-024	2 Level Plate 24mm
10-02-026	2 Level Plate 26mm
10-02-028	2 Level Plate 28mm
10-02-030	2 Level Plate 30mm
10-02-032	2 Level Plate 32mm
10-02-034	2 Level Plate 34mm
10-02-037	2 Level Plate 37mm
10-02-040	2 Level Plate 40mm
10-02-043	2 Level Plate 43mm
10-02-046	2 Level Plate 46mm
10-03-039	3 Level Plate 39mm
10-03-042	3 Level Plate 42mm
10-03-045	3 Level Plate 45mm
10-03-048	3 Level Plate 48mm
10-03-051	3 Level Plate 51mm
10-03-054	3 Level Plate 54mm
10-03-057	3 Level Plate 57mm
10-03-060	3 Level Plate 60mm
10-03-063	3 Level Plate 63mm
10-03-066	3 Level Plate 66mm
10-03-069	3 Level Plate 69mm
10-04-060	4 Level Plate 60mm
10-04-064	4 Level Plate 64mm
10-04-068	4 Level Plate 68mm
10-04-072	4 Level Plate 72mm
10-04-076	4 Level Plate 76mm
10-04-080	4 Level Plate 80mm
10-04-084	4 Level Plate 84mm
10-05-085	5 Level Plate 85mm
10-05-090	5 Level Plate 90mm
10-05-095	5 Level Plate 95mm
10-05-100	5 Level Plate 100mm

Screws

Reference number	Description
10-11-010	Fixed - Ø4.0mm Self Tapping 10mm
10-11-012	Fixed - Ø4.0mm Self Tapping 12mm
10-11-014	Fixed - Ø4.0mm Self Tapping 14mm
10-11-016	Fixed - Ø4.0mm Self Tapping 16mm
10-11-018	Fixed - Ø4.0mm Self Tapping 18mm
10-13-010	Fixed - Ø4.5mm Self Tapping 10mm
10-13-012	Fixed - Ø4.5mm Self Tapping 12mm
10-13-014	Fixed - Ø4.5mm Self Tapping 14mm
10-13-016	Fixed - Ø4.5mm Self Tapping 16mm
10-13-018	Fixed - Ø4.5mm Self Tapping 18mm
10-17-010	Fixed - Ø4.0mm Self Drilling 10mm
10-17-012	Fixed - Ø4.0mm Self Drilling 12mm
10-17-014	Fixed - Ø4.0mm Self Drilling 14mm
10-17-016	Fixed - Ø4.0mm Self Drilling 16mm
10-17-018	Fixed - Ø4.0mm Self Drilling 18mm
10-12-010	Variable - Ø4.0mm Self Tapping 10mm
10-12-012	Variable - Ø4.0mm Self Tapping 12mm
10-12-014	Variable - Ø4.0mm Self Tapping 14mm
10-12-016	Variable - Ø4.0mm Self Tapping 16mm
10-12-018	Variable - Ø4.0mm Self Tapping 18mm
10-14-010	Variable - Ø4.5mm Self Tapping 10mm
10-14-012	Variable - Ø4.5mm Self Tapping 12mm
10-14-014	Variable - Ø4.5mm Self Tapping 14mm
10-14-016	Variable - Ø4.5mm Self Tapping 16mm
10-14-018	Variable - Ø4.5mm Self Tapping 18mm
10-18-010	Variable - Ø4.0mm Self Drilling 10mm
10-18-012	Variable - Ø4.0mm Self Drilling 12mm
10-18-014	Variable - Ø4.0mm Self Drilling 14mm
10-18-016	Variable - Ø4.0mm Self Drilling 16mm
10-18-018	Variable - Ø4.0mm Self Drilling 18mm



Instruments

Reference number	Description
10-90-000	Tempus Cervical Plate System Tray
10-90-000-01	1 Level Plate Caddie
10-90-000-02	2 Level Plate Caddie
10-90-000-03	3 Level Plate Caddie
10-90-000-04	4 Level Plate Caddie
10-90-000-05	5 Level Plate Caddie
10-90-000-06	Tempus Screw Caddie 1
10-90-000-07	Tempus Screw Caddie 2
10-90-001	Screwdriver
10-90-003	Temporary Fixation Pin
10-90-004	Temporary Fixation Pin Inserter
10-90-005	Plate Bender
10-90-006	Plate Holder
10-90-007	Plate Sizer
10-90-008	Fixed Angle Drill Guide
10-90-009	Double Barrel Drill Tap Screw Guide
10-90-010	Variable Angle Drill Guide
10-90-011	All in One Tap









Reference number	Description	
10-90-012	Single Barrel Drill Tap Screw Guide	
10-90-013	8mm Awl for Use with Drill Guide	
10-90-015-010 10-90-015-012 10-90-015-014 10-90-015-016 10-90-015-018	Drill Bits 10mm Drill Bits 12mm Drill Bits 14mm Drill Bits 16mm Drill Bits 18mm	
10-90-016	Stand Alone Tap	
10-90-017	Non-Ratch Palm Style Handle	
10-90-018	Ratch Axial Handle with A/O Connector	
10-90-019	Revision Driver	
10-90-020	Flat Head Plate Locking Driver	
10-90-025	Plate Locking Driver	

Important product information tor Tempus

Non-sterile product

Description

The Tempus Cervical Plate System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The Tempus Plates include locking pins that cover the heads of the bone screws to reduce the potential for screw back-out. The locking pins come preassembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The Tempus Cervical Plate System implant components are made from titanium alloy such as described by ASTM F136. This material is not compatible with other metal alloys. Do not use any of the Tempus Cervical Plate System components with the components from any other system or manufacturer. Neurostructures, Inc. expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Indications

The Tempus Cervical Plate System is intended for anterior cervical fixation (C2-T1) 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, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Warning

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

Contraindications

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the indications.
14. Any patient unwilling to cooperate with the post operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

Potential adverse events

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis Tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
14. Non-union (or pseud-arthrosis). Delayed union. Mal union.
15. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
16. Bone loss or decrease in bone density, possibly caused by stress shielding.
17. Graft donor site complications including pain, fracture, or wound healing problems.
18. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.

19 Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.

20. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
21. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
22. Change in mental status.
23. Death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings and precautions
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The Tempus Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Tempus Cervical Plate System is utilized. Use of the product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone.

In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the Tempus Cervical Plate System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

Magnetic resonance environments
The Tempus Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The Tempus Cervical Plate System has not been tested for heating or migration in the MR environment.

Physician note
Although 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.

Caution
FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS:

Implant selection
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
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.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. Adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. 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 Tempus Cervical Plate System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative
1. Any available instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

7. Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Lock the anti-migration caps over the heads of the bone screws. Failure to do so may result in screw loosening.

Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

Postoperative

The physician's postoperative directions and warning to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, 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.
2. 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 other type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
3. 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.
4. If a non-union develops or if the components loosen, bend, 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 bending, loosening, or breakage of the device(s). It is important that the 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 insure cooperation until bony union is confirmed.
5. The Tempus Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position possibly 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. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. 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 removal. Implant removal should be followed by adequate postoperative management to avoid fracture.
6. 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 Tempus Cervical Plate System components should ever be reused under any circumstances.

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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Manufactured by:
Neurostructures, Inc.
16 Technology Dr. Suite 165
Irvine, CA 92618
Phone: 800 352 6103

Distributed in the USA by:
STRYKER Spine
2 Pearl Court
Allendale, New Jersey 07401
Phone: 201 749 8000