

Instructions for Use Reform[®] POCT System

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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DEVICE DESCRIPTION:

The **Reform POCT System** is a posterior spinal fixation system intended for fusion of the Occipital, Cervical, and Thoracic regions of the spine (Occiput-T3). The system consists of a variety of rods, occipital plates, occipital screws, polyaxial screws, cross-connectors, lateral offset, domino connectors, and hooks to achieve an implant construct that closely matches patient anatomy. The Reform POCT System implants are fabricated from titanium, titanium alloy, or cobalt chromium alloys as described by standards such as ASTM F136, ASTM F1537, or ISO 5832-3. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together, however, should not be used with stainless steel. The system also includes the instruments necessary for inserting and securing the implants. The components are supplied clean and "NON-STERILE". All implants are single use only and should not be reused under any circumstances.

INDICATIONS:

The **Precision Spine Reform POCT System** is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The **Precision Spine Reform POCT System** is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

PRECAUTIONS:

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the **Reform POCT System**. The implantation of the **Reform POCT System** should be performed only by experience spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.

CONTRAINDICATIONS:

The **Reform POCT System** contraindications include, but are not limited to:

1. Use in the thoracic-lumbar-sacral spine below T3
2. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probably metal and/or coating intolerance
3. Patients with fever, tumors, elevated white blood count and other medical conditions
4. Obesity
5. Mental Illness
6. Pregnancy
7. Local infection or inflammation

8. Any case needing to mix metals from different components
9. Any patient unwilling to cooperate with postoperative instructions
10. All cases not stated in the indications

POTENTIAL ADVERSE EFFECTS:

The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects. The following are potential adverse effects, but not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Non-Union or delayed union
4. Foreign body reaction to the implants
5. Hemorrhaging
6. Loss of neurological function, dural tear, pain, and/or discomfort
7. Bone graft fracture, vertebral body fracture or discontinued growth of fused bone at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of all components
9. Pain or discomfort
10. Change in mental status
11. Bursitis
12. Bone loss and/or bone fracture due to stress shielding
13. Inability to resume normal daily activities
14. Revision surgery
15. Death

WARNINGS:

The following are warnings for this device.

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, hypnosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition is unknown.
2. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
3. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
4. Single use only. **AN IMPLANT SHOULD NEVER BE RE-USED.** 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. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
5. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
6. To facilitate fusion, a sufficient quantity of autograft bone should be used.
7. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
8. The implantation of pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
9. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
10. The plates, screws, rods, cap screws, cross-connectors, offsets, dominos, hooks, and instruments are sold "NON-STERILE", and therefore must be sterilized before use.
11. The components of this system should not be used with components of any other system or manufacturer.
12. Titanium components should not be used with stainless steel components within the same system.

PREOPERATIVE MANAGEMENT:

1. The surgeon should consider for surgery only those patients indicated for the use of the **Reform® POCT System**.
2. The surgeon should not consider for surgery those patients contraindicated for the use of the **Reform POCT System**.
3. The surgeon should have a complete understanding of the surgical technique and of the system’s design rationale, indications, contraindications and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

INTRAOPERATIVE:

1. The primary goal of this surgery is to arthrodesis selected vertebrae.
2. Adequate exposure bony preparation and grafting is essential to achieving this result.
3. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting the screws.
4. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or hospital personnel.
5. The implants must be handled and contoured carefully to avoid notching or scratching the surface.
6. Before closing the soft tissues, all of the locking cap screws should be tightened firmly according to the operative technique.
7. Ex-planted implants must never be reused.
8. The placement of screws should be checked radiographically prior to assembly of the rod construct.
9. During construct assembly do not cross thread locking cap screws. Rotate locking cap screws counter clockwise for 1 to 2 revolutions in screw head before attempting to thread locking cap screw into screw head.

POSTOPERATIVE:

1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation devices.
2. Surgical implants must be never reused. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible.
3. Adequate postoperative management to avoid fracture, re-fracture or other complications should follow implant removal.

PACKAGING AND STERILITY

The **Reform POCT System** is supplied as a clean, non-sterile implant and must be sterilized prior to use. Remove all packaging before sterilization. Implants and instruments should be autoclave sterilized using the following validated cycle parameters.

Method	Cycle Type	Sterilization Temperature	Minimum Exposure Time	Drying Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes
Steam	Gravity	270°F (132°C)	15 minutes	30 minutes

For USA: Use only FDA cleared sterilization wraps to enclose the sterilization tray.

MAGNETIC RESONANCE ENVIRONMENT

The **Reform POCT System** has not been evaluated for safety and compatibility in the Magnetic Resonance environment. The **Reform POCT System** has not been tested for heating or migration in the Magnetic Resonance environment.

CLEANING AND DECONTAMINATION

All instruments and implants must be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a de-ionized water rinse.

STORAGE INSTRUCTIONS

All products should be stored in a cool dry place.

HOW SUPPLIED

The required components and specialized instruments are supplied non-sterile in a container suitable for steam sterilization or individually packaged as replacement product. All components and instruments may be purchased independently.

CARE AND HANDLING:

- All torque handles should be returned to the manufacturer for recalibration every six months.
- Please refer to ASTM standards such as F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Surgical instruments are subject to wear with normal usage. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should be used only for their intended purpose.
- **Precision Spine®** recommends that all instruments be visually inspected for wear and disfigurement, as well as tested to ensure instruments are functioning properly prior to use. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **DO NOT USE**.

CLEANING AND DECONTAMINATION OF INSTRUMENTS (NOT SCREWS):

- These instructions are to be followed prior to initial use and reprocessing of the instruments.
- Reprocessing the instruments using the methods described herein, will not limit the useful life of the instruments. The useful life of the product is typically determined by wear and damage due to use.
- Transport trays should be considered reusable devices, and inspected for visible soils and must be cleaned.
- **WARNING:** The following Cleaning instructions have been validated. Failure to follow all steps may result in an improperly cleaned and sterilized instrument (Non-Sterile).
- **CAUTION:** In order to preserve optimal efficiency and safety of the instruments, the following instructions must be followed.
 - The use of metallic brushes, scrub pads or other articles that are likely to damage the instrument must be avoided.
 - Chemicals, such as chlorine or soda as well as organic or ammoniated acids or solvents (e.g. Acetone) that are likely to damage the instrument, must not be used.
 - Mercurial solutions are not recommended, as they corrode metal parts.
 - If applicable, disassemble instruments prior to Cleaning. Articulated instruments must be opened in order to allow the cleaning of all interstices.
 - Immediately after the surgical procedure, disallowing organic debris to dry on the instruments, remove as much debris as possible from each instrument using a water moistened gauze pad or wipe, exchanging the gauze pad or wipe as it becomes soiled. Do not allow organic debris to dry.
 - Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions with warm tap water (35-40°C).
 - Immerse the instruments in the cleaning solution for a minimum of 10 minutes, activating any mechanisms 5X, so the enzymatic cleaner contacts all mated surfaces. Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solutions. Be sure that thorough scrubbing also includes any lumens with an appropriately sized brush that contacts all surfaces. Change the soak solution after each utilization or if grossly soiled.
 - Rinse the instruments in warm tap water (35-40°C) for at least one minute.
 - Transfer the instruments into fresh enzymatic cleaning solution. Sonicate the instruments while immersed in the cleaning solution for a minimum of 15 minutes.
 - Thoroughly rinse all instruments and lumens with warm running water (35-40°C), for at least one minute each until flushing water runs clear. Use a hose or water jet to rinse any lumens, holes, or complex interfaces. Perform a second rinse with DI water, again using a hose or water jet to rinse any lumens, holes, or complex interfaces.
 - Dry with a sterile gauze, clean cloth and/or clean compressed air. Inspect instruments for cleanliness, function, and residual moisture. Any device that is not visually clean must be reprocessed.

LUBRICATION:

To protect instruments from staining and rusting during sterilization and storage, they should be lubricated with a water-soluble, preserved lubricant after each cleaning. Since effective ultrasonic cleaning removes all lubricant, re-lubrication is important. The lubricant should contain a chemical preservative to prevent bacterial growth in the lubricant bath. The bath solution should be made with demineralized water. A lubricant containing a rust inhibitor helps prevent electrolytic corrosion of points and edges. Immediately after cleaning, instrument should be immersed for 30 seconds and allowed to drain off, not wiped off. A lubricant film will remain through the sterilization to protect them during storage.

SPECIAL NOTE FOR TORQUE LIMITING HANDLES:

(This note only applies to customers who purchase Torque Limiting Handles).

The following are suggested guidelines for calibration cycles of Torque Limiting Handles. Note that these are general recommendations only and users are encouraged to determine specific calibration cycles for each product depending on their particular situation or usage. Return product after six months of use or, after 150 autoclave cycles or, after approximately 3000 actuations (Clicks) whichever comes first.

MATERIAL SPECIFICATION

All components are made from medical grade titanium or titanium alloy described by such standards as ASTM F-136 or ISO 5832-3. The products are supplied clean and "NON-STERILE".

PRODUCT COMPLAINTS

Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to **Precision Spine®**. If any of the implants or instruments "malfunction" (i.e., do not meet any of their performance specifications or do not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, **Precision Spine** should be notified immediately by phone, fax or written correspondence. When filing a complaint, please provide the product description, product number, lot number, your name and address, and the nature of the complaint.

CLINICAL HISTORY:

These instructions for use are based upon current experience. The physician may wish to vary the procedure in accordance with clinical judgment.

ADDITIONAL INFORMATION:

The surgical technique guide for the implantation of the **Reform® POCT System** is available upon request. If further information is required, please contact the manufacturer.



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SEE PACKAGE INSERT FOR LABELING LIMITATIONS	NOT STERILE	SINGLE USE ONLY	SALE BY PHYSICIAN PRESCRIPTION FOR USA ONLY
MANUFACTURED BY			