Instructions for Use

Dakota ACDF™ 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

There is no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on **Precision Spine®** product(s) described in this publication. Under no circumstances shall **Precision Spine** be liable for any direct, incidental, or consequential damages other than as expressly provided by specific law. No person has the authority to bind **Precision Spine** to any representation or warranty except as specifically set forth herein.

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DEVICE DESCRIPTION

The **Dakota ACDF** System implants are available in various heights and geometric footprints to accommodate individual patient anatomy and graft material size. **Dakota ACDF** Interbody devices are inserted through an anterior cervical approach and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebral bodies to aid in expulsion resistance, while screws are inserted through the anterior titanium portion of the implant for bone fixation. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

All implantable components are made from medical grade polyetheretherketone (PEEK), tantalum, and titanium or titanium alloy as described by such standards as ASTM F2026, ASTM F560, and ASTM F136 or ISO 5832-3. The products are supplied clean and “NON-STERILE”.

INDICATIONS:

The **Dakota ACDF** System is a standalone cervical interbody device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one- or two-disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The **Dakota ACDF** implants are used with two titanium alloy screws and filled with autogenous bone graft material to facilitate fusion in the cervical spine. The device is placed via an anterior approach at the C2 to T1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

PRECAUTIONS:

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, and other patient conditions, etc., which may impact the performance of the intervertebral body fusion device.

The implantation of **Dakota ACDF** intervertebral fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting risk of serious injury to the patient.

All system implants are single use only. Reuse of the device may result in the following:

1. Infection
2. Loosening
3. Fracture / mechanical failure of the device
4. Inability to properly engage surgical instrumentation
5. Pyrogenic reaction

CONTRAINDICATIONS:

The **Dakota ACDF** System contraindications include, but are not limited to:

1. Prior fusion at the level(s) to be treated.
2. Any condition not described in the Indication for Use
3. Previous vascular approach
4. Iliofemoral arteriosclerosis

5. Morbid obesity
6. Mental Illness
7. Pregnancy
8. Local infection or inflammation
9. Any case requiring the use of different metals from components
10. Any patient unwilling or unable to follow postoperative care instructions
11. All cases not stated in the Indications for Use
12. Reuse, or multiple uses

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. Potential adverse effects include, but are not limited to the following:

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 at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of the 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 activities of normal daily activities
14. Revision surgery
15. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS:
The following are warnings for this device.

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. 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, necrosis of the bone, neurological injury, and/or vascular or visceral injury.
3. The benefit of spinal fusions utilizing any interbody fusion device has not been adequately established in patients with stable spines.
4. 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. Patients who smoke, or abuse alcohol, are poor candidates for spinal fusion.
5. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
6. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters.
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 may compromise the results.
8. Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the **Dakota ACDF™** System. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants, are essential considerations in the utilization of this device.
9. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
10. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **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.

PREOPERATIVE:

1. The surgeon should consider utilizing the **Dakota ACDF™** System only with those patients that meet the criteria described in the indications.
2. The surgeon should avoid utilizing this device with those patients who meet the criteria described in the listed contraindications.
3. The surgeon should make sure that all implants and instruments are unpacked, sterilized, and available prior to surgery.
4. The implant and instruments are provided non-sterile and must be cleaned and sterilized prior to use.
5. Implants and instruments should be inspected for surface flaws and scratches and should not be used in the presence thereof. If such instruments will not function optimally, they should be returned to **Precision Spine®** for replacement.
6. The surgeon should have a complete understanding of the surgical technique, design rationale, indications, and contraindications.
7. The surgeon should have a complete understanding of the surgical technique guide.

INTRAOPERATIVE:

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. Damage to the nerves will cause loss of neurological functions. Extreme caution should be taken to avoid the spinal cord and nerve roots at all times, especially during endplate preparation, and insertion of the interbody and fixation screws.
3. Careful use of the implants and instruments should be taken. Misuse of the components may cause injury to the patient or operative personnel.
4. Bone graft should be packed inside the device prior to insertion and around the device after insertion. Bone graft must be placed in the area to be fused. The bone graft must extend from the upper to the lower vertebrae to be fused.
5. Notching and scratching of implants should be avoided.
6. The **Dakota ACDF** System should be supported by inferior and superior fixation bone screws.

POSTOPERATIVE:

1. The physician's postoperative directions, warnings to the patient and the corresponding patient's compliance are extremely important.
2. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process.
3. The patient should be warned about the limitation of bending at the point of spinal fusion.
4. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts, or other movements preventing proper healing and/or fusion.
5. The removed implants should be properly disposed of and are not to be reused under any circumstance.

STERILIZATION

The **Dakota ACDF** System is supplied clean and non-sterile and must be sterilized prior to use. Remove all packaging before sterilization. Implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

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

To assure maintenance of sterility we recommend

- Utilization of a minimum drying time of 30 minutes in accordance with ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health facilities.*
- For USA: Use only FDA cleared sterilization wraps to enclose the sterilization tray.

MAGNETIC RESONANCE ENVIRONMENT

The **Dakota ACDF** System has not been evaluated for safety and compatibility in the MR environment. The **Dakota ACDF** System has not been tested for heating, migration, or image artifact in the MR environment. The safety of **Dakota ACDF** System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 only be used 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

- 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 implantable components are made from medical grade polyetheretherketone (PEEK), tantalum, and titanium or titanium alloy as described by such standards as ASTM F2026, ASTM F560, and ASTM F136 or ISO 5832-3. The products are supplied clean and "NON-STERILE".

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

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.

ADDITIONAL INFORMATION:
The surgical technique guide for the implantation of the **Dakota ACDF™** is available upon request. If further information is required, please contact the manufacturer.

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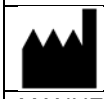
			**RX only**
SEE PACKAGE INSERT FOR LABELING LIMITATIONS	NOT STERILE	SINGLE USE ONLY	SALE BY PHYSICIAN PRESCRIPTION FOR USA ONLY
			
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