Surgical Instruments for Intervertebral Disc Preparation - English

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

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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 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	Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. 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 Tap water for 1 minute. Then dry with a clean cloth and/or allow to air dry.
6	Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at the visual inspection, repeat the cleaning steps. Contaminated instruments should not be used and should be returned to SeaSpine. Contact your local representative or SeaSpine directly for any additional information related to cleaning of SeaSpine surgical instruments.

Automated Cleaning Procedure

1	Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. 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 a minimum of 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 for a minimum of 2 minutes.
5	ENZYME WASH: Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer's recommendations, hot tap water for a minimum of 4 minutes.
6	DETERGENT WASH: Detergent wash using detergent (such as Prolystica® 2X Alkaline) per manufacturer's recommendations, hot tap water (minimum temp of 66°C/150°F) for a minimum of 2 minutes.
7	RINSE 1: Rinse, hot tap water for a minimum of 2 minutes.
8	RINSE 2: Purified water rinse (minimum temp of 66°C/150°F) for a minimum of 15 seconds.
9	DRYING: Hot air dry (minimum temp of 82°C/180°F) for a minimum of 12 minutes.
10	Remove items from the washer and remove any residual moisture with a lint free clean cloth.
11	Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used and should be returned to SeaSpine. Contact your local representative or SeaSpine directly for any additional information related to cleaning of SeaSpine surgical instruments.

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^{-6}.

Method	**Steam**
Cycle	**Pre-vacuum**
Temperature	**270°F (132°C)**
Exposure Time	**4 minutes**
Minimum 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 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

This warranty ("Warranty") applies to the Products (defined below) purchased on or following the date set forth above. SeaSpine provides this Warranty only to the entity that purchases the Product directly from SeaSpine, (the "Purchaser").

"Products" means the following products of SeaSpine Orthopedics Corporation or its affiliates including SeaSpine Sales LLC, IsoTis OrthoBiologics, Inc., and SeaSpine, Inc. (collectively referred to herein as "SeaSpine"):

i. Medical devices or accessories used to perform actions during surgery, but not intended to be implanted in the patient, provided in non-sterile condition and sterilized by the end-user prior to use ("Instruments");

ii. Medical devices intended for implantation provided in non-sterile condition and sterilized by the end-user prior to use ("Non-Sterile Implants"); and

iii. Medical devices or biologics intended for implantation delivered in sterile condition ("Sterile Implants").

1. Warranty.

Instruments. SeaSpine warrants to the Purchaser only that the Instrument is free from manufacturing defects in material and workmanship under normal use and service (i) with respect to new Instruments, for a period of two (2) years commencing on the date of delivery by SeaSpine to the Purchaser, and (ii) with respect to used Instruments, for a period of one (1) year commencing on the date of delivery by SeaSpine to the Purchaser.

Non-Sterile Implants. SeaSpine warrants to the Purchaser only that the Non-Sterile Implant is free from manufacturing defects in material and workmanship under normal use and service for a period of commencing on the date of delivery by SeaSpine to the Purchaser and ending one hundred eighty (180) days after the date of such delivery.

Sterile Products. SeaSpine warrants to the Purchaser only that the Sterile Product is free from manufacturing defects in material and workmanship under normal use and service for a period commencing on the date of delivery by SeaSpine to the Purchaser and ending on the earlier of (i) one hundred eighty (180) after such delivery date, or (ii) the expiration date stated on the Product's labeling.

2. Warranty Conditions.

This Warranty shall not apply (i) if the Product is not used or stored in accordance with the Product's instructions for use supplied by SeaSpine and/or included in the product packaging, (ii) to any Product that has been repaired by anyone other than an authorized SeaSpine service representative or altered in any way so as, in SeaSpine's judgment, to affect its stability or reliability, or (iii) to any Product which has been subject to misuse, negligence or accident.

If the Purchaser seeks to invoke the terms of the Warranty, the Purchaser must notify the SeaSpine customer service department at the address set forth in the product labeling, which can be found at www.seaspine.com, of the covered defect during the warranty period, and the Product must be returned as directed by SeaSpine. The defective Product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to SeaSpine shall be at sender's risk.

SEASPINE'S SOLE RESPONSIBILITY AND LIABILITY UNDER THIS WARRANTY SHALL BE, AT SEASPINE'S SOLE DISCRETION, REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT, OR REFUND OR CREDIT OF THE PRICE PAID FOR THE DEFECTIVE PRODUCT, SUBJECT TO THE TERMS OF THIS WARRANTY AND APPLICABLE AGREEMENTS. SEASPINE DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY. No warranty or guarantee may be created by any act or statement nor may this warranty be modified in any way, except as a result of a writing signed by an officer of SeaSpine. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

3. Liability Limitations.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, IN NO EVENT, REGARDLESS OF THE FAILURE OF THE SOLE AND EXCLUSIVE REMEDY SET FORTH HEREIN, SHALL SEASPINE BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY SEASPINE PRODUCT.