



Oracle Expandable Retractor System Surgical Instrumentation Instruction for Use



ChoiceSpine, LLC
400 Erin Drive
Knoxville, TN 37919
USA

General Description:

The instrument(s) shipped with this insert is designed to provide and maintain minimally invasive access down to the bony anatomy of the thoracolumbar spine. A range of surgical procedures may be performed by passing instruments and implants through the operative channel. Prior to use of this instrument, please refer to the Oracle Expandable Retractor Instrument Guide.

Instructions for Use:

The surgeon using the Oracle Retractor is expected to be fully educated and trained in the techniques necessary to use the device. Refer to the **Oracle Expandable Retractor Instrument Guide** for recommended procedures. The techniques for using the Oracle Retractor should be reviewed by the surgeon prior to use of the system. The surgeon should inspect the components of the Oracle Retractor system before surgery to assure that all necessary components are present.

Warnings and Precautions:

1. Use caution during cleaning and sterilization so as not to damage delicate instruments.
2. Only sterile instruments should be used in surgery.
3. Wear appropriate clothing and protective garb when handling biologically contaminated instruments.
4. Avoid application of excessive stress on surgical instrumentation.
5. Avoid use of abrasive cleaners on surgical instrumentation.
6. Store instruments only in a dry, protected environment.
7. Carefully read and follow any package insert which accompanies this instrumentation.
8. Instruments must be cleaned and sterilized before they are returned to the manufacturer for any reason.
9. Carefully inspect all instruments prior to use. Do not use an instrument that is severely marred or worn. Note that at some point in time, instruments may wear out and should be replaced.
10. The ChoiceSpine Oracle Expandable Retractor System has not been tested for safety and compatibility in the MR environment. The ChoiceSpine Oracle Expandable Retractor System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ChoiceSpine Oracle Expandable Retractor System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

How Supplied:



The Oracle Expandable Retractor instrument is supplied non-sterile, and must be properly cleaned and sterilized prior to use. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:

All instruments must first be cleaned using methods recommended in this document or established hospital methods before sterilization and introduction into a sterile surgical field.

Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using methods recommended in this document or established hospital methods before sterilization and reintroduction into a sterile surgical field.

Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:

The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized in the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High.

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold tap water	N/A
Enzyme Wash	1:00	Hot tap water	Enzol® at 1oz per 1 gal water
Wash 1	2:00	60°C	Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water
Rinse 1	1:00	Hot tap water	N/A
Drying	7:00	115°C	N/A

4. Remove instruments and inspect for soil, repeat cleaning if necessary

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzo® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.

2. Prepare Enzo[®] solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, “Standard Guide for Care and Handling of Stainless Steel Surgical Instruments” for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities, DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Sterilization:

ChoiceSpine instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments are recommended to be steam sterilized by the hospital using the following process parameters (Alternative methods or cycles may be used, but should be validated according to hospital practices and procedures).

Steam Sterilizer Type: Pre-vacuum

Temperature: 132°C

Duration: 4 minutes

Drying Time: 40 minutes

All devices are to be wrapped in two-layer of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature).

Alternative sterilization methods or cycles may be used, but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

Storage and Handling:

The Oracle Expandable Retractor instrument should be stored in a clean area until ready for use.

Limitations and Restrictions:

Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly.

The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved.

These instructions have been validated as being capable of sterilizing these ChoiceSpine implants and instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Information:

See www.choicespine.com/patents.html for details.

For product complaints please contact:

ChoiceSpine, LLC
 Quality/Regulatory Department
 400 Erin Drive
 Knoxville, TN 37919
 Phone: 865-246-3333; Fax: 865-588-4045

For additional Product information please contact:

ChoiceSpine, LLC
 Customer Service Department
 400 Erin Drive
 Knoxville, TN 37919
 Phone: 865-246-3333; Fax: 865-588-4045
customerservice@choicespine.com

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European Medical Devices
	Authorized representative in the European Community