



OBLIQUE ACCESS 51 SYSTEM (0A51S) RETRACTOR SYSTEM

INSTRUCTIONS FOR USE

PLEASE READ CAREFULLY

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.

INTENDED USE:

The 4WEB 0A51S Retractor System is intended to temporarily provide retraction and direct visualization of targeted anatomy during invasive surgery.

DEVICE DESCRIPTION:

The 0A51S System consists of a set of retractor blades of varying lengths and widths to enable retraction of soft tissue and anatomical features during access to the lumbar spine via the oblique lateral approach. The blades are available in several tip curvature configurations including standard vein retractors and Wylie type retractors. The retractor blades allow insertion of pins to secure the retractor construct, and light cables to aid visualization of the surgical site. The 0A51S System utilizes articulated connector arms to secure the blades relative to one another, and a table arm to secure the construct in the surgical field.

INDICATIONS FOR USE:

The 4WEB 0A51S Retractor System is intended to be used to provide retraction and direct visualization of targeted anatomy during implantation of a lumbar interbody fusion device.

CONTRAINDICATIONS:

- The 0A51S Retractor System should not be used for patients with:
- An active infection at the operative site or other active systemic infections
 - Tumor involvement at the operative site
 - Prior fusion at the level(s) to be treated
 - Known sensitivity to the material

WARNINGS AND PRECAUTIONS:

Safety and effectiveness have not been established in the following conditions:

- Gross obesity
- Smoking
- Three or more levels to be fused
- Symptomatic cardiac disease
- Pregnancy
- Previous fusion attempts at the involved level(s)
- Spondylolisthesis or retrolisthesis greater than Grade I
- Significant loss of bone stock as seen with osteoporosis or osteomalacia
- Conditions requiring chronic corticosteroid use
- Active drug abuse

Bending or fracture of the instruments can occur if not handled properly.

All instrumentation contained within sterilization containers is provided non-sterile and must be steam sterilized prior to use.

All instrumentation should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to 4WEB.

Only surgeons trained in lumbar spine fusion procedures should use this device.

OPERATIVE PRECAUTIONS:

The surgeon is to be thoroughly familiar with the 0A51S Retractor System, methods of application, instruments and surgical technique. Correct positioning of the Interbody Fusion Device relative to the vertebrae should be checked intraoperatively with x-ray. The size (and more particularly the height) of the Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction.

POTENTIAL ADVERSE EVENTS:

Potential adverse events may be related to surgery in general, spine surgery specifically or the device. These may include, but are not limited to the following:

- Adverse events related to any surgery: reactions to anesthesia, the anesthetic or other medications; bleeding; infection; ileus; blood vessel damage, nerve or soft tissue damage, atelectasis; pneumonia; hematoma; seroma; wound dehiscence or incisional hernia; urologic problems; embolism; anemia; colitis; thrombophlebitis; heart attack; stroke; or death.
- Adverse events related specifically to spine surgery: dural tear and CSF leak; nerve damage leading to radiculopathy, myelopathy, paraparesis, paresthesia or paralysis; meningitis; vertebral body damage or fracture; ligament damage; fractured sacrum; or retrograde ejaculation.

POSTOPERATIVE CARE:

- The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on the use and limitations of the device must be given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
 - The patient must be advised not to smoke or consume alcohol during period of the bone fusion process.
 - The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
 - It is critical that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices must be revised and / or removed immediately before serious injury occurs.

MRI SAFETY INFORMATION:

The 4WEB 0A51S Retractor System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the 0A51S Retractor System in the MR environment is unknown.

PACKAGING:

0A51S instrumentation (except the 4WEB-0A51S-LC Light Cable) is provided non-sterile and is supplied in a tray that is used for steam sterilization prior to use in the operating room. 0A51S Light Cables are provided in sterile packaging and do not require steam sterilization prior to use in the operating room. In the case of instrument restock, individual items will be sent in a plastic bag, labeled for that device.

Storage conditions must maintain the integrity of the instruments and their respective packaging. The condition of all instruments must be checked before use. Damaged products must not be used and should be returned to 4WEB.

INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS:

CAUTION: THESE INSTRUCTIONS DO NOT APPLY TO SINGLE-USE DEVICES.

The 0A51S Retractor System instruments do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to bone contact, impaction, routing, cleaning, and sterilization processes. Instruments should be carefully inspected before use to ensure that they are fully functional.

0A51S Retractor System instruments are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use. Decontamination reduces the population of microorganisms and facilitates the subsequent cleaning stage. Strict compliance with the instructions for use pertaining to decontamination and cleaning is mandatory, particularly the concentration and exposure time requirements. Thorough rinsing with water must be conducted following decontamination and cleaning.

- Decontamination: Each hospital must use their own validated decontamination procedures.
- Cleaning: Wash instruments in a LANCER type or equivalent ISO 15883-1 and ISO 15883-2 compliant washing machine with the appropriate cleaning products, rinse, and dry. Any product which may alter the material is prohibited, i.e. bleach, formalin, hypochlorite solutions, saline solution, etc.

The reprocessing instructions provided have been validated as being capable of preparing reusable 4WEB instruments. It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

WARNINGS:

- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- Do not exceed 140° C (284° F) during reprocessing steps.
- Highly alkaline conditions can damage products with aluminum parts.
- Avoid exposure to hypochlorite solutions, as these will promote corrosion.
- Scratches or dents can result in breakage.
- For instruments produced by another manufacturer, reference the manufacturer's instructions for use.
- Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument.

LIMITATIONS ON REPROCESSING:

- End of useful life is generally determined by wear or damage in surgical use.
- Carefully inspect instruments between uses to verify proper functioning and configuration.
- Damaged instruments must be replaced to prevent potential patient injury such as loss of metal fragments into the surgical site.

DECONTAMINATION CONSIDERATIONS – CREUTZFELDT-JAKOB DISEASE (CJD):

- For patients with, or suspected with, Creutzfeldt-Jakob disease (CJD), variant CJD or other transmissible spongiform encephalopathy (TSE) and related infections, it is recommended to treat the patient using single-use instruments.

REPROCESSING INSTRUCTIONS

CARE AT THE POINT OF USE:

- Use purified water obtained via ultra-filtration, RO, DI and/or distilled.
- Thoroughly clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible pH neutral detergent solution and purified water to prevent drying and encrustation of surgical soil.

- Avoid prolonged exposure to saline to minimize the chance of corrosion.
- Remove excessive soil with a disposable low lint wipe.

CLEANING:

ALL INSTRUMENTS

- Instructions for instruments requiring disassembly for cleaning may be found in the Surgical Technique Manual (ST-0A51S-01).
- Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions (1oz Enzol, or equivalent, per gallon of purified water). **Note:** the enzyme solution must be changed on a regular basis.
- Soak soiled instruments for 5 minutes in the enzymatic solution.
- Use a soft bristle brush to remove all traces of blood and debris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices.
- Rinse the instrument thoroughly with purified water.
- Dry the instrument immediately after final rinse.
- Clean the instruments using a validated washer disinfectant and the following parameters:

Process	Time	Reagent	Water Temperature
Pre-wash	2 min	Not applicable	Cold water
Enzyme wash	2 min	Enzol (2oz/gal) or equivalent	Hot water
Wash 1	2 min	Valsure Neutral (1oz/gal) or equivalent	65.5°C
Rinse 1	2 min	Not applicable	Hot water
Thermal rinse	1 min	Not applicable	90°C
Drying*	6 min	Not applicable	98.8°C

*Use lint-free cloths to dry residual water and filtered pressurized air at < 20 psi

- Place heavier instruments on the bottom of containers. Do not place heavy instruments on top of delicate instruments.
- For instruments with concave surfaces, such as curettes, place instrument with the concave surface facing downward to facilitate draining.

CLEANING INSPECTION:

- Inspect all instruments to verify that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process.

MAINTENANCE INSPECTION AND FUNCTIONAL TESTING:

- Visually inspect all instruments to ensure no damage and wear.
- Ensure there are no cracked handles and shafts are secure in handles.
- Ensure long instruments are free of any bending and distortion.
- Ensure instrument tips are free of defects or burrs.
- Ensure complex instruments with moving parts function appropriately.

WRAPPING:

WRAPPING TECHNIQUE

- Use instrument trays to contain instruments that are provided in sets.
- Biological or Chemical Indicators (BIs or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped trays. They should be tested according to the BI or CI manufacturer's directions.
- Double wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST79.
- Use only FDA-cleared wraps.
- Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system.
- Allow 1 inch of free space between the instrument tray and the inside of the container lid for effective processing.

STERILIZATION:

- Use a validated, properly maintained and calibrated steam sterilizer.
- Effective steam sterilization can be achieved using the following cycle to achieve an SAL of 10⁻⁶.

Cycle	Temperature	Duration	Dry Time	Preconditioning pulses
Prevacuum	132°C (270°F)	4 min	60 min	4
*Prevacuum	134°C (273°F)	3 min	60 min	4

* The Prevacuum 134° C Sterilization Cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. 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).

NOTE: STERILIZATION DOES NOT REPLACE DECONTAMINATION OR CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

PRODUCT COMPLAINTS:

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any 0A51S products should notify 4WEB, or, where applicable, their distributor, and the competent authority of the Member State in which the user and/or patient is established.

SURGICAL TECHNIQUE MANUAL:

To receive additional copies of the Surgical Technique Manual (ST-0A51S-01), contact your local sales representative or the company at the address below.

USA:

4WEB
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Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied.			
Symbol	Ref. Number	Title	Description of Symbol
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	5.4.2	Do not re-use	Indicates 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	Indicates the need for the user to consult the instructions for use.
	5.1.5	Lot number	Indicates the manufacturer's lot number so that a specific medical device can be identified.
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42 EEC, and 98/79 EC.
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	5.2.4	Sterile	Sterilized using ethylene oxide. Indicates a medical device that has been sterilized using ethylene oxide.
	5.2.6	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	21 CFR 801.109	Prescription only	Requires prescription in the United States.