Instructions for Use

Product:
CORUS™ Spinal System-X (DX-22-300), and CORUS™ Guide Tube Adapter (PD-04-470)

REF **DX-22-300**
PD-04-470

Providence Medical Technology, Inc.
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℞ Only

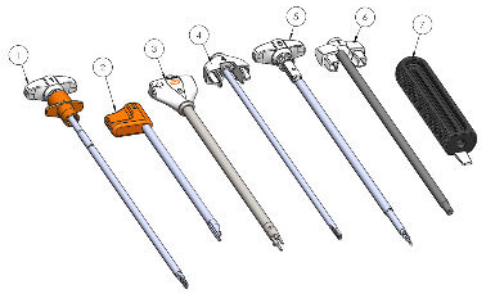
Before using a product placed on the market by Providence Medical Technology, the operating surgeon should carefully study the following recommendations, Contraindications, Warnings, Precautions and Instructions. Providence Medical Technology is not liable for complications that may arise from the use of the device in circumstances outside of the company's control, including, but not limited to, product selection and deviation(s) from the Indications for Use or recommended surgical technique.

Device Description

The CORUS Spinal System-X disposable instruments are used to access and prepare the posterior cervical or lumbar spine for joint fusion by decortication of bone surfaces, including the posterior lateral mass and facet joints, combined with application of allograft or autograft in patients with or without anterior or posterior instrumentation. 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.

PACKAGE CONTENTS:

DX-22-300 CORUS Spinal System-X ***(#1-7, PACKAGED AND SOLD TOGETHER)***	
Item #	**Description**
1	Access Chisel with Detachable Handle
2	Trephine Decorticator
3	Guide Tube
4	Rasp Decorticator
5	Rotary Decorticator
6	Bone Graft Tamp
7	Multi-Tool



PD-04-470 CORUS Guide Tube Adapter ***(PACKAGED AND SOLD SEPARATELY, Component of CORUS Spinal System-X)***	
Item #	**Description**
1	Guide Tube Spacer

DESCRIPTION OF COMPONENTS:

Refer to Surgical Technique Guide for more details.

DX-22-300:
1. **ACCESS CHISEL WITH DETACHABLE HANDLE:** An instrument used to provide access to the facet joint. The instrument includes a detachable handle.
2. **TREPHINE DECORTICATOR:** An instrument that slides over the Access Chisel to decorticate the spine to promote bone growth and fusion.
3. **GUIDE TUBE:** The Guide Tube serves to keep the joint distracted while instruments are passed through its bore for decortication and injection of autograft or allograft.
4. **RASP DECORTICATOR:** A rasp for abrading the interarticular surfaces of the facet to promote spinal fusion.
5. **ROTARY DECORTICATOR:** An instrument to decorticate the surfaces in and around the facet to promote spinal fusion.
6. **BONE GRAFT TAMP:** A plunger that is used to pack and move autograft or allograft material through the Guide Tube.
7. **MULTI-TOOL:** An instrument used for light malleting of instruments and as an aid to release instruments.

PD-04-470 (Packaged and sold separately):
1. **GUIDE TUBE ADAPTER:** A spacer for optional repositioning of instruments used with the Guide Tube.

INDICATIONS FOR USE:

FOR CERVICAL FUSION:
The CORUS™ Spinal System-X is a set of instruments indicated to be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.

FOR LUMBAR FUSION:
The CORUS™ Spinal System-X is a set of instruments indicated to be used to perform posterior lumbar fusion in patients with lumbar degenerative disc disease.

CONTRAINDICATIONS:

Devices 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:

- Physician users should have significant experience and proper training in spinal surgery including spinal fusion.
- Do not clean, resterilize, or reuse. Attempting to clean or resterilize instruments may compromise the dimensional and mechanical integrity of the device and may lead to patient or user injury.
- Do not use 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 use medical devices in accordance with their labeled indications and the manufacturer's instructions, especially during insertion and removal.
- Use the instruments only as specifically designed for use with the associated procedure.

Verify package integrity prior to use. Do not use any components if the packaging is damaged or if the expiration date is exceeded.

- Radiographs should be made if there is any question as to the location of the instruments.
- Do not use if the package is damaged or any portion of the package has been previously opened.

INTRAOPERATIVE PRECAUTIONS:

- Extreme caution should be used around the spinal cord and nerve roots during the procedure. Damage to the nerves may cause loss of neurological functions.
- Breakage or misuse of instruments may cause injury to the patient or operator.
- 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.
- Radiographically document all phases of spinal instrumentation to verify the placement of the instrument in the intended location.

POSTOPERATIVE PRECAUTIONS:

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

INSTRUCTIONS AND TECHNIQUES:

- A recommended Surgical Technique Guide for the use of these instruments is available upon request from:
  Providence Medical Technology, Inc.,
  Pleasanton, CA 94588 USA
  www.providencemt.com/contact-us

- Surgeons should not use these instruments until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events.

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.

STERILITY:

Devices are provided **STERILE** and the instruments are **SINGLE-USE** devices.

STORAGE AND DISPOSAL:

- Devices must be stored in a clean, dry environment and be protected from sunlight and temperature extremes.
- Dispose of the contaminated instruments and/or packaging materials using standard hospital procedures and universally accepted practices for bio-hazardous wastes.

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 Indicates:
	5.1.1 Manufacturer	the medical device manufacturer.
	5.1.4 Use-By date	the date after which the medical device is not to be used.
	5.1.5 Batch code	the manufacturer's batch code so that the batch or lot can be identified.
	5.1.6 Catalog Number	the manufacturer's catalog number so that the medical device can be identified.
	5.2.4 Sterilized using irradiation	a medical device that has been sterilized using irradiation.
	5.2.8 Do not use if package is damaged	a medical device that should not be used if the package has been damaged or opened.
	5.3.2 Keep away from sunlight	a medical device that needs protection from light sources.
	5.3.4 Keep Dry	a medical device that needs to be protected from moisture
	5.4.2 Do not reuse	a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.3 Consult instructions for use	the need for the user to consult the instructions for use.
	5.4.4 Caution	the need for the user to consult the instructions for use for important cautionary information.
	21 CFR 801.15(c)(1)(i)F	Requires prescription in the United States.