MORE THAN POSSIBLE.™

Instructions For Use

Non-Sterile Interbody Fusion Instruments

Instructions for Use

Surgalign Spine Technologies |
520 Lake Cook Rd Ste 315
Deerfield, IL 60015 United States
Phone: +1 844 894 7752| www.surgalign.com

MORE THAN POSSIBLE.™

Instructions For Use

DESCRIPTION

The Interbody Fusion Device Instruments include general manual surgical instruments (e.g. tamps, inserters, trial spacers, screwdrivers, awls, drills, slap hammers, graft packers, rasps, and implant removal/positioning tools) that are used to facilitate the insertion or removal of various interbody spinal fusion (IBF) devices. Interbody spinal fusion devices can be implanted in the cervical spine via an anterior surgical approach or in the lumbar spine via anterior, posterior, transforaminal or lateral surgical approaches. The instruments are similar in form and function but vary based on the surgical approach (e.g. Anterior, Posterior, Lateral, Transforaminal) and corresponding implant shape in fit (e.g., instrument size, trial shape).

INTENDED USE

The surgical instruments are intended to manipulate tissue and to facilitate the insertion and removal of interbody spinal fusion devices.

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

PRECAUTIONS

Prior to use the surgeon must become familiar with the device system and the surgical procedure. Use surgical accessories and surgical technique guide provided with this device system. The methods of use of these instruments are to be determined by the user's experience and training. Do not use these instruments for any action for which the device was not intended such as hammering, prying, or lifting. Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver. Instruments are subject to damage during use as well as long-term potentially damaging effects such as wear. Damage may result in significant risks to safety and/or inability to function as intended. If instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the surgeon's responsibility to carefully consider the risks and benefits of retrieving the fragments. If the fragment is retained in the patient, it is recommended that the surgeon advise the patient of specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.

Caution: Federal (USA) law restricts the device to sale by or on the order of a physician.

GENERAL INSTRUCTIONS FOR USE

This package insert is designed to assist in using surgical instruments only and is not intended to provide information on surgical technique for specific Fortilink with TiPlus Technology devices. Contact Surgalign customer service for the specific product Surgical Technique Manual.

CLEANING

Manual Cleaning:

1. Disassemble the device(s), if applicable.
2. Rinse soiled device under running, cold tap water for a minimum of two (2) minutes. Remove gross soil using a soft bristle brush or soft, lint-free cloth.
3. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43°C (92-110°F)), per the manufacturer's recommended instructions.
4. Soak devices in freshly prepared neutral pH enzymatic solution for a minimum of ten (10) minutes.
5. Rinse device using cool running tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features under running water to rinse thoroughly.
6. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43°C (92-110°F)), per the manufacturer's recommended instructions.
7. Manually clean devices for a minimum of five (5) minutes in freshly prepared neutral pH enzymatic solution. Use a syringe, pipette, or water jet to flush lumens and channels. Use a soft bristled brush to remove soil and debris. Actuate joints, handles, and other movable device features to expose all areas to detergent solutions. Clean device under water to prevent aerosolization of contaminants.
8. Rinse device using deionized (DI) running water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable device features to rinse thoroughly under running water.
9. Visually inspect device for residual soil. If present, repeat steps 1-8 above.
10. Gently wipe down the device components with a soft lint-free cloth. Ensure the device is completely dry. Visually inspect the device; it should be clean, dry and residue-free.
11. Reassemble device(s), if applicable, following instructions in the surgical technique manual.

Automated (Mechanical) Cleaning

Pre-Cleaning

1. Disassemble device(s), as applicable. See surgical technique manual for specific instructions.
2. Rinse the device components under running lukewarm running tap water (22-43°C (72-110°F)) for a minimum of one (1) minute. After rinsing, remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth.
3. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
4. Fully immerse the device components in the fresh, newly prepared neutral pH enzymatic cleaning solution for a minimum of five (5) minutes.
5. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the cleaning solution.

6. Remove the device components from the cleaning solution and place the device components in a bath of lukewarm tap water (22-

43°C (72-110°F)) for a minimum of one (1) minute. Ensure that the water immerses the device components. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the water.

Automated Cleaning

1. Place the device components in the automated washer.
2. Perform the automated cycle per instructions in the table below.
3. Visually inspect the device; it should be clean, dry and residue-free.
4. Reassemble device(s), if applicable.

Automated (Mechanical) Cleaning Parameters			
Cycle	Time (Minutes)	Minimum Temperature	Detergent
Enzyme Wash	4:00	Hot Water 60°C (140°F)	Enzymatic cleaner (neutral pH) prepared per manufacturer's instructions
Wash	2:00	Hot water	Neutral detergent prepared per manufacturer's instructions
Rinse	2:00	Heated deionized or high purity water 70°C (158°F)	N/A
Dry	15:00	80 °C (176°F)	N/A

STERILIZATION

Independent testing has shown the following conditions to be effective:

Method	Steam
Cycle	Pre-vacuum (Wrapped)
Temperature	132°C (270°F)
Recommended Exposure Time	4 Minutes
Recommended Dry Time	40 Minutes

- Use of an FDA cleared wrap is recommended to ensure product sterility.
- The values specified here (duration/temperature) can achieve a sterility assurance level (SAL) of at least 10-6.

LIMITED WARRANTY

This limited warranty gives the original purchaser specific legal rights. the original purchaser may have additional or alternative legal rights under contract or statute, which vary from jurisdiction to jurisdiction. nothing in this limited warranty shall be construed as limiting such additional or alternative legal rights. the legal manufacturer of the product, as reflected on the product label (the "manufacturer"), extends this limited warranty to the original purchaser of the product. such warranty does not extend to any subsequent transferee of the product. this limited warranty covers malfunctions or defects in materials and workmanship for a period of one (1) year from the date of purchase, or for the remaining shelf life, whichever is less (the "limited warranty period"). with respect to any such malfunctions or defects occurring in the product during this limited warranty period, the original purchaser's remedy shall be limited as follows: the manufacturer, in its sole discretion, will either: (a) repair or replace such product (or part thereof) at no charge; or (b) refund to the original purchaser the purchase price paid for such product. under this limited warranty, all other express and implied warranties for the product, including but not limited to any implied warranties and conditions of merchantability and fitness for a particular purpose, are specifically excluded. if and to the extent a jurisdiction does not allow exclusion of implied warranties in a limited warranty, the manufacturer additionally limits the duration of any implied warranty to the duration of the limited warranty period. under this limited warranty, no warranties whether express or implied, will apply after the limited warranty period has expired. the maximum amount of the manufacturer's liability under this limited warranty will be no more than the purchase price paid for the product that is the subject of any claim under this limited warranty. under this limited warranty, the manufacturer does not accept any liability beyond the remedies provided in this limited warranty, or for consequential or incidental damages, including, without limitation, any liability for third-party claims for damages. this limited warranty is subject to the laws of the country (withoutreference to its conflicts of law rules) where the manufacturer ofthe product has ist registered seat of business. any and all disputes in relation to this limited warranty shall be exclusively conferred to the courts in such registered seat of business of the manufacturer.

PRODUCT COMPLAINTS

Complaints or dissatisfaction with the device quality, safety, reliability, durability, effectiveness and/or performance, brought forth by a Health Care Professional, whether via a customer or user of the product, should be immediately conveyed to the attention of your distributor via telephone, FAX or written correspondence sent by express mail. It is important to note that when filing a complaint, the following information must be included in order to properly respond to the complaint: Name and address; nature of the complaint; the component(s) trade name and catalog number; applicable lot number(s); and notification of whether or not a written report from the distributor is being solicited.

It is important to note that when filing a complaint, the following information must be included to properly respond to the complaint:

Name and address; nature of the complaint; the component(s) trade name and catalog number; applicable lot number(s); and notification of whether a written report is being solicited.

FOR FURTHER INFORMATION

MORE THAN POSSIBLE.™

Instructions For Use

For product information including surgical technique manuals, brochures, or questions pertaining to sales and service, please contact Surgalign customer service via telephone at (844) 894-7752 or email at customerservice@surgalign.com.

SYMBOLS

	Distributer
LOT	Lot number
REF	Catalog number
	Non-sterile
	Do not use if package is damaged
	Keep dry
	Consult instructions for use at this website.
	Caution
QTY	Content of usable units(s)
Rx only	Federal law restricts this device to sale by or on the order of a physician.

Surgalign Spine Technologies |
520 Lake Cook Rd Ste 315
Deerfield, IL 60015 United States
Phone: +1 844 894 7752| www.surgalign.com