

# Instructions for Use

**Product: DTRAX® Spinal System-L**

**REF DX-22-600**

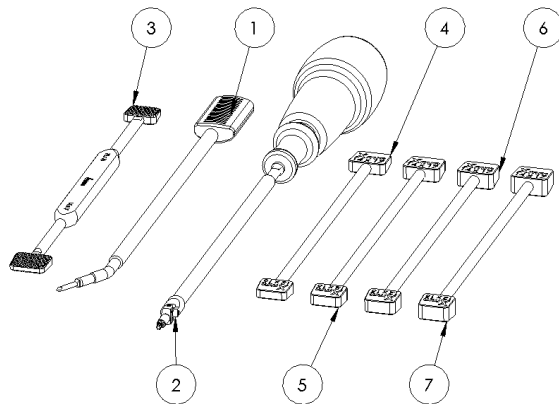


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**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

## PACKAGE CONTENTS:

Item #	Quantity	Description
1	1	Awl
2	1	Torque Driver
3	1	Cage Rasp
4	1	Double Cage Trial – 6mm
5	1	Double Cage Trial – 7mm
6	1	Double Cage Trial – 8mm
7	1	Double Cage Trial – 9mm



## ITEM DESCRIPTION:

- AWL:** An instrument with a trocar-tip point for puncturing cortical bone. The tip is set at a 40-degree angle from the shaft axis.
- TORQUE DRIVER:** An articulated driver with #8 Hexalobular bit. The handle has a torque-limiter mechanism set at 15 in-lb.
- CAGE RASP:** An instrument for decorticating the intervertebral disc space, at 6mm height.
- DOUBLE CAGE TRIAL – 6mm:** A trial sizer instrument for sizing intervertebral disc space, at 6mm height.
- DOUBLE CAGE TRIAL – 7mm:** A trial sizer instrument for sizing intervertebral disc space, at 7mm height.
- DOUBLE CAGE TRIAL – 8mm:** A trial sizer instrument for sizing intervertebral disc space, at 8mm height.
- DOUBLE CAGE TRIAL – 9mm:** A trial sizer instrument for sizing intervertebral disc space, at 9mm height.

## INTENDED USE AND INDICATIONS:

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

## CONTRAINDICATIONS:

The DTRAX® Spinal System-L 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-L 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 PRECAUTIONS:**

**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.
- Verify that any existing hardware at the surgical site from previous surgeries will not interfere with proper use of the Spinal System-L instruments.
- 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 INDICATIONS.
- 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.
- 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.
- Be aware of any existing hardware at the surgical site from previous surgeries that may interfere with proper use of the Spinal System-L instruments.

**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-steroidal 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-L instruments are used to prepare the cervical spine for joint fusion.

**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.

Using the Double Cage Trials:

- The Double Cage Trials can be used to assess intervertebral disc space heights, to aid in implant size selection.

Using the Cage Rasp:

- The Cage Rasp can be used to decorticate the intervertebral disc space, to aid in fusion of the disc space.

**CAUTION:** When using the Double Cage Trials and Cage Rasp, do not over insert the instruments into the intervertebral disc space.

Using the Awl:

- The Awl can be used to create a starter or pilot hole in bone.
- The Awl handle can be malleted to assist in driving the Awl into bone.

Using the Torque Driver:

- The Torque Driver can be used to drive a bone screw or other implants/instruments that is designed to accept a #8 Hexalobular bit, and is compatible with a 15 in-lb torque limit.
- Engage the driver bit securely in the receiving socket of the implant/instrument being driven.

**CAUTION:** When using the Torque Driver, ensure that the articulating joint is not bent beyond a 45-degree angle.

- Turn the Torque Driver handle clockwise to drive.
- Once the 15 in-lb torque limit is reached, the handle mechanism will ratchet and indicate the limit by an audible click.
- Disengage the Torque Driver from the implant/instrument.


**CLEANING AND STERILIZATION:**

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

**CAUTION:** The DTRAX® Spinal System-L should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Providence Medical Technology does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.












**STORAGE CONDITIONS:**

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

	<p>Verify package integrity prior to use. Do not use any components if packaging is damaged.</p>
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**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.
	5.1.5 Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.6 Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	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.