Instructions for Use

Product: DTRAX® Spinal System

REF **DX-22-100**

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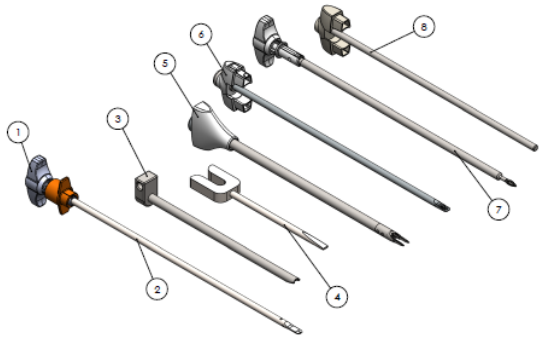
CAUTION: Federal law restricts this device to sale by or on the order of a physician.

PACKAGE CONTENTS:

Item #	Quantity	Description
1	1	Access Chisel Handle
2	1	Access Chisel
3	1	Decortication Trephine
4	1	Fork Mallet
5	1	Guide Tube
6	1	Decortication Rasp
7	1	Decortication Burr
8	1	Bone Graft Tamp



ITEM DESCRIPTION:

1. **ACCESS CHISEL HANDLE: A** manually detachable handle to provide comfortable grip and better manipulation during access chisel insertion.
2. **ACCESS CHISEL:** An instrument with a wedge-shaped tip to provide access to a target area of the spine.
3. **DECORTICATION TREPHINE:** The Decortication Trephine is a hollow tubular structure that slides over the Access Chisel with the distal end lined with teeth that act like a rasp or file. It is used to decorticate the spine to promote bone growth and fusion.
4. **FORK MALLET:** The Fork Mallet is used for light malleting of instruments as well as controlled separation of the instruments. The mallet head has a feature designed for use with the DTRAX® Cervical Cage-B deployment instrument.
5. **GUIDE TUBE:** The Guide Tube has a tapered end that serves to keep the joint distracted while instruments are passed through its bore for decortication, implant placement and injection of bone graft.
6. **DECORTICATION RASP:** A rasp for abrading the interior surface of a joint to promote spinal fusion.
7. **DECORTICATION BURR:** An instrument with a burr tip to abrade or scrape the interior surface of a joint to promote spinal fusion.
8. **BONE GRAFT TAMP:** This instrument serves as a simple plunger within the Guide Tube. Bone graft material is injected into the Guide Tube followed by insertion of the delivery tool. The Bone Graft Tamp is pushed forward within the Guide Tube, injecting the bone graft material into the joint space.

INTENDED USE AND INDICATIONS:

The DTRAX® Spinal System is a set of instruments intended and indicated for access and preparation of a spinal joint to aid in fusion.

CONTRAINDICATIONS:

The DTRAX® Spinal System 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:

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 their labeled indications and the manufacturer's instructions for use (IFU), especially during insertion and removal.
- 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.
- Radiographically document all phases of spinal instrumentation to verify placement of the instrument in the intended location. Reference the Instructions and Techniques section of this document.

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:

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.

The DTRAX® Spinal System instruments are used to access and prepare cervical spine for joint fusion. It is recommended that commercially available bone graft be used to aid fusion. Bone graft material is not supplied as part of the system.

1. Use AP & Lateral fluoroscopy to verify the cervical joint level being treated and the intended instrument location.
2. Using standard surgical procedure, make an incision through the skin, subcutaneous tissues and fascia over the joint space to be treated.

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.

3. Distract the joint with the Access Chisel.
4. Remove or detach the Access Chisel Handle by pulling the handle back on the lock sleeve and hold in that position while removing it from the Access Chisel. See **Figure 1**.

Figure 1

5. Slide the Decortication Trephine over the Access Chisel. With light malleting using the decortication fork as needed and rotation of the device, decorticate the surrounding bone and then remove the Decortication Trephine.
6. Slide the Guide Tube over the Access Chisel and into the joint. Gently tap the Guide Tube with the Fork Mallet as necessary. Tap on the metal button provided for this purpose on the proximal end of the Guide Tube.

NOTE: The distal tip of the Guide Tube has several markers that can be seen with fluoroscopy; bumps above and below on the fork and a radiolucent hole that can be seen in lateral fluoroscopy (see **Figure 2**). Use these markers to gage the depth of penetration.

Figure 2

7. Remove the Access Chisel. The Guide Tube will maintain distraction of the joint.
8. The distal tip of the Decortication Rasp is wedge-shaped with cutting surfaces on each side of the wedge. The surface features are not symmetrical. Fully insert the Decortication Rasp into the Guide Tube until both handles lock together. Remove (press on side buttons to disengage) and reinsert the Decortication Rasp a few times to decorticate internal surfaces. Remove the Decortication Rasp, rotate the Decortication Rasp 180 degrees and repeat the decortication process.
9. In addition to rasping with the Chisel Rasp, the Decortication Burr is supplied to provide further decortication as an option. If the Decortication Burr is used, insert the Decortication Burr through the Guide Tube to the point where the Burr tip touches the spinal facet joint.
10. Turn the Decortication Burr clockwise to start decorticating the interior joint surfaces. Advance the Decortication Burr until decortication is complete. Pull the decortication burr to remove it from the joint. Slightly rotate the burr to facilitate the removal if necessary.

> Repeating this decortication process is not
> ry
> or recommended. Decorticating the joint once should be adequate.

11. If using this system with the CAVUX® Cervical Cage-B product, the concave feature on the Fork Mallet can be used to aid in unlocking the Cage Release Knob on the CAVUX® Cervical Cage-B delivery instrument. See **Figure 3**.

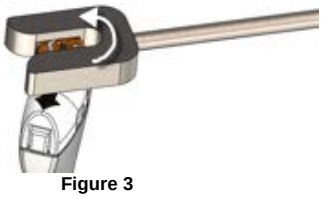


Figure 3

12. Place bone graft material within the Guide Tube and inject the material into the joint by using the Bone Graft Tamp as a plunger.
13. Remove the Bone Graft Tamp and the Guide Tube from the joint.
14. Close the incision using standard procedures.

CLEANING AND STERILIZATION:

DTRAX® Spinal System is provided **STERILE** and are **SINGLE-USE** devices.

> **CAUTION:** The DTRAX® Spinal System 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 implants 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.

SYMBOL GLOSSARY:

Reference: ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied*

Symbol	Symbol Number and Title	Brief Description
	5.1.1 Manufacturer	Indicates the medical device manufacturer.
	5.1.4 Use-By date	Indicates the date after which the medical device is not to be used.
LOT	5.1.5 Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	5.1.6 Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
STERILE R	5.2.4 Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	5.2.8 Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.3.2 Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	5.3.4 Keep Dry	Indicates a medical device that needs to be protected from moisture
	5.4.2 Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.3 Consult instruction for use	Indicates the need for the user to consult the instructions for use.
	5.4.4 Caution	Indicates the need for the user to consult the instructions for use for important cautionary information.