Instructions for Use

Product: DTRAX® Allograft Delivery Instrument

REF **PD-10-400**

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CAUTION: Federal law restricts this device to sale by or on the order of a physician.

PACKAGE CONTENTS:

Item #	Quantity	Description
1	1	DTRAX® Allograft Delivery Instrument

ITEM DESCRIPTION:

1. **ALLOGRAFT DELIVERY INSTRUMENT:** A manual orthopedic surgical instrument used to deliver structural bone graft to a target area of the spine. The Allograft Delivery Instrument is manufactured using medical grade polycarbonate resin and stainless steel.

INTENDED USE AND INDICATIONS:

The DTRAX® Allograft Delivery Instrument is intended and indicated for the delivery of structural bone graft to a target area of the spine.

CONTRAINDICATIONS:

The DTRAX® Allograft Delivery Instrument should not be used in any of the following instances:

- Absence of posterior spinal elements including the pedicle, pars interarticularis, facet joints, spinous process and the majority of the lamina.
- Active infection process or significant risk of infection (immunocompromised).
- Local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any medical or surgical condition which would preclude the potential benefit of a spinal allograft surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
- Any case where a bone graft and fusion is unnecessary or where fracture healing is not required.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Infection, local to operative site.
- Cancer of the spine.
- Any patient unwilling to follow post-operative instructions.
- Any case not described in the indications.

WARNINGS:

- their labeled indications and the manufacturer's instructions for use (IFU), especially during insertion and removal.

In any surgical procedure, the potential for complications exists. All of the adverse events associated with general surgery or spinal fusion surgery are possible. A listing of possible adverse events includes but are not limited to:

- There are no particular risks expected during other investigations and/or treatment
- Physicians using DTRAX® Spinal System should have significant experience in spinal surgery including spinal fusion.
- Bursitis.
- Loss of neurological function, including paralysis (complete or incomplete), radiculopathy and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Cauda equine syndrome, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, spinous process, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Non-union (or pseudarthrosis).
- Delayed union or mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function. Inability to perform activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Herniated nucleus pulposus, disc disruption or degeneration.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
- Reproductive system compromise such as sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.
- Additional surgery may be necessary to correct some of these adverse events.
- Advanced diabetes.

Additional conditions presenting increased risk of failure include:

- Uncooperative patient or patient with neurologic disorders, incapable of following instructions;
- Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
- Metabolic disorders that may impair bone formation;
- Osteomalacia; and
- Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

PRECAUTIONS:

PRE-OPERATIVE:

CAUTION: Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those addressed in the contraindications should be avoided.

- The surgeon should be familiar with the various components before using the equipment and should verify that all necessary instruments are present before the surgery begins.
- Additional sterile components and/or instruments should be available in case of unexpected need.
- The surgeon must be thoroughly familiar with the surgical procedure prior to performing surgery.
- The surgeon should also use medical devices in accordance with
- Patient should be in the previously described diagnostic categories described under INTENDED USE AND INDICATONS.

- Sterilization and handling procedures conforming to accepted standards are mandatory.
- Radiographs should be made if there is any question as to the location of the intended or the actual instruments.
- Components should be received and accepted only in packages that have not been damaged or tampered with. Damaged instruments should not be used.
- Components must be carefully handled and stored in a manner that prevents scratches, damage and corrosion.
- As a precaution, before patients receive any surgery, prophylactic antibiotics may be considered, especially for high risk patients.

INTRAOPERATIVE PRECAUTIONS:

- Extreme caution should be used around the spinal cord and nerve roots during procedure. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments may cause injury to the patient or operative. It is recommended to place bone graft material in the area to be fused. The graft material should extend from the upper to the lower vertebrae being fused.
- Do not mix instruments from different manufacturers.
- While rare, breakage of instruments may occur especially with extensive use or excessive force.
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.

POSTOPERATIVE PRECAUTIONS:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important. Detailed instructions should be given to the patient.

- The patient should be warned to avoid falls or sudden jolts in order to allow the chance for an optimal surgical result.
- The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation.
- The patient should be advised not to smoke tobacco or use nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications during the bone graft healing process.
- The patient should immediately consult the surgeon if there is a problem of the treated condition.
- Periodic follow-up is recommended to monitor the state of the patient and the condition of the bone.
- The patient is expected to follow the detailed instructions, limitations, and warnings from the operating surgeon.
- The surgeon is expected to supply detailed instructions to the patient regarding postoperative activities. The patient should be advised at their inability to bend at the point of spinal fusion and receive training on how to compensate for this loss of motion.

INSTRUCTIONS AND TECHNIQUES:

The DTRAX® Allograft Delivery Instrument is used to deliver structural bone graft to a target area of the spine. Bone graft material is not supplied as part of the system.

1. Using standard surgical procedure, make an incision through the skin, subcutaneous tissues and fascia over the joint space to be treated.
2. Load the structural bone graft onto the distal end of the instrument.
3. Use the loaded DTRAX® Allograft Delivery Instrument to deliver the bone graft to the target area.
4. Push the orange deployment plunger button to deploy the bone graft.
5. Close the incision using standard procedures.

CAUTION: The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

CAUTION: Use fluoroscopy when appropriate to ensure tools do not impinge on nerve structures during use/insertion and to confirm proper placement of tools and bone graft.

CLEANING AND STERILIZATION:

DTRAX® Allograft Delivery Instrument is provided **STERILE** and are **SINGLE-USE** devices.

CAUTION: The DTRAX® Allograft Delivery Instrument should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Providence does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

STORAGE CONDITIONS:

All products must be stored in a clean, dry environment and be protected from sunlight and temperature extremes.

Verify package integrity prior to use. Do not use any components if packaging is damaged.

SYMBOLS USED ON THIS PRODUCT:

STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Do not reuse
	Caution
	Consult instruction for use
	Keep Dry
REF	Catalog Number
LOT	Lot code
	Use-By date
	Keep away from sunlight
	Manufacturer
EC REP	Authorized representative in the European Community
CE 0470	CE Mark by Notified Body number