

# Surgical Instruments for Intervertebral Disc Preparation - English

**Rx Only Caution:** Federal Law restricts this device to sale by or on the order of physician

**Manufacturer:**  
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## DESCRIPTION

The Intervertebral Disc Prep Surgical Instruments are intended for use during surgical procedures for cutting, scraping, retracting, or similar procedures. Prior to use of this instrument, please refer to the product instructions for use specific to the product line and the surgical procedure to be followed.

## INDICATIONS FOR USE

The surgical instruments are intended to manipulate tissue or for use with other devices in orthopedic and spine surgery.

## MATERIALS

One or more of the following materials: Stainless steel, Silicone, Aluminum, Acetal (plastic), Polypropylene (plastic)

## CONTRAINDICATIONS

Refer to the contraindications for specific Spinal Systems and implants that may be used with these surgical instruments. With any surgery, the following contraindications exist:

- Infection in or around the operative site
- Allergy or sensitivity to instrument materials
- Use of incompatible materials from other systems
- Any case not described in the indication

## INSPECTION

Please inspect all instruments prior to use for possible damage, unacceptable wear, or non-functioning components. Damaged instruments should not be used. Contact your local sales representative or distributor for repair or replacement.

## WARNINGS AND PRECAUTIONS

- SeaSpine instruments should only be used with SeaSpine implants. Do not attempt to use with other competitive devices.
- Avoid application of excessive stress on surgical instrumentation.
- Carefully read and follow any package insert which accompanies the implants to be used with this instrumentation.
- Instruments must be cleaned and decontaminated before they are returned to the manufacturer for any reason.
- Carefully inspect all instruments prior to use. Do not use an instrument that has deteriorated or a cutting instrument with dull edges.

## CLEANING AND DECONTAMINATION

All surgical instruments that have been previously taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field. The following recommendations are for the manual cleaning and decontamination of surgical instruments. These recommendations are considered

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guidelines with the ultimate responsibility for verifying adequate cleaning remaining with the user. Automated cleaning systems differ between hospitals and therefore must be qualified by the hospital.

## Manual Cleaning Procedure

|   |  |
|---|--|
| 1 | Remove all gross visible soil with a damp gauze pad or wipe.   |
| 2 | Prepare an enzymatic cleaning solution (such as Prolystica® 2X Enzymatic) per manufacturer's instructions.   |
| 3 | Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.  |
| 4 | Transfer the instruments to fresh cleaning solution (such as Prolystica® 2X Enzymatic). Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solution. Be sure that thorough scrubbing also includes any lumens with an appropriate size brush. Actuate device to allow access to hard to reach areas. |
| 5 | Thoroughly rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.   |

## Automated Cleaning Procedure

|   |  |
|---|--|
| 1 | Remove all gross visible soil with a damp gauze pad or wipe. Special attention will be required to examine products with tight crevices, voids, and lumens. Lumens may require pre-cleaning with dampened soft bristle brushes and tight crevices, voids, lumens should be flushed with a syringe. |
| 2 | Prepare an enzymatic cleaning solution (such as Prolystica® 2X) per manufacturer's instructions. Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.   |
| 3 | Transfer items to a washer and run a cycle with the parameters listed in the following steps.  |
| 4 | PRE-WASH: Cold tap water [2 minutes].  |
| 5 | ENZYME WASH: Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer's recommendations, hot tap water [4 minutes].   |
| 6 | DETERGENT WASH: Detergent wash using detergent (such as Prolystica® 2X Alkaline) per manufacturer's recommendations, hot tap water (66°C/150°F) [2 minutes].   |

Single Use Only

Lot Number (Batch Code)

Authorized Representative in the European Community

Manufacturer

Consult Instructions for Use [www.seaspine.com/elifu](http://www.seaspine.com/elifu)

REF Catalog Number

NON STERILE Non-Sterile

Caution, Consult Accompanying Documents

Product Complies with the Requirements of Directive 93/42/EEC (Class I Devices Only)

MATL Material

|    |   |
|----|---|
| 7  | RINSE 1: Rinse, hot tap water [2 minutes].  |
| 8  | RINSE 2: Purified water rinse (66°C/150°F) [15 seconds].                                    |
| 9  | DRYING: Hot air dry (82°C/180°F) [12 minutes].  |
| 10 | Remove items from the washer and remove any residual moisture with a lint free clean cloth. |

## STERILIZATION

The recommended sterilization process is high temperature steam autoclave sterilization. It is also recommended that the trays be doubled wrapped using two standard sterilization wraps. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10<sup>-6</sup>.

|                               |                             |
|-------------------------------|-----------------------------|
| Method                        | Steam                       |
| Cycle                         | Pre-vacuum                  |
| Temperature and Exposure Time | 270°F (132°C) for 4 minutes |
| Drying Time                   | 30 minutes                  |

## PACKAGING

If the package or product is damaged, the product should not be used and should be returned. The product must be handled, stored, and opened in such a way that it is protected from inadvertent damage or contamination. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage before use.

## SURGICAL TECHNIQUE

This package insert is designed to assist in using surgical instruments only and is not intended to provide information on surgical technique for specific Spinal System or Implants. Contact a SeaSpine Representative, [customerservice@seaspine.com](mailto:customerservice@seaspine.com) or 760-727-8399 for specific product Surgical Technique Guide.

## COMPLAINTS

Immediately notify SeaSpine or a SeaSpine representative by phone, fax or email regarding complaints, malfunctions or adverse events associated with this product. When possible, retain the product involved in the complaint and return to SeaSpine as instructed by SeaSpine Customer Service.

## PRODUCT INFORMATION DISCLOSURE

SeaSpine has exercised reasonable care in the selection of materials and the manufacture of these products. SeaSpine warrants to the original purchaser only that each new SeaSpine product is free from manufacturing defects in material and workmanship under normal use and service for a period of six (6) months from the date of delivery by SeaSpine to the original purchaser, but in no event beyond the expiration



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