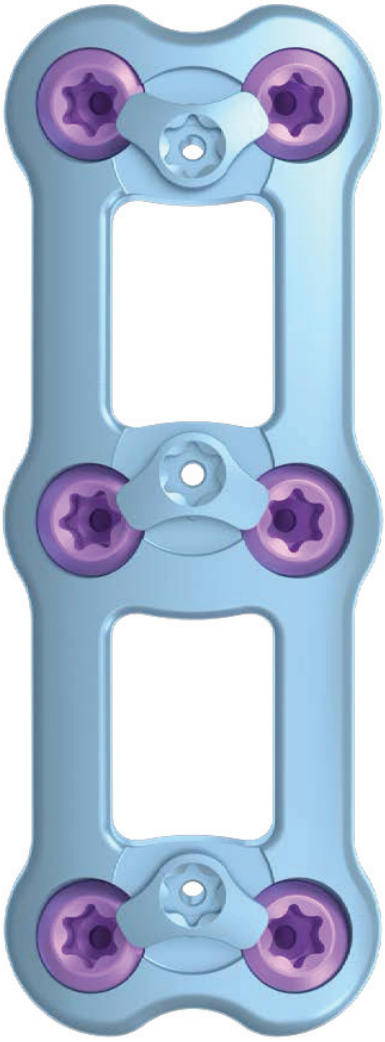
Defender®

Anterior Cervical Plate

SURGICAL TECHNIQUE



SpineWave

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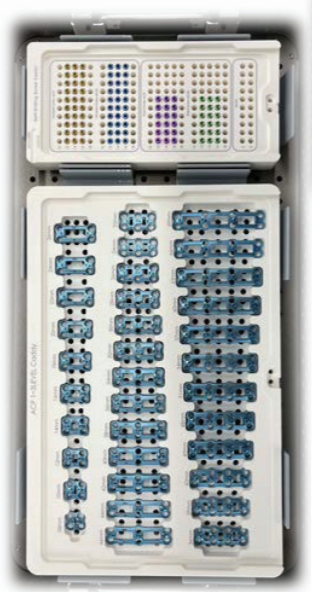
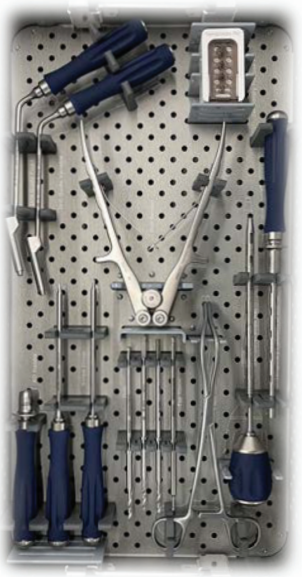
DEFENDER® ACP ORDERING GUIDE

Needed for Every Case

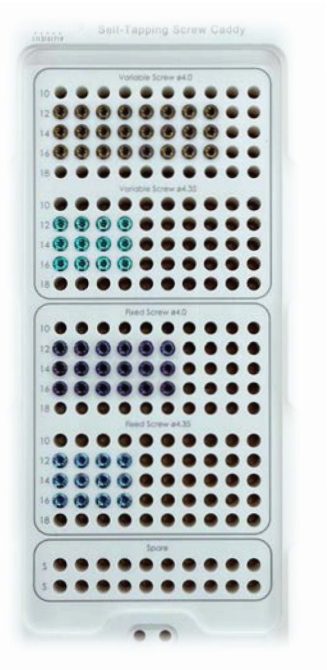
Catalog Number	Set
15-5100	Defender® Anterior Cervical Plate System

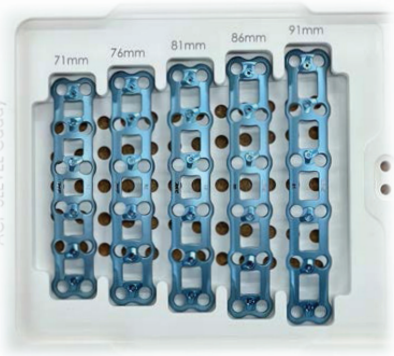




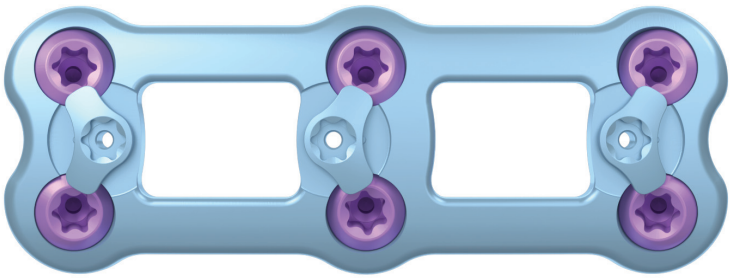
Optional Caddies

Catalog Number	Set
15-5200	Self Tapping Screw Caddy (Fixed/Variable)
15-5400	Defender® ACP 4 Level Plate Caddy
15-5500	Defender® ACP 5 Level Plate Caddy

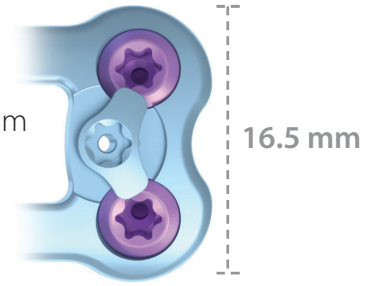


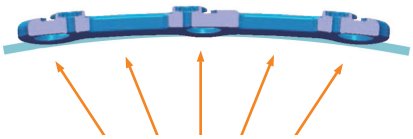


IMPLANT SPECIFICATIONS

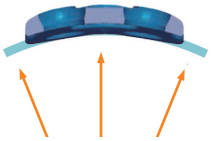


- Plate width is 16.5 mm
- Profile is 2.2 mm





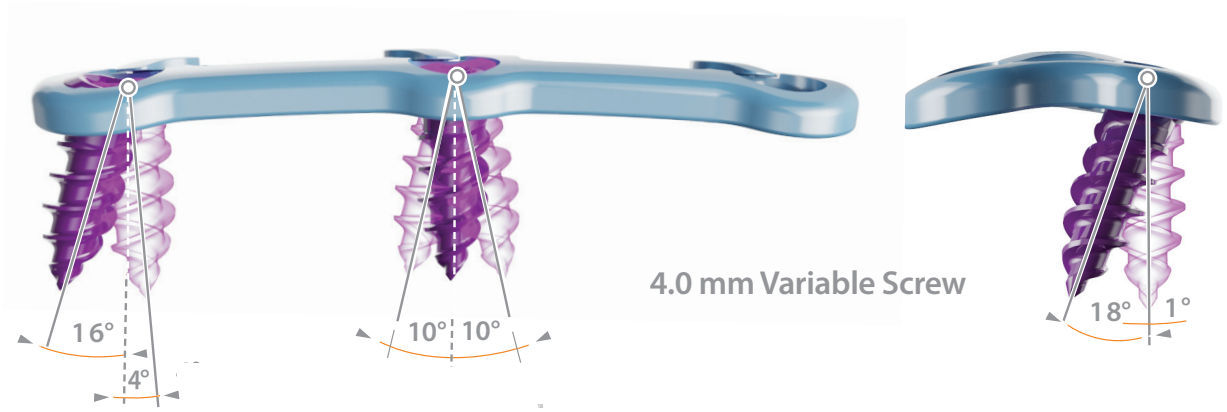
Sagittal Plane



Axial Plane

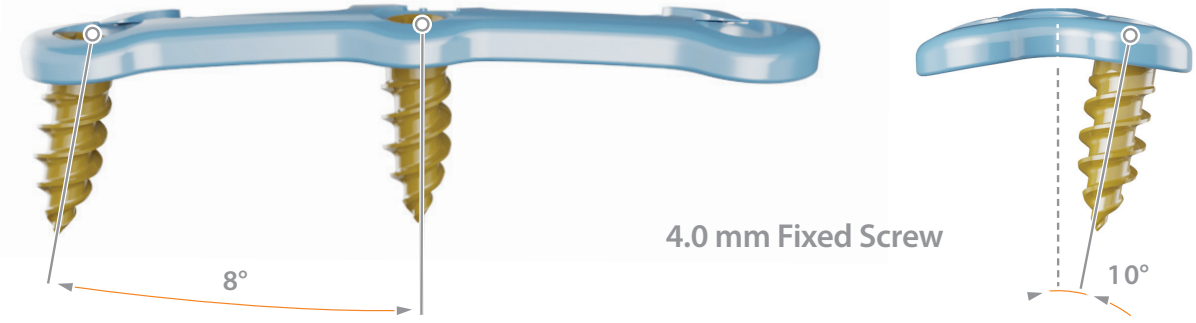
Radius of Curvature

- Sagittal Plane
  - 1 Level: 120 mm
  - 2-4 Level: 200 mm
- Axial Plane: 25 mm



4.0 mm Variable Screw

- Hexalobe (T10) interface
- Dual lead thread design
- Screw diameters of 4.0 mm and 4.35 mm
- Screw lengths range from 10 – 22 mm
- Screw types include self-drilling, self-tapping, variable and fixed angle



4.0 mm Fixed Screw

SITE PREPARATION & PLATE SIZE SELECTION

Site Preparation

The patient is placed in the supine position with the neck supported posteriorly to achieve normal segmental lordosis (see Figure 1).

A standard incision is used to access the cervical spine, and the longus colli muscles are elevated with medial/lateral retractor blades. Cranial/caudal retractor blades may also be used (see Figure 2).

FIGURE 1

FIGURE 2

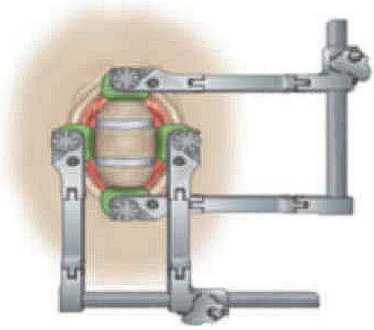


Plate Size Selection

The Defender® Anterior Cervical Plates offer sizes from 1 to 5 levels ranging from 8 to 91 mm (hole-to-hole).

Using the plate holder, position the appropriate plate on the vertebral column to confirm proper size (see Figure 3).

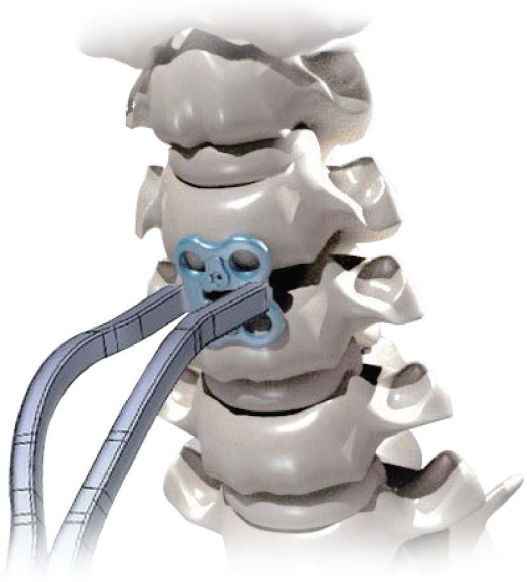


FIGURE 3

PLATE CONTOURING & PLATE POSITIONING

Plate Contouring

The Defender® Anterior Cervical Plates come pre-lordosed. When additional contouring is required, insert the plate into the plate bender (see Figure 4A) and squeeze the handles.

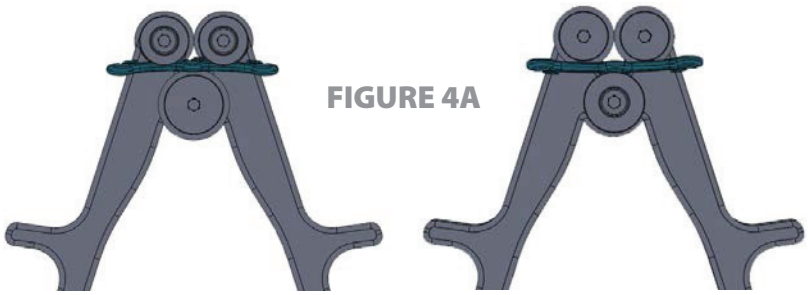


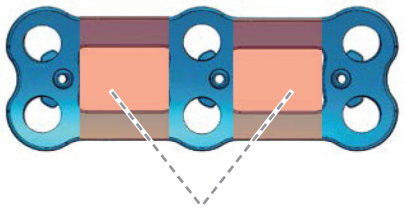
FIGURE 4A

Increase Lordotic Curvature

Decrease Lordotic Curvature

The Defender® Anterior Cervical Plate is provided with a dual cam-lock mechanism and should be bent across the bend zones (see Figure 4B). Plates should be bent in one direction, kyphosis or lordosis only. Never reverse the bend as this may create micro fractures that will weaken the plate. Short plates of each level do not have bend zones and therefore cannot be bent.

FIGURE 4B



Bend Zones

Positioning & Temporary Fixation Pins

Using the temporary fixation pin inserter, re-position the plate on the vertebral bodies. Insert a temporary fixation pin into one of the cephalad and one of the caudal screw holes of the plate (see Figure 5).

FIGURE 5

SCREW SELECTION

Screw Selection

The Defender® Anterior Cervical Plate offers surgeons the versatility to place their screws at various angles into the vertebral bodies (see Figures 6 & 7). The system offers self-tapping and self-drilling screw options in both 4.0 mm and 4.35 mm diameters (see Figure 8). The screw incorporates a dual-lead thread pattern designed to maximize interface with cancellous bone.

FIGURE 6

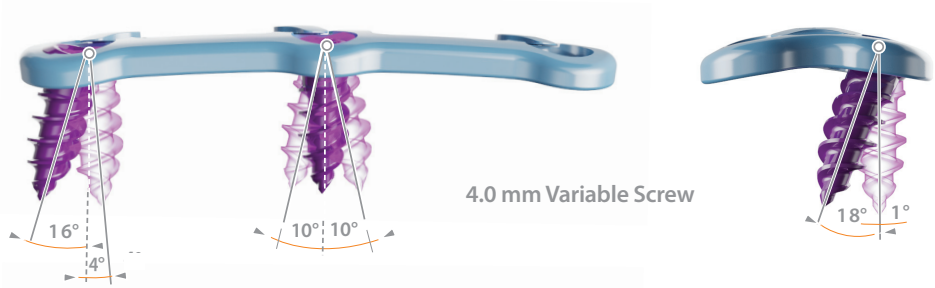


FIGURE 7

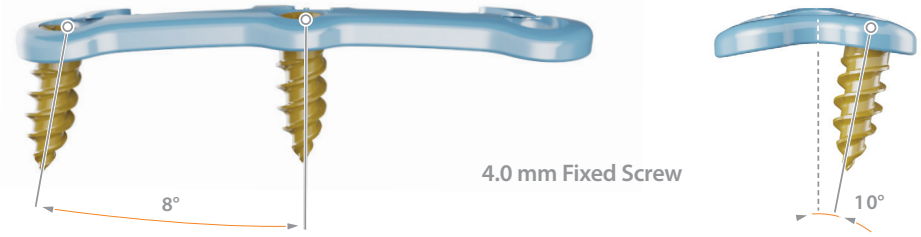


FIGURE 8

Fixed Self-drilling Screw *Fixed Self-tapping Screw* *Variable Self-drilling Screw* *Variable Self-tapping Screw*

Using the Self-Contained Awl

Once the plate is positioned and temporarily fixed to the vertebral bodies, place the tip of the self-contained awl in the screw hole and press it in the direction of the desired screw angle. The self-contained awl can protrude into the bone up to a depth of 8.5 mm (see Figure 9). To penetrate dense cortical bone, strike the handle of the self-contained awl with a mallet.

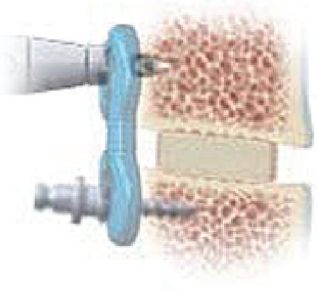


FIGURE 9

SCREW POSITIONING & INSERTION

Screw Positioning

Attach the desired drill bit onto the AO handle or power drill. Advance the drill bit through the drill guide until the shelf of the drill contacts the guide (see Figure 10). The Defender® Anterior Cervical Plate provides both self-drilling and self-tapping screws. A 10 mm tap is provided should tapping be required.

FIGURE 10

Screw Insertion

Use the screw driver to pick up the appropriate bone screw and insert the screw tip into the prepared hole in the bone (see Figure 11). Use fluoroscopic imaging to confirm the final trajectory of the screw and plate position before screws are fully tightened and secured with the dual cam-lock.

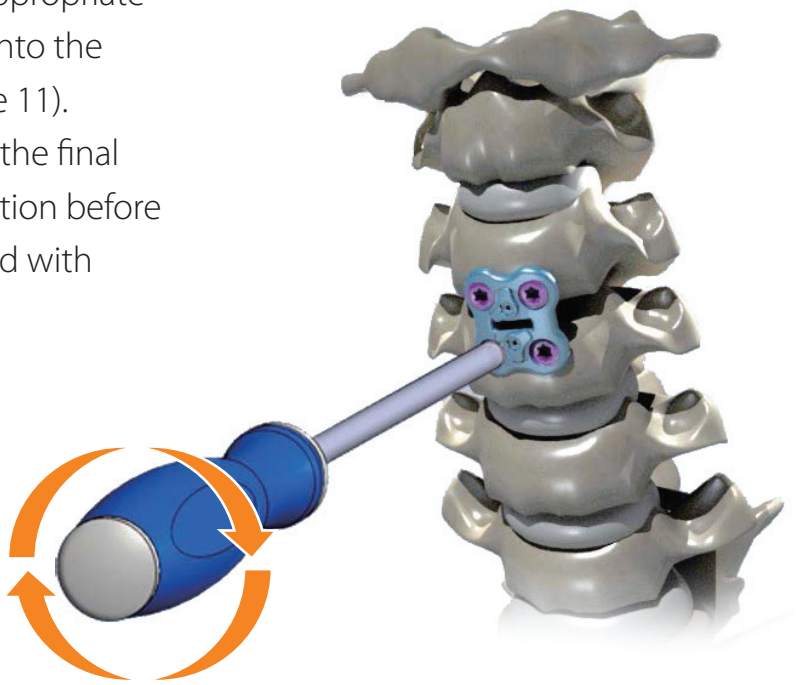


FIGURE 11

FINAL LOCKING & OPTIONAL INSTRUMENTATION

Final Locking

The Defender® Anterior Cervical Plate includes an attached dual cam-lock mechanism. Insert the tip of the screw driver into the dual cam-lock ensuring the screw driver is fully seated within the hexalobe (see Figure 12). Rotate the dual cam-lock clockwise until it is in-line with the vertebral body (see Figure 13). Be careful to ensure the dual cam-lock is not over turned, as damage may occur.

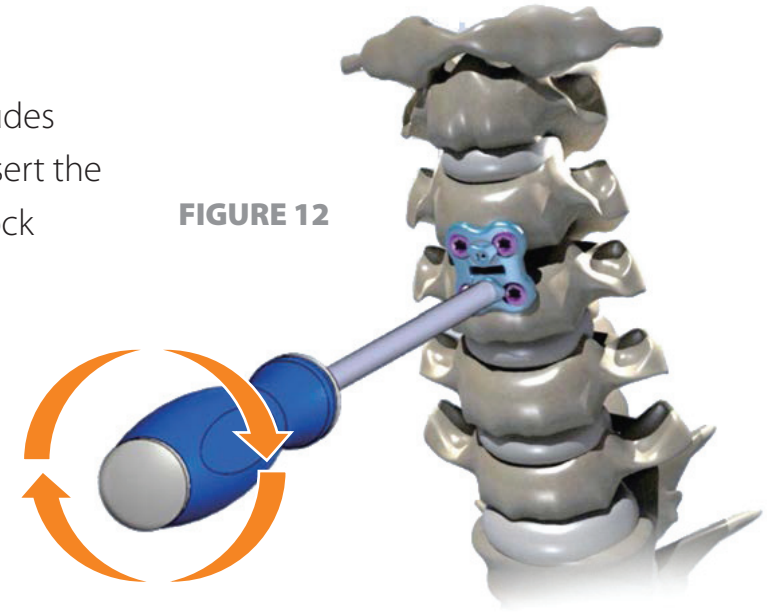


FIGURE 12

FIGURE 13

Unlocked *Locked*

Note: There is a small detent that is designed to provide resistance from over turning the dual cam-lock.

Optional: Double Drill/Tap/Screw Guide

To attach the double DTS guide, begin with the guide off the distal end of the plate. Place one side of the guide in the side slot on the plate (see Figure 14). Next, twist the opposite side into position. Typically, it is easier to attach the double DTS guide when downward pressure is maintained on the guide to keep contact between the guide and the plate. To determine the cephalad/caudal angle, adjust the drill guides by hand and then tighten the blue knob to lock in the desired orientation.

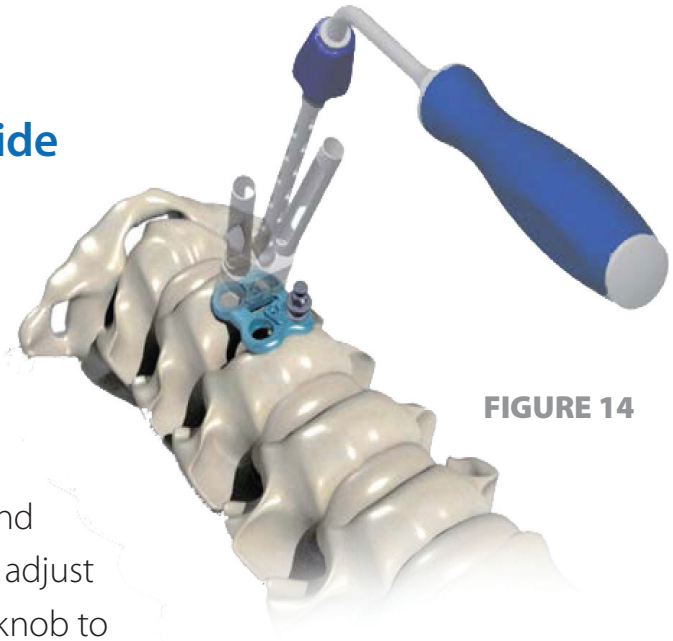


FIGURE 14

Note: Single DTS guide is also available

REMOVAL TECHNIQUE

Unlocking the Dual Cam-Lock

Insert the tip of the screw driver into the hexalobe on the dual cam-lock ensuring the screw driver is fully seated within the hexalobe.

Rotate the dual cam-lock counter-clockwise (see Figures 15 &16).

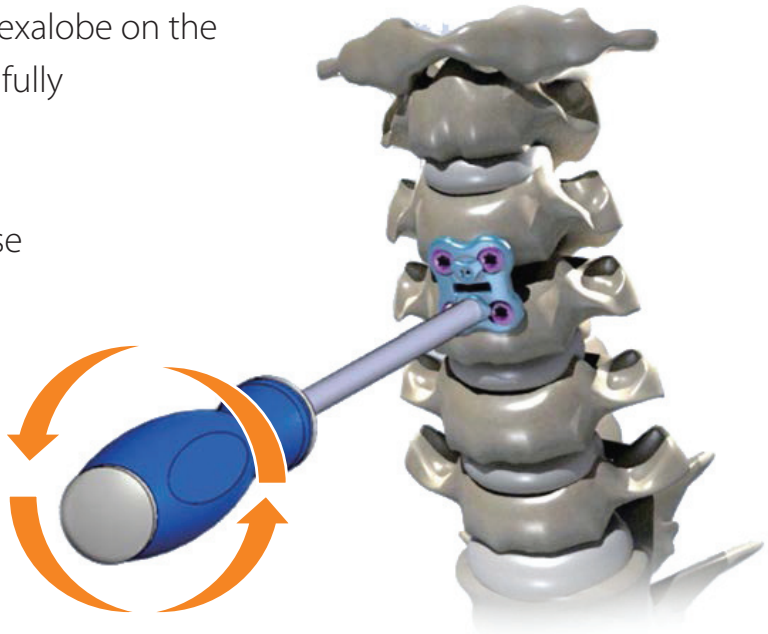
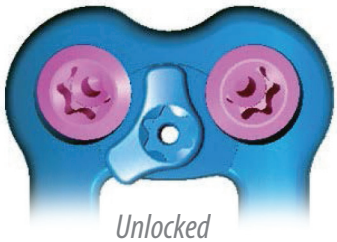


FIGURE 15

FIGURE 16



Unlocked

Removing the Screws

Insert the screw driver ensuring the tip is fully seated within the hexalobe of the screw.

The shaft of the screw driver should be aligned with the screw head.

Disengage the screws from the plate turning the screw driver counter-clockwise (see Figure 17).

Repeat for all screws.

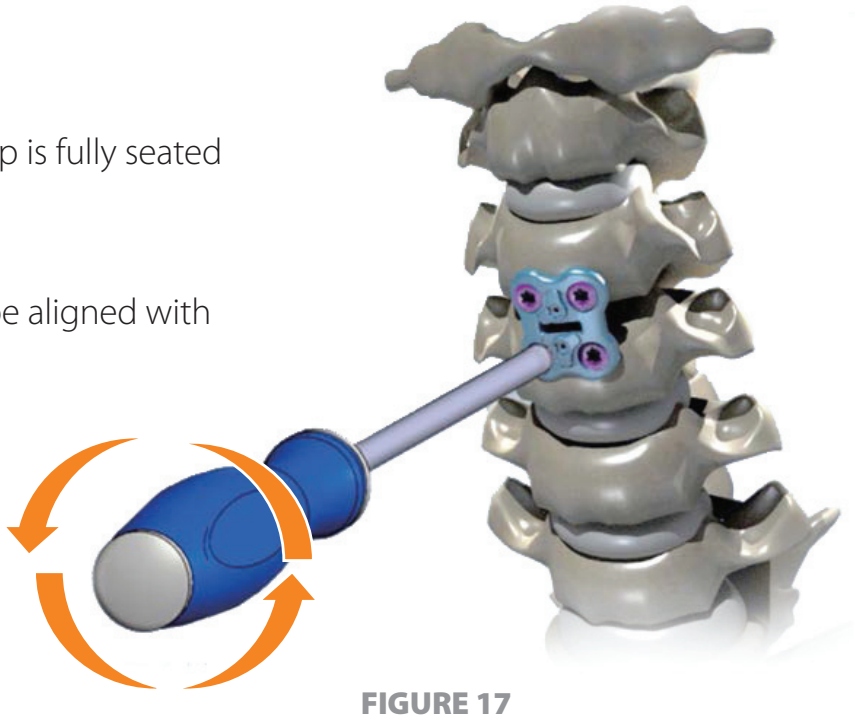
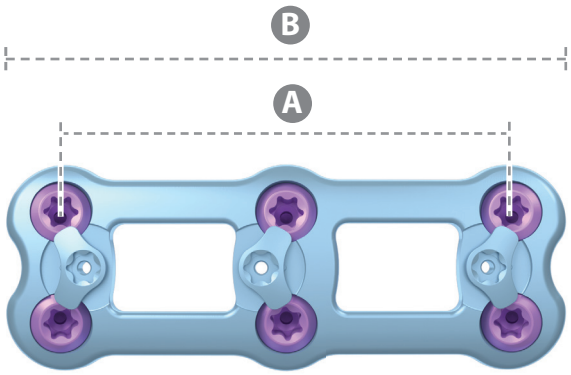


FIGURE 17

DEFENDER® ANTERIOR CERVICAL PLATE MEASUREMENTS

Standard Set

Catalog #	Description	A	B
15-5108	1 level 8 mm	8 mm	17 mm
15-5110	1 level 10 mm	10 mm	19 mm
15-5112	1 level 12 mm	12 mm	21 mm
15-5114	1 level 14 mm	14 mm	23 mm
15-5116	1 level 16 mm	16 mm	25 mm
15-5118	1 level 18 mm	18 mm	27 mm
15-5120	1 level 20 mm	20 mm	29 mm
15-5122	1 level 22 mm	22 mm	31 mm
15-5124	1 level 24 mm	24 mm	33 mm
15-5126	1 level 26 mm	26 mm	35 mm
15-5222	2 level 22 mm	22 mm	31 mm
15-5224	2 level 24 mm	24 mm	33 mm
15-5226	2 level 26 mm	26 mm	35 mm
15-5228	2 level 28 mm	28 mm	37 mm
15-5230	2 level 30 mm	30 mm	39 mm
15-5232	2 level 32 mm	32 mm	41 mm
15-5234	2 level 34 mm	34 mm	43 mm
15-5236	2 level 36 mm	36 mm	45 mm
15-5238	2 level 38 mm	38 mm	47 mm
15-5240	2 level 40 mm	40 mm	49 mm
15-5242	2 level 42 mm	42 mm	51 mm
15-5244	2 level 44 mm	44 mm	53 mm
15-5246	2 level 46 mm	46 mm	55 mm
15-5336	3 level 36 mm	36 mm	45 mm
15-5339	3 level 39 mm	39 mm	48 mm
15-5342	3 level 42 mm	42 mm	51 mm
15-5345	3 level 45 mm	45 mm	54 mm
15-5348	3 level 48 mm	48 mm	57 mm
15-5351	3 level 51 mm	51 mm	60 mm
15-5354	3 level 54 mm	54 mm	63 mm
15-5357	3 level 57 mm	57 mm	66 mm
15-5360	3 level 60 mm	60 mm	69 mm
15-5363	3 level 63 mm	63 mm	72 mm
15-5366	3 level 66 mm	66 mm	75 mm
15-5369	3 level 69 mm	69 mm	78 mm



4 Level Plate Caddy

Catalog #	Description	A	B
15-5446	4 level 46 mm	46 mm	55 mm
15-5450	4 level 50 mm	50 mm	59 mm
15-5454	4 level 54 mm	54 mm	63 mm
15-5458	4 level 58 mm	58 mm	67 mm
15-5462	4 level 62 mm	62 mm	71 mm
15-5466	4 level 66 mm	66 mm	75 mm
15-5470	4 level 70 mm	70 mm	79 mm
15-5474	4 level 74 mm	74 mm	83 mm
15-5478	4 level 78 mm	78 mm	87 mm

5 Level Plate Caddy

Catalog #	Description	A	B
15-5571	5 level 71 mm	71 mm	80 mm
15-5576	5 level 76 mm	76 mm	85 mm
15-5581	5 level 81 mm	81 mm	90 mm
15-5586	5 level 86 mm	86 mm	95 mm
15-5591	5 level 91 mm	91 mm	100 mm

DEFENDER® SCREW IMPLANTS

Self-Drilling Screws

Catalog #	Description
15-5610	Fixed Self-Drilling Screw 4.0 X 10 mm
15-5612	Fixed Self-Drilling Screw 4.0 X 12 mm
15-5614	Fixed Self-Drilling Screw 4.0 X 14 mm
15-5616	Fixed Self-Drilling Screw 4.0 X 16 mm
15-5618	Fixed Self-Drilling Screw 4.0 X 18 mm
15-5620	Fixed Self-Drilling Screw 4.0 X 20 mm
15-5622	Fixed Self-Drilling Screw 4.0 X 22 mm
15-5630	Fixed Self-Drilling Screw 4.35 X 10 mm
15-5632	Fixed Self-Drilling Screw 4.35 X 12 mm
15-5634	Fixed Self-Drilling Screw 4.35 X 14 mm
15-5636	Fixed Self-Drilling Screw 4.35 X 16 mm
15-5638	Fixed Self-Drilling Screw 4.35 X 18 mm
15-5640	Fixed Self-Drilling Screw 4.35 X 20 mm
15-5642	Fixed Self-Drilling Screw 4.35 X 22 mm
15-5810	Variable Self-Drilling Screw 4.0 X 10 mm
15-5812	Variable Self-Drilling Screw 4.0 X 12 mm
15-5814	Variable Self-Drilling Screw 4.0 X 14 mm
15-5816	Variable Self-Drilling Screw 4.0 X 16 mm
15-5818	Variable Self-Drilling Screw 4.0 X 18 mm
15-5820	Variable Self-Drilling Screw 4.0 X 20 mm
15-5822	Variable Self-Drilling Screw 4.0 X 22 mm
15-5830	Variable Self-Drilling Screw 4.35 X 10 mm
15-5832	Variable Self-Drilling Screw 4.35 X 12 mm
15-5834	Variable Self-Drilling Screw 4.35 X 14 mm
15-5836	Variable Self-Drilling Screw 4.35 X 16 mm
15-5838	Variable Self-Drilling Screw 4.35 X 18 mm
15-5840	Variable Self-Drilling Screw 4.35 X 20 mm
15-5842	Variable Self-Drilling Screw 4.35 X 22 mm

Self-Tapping Screws

Catalog #	Description
15-5710	Fixed Self-Tapping Screw 4.0 X 10 mm
15-5712	Fixed Self-Tapping Screw 4.0 X 12 mm
15-5714	Fixed Self-Tapping Screw 4.0 X 14 mm
15-5716	Fixed Self-Tapping Screw 4.0 X 16 mm
15-5718	Fixed Self-Tapping Screw 4.0 X 18 mm
15-5720	Fixed Self-Tapping Screw 4.0 X 20 mm
15-5722	Fixed Self-Tapping Screw 4.0 X 22 mm
15-5730	Fixed Self-Tapping Screw 4.35 X 10 mm
15-5732	Fixed Self-Tapping Screw 4.35 X 12 mm
15-5734	Fixed Self-Tapping Screw 4.35 X 14 mm
15-5736	Fixed Self-Tapping Screw 4.35 X 16 mm
15-5738	Fixed Self-Tapping Screw 4.35 X 18 mm
15-5740	Fixed Self-Tapping Screw 4.35 X 20 mm
15-5742	Fixed Self-Tapping Screw 4.35 X 22 mm
15-5910	Variable Self-Tapping Screw 4.0 X 10 mm
15-5912	Variable Self-Tapping Screw 4.0 X 12 mm
15-5914	Variable Self-Tapping Screw 4.0 X 14 mm
15-5916	Variable Self-Tapping Screw 4.0 X 16 mm
15-5918	Variable Self-Tapping Screw 4.0 X 18 mm
15-5920	Variable Self-Tapping Screw 4.0 X 20 mm
15-5922	Variable Self-Tapping Screw 4.0 X 22 mm
15-5930	Variable Self-Tapping Screw 4.35 X 10 mm
15-5932	Variable Self-Tapping Screw 4.35 X 12 mm
15-5934	Variable Self-Tapping Screw 4.35 X 14 mm
15-5936	Variable Self-Tapping Screw 4.35 X 16 mm
15-5938	Variable Self-Tapping Screw 4.35 X 18 mm
15-5940	Variable Self-Tapping Screw 4.35 X 20 mm
15-5942	Variable Self-Tapping Screw 4.35 X 22 mm

Note: 18, 20, and 22 mm screws need to be ordered separately as they are not standard in the set.

IMPORTANT INFORMATION ON DEFENDER® ACP

DEVICE DESCRIPTION

The Defender® Anterior Cervical Plate System is intended for anterior cervical intervertebral body screw fixation from C2 to T1. Rigid fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.
Implant components consist of a variety of shapes and sizes of plates, bone screws and associated instruments.
Locking caps are pre-assembled to the plates. They cover the heads of the bone screws to reduce the potential for screw back-out. With this locking mechanism, implant components can be rigidly locked into many different configurations to suit the individual pathology and anatomical conditions of the mature patient. They are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136. Implants must not be used with the components from any other system or manufacturer in a construct.

INDICATIONS

The Defender® Anterior Cervical Plate System is intended for anterior interbody screw fixation from 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) Spinal Stenosis
5) Tumors
6) Deformity (defined as kyphosis, lordosis, or scoliosis)
7) Pseudarthrosis
8) Failed previous fusions.

CONTRAINDICATIONS

The Defender® Anterior Cervical Plate System is not designed, intended, or sold for uses other than those indicated. This system should not be used if the patient has or shows the following conditions:

1. Any abnormality present which affects the normal process of bone fusion including, but not limited to;
   - Rapid joint disease, disc disease, osteomalacia, or osteoporosis involving the spine
   - Bone absorption, osteopenia, primary or metastatic tumors involving the spine
   - Certain metabolic disorders affecting osteogenesis
2. Any medical or surgical condition which would preclude the potential benefit of spinal surgery with implantation including, but not limited to;
   - Presence of tumors, congenital abnormalities leading to grossly distorted anatomy, elevation of sedimentation rate unexplained by other diseases
   - Elevation of white blood cell count (WBC), or marked left shift in the WBC differential count
   - Radio- or chemotherapy for cancer, kidney dialysis
3. Unstable burst and compression fractures of vertebral body
4. Active systemic infection or infection localized to the site of operation or adjacent to the spine or spinal structures
5. Marked local inflammation
6. Immature patient
7. Pregnancy
8. Suspected or documented allergy, intolerance, or oversensitivity to any of the implant materials.
9. Old age, mental defect, alcoholic, medicinal poisoned or neurological disc muscle disorder which may cause failure during surgery, complications after surgery or disability of following post-operative instructions.
10. Anomalous neural anatomy
11. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
12. Any patient unwilling to cooperate with postoperative instructions.
13. Fever or leukocytosis.
14. Morbid obesity can cause failure of fusion which places unsafe load level on the device during the healing period or failure of the device itself due to excess weight near surgery area. Obesity is defined according to the W.H.O. standards.
15. Diagnosis outside the indications for use and physician determines that the product is not appropriate for use on the patient.
16. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
17. Any case not needing a bone graft and fusion or where fusion is not required.
18. Open wounds.
19. Any case not described in the indications.
20. Any case requiring the mixing of metals from different components
21. Grossly distorted anatomy due to congenital abnormalities

These contraindications are relative or absolute and must be considered by the physician when making their decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.
This device is intended for anterior cervical intervertebral body fusions only. Although not absolute contraindications, conditions to be considered as potential factors for not using this device include severe bone resorption.

POTENTIAL COMPLICATIONS AND ADVERSE SIDE EFFECTS

The following complications and adverse reactions have been shown to occur with the use of spinal instrumentation. These effects and any other known by the surgeon should be discussed with the patient preoperatively.
A listing of possible adverse events or complications include, but are not limited to:

1. Inappropriate or improper surgical placement of other fixation device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
2. Implant migration, disassembly, bending, dislocation and/or breakage of any or all of the device components may result from inadequate implantation, latent infection, premature loading of the device or trauma.
3. Early or late loosening of any or all of the components.
4. Displacement of a screw due to incorrect positioning or implant size.
5. Additional surgery (revision surgery) may be necessary to correct some of these anticipated adverse events.
6. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
7. Bone loss or decrease in bone density, possibly caused by stress shielding or unbalanced physical pressure.
8. Heterotopic bone formation.
9. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
10. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Vertebral endplate injury or subsidence of the device into vertebral body(ies).
13. Bursitis, hemorrhage, hematoma, thrombus, occlusion, seroma, edema, embolism, stroke, excessive bleeding, myocardial infarction, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
14. Superficial or deep-set infection and inflammatory phenomena at the implantation site
    - Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures also have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

IMPORTANT INFORMATION ON DEFENDER® ACP (CONTINUED)

15. Soft tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
16. Neuropathy, neurological deficits (transient or permanent), monoplegia, bilateral paraplegia, reflex deficits, arachnoiditis, and/or muscle loss.
17. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
18. Neurological damage (a breach of the dura mater, lesion of a spinal root) from surgical trauma
19. Delayed union (late bone fusion), non-union (cessation of any potential growth of the operated portion of the spine or no visible fusion mass or pseudoarthrosis) or malunion
20. Loss of spinal mobility or function.
21. Inability to perform the activities of daily living.
22. Change in mental status.
23. Death.
24. Infection
25. Dysphagia
26. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
27. Bronchopulmonary disorders or development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
28. Damage or transformation of the product, collapse of vertebral body because of dislocation or expulsion of the implant before bone fusion, which requires another surgical procedure.
29. Damage or transformation of the product due to heavy physical exercise or pressure.
30. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
31. Foreign body (allergic) reaction to implants, debris, corrosion products, including inflammation, staining, tumor formation and/or autoimmune disease.
32. Fracture, microfracture, resorption, damage, penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
33. Discontinued growth of fused bone at, above and/or below the surgery level
34. Retropulsed graft
35. Gastrointestinal complications such as gastritis, ileus
36. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
37. Loss of bowel and/or bladder control or other types of urological system compromise.
38. Graft donor site complications including pain, fracture, infection, or wound healing problems. Other complications than those listed above events may occur. The surgeon must warn the patient of these potential adverse events as deemed necessary. If an event such as device component fracture, loss of fixation, non-union, fracture of the vertebrae, and necrosis of bone, neurological injury and vascular or visceral injury etc.,occurs, an additional surgical procedure may be required.

WARNINGS

1. While the expected life of spinal implant components is difficult to estimate, its life span is finite. These components are made of foreign materials and placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical, and physicochemical factors, these devices are affected and cannot be expected to withstand the activity level and loads of normal healthy bone.
2. Do not use this product other than for its indication.
3. The Defender® Anterior Cervical Plate System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended 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 Defender® Anterior Cervical Plate System is utilized. Use of this 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.
4. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues. The implant must be discarded.
5. This product is single use only and must never be reused. Reuse of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time and may result in premature failure. While the device may appear to be undamaged, it may have small defects or internal stress patterns, because of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for implants which have been reused.
6. Non-sterile implants must be sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
7. All instruments are delivered non-sterile and therefore, must be cleaned, sterilized, and decontaminated prior to surgical use as instructed by the manufacturer.
8. A wrong choice of implant size may cause damage to the product and may result in an unsuccessful surgery. Therefore, product's design and size should be selected after full consideration of patient's weight, amount of exercise, area of vertebrae checked by X-ray, levels of implantation, compliance of the patient, and other patient conditions which may have an impact on the performance and results of this system. Please refer to "the choice of implant".
9. The device should not be used with another product without validation regarding safety and effectiveness. If it is used with other product, the manufacturer does not take any responsibility.
10. Where material oversensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
11. It is important for surgeon and medical staff to be well informed of the following information and provide it to patient before the procedure, to be warned of the potential consequences and ensure success of the surgical implantation:
    - Clinical data show that patients who smoke tend to have less optimum bony density, as well as patients who are undernourished, alcoholic, obese, or patients with drug abuse, muscle weakness or nerve paralysis.
    - To aid bone healing it is important to limit use of nicotine and non-steroidal medicinal products (ex.: aspirin).
    - The implanted device must not be subjected to exposure to unwanted forces such as mechanical vibrations. Consequently, the patient must be informed of limiting his or her physical activity (athletic and occupational), especially in the cases of lifting, twisting, and crushing.
    - Throughout the period of consolidation, the patient must follow the surgeon's instructions and recommendations.
    - These implants do not present any known risk of interference with other medical equipment.
    - Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting.
12. Spinal surgery is not recommended for patients with alcohol abuse, morbid obesity, poor bone and muscle quality and/or nerve paralysis.
13. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

IMPORTANT INFORMATION ON DEFENDER® ACP (CONTINUED)

CAUTION

1. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
2. The benefit of spinal fusions utilizing any intervertebral body fusion device has not been adequately established in patients with stable spines.
3. A condition of senility, mental illness, or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
4. Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection and positioning of implants are important factors in success of use of the system by the surgeon. Knowledge and experience in spinal surgery are prerequisites.
5. Physician note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.
6. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Also, patients who smoke or abuse alcohol are poor candidates for spinal fusion as someone who should be advised and warned of the consequences of the fact that an increased incidence of nonunion has been reported with such patients.
7. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions or many extenuating circumstances may compromise the results.
8. Non-sterile implants must be sterilized before for use.
9. Never reuse the implant under any circumstances. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.
10. The compatibility needs to be verified before use with other product.
11. The products must be stored away from contact with metal or abrasive materials to prevent cracks or scratches. The product may be damaged from loads due to scratches not visible without magnification.
12. The use of implants may interfere with the anatomical structure or physiological performance of the patient. The radiological diagnosis and the potential side effects should be reviewed carefully before the procedure.
13. Defender® Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Defender® Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
14. Without solid bone fusion, this device cannot be expected to support the cervical spine indefinitely and may fail due to bone-metal interface, metal, or bone failure.
15. Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

PACKAGING

1. This product is disposable, supplied non-sterile and individually packed, packed by transparent PE bag.The packaging should not be damaged before usage.
2. Packaging should be removed before sterilization.
3. The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

CLEANING

In accordance with the reprocessing manual, instruments should be cleaned and sterilized before use. Implant should not be cleaned and only non-sterile implant should be sterilized before use. Cleaning, maintenance, and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.

1. Cleaning before sterilization:
   If the packing is not damaged, the instruments do not need to be washed. Otherwise, they must be washed with a damp gauze pad or wipe to remove all gross visible soil. The cleaning must be done before sterilization; an ultrasonic wash with water soluble neutral cleaner is advised. Cleaner's composition and cleaning method must follow by the reprocessing manual. The solution must be within pH range 6-8.
2. Avoid cleaning the product in high temperature for long period.
3. Use of corrosive object including abrasive sponges and metal brushes must be avoided.
4. Verify that the product is in operating condition without any foreign substance in them after cleaning.
5. Unacceptable cleaning agents:
   It is inadequate to use strong acidic or basic cleaning solution such as sulphuric acid, nitric acid, or chloric acid. Sodium hydroxide (NaOH) is also prohibited.
6. Cautions when cleaning:
   Forbid using abrasive product or instrument. After cleaning, the product's capability and condition as well as existence of foreign substance in implant should be checked. Each hospital's instrument cleaning method needs to be verified.

DRYING

Surgical instrument and product should be dried without any water before sterilization.

STERILIZATION

All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization.For storage before sterilization and surgery, use sterilized storage tray. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile implants and instruments must be sterilized by autoclave using the following validated cycle parameter. The individual products are recommended to be steam sterilized by the hospital in a gravity displacement.

Method	Cycle Type	Temperature	Exposure time	Drying Time
Steam	Gravity (Wrapped)	132°C(270°F)	15 min	30 min
Steam	Pre-vaccuum (Wrapped)	132°C(270°F)	4 min	30 min

If different sterilization method is used, verification is required to show that the sterilization method is valid enough to be safe for usage. Depending on sterilization method, hospital should check the certification and needs to check sterilization time and temperature regularly. If sterilization is done with paper filter, filter should be changed every time it is used. If water remains on sterilized tray and product after sterilization, it should be re-sterilized.

STORAGE

1. If non used product is exposed to waste, it must be sterilized and dried for storage. Product must be stored at a dry room temperature of 1 to 25° C and must be away from direct ray of light.
2. The product must be stored away from contact with metal or abrasive materials or corrosive environments to prevent damage such as cracks, scratches, nicks, or notches. Also, the product may be damaged from loads due to scratches not visible with naked eyes.

COMPLAINTS

If you are unsatisfied with the product or have complaints, please contact your Spine Wave representative. If you suspect the product is having problems, please notify us immediately. If our products have caused damage, side effect, fatal injury to patient, please contact us immediately with the provider's information via fax, telephone, or letter. For all other complaints, please provide product catalog number, lot number, your contact information including your name and telephone number, and detailed information about problems you are having. For more information, please contact us below.

For more complete information, refer to the package insert.

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