Instructions for Use

Product: DTRAX® Spinal System

REF **DX-22-100**

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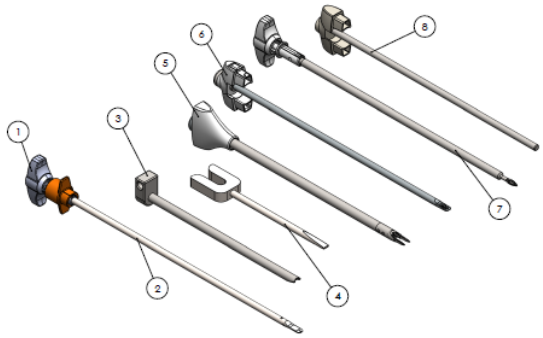
℞ Only

Before using a product placed on the market by Providence Medical Technology, the operating surgeon should study carefully the following recommendations, warnings and instructions. Providence Medical Technology is not liable for complications that may arise from the use of the device in circumstances outside of the company's control, including, but not limited to, product selection and deviation from the device's indicated uses or surgical technique.

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 the facet joint.
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 and as an aid to release instruments.
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 and injection of autograft or allograft.
6. **DECORTICATION RASP:** A rasp for abrading the interarticular surfaces of the facet to promote spinal fusion.
7. **DECORTICATION BURR:** An instrument with a burr tip to abrade or scrape the interarticular surfaces of the facet to promote spinal fusion.
8. **BONE GRAFT TAMP:** A plunger that is used to pack and move autograft or allograft material through the Guide Tube.

INDICATIONS FOR USE:

The DTRAX® Spinal System is a set of instruments indicated to be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.

CONTRAINDICATIONS:

The DTRAX® Spinal System should not be used in any of the following instances:

- Absence of the pedicle, lateral mass, or facet joints at the segment to be fused.
- Allergy to any of the materials in the System.
- Pregnancy.
- Non-skeletally mature patients.

WARNINGS:

- Physicians using DTRAX® Spinal System should have significant experience and proper training in spinal surgery including spinal fusion.
- Do not clean, resterilize or reuse the DTRAX® Spinal System. Attempting to clean or resterilized disposable instruments may compromise the dimensional and mechanical integrity of the device and may lead to patient or user injury.
- Do not use disposable instruments that are deformed or damaged.
- Do not subject instruments to high loads or excessive impact as breakage may occur.

PRECAUTIONS:

PRE-OPERATIVE:

- 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 posterior cervical fusion 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.
- Use the instruments only as specifically designed for use with the associated procedure.
- 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.

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, or misuse of instruments may cause injury to the patient or operative. It is indicated to place autograft or allograft material in the area to be fused. The graft material should extend from the upper to the lower vertebrae surface being fused, including the lateral mass and articulating surfaces of the facet.
- 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.

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 the cervical spine for joint fusion. It is recommended that commercially available autograft or allograft be used to aid fusion. Autograft or allograft 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 autograft or allograft.

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**.

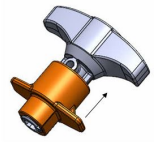


Figure 1

5. Slide the Decortication Trephine over the Access Chisel. With light malleting using the decortication fork as needed and by rotation of the device, decorticate the adjacent superior and inferior lateral masses 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. Remove the Decortication Rasp, rotate the Decortication Rasp 180 degrees and repeat the decortication process as necessary.
9. In addition to rasping with the Chisel Rasp, the Decortication Burr is supplied to provide further decortication. To use the Decortication Burr, insert through the Guide Tube until the burr handle contacts the Guide Tube.
10. Turn the Decortication Burr clockwise to start decorticating the interarticular surfaces of the facet. Continue rotating and 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.
11. Place no more than 2.5cc of autograft or allograft material at a time within the Guide Tube and inject the material into the joint by using the Bone Graft Tamp as a plunger. Note: autograft or allograft material is not included as part of the DTRAX® Spinal System.
12. Remove the Bone Graft Tamp and the Guide Tube from the joint.
13. Close the incision using standard procedures.

STERILITY:

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

STORAGE CONDITIONS:

DTRAX® Spinal System 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. Do not use the DTRAX Spinal System if the expiration date has been exceeded.

SYMBOL GLOSSARY:

References: ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied; 21 CFR 801*

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.
Rx Only	21 CFR 801.15(c)(1)(i)F	Requires prescription in the United States.