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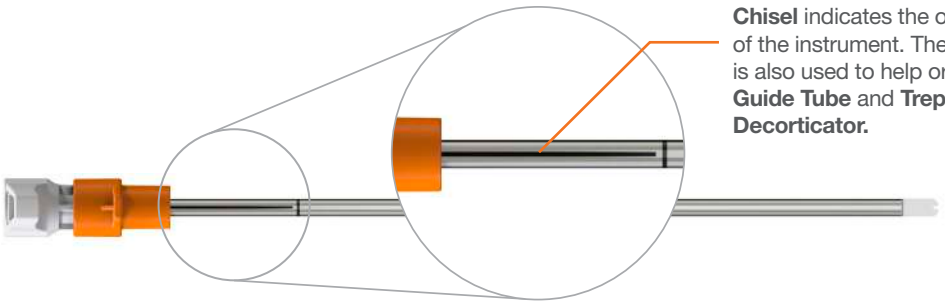
DTRAX® | Cage–SE System In-Service Guide

Providence Medical Technology Inc. has updated its GL–DTRAX® Cervical Cage–SE System. Its features are designed to improve instrument control, ease of use, and procedural efficiency. This document is intended to guide company representatives on how to introduce the updated GL–DTRAX Cervical Cage–SE System to surgeons and hospital staff.

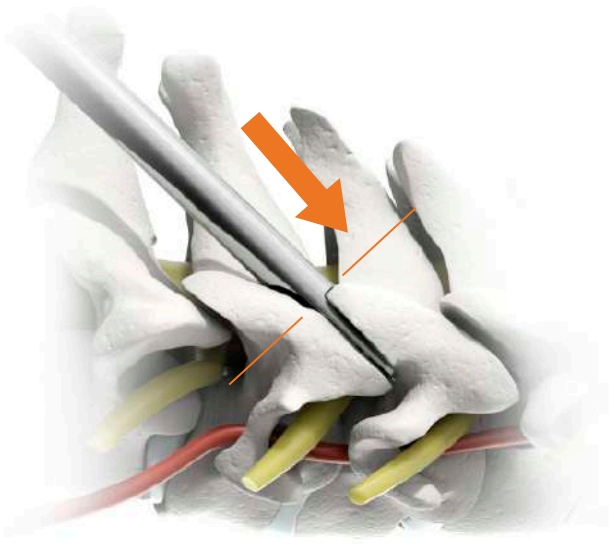
Review with your Surgeon

1. Access Chisel and Guide Tubes are unidirectional. Markings on shaft should be facing cranially.



The black line on the **Access Chisel** indicates the orientation of the instrument. The black line is also used to help orient the **Guide Tube** and **Trephine Decorticator.**

2. Access Chisel will have greater resistance entering the joint due to the new teeth. The teeth are designed to provide improved positioning control to the surgeon. In tighter joints, the “drop in” tactile feedback will be reduced.



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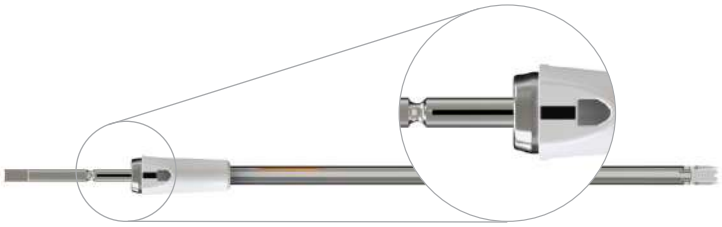
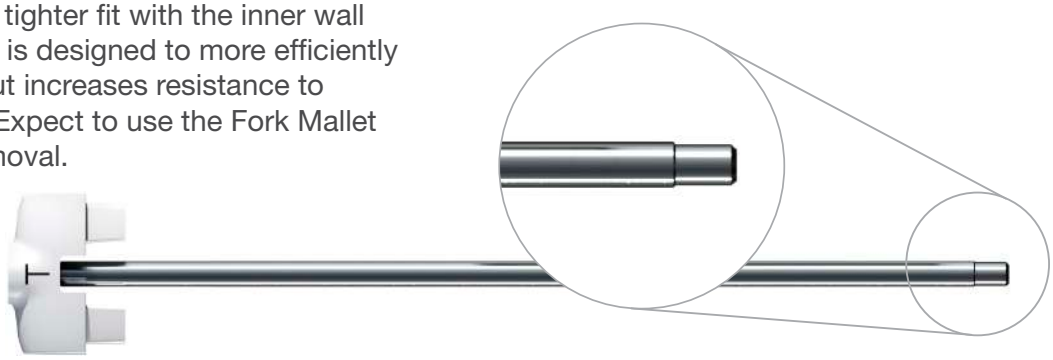
Review with your Surgeon (Continued)

3. Access Chisel and Guide Tube have "positive stop" features that control depth into joint. **Caution:** The Access Chisel positive stop feature serves as an aid to instrument positioning. It is not intended to be the sole indicator for determining correct depth. Users should first rely on fluoroscopic or direct visual guidance.



Guide Tube placed over **Access Chisel** with proper alignment

4. Bone Graft Tamp has a tighter fit with the inner wall of the Guide Tube. This is designed to more efficiently deploy graft material but increases resistance to insertion and removal. Expect to use the Fork Mallet pry feature to aid in removal.



5. Numbered instruments clarify procedural order and O.R. communication

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Please consult product IFUs for safety information, warnings, indications, and contraindications.

To learn more, visit **www.providencemt.com**

 MKT-PMT-451 Rev 0

Safe, Effective, Tissue-Sparing.

Multiple clinical publications on Posterior Cervical Fusion with DTRAX® demonstrate that the procedure is safe and effective at relieving neck and arm pain associated with cervical radiculopathy.[1–5]

Average patient satisfaction rating of 4.5 out of 5 at 24 months after surgery[6]

Posterior Cervical Fusion with DTRAX® can be performed using tissue-sparing technique. The diameter of the largest instrument is just 1cm in diameter.

Providence's family of products offers a variety of surgical options to treat cervical radiculopathy. Patients should always consult their physician to determine which course of treatment is most appropriate.

Contraindications:

Posterior Cervical Fusion with DTRAX® should not be used in any of the following instances:

– Obesity, pregnancy, advanced diabetes or cancer of the spine
– Rapid joint disease, bone absorption, osteopenia and/or osteoporosis
– Active infections, local inflammation, fever or leukocytes
– Any medical or surgical condition that would preclude the potential benefit of spinal surgery (e.g., elevation of white blood count, tumors, congenital abnormalities)
– Any case not described in the indications for use for a product

Warning:

As in any surgical procedure, the potential for complications exist. Some of these complications include, but are not limited to:

– Infection or painful, swollen or inflamed surgical site
– Loosening, bending, breakage or dislocation of an implant requiring revision surgery
– Allergic or physiological reactions to foreign body intolerance
– Histological responses possibly involving macrophages and/or fibroblasts
– Bone resorption and/or overproduction

Any surgical techniques shown are for illustrative purposes only. The technique(s) employed in each case will always depend on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Each product carries its own full list of warnings and precautions in its Instructions for Use (IFU). Please contact your physician or Providence Medical Technology for additional information on a specific product or procedure.

To learn more, please visit
www.providencemt.com

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Providence Medical Technology is a private corporation focused on innovative spinal therapies. We are committed to developing new products and procedures that are less disruptive to patients, less expensive for responsible parties, and provide positive outcomes for patients and surgeons.

Posterior Fusion with DTRAX®

For the Treatment of Cervical Radiculopathy

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Providence's family of products offers a minimally invasive alternative for patients suffering from cervical radiculopathy.

An Innovative Approach

Posterior Cervical Fusion with DTRAX® enables an innovative posterior (from the patient's back) approach that typically requires one to two small incisions at the base of the patient's neck.

Two incision option

Benefits of Posterior Cervical Fusion with DTRAX® may include:

– Shorter hospital stay*,[5]
– Reduced blood loss*,[5]
– Low rate of complications[7]
– Significant improvement in symptoms as early as two weeks after procedure[1]
– Leaves future surgical options open
– Eliminates risk of swallowing and speaking problems that can occur with anterior fusion surgery.

* Compared to posterior cervical fusion with lateral mass screws and rods.

A Closer Look

First your surgeon relieves irritation and pressure on your spinal nerve roots by distracting (opening) the joints. Then small implants and graft material are inserted to stabilize and enable fusion of these joints.

Indications

The GL-DTRAX® instruments, cages, and bone screws are indicated for use in skeletally mature patients for posterior cervical treatment at C3–C7 (inclusive) spinal levels for patients with single level radiculopathy due to degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facets.

Ask your doctor if Posterior Cervical Fusion with DTRAX® is right for you

What to Expect

Posterior Cervical Fusion with DTRAX is performed by a specially trained surgeon. Published clinical data demonstrates that patients experience significant reductions in pain and disability.[1–5]

References

1. Lenzi, et al. World Neurosurgery, Volume 100, 7–14
2. McCormack et al. J Neurosurg Spine. 2013 Mar;18(3):245-54
3. McCormack et al. Spine Research, Published January 20, 2016
4. Siemionow et al. J Neurol Surg A Cent Eur Neurosurg. 2016 Nov;77(6):482-488
5. Smith et al. Oper Neurosurg (Hagerstown). 2017 Jun 14
6. Providence Clinical Study Report - CLN-DTX-105 Rev 1
7. Siemionow et al. J Craniovertebr Junction Spine. 2017 Oct-Dec;8(4):342-349

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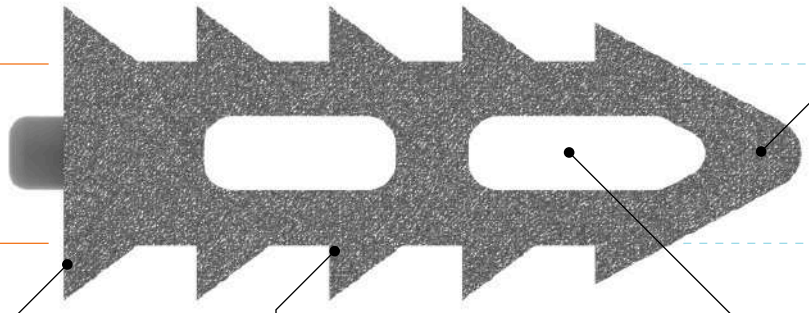
Cervical Cage Comparison

GL-DTRAX® Cervical Cage–SE

GL-DTRAX® Cervical Cage–T

GL-DTRAX Cervical Cage–SE

NEW



Parallel upper and lower surfaces

0˚ lordotic angle

Tapered nose for ease of insertion

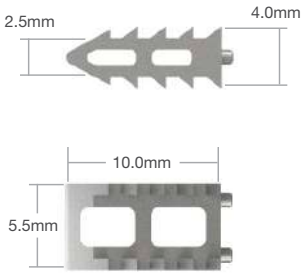
Single-piece titanium alloy with proprietary surface treatment

Graft window aids lateral visualization

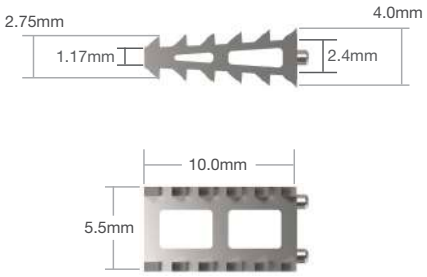
Superior and inferior surfaces feature teeth designed to reduce joint translation and prevent implant migration

Comparative Dimensions

GL-DTRAX Cervical Cage–SE



GL-DTRAX Cervical Cage–T



Implant	Total Surface Area (mm^2)	Total Volume (cc)
Cage–SE	44.9	0.06
Cage–T	44.8	0.05

Cage delivery instrument

Cage–SE **Cage–T**

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GL–DTRAX® Cervical Cage–SE and Cervical Cage–T Systems

The GL-DTRAX® Spinal System is a set of manual orthopedic surgical instruments that provide tissue-sparing access, bone preparation, and graft delivery to facilitate spinal fusion.

GL-DTRAX Cervical Cage-SE System: DX-10-600

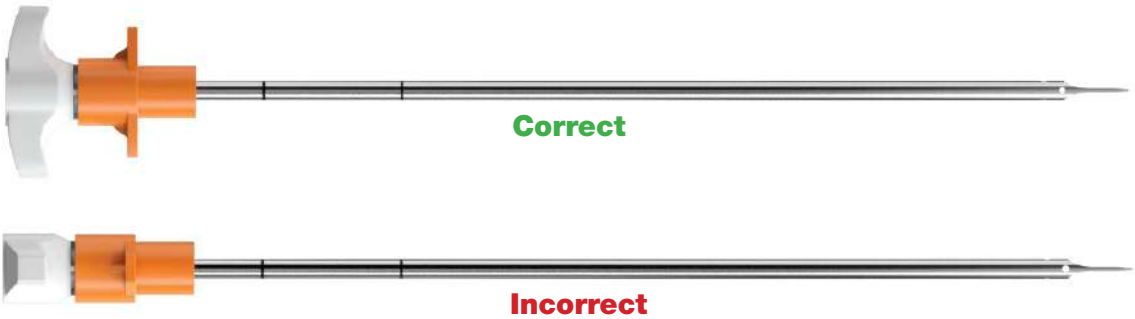
GL-DTRAX Cervical Cage-T System: DX-10-500

Quick-Release Handle

– When properly attached the quick-release handle is perpendicular to the tip of the access chisel

– Pull back on the orange locking sleeve to detach the handle.

– The Access Chisel can be lightly malleted while the handle is attached by striking the center of the handle. If heavy malleting is required, remove the handle to prevent damage.



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