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FloSpine

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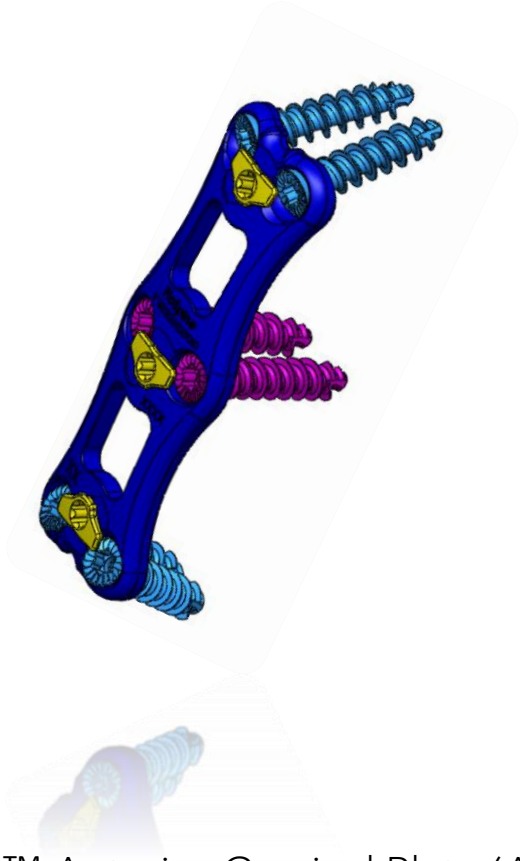
The Panama Anterior Cervical Plate System

Cervical Plate

Surgical Technique Guide



The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System is designed to provide biomechanical stabilization as an adjunct to fusion in skeletally mature patients. The system can be rigidly locked into a variety of configurations, with each construct being customized to the patient's anatomy. All implants are single use only and should not be reused under any circumstances. The implant system is intended to be removed after solid fusion has occurred.

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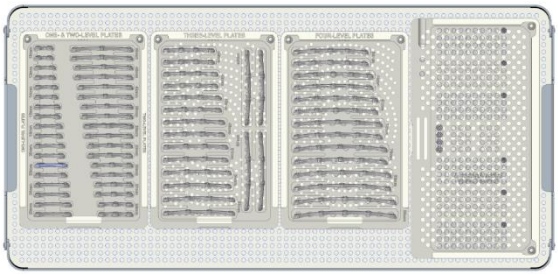
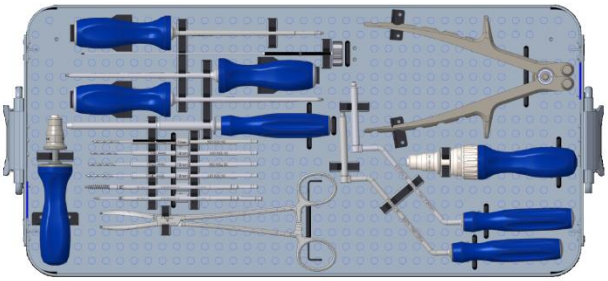
The Panama Anterior Cervical Plate Screw system provides an optimized kit configuration solution for anterior cervical spine fixation. The minimized, two kit configuration is an easy to follow color-coded tray layout tailored to potentially reduce reprocessing and sterilization costs, improve operating room efficiency and offers the potential to shorten the surgical staffs learning curve.





The Cervical Plate System

The Panama Anterior Cervical Plate System includes the following instruments and implants:

- Cervical Plates for 1-4 Level fusion, with varying lengths at each level. 5 level plates are available on request.
- Fixed and variable angle screws are available in two sizes (4.0 and 4.5mm rescue screws) and two types: tapping and self-drilling screws.
- Screw retaining screwdrivers that interface with the screws and the cover plate.
- Screwdrivers for the screws with a threaded inserter through the driver.
- Plate benders to contour plates as needed.
- Drills with a stops that control hole depth when used with fixed and variable angle drill guides.
- Awls to start holes.
- A plate holder to keep the plate in place during implantation.
- A detachable handle for the drills, awl, tap, and pull-connect type screwdrivers.
- Temporary fixation pins and inserter.

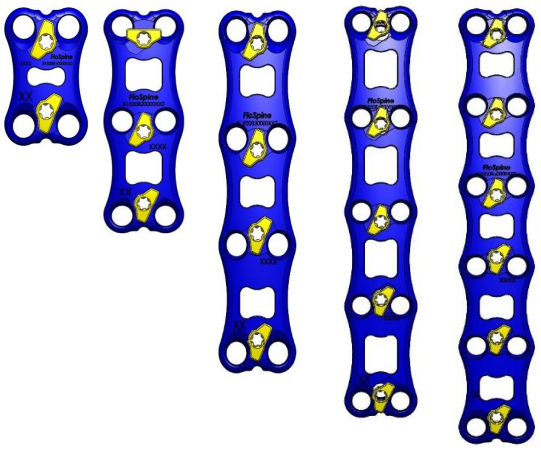
Patient Positioning (Step 1)

Place the patient in a supine position with the head in slight extension and slight rotation opposite side of the incision. Following appropriate positioning and padding, the patient is prepped and draped in a sterile manner.

Surgical Exposure (Step 2)

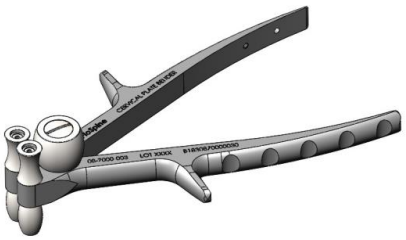
Exposure is accomplished using a standard anterior approach to the mid and lower cervical spine. This can be through one of several incisions with the exposure typically medial to the carotid sheath and lateral to the trachea and esophagus. Adequate fascial plane release is important for optimal exposure. After identification of the disc space through intraoperative confirmation of levels with x-ray, preparation for anterior interbody fusion is begun.

Implant Selection (Step 3)



Choose appropriate length plate and screws. Length indicated on plates corresponds to the end-hole to end-hole spacing. The screw length is the depth the screw extends below the plate. Ensure that the plate length provides sufficient area for cephalad and caudal screw angulation.

Plate Bending (Step 4)



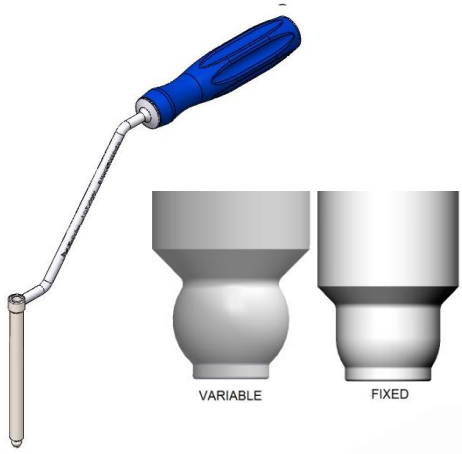
Plates are pre-contoured with a lordotic curve. If forming is required to provide a better match for the anatomy, the plate benders may be used for contouring.
Warning: Do not bend the plate in the proximity of the screw holes. Do not bend plates more than once.

Plate Placement (Step 5)

Place the plate into position using the provided plate holder.

Temporary fixation pins may be placed in the notches at the caudal or cephalad ends of the plate or in any of the screw holes. The temporary fixation pin holder is used for insertion and removal of pins. Ensure that fixation pins are removed before completing case.

Hole Preparation (Step 6)



There are two options to do the hole preparation:

Option 1: Fixed angle drill guides are aligned to the holes with the small pilot diameter on the tip of the drill guide.

Option 2: Variable angle drill guides allow for free hand angle selection.

The hole can be created with the Awl (which creates up to a 10mm deep hole), or drill. If using the drill, select the drill that corresponds to the screw length and attach to the AO quick connect handle.

Using the limited depth awl, penetrate the cortical bone at the location of the screw entry point.

The drill is designed to be inserted into the drill guide. There are 4 different drill lengths available, 12,14,16 and 18mm. The drill should be advanced until it stops on the drill guide to achieve the depth specified.

Tap drilled holes with the 4mm tap. Tapping may also be done with the self-tapping screws.

Screw Insertion (step 7)

Load the appropriate length screw on the T-10 screwdriver. Advance the screw until it seats firmly inside the pocket in the plate. Screws must be seated completely to allow screw locks to be engaged. There are two screwdriver options:

Option 1: A screwdriver with a threaded inserter passing through the driver that threads into the screw to retain the screws.

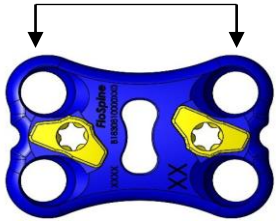
Option 2: A self-retaining screwdriver to which the screws snugly fit.

Lock Screws (step 8)

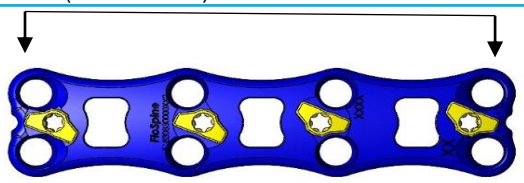
Each pair of screws is locked by rotating the lock ¼ turn clockwise using the same driver that is used to insert the screws. It is recommended not to rotate from unlocked to locked more than two times.
Warning: Excessive medial angulation of screws may lead to the screw heads blocking the locking plate.

Removal process (Step 9)

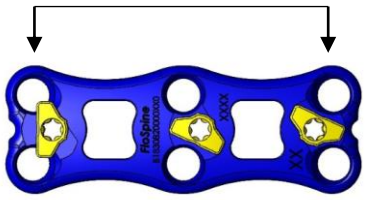
The removal of the Panama Anterior Cervical Plate System is accomplished by reversing the order of the implant procedure step 8 and 7.



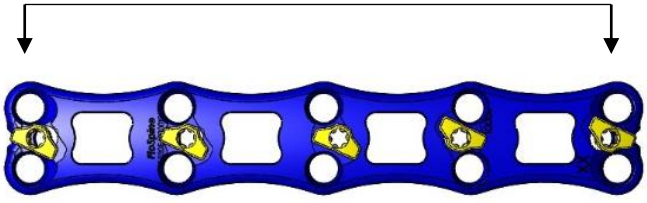
1-Level cervical plate	Part Number
10mm (Dark Blue)	08-1000-010
12mm (Dark Blue)	08-1000-012
14mm (Dark Blue)	08-1000-014
16mm (Dark Blue)	08-1000-016
18mm (Dark Blue)	08-1000-018
20mm (Dark Blue)	08-1000-020
22mm (Dark Blue)	08-1000-022
24mm (Dark Blue)	08-1000-024
26mm (Dark Blue)	08-1000-026



3-Level cervical plate	Part Number
39mm (Dark Blue)	08-3000-039
42mm (Dark Blue)	08-3000-042
45mm (Dark Blue)	08-3000-045
48mm (Dark Blue)	08-3000-048
51mm (Dark Blue)	08-3000-051
54mm (Dark Blue)	08-3000-054
57mm (Dark Blue)	08-3000-057
60mm (Dark Blue)	08-3000-060
63mm (Dark Blue)	08-3000-063
66mm (Dark Blue)	08-3000-066
69mm (Dark Blue)	08-3000-069



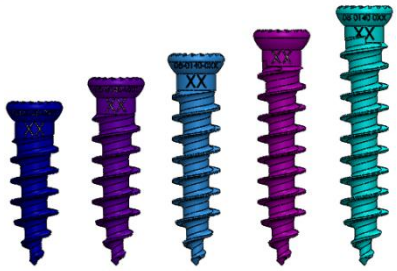
2-Level cervical plate	Part Number
24mm (Dark Blue)	08-2000-024
26mm (Dark Blue)	08-2000-026
28mm (Dark Blue)	08-2000-028
30mm (Dark Blue)	08-2000-030
32mm (Dark Blue)	08-2000-032
34mm (Dark Blue)	08-2000-034
37mm (Dark Blue)	08-2000-037
40mm (Dark Blue)	08-2000-040
43mm (Dark Blue)	08-2000-043
46mm (Dark Blue)	08-2000-046



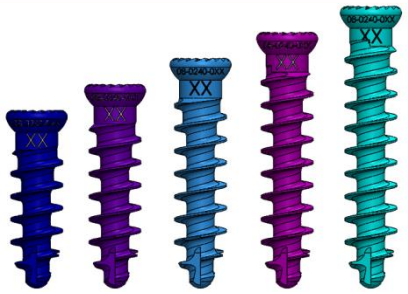
4-Level cervical plate	Part Number
60mm (Dark Blue)	08-4000-060
64mm (Dark Blue)	08-4000-064
68mm (Dark Blue)	08-4000-068
72mm (Dark Blue)	08-4000-072
76mm (Dark Blue)	08-4000-076
80mm (Dark Blue)	08-4000-080
84mm (Dark Blue)	08-4000-084

5-Level cervical plate	Part Number
85mm (Dark Blue)	08-5000-085
90mm (Dark Blue)	08-5000-090
95mm (Dark Blue)	08-5000-095
100mm (Dark Blue)	08-5000-100

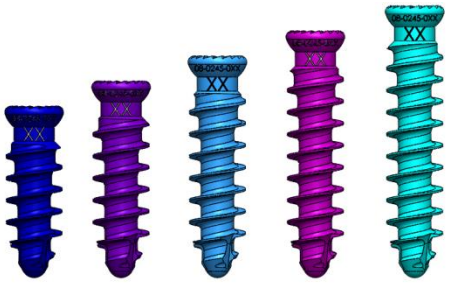
The Anterior Cervical Plate Implants



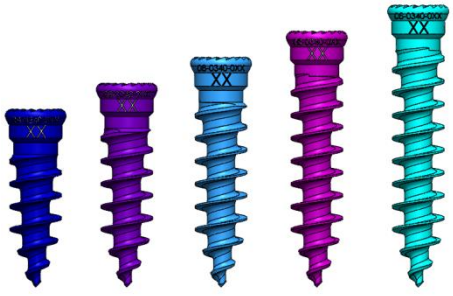
Self Drilling Variable Screw	Part Number
4.0mm x 12mm (Dark Blue)	08-0140-012
4.0mm x 14mm (Purple)	08-0140-014
4.0mm x 16mm (Light Blue)	08-0140-016
4.0mm x 18mm (Magenta)	08-0140-018
4.0mm x 20mm (Aqua)	08-0140-020



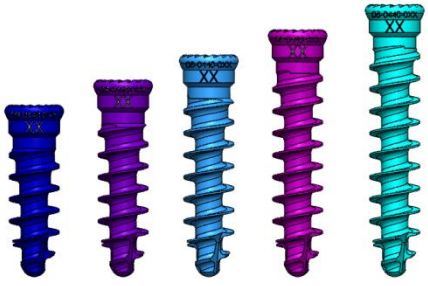
Self Tapping Variable Screw	Part Number
4.0mm x 12mm (Dark Blue)	08-0240-012
4.0mm x 14mm (Purple)	08-0240-014
4.0mm x 16mm (Light Blue)	08-0240-016
4.0mm x 18mm (Magenta)	08-0240-018
4.0mm x 20mm (Aqua)	08-0240-020



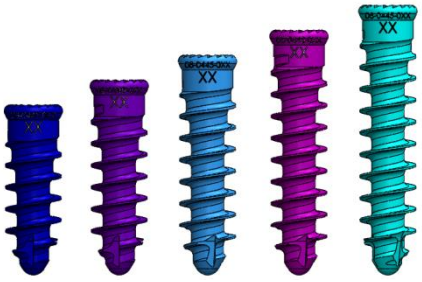
Self Tapping Rescue Variable Screw	Part Number
4.5mm x 12mm (Dark Blue)	08-0245-012
4.5mm x 14mm (Purple)	08-0245-014
4.5mm x 16mm (Light Blue)	08-0245-016
4.5mm x 18mm (Magenta)	08-0245-018
4.5mm x 20mm (Aqua)	08-0245-020



Self Drilling Fixed screw	Part Number
4.0mm x 12mm (Dark Blue)	08-0340-012
4.0mm x 14mm (Purple)	08-0340-014
4.0mm x 16mm (Light Blue)	08-0340-016
4.0mm x 18mm (Magenta)	08-0340-018
4.0mm x 20mm (Aqua)	08-0340-020



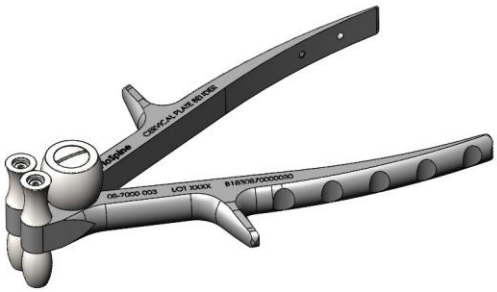
Self Tapping Fixed Screw	Part Number
4.0mm x 12mm (Dark Blue)	08-0440-012
4.0mm x 14mm (Purple)	08-0440-014
4.0mm x 16mm (Light Blue)	08-0440-016
4.0mm x 18mm (Magenta)	08-0440-018
4.0mm x 20mm (Aqua)	08-0440-020



Self Tapping Rescue Fixed Screw	Part Number
4.5mm x 12mm (Dark Blue)	08-0445-012
4.5mm x 14mm (Purple)	08-0445-014
4.5mm x 16mm (Light Blue)	08-0445-016
4.5mm x 18mm (Magenta)	08-0445-018
4.5mm x 20mm (Aqua)	08-0445-020

T10 Driver Inserter	Part Number
	08-7000-001

T10 Stab And Grab Driver	Part Number
	08-7000-002



Cervical Plate Bender	Part Number
	08-7000-003

Drill	Part Number
12mm Drill	08-7000-004
14mm Drill	08-7000-005
16mm Drill	08-7000-006
18mm Drill	08-7000-007
20mm Drill	08-7000-008

Awl	Part Number
	08-7000-009

4mm Tap	Part Number
	08-7000-010

Cervical Plate Holder	Part Number
	08-7000-011

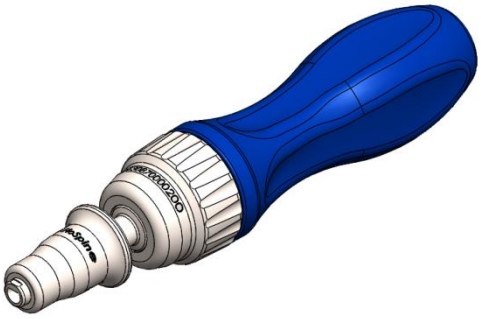
Temporary Fixation Pin	Part Number
	08-7000-012

Temporary Fixation Pin Driver	Part Number
	08-7000-013

Quick Connect Handle	Part Number
	08-7000-014

Fixed-Angle Single Barrel Drill Guide	Part Number
	08-7000-015

Variable-Angle Single Barrel Drill Guide	Part Number
	08-7000-016



Quick Connect Ratchet Handle	Part Number
	08-7000-020

AO T10 Self Retaining Driver	Part Number
	08-7000-021

DEVICE DESCRIPTION

The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System is designed to provide biomechanical stabilization as an adjunct to fusion in skeletally mature patients. The system can be rigidly locked into a variety of configurations, with each construct being customized to the patient's anatomy. All Implants are single use only and should not be reused under any circumstances. The implant system is intended to be removed after solid fusion has occurred.

The System also includes instrumentation for insertion, securing and removal of the implants. All implants are made from medical grade titanium alloy.

INDICATIONS

The FloSpine PANAMA™ Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at levels C2-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 degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

CONTRA-INDICATIONS

Use of the Panama Anterior Cervical Plate System and spinal fixation surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to:

- Overt infection of distant foci of infections
- Local inflammation, with or without fever or leukocytosis
- Pregnancy
- Diseases or conditions other than those specifically described in the Indications section
- Use in posterior elements of the cervical, thoracic, or lumbar vertebrae.
- Rapid Joint Disease, bone absorption, osteopenia, and/ or osteoporosis.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Suspected or documented metal allergy or intolerance
- Use in the posterior elements of the cervical, thoracic or lumbar vertebrae
- Where attempted correction exceeds the limits of physiological conditions
- Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions
- Metabolic disorders that may impair bone formation
- Inadequate bone stock to support the device
- Inability to restrict high activity level
- Obesity
- Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)

WARNING:
Following are specific warnings, precautions, and 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.

- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
- The FloSpine PANAMA™ ACP 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 FloSpine PANAMA™ ACP System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POTENTIAL ADVERSE EFFECT:
Occurrence of any adverse effects may require re-operation or removal of the implant. Adverse effects may include but not be limited to:

- Device component breakage
- Loss of fixation/loosening
- Non-union
- Vertebral fracture
- Neurologic
- Vascular or visceral injury.

PRECAUTION:

1. PATIENT SELECTION. Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATION section of this document and who do not have any conditions set fourth under the CONTRAINDICTIONS section of this document should be considered for spinal fixation surgery using Panama system. In addition, patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Based upon the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the system.
2. PATIENT EDUCATION. Preoperative instructions to the patient are essential. The patient should be aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken, or loose implant components. The patient must be made aware that implant components may bend, break or loose even though restrictions in activity are followed.
3. HANDLING. Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the plate or screw surfaces as these may induce premature failure of the component.
4. IMPLANT SELECTION. The Panama System components are available in a variety of sizes to insure proper fit of the implanted device. The potential for the success of the fusion is increased by selecting the correct size of the implant. These devices are not intended to be used as the sole support for the spine.
5. MIXED METALS. The Panama System is available in titanium. It is imperative that this metal does not come into contact in with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.
6. SINGLE USE ONLY. These devices are provided as single use only implants and are not to be reused or re-implanted regardless of an apparent undamaged condition.
7. DELAYED UNION OR NONUNION. The Panama System is designed to assist in providing an adequate biomechanical environment for fusion. It is not intended to be and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.

CLEANING AND DISINFECTING PROCEDURES:

The PANAMA™ Anterior Cervical Plate (ACP) System devices are provided clean but non-sterile and must be sterilized prior to use. Implants are intended for single use only. Instruments can be reprocessed using the recommend cleaning instructions.

- All reusable instruments should be cleaned and disinfected between uses. Directions are below to properly clean and disinfect reusable instruments prior to sterilization.
    1. Disassemble all instruments prior to cleaning, disinfection and sterilization.
    2. Decontamination by saturating the entire surface with full strength disinfectant/cleaner and allow it to remain in contact for 5 minutes. Do not use high acidic (pH <4) or high alkaline (pH>10) products.
    3. Precleaning by removing gross contaminants by immersing devices in neutral Ph enzymatic cleaner. Scrub with an appropriate soft-bristle brush until clean.
    4. Washing devices using either ultrasonic or mechanical washing machine for 5 minutes.
    5. Rising thoroughly for 3 minutes with deionized or distilled water.
    6. Allow instruments to thoroughly dry before storage or sterilization preparation.
    7. Inspect the instrument to assure there is no visual contamination. If any is noted, repeat the cleaning process.
    8. Assemble all the instruments that were previously disassembled. Perform a visual and functional inspection of all instruments to verify that they are in working order. Replace any reusable instruments that are cracked or damaged or do not function.
    9. Return the instruments to the instrument trays for sterilization
- All implants that have been implanted and then removed must be discarded.

NOTE:

Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

STERILIZATION:

The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System components are supplied clean and not sterile. All implants and instruments should be cleaned and sterilized prior to surgery. ANSI/AAMI ST79 guidelines for in-hospital sterilization should be followed for all implants and instruments. Implants and instruments should be sterilized in the sterilization case provided. Sterilization cases should be wrapped with FDA-Cleared wrap, with a surgical towel placed between the bottom of the tray and the wraps. Using a properly functioning and calibrated steam sterilizer, the following parameters may be used for effective :

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

LIMITATIONS AND RESTRICTIONS:
Repeated sterilization according to these instructions has a minimal effect on FloSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly.

The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials, and personnel used in their facility to ensure the desired results are achieved.

These instructions have been validated as being capable of sterilizing these choice spine implants. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

PRODUCT COMPLAINTS:
Any dissatisfaction with the product quality, labeling, or performance should be reported to FloSpine immediately. Furthermore, FloSpine should be notified immediately of an implant malfunction by telephone, fax, or written correspondence. When filing a complaint, the name, part number, and lot number of the part should be provided along with the name and address of the person filing the complaint.

PREOPERATIVE

- Usage of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments.
- Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.
- Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
- FloSpine does not specify the maximum number of times re-usable instrument may be re-used. The useful life of these instruments is highly dependent on numerous factors including the frequency and way they are used and the handling they experience in between uses. Inspection and, where appropriate, functional testing prior to using, is the best way to determine whether an individual device should be used.

INTRAOPERATIVE

- If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. Do not repeatedly or excessively bend the implant.
- Bone integrity should be verified.
- Care should be taken during pedicle preparation to avoid penetrating too deep.
- Care should be taken to minimize soft tissue damage during surgery.
- If any implant or instrument encounters a non-sterile surface it should not be used.

POSTOPERATIVE

- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in fracture. The patient should understand that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
- The Panama Anterior Cervical Plate System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and may be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.

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