PANAMA™ Anterior Cervical Plate System
Instruction for Use

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We've Got Your Back®

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

IMPORTANT:
The users acknowledge that they have read and agreed on the conditions in this insert, which are considered to be contractual.

CAUTION:
Federal Law restricts these devices to sale by or on the order of a physician.

PRECAUTION:
The implantation of anterior cervical spinal implant systems should be performed only by experienced spinal surgeons with specific training in the use of this anterior cervical spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

IMPORTANT NOTE TO OPERATING SURGEON:
The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System is designed to provide biomechanical stabilization as an adjunct to fusion in skeletally mature patients. For best results, a detailed, preoperative diagnostic with surgical technique as well as adapted postoperative care are essential. Spinal fixation should only be undertaken after the surgeon has had hands on training and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available and describes in detail the important aspects of this surgical procedures.

Preoperative instructions to the patients are essential. It is most important that the patient and the surgeon are fully aware of the risks and complications inherent to this type of surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implants components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant status is necessary. The surgeon may remove the implant once a solid fusion is obtained (confirmed by clinical and radiographic examination). The patient must be informed of the potential for this second surgical procedure and the associated risks.

DESCRIPTION:
The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System consists
- Cervical Plates for 1-5 Level fusion, with varying lengths at each level.
- Fixed and variable angle screws available in 4.0mm and 4.5mm diameters with the overall lengths from 12mm to 20mm and two types: tapping and self-drilling screws.
- Screws will feature a threaded hole at the bottom of the drive for easy insertion.
- The instruments for implantation will include drivers that interface with the lock, drivers for the screws with threaded inserter through the driver, plate benders to contour plates as needed, drills with a physical stop, fixed and variable angle drill guides, awls, a plate holder, and a detachable handle for the drills and awls.

MATERIALS:
All components are manufactured from m titanium alloy (Ti-6AI-4V ELI) as described by ASTM F136 or commercially pure titanium (Grade 2 or Grade 4) according to ASTM F67.

INDICATIONS:
The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System is intended for anterior cervical Spine (Levels C2 – T1) fixation system. 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 with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), spondylolisthesis, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

CONTRADICTIONS:
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)

See also the WARNING, POTENTIAL ADVERSE AFFECTS, and PRECAUTION section of this insert.

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 INDICATIONS 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 the 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 loosen 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 with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.

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PRECAUTION (continued):

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 will fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.

CLEANING AND DISFECTING PROCEDURES:

The FloSpine 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. Wash devices using either an ultrasonic or mechanical washing machine for 5 minutes.
    5. Rinse thoroughly for 3 minutes with deionized or distilled water.
    6. Allow instruments to thoroughly dry before storage or sterilization preparation.
    7. Inspect the instruments 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, 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 vary 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.

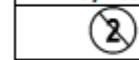
These instructions have been validated as being capable of sterilizing these choice spine implants. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

SURGICAL TECHNIQUE MANUAL

The FloSpine PANAMA™ Anterior Cervical Plate (ACP) System Surgical Technique Manual is available by contacting FloSpine at 561-705-3080.

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.

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile

CONTROLLED