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ORBIT™ DISCECTOMY INSTRUMENTS

GENERAL INFORMATION

The ORBIT Discectomy Instrument sets are comprised of reusable instruments that are intended to facilitate a complete discectomy in preparation for an intervertebral fusion surgery. The instruments are manufactured from stainless steel, aluminum and polymeric materials. The perforated instrument tray is comprised of aluminum and has various silicone and aluminum brackets to hold the instruments in place during handling and storage.

INTENDED USE

The ORBIT Discectomy Instruments are intended to facilitate a complete discectomy in preparation for lumbar interbody fusion surgery through a posterior or posterolateral approach.

WARNINGS

Unless otherwise indicated, instrument sets are NOT sterile and must be thoroughly cleaned and sterilized prior to use. Unwrapped instrument trays DO NOT maintain sterility. Utilize an approved sterilization wrap.

Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling instruments with sharp points or cutting edges to prevent cutting surgical gloves. Care should be taken to avoid penetrating or cutting injuries to the user or patient.

Follow the instrument layout guide for placing instruments in their proper locations within the instrument tray. Insert the instruments completely into their respective silicone brackets for full security. Failure to do so can compromise the steam sterilization processing.

Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft bristled, nylon brushes and pipe cleaners should be used. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices. The effectiveness of subsequent decontamination processes depends on prior removal of gross soil as it may be impaired by dried or coagulated protein. Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution. Instruments should only be lubricated with biocompatible, water-soluble instrument milk that is compatible with steam sterilization (Miltex® or equivalent). Silicone lubricants SHOULD NOT be used because they coat microorganisms, prevent direct contact of the surface with steam, and are difficult to remove. Instruments must be removed from instrument tray for recommended manual cleaning procedures. Instrument trays and lids must be cleaned separately. Stacking of instrument trays will adversely affect sterilization and drying effectiveness. DO NOT STACK trays in the autoclave chamber. DO NOT load instrument trays into the autoclave chamber on sides. Load trays on cart or shelf so that the lid is always facing upward. This will allow for proper drying. The instrument trays are designed to drain in this position. DO NOT load any instruments into the instrument tray that are not intended for use with the ORBIT Discectomy Instrument Set. This will adversely affect sterilization and drying effectiveness.

Validated sterilization cycle parameter are noted in the STERILIZATION section of this insert.

Surgical procedures should be performed only by experienced surgeons with training in the use of the device. This is a technically demanding procedure presenting a risk of serious injury to the patient. Further, the proper selection and compliance of the patient will greatly affect the results.

Physician Note: The physician is the learned intermediary between the company and the patient. The intended use and warnings given in this document must be conveyed to the patient.

POSSIBLE ADVERSE EFFECTS

Potential risks associated with the use of the ORBIT Discectomy Instruments are similar to those associated with any surgical instrument with the same intended use. The most frequent risks are:

1. Bleeding
2. Damage to the surrounding soft tissue
3. Infection

Additional risks associated with the use of the ORBIT Discectomy Instruments, may be instrument malfunction, such as:
1. Bending
2. Fragmentation
3. Loosening and/or breakage (whole or partial)

CLEANING AND MAINTENANCE

GENERAL INFORMATION
ORBIT Discectomy Instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments.

CLEANING AND MAINTENANCE
Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

POINT-OF-USE PREPARATION FOR REPROCESSING
1. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.
2. Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning. These enzymatic solutions break down protein matter and prevent blood and protein-based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.
3. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
4. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

CLEANING AGENTS AND EQUIPMENT
1. Detergents: Mild enzymatic detergent (Enzol®, Klenzyme® or equivalent) should be used for gross soil removal. Neutral pH detergent (ValSure®, Neutrad® or equivalent) should be used with ultrasonic cleaners. Always refer to the manufacturer's recommendations for detergent preparation.
2. Water: Warm (38-49°C) tap water should be used for rinsing and cleaning. The quality of tap water should be considered as water hardness can leave deposits on instruments that may result in ineffective cleaning and decontamination. Reverse osmosis/deionized (RO/DI) water should be used for final rinsing.
3. Ultrasonic Cleaners: Ultrasonic cleaners are designed for fine cleaning of medical devices, not for disinfection or sterilization. They are used to remove soil from joints, crevices, cannulations and other difficult-to-access locations. Follow the manufacturer's recommendations. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of ultrasonic cleaning equipment.
4. Cleaning Tools: General purpose cleaning brushes, pipe cleaners, nonabrasive low-lint cloths, ultrasonic cleaner. Note: Brushes and pipe cleaners should have a tight fit but be able to move back and forth in the area being cleaned.
5. Lubricants: Biocompatible instrument milk (Miltex® or equivalent) should be used for lubricating instruments with moving parts.

MANUAL CLEANING INSTRUCTION
Follow the instructions listed below for manual cleaning prior to sterilization.

1. Rinse the instruments under running tap water to remove gross soil. Actuate instruments while rinsing. Detach all handles and rinse under running tap water.

2. Prepare enzymatic detergent (Enzol, Klenzyme or equivalent) per manufacturer's recommendation at 1oz. per gallon of lukewarm tap water.
3. Fully immerse the instruments and detached handles and allow them to soak in the prepared detergent solution for a minimum of 10 minutes.
4. Following the soak time, brush the instruments with a soft-bristled brush and lumen brush. Agitate the instruments in the solution while brushing.
5. Rinse the instruments under running tap water at 38-49°C and thoroughly flush all lumens, holes and other difficult to reach areas with a syringe.
6. Place the instruments in a warm (38-49°C) tap water bath and agitate for at least one (1) minute. Using fresh tap water at 38-49°C, repeat this step for a total of 3 rinses.
7. Prepare a neutral pH detergent (ValSure, Neutrad or equivalent) in a sonicator according to the manufacturer's recommendations at ½ oz. per gallon of warm (38-49°C) tap water.
8. Fully immerse the instruments and allow them to sonicate for 20 minutes.
9. Thoroughly rinse the instruments under running reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry the instruments using clean, lint-free cloths.

INSPECTION, MAINTENANCE, TESTING AND LUBRICATION

1. Carefully inspect each instrument to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
2. Visually inspect for completeness, damage and/or excessive wear. If damage or wear is noted that may compromise the function of the instrument.
3. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
4. The rotating and articulating instruments should be lubricated with an instrument product (e.g., instrument milk or equivalent lubricant) specifically designed for compatibility with steam sterilization.

STERILIZATION

Devices are provided non-sterile and must be sterilized before use. Non-sterile devices should be autoclave sterilized using the validated cycle parameters presented below.

Brackets designated for specific instruments shall contain only devices specifically intended for those areas. Additional instruments should not be added to this instrument tray.

The instrument tray may be wrapped in standard, medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.

Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded

Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contract with all surfaces.

Ethylene oxide or gas plasma sterilization methods should not be used.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

The sterilization parameters for wrapped instruments were validated per *ANSI-AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

INFORMATION

REF	Catalog Number	MAT	Material
LOT	Batch Code	QTY	Packaged Quantity
	Manufacturer		Date of Manufacture
	Caution, Consult Accompanying Documents		Do Not Re-Use

NON-STERILE Device Not Sterile

℞ Only Prescription Only

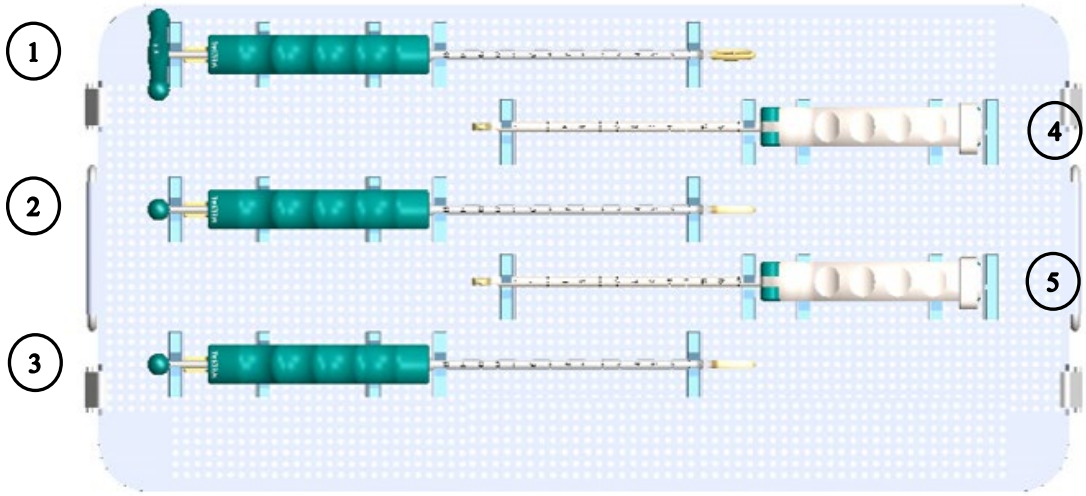
Instruction for Use are provided electronically at ifu.spinalelements.com

Patent: patent.spinalelements.com

For additional information regarding any of Spinal Elements' devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

Discectomy Instrument Set Layout Guide



Item	Part Number #	Name	QTY
1	ORB1007	ORBIT™ SHAVER, 7MM	1
2	ORB1009	ORBIT™ SHAVER, 9MM	1
3	ORB1011	ORBIT™ SHAVER, 11MM	1
4	CUT1001	ORBIT™ PIVOT SCRAPER, LARGE	1
5	CUT1003	ORBIT™ PIVOT RASP	1