

Gold Standard Orthopaedics, LLC

Address:
2987 Industrial Parkway
Jeffersonville, IN 47130

Contact Information:
Phone: 812-913-4727
Fax: 812-913-4726

Important Information Concerning GSO Surgical Instruments

ATTENTION: Read this product insert carefully before using this product, it contains important information about the use and care of Gold Standard Orthopaedics, LLC (GSO) manual general surgical instruments. Follow the instructions carefully, not doing so may result in hazards to users or patients. This product insert may contain new information. This information does not take the place of appropriate training or experience.

PURPOSE:

This GSO manual surgical instrument is a non-powered, hand-held, or hand-manipulated device, either reusable or disposable, intended for various orthopedic procedures.

DESCRIPTION AND INTENDED USE:

Medical instrument grade stainless steel, aluminum, titanium, or plastic materials make up the construction of this manual surgical instrument. Read the following instructions carefully to avoid interactions with cleaning and disinfection agents that may compromise the operation and or longevity of the subject surgical instrument. Devices that cannot be reused may be labeled with the **②** (Do Not Reuse, Single Use Only) symbol.

This instruction is not applicable to air driven or electrically powered equipment. However, it is applicable to functional attachments (e.g. reamers and drill bits) that are connected to powered equipment for use.

INDICATIONS:

This orthopedic surgical instrument facilitates implantation of various spinal fixation devices. This instrument is supplied non-sterile and must be cleaned and sterilized before each use.

CONTRAINDICATIONS:

Manual surgical instruments or parts of manual surgical instruments are not intended for implantation.

POTENTIAL ADVERSE EVENTS:

All of the following possible adverse events associated with orthopedic procedures are possible. A listing of potential adverse events associated with manual surgical instruments includes, but is not limited to the following.

- i) Breakage of instruments or implants during the course of the surgery
- ii) Tissue or nerve damage caused by improper positioning and placement of implants or instruments
- iii) Infection

Note: Medication and or additional surgery may be necessary to correct some of these potential adverse events.

WARNING AND PRECAUTIONS:

Surgeons and surgical staff should use extreme care during the use of these instruments to avoid patient injury. Instrument sets should be considered NOT STERILE unless thoroughly cleaned and sterilized prior to use. Do NOT flash-autoclave instruments inside the instrument case. Flash-autoclaving of individual instruments should be avoided.

Universal /Standard Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices, especially devices with sharp points or cutting edges, including Personal Protective Equipment (PPE) to avoid accidental exposure. Use only soft bristled nylon brushes and or pipe cleaners when necessary. Completely submerge instruments in low foaming agent to visualize cleaning and prevent generation of aerosols and splashing which may spread contaminants. Completely rinse after pre-manual cleaning to prevent accumulation of detergent residue.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

PREOPERATIVE: Surgical instruments must always be clean and sterile before use.

If the surgery requires sterile devices, additional sterile instruments should be available in case of an unexpected need. Since mechanical parts are involved, the physician should be familiar with the operation of the surgical instruments before using in surgery. It is imperative to verify that all necessary instruments are present before the surgery begins.

INTRAOPERATIVE: Use extreme caution around spinal anatomy. Damage to adjacent anatomy may cause postoperative complications. Breakage, slippage, or misuse of instruments may cause injury to the patient. Always inspect surgical instruments prior to each surgery. Unless stated otherwise, do not use GSO driver instruments for any other devices or purposes than the GSO System.

Always use care in the handling and storage of surgical instruments. Do not drop or otherwise damage instruments. Do not use a damaged instrument

PACKAGING:

Packaged instruments should be intact upon receipt. Always check each package carefully for completeness and ensure that there is no damage prior to use. Do not use these products if the package is damaged; return the product immediately to GSO.

CLEANING AND DECONTAMINATION:

Clean surgical instruments as soon as possible after use. Handle all instruments with care to avoid damage.

Note: Do not use certain cleaning solutions such as those containing bleach or formalin because they may damage some instruments.

The following cleaning methods provide protection from cross-contamination, prevent damage to the instrument, and provide protection to the cleaning personnel:

- i) Use only cleaning agents with proven efficacy (FDA approved). Non-approved solutions are any that do not specifically state on the label that uses include surgical instruments, stainless steel, and sterilization. Agents used during the validation of this

processing instruction are: Steris®, Prolystica™ 2X Enzymatic Pre Soak and Cleaner, Prolystica™ Ultra Concentrate Neutral Detergent

- ii) Do not allow blood and debris to dry on surgical instruments. The cleaning process should begin within 10 minutes after surgery, even if sterilization will take place much later. Cleaning instruments within a few minutes immediately following surgery helps prevent corrosion, pitting, and staining.
- iii) Immediately following surgery, place the instruments in a basin filled with a water / neutral enzymatic cleaning agent mixture (5.5 fl oz per gallon of water), cover, and proceed to the decontamination area.
- iv) Particular attention should be given to the pre manual cleaning of acute and sharp angles, joints, open and blind lumens, devices that cannot be locked open, and rough surfaces.
- v) Cleaning should be carried out with a combination of pre manual and automatic cleaning / washing that includes ultrasonic cleaning. This method is useful in cleaning devices with joints and lumens that are difficult to reach manually.

CLEANING INSTRUMENTS PRIOR TO STERILIZATION:

Note: The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g. FDA approval or CE mark) should be used. All instruments must be cleaned before sterilization and introduction into a sterile surgical field. The following table provides a validated recommended method for cleaning reusable surgical instruments.

Manual Pre-Cleaning:
Cold water rinse for 3 minutes or until the rinse stream is clear in 25°C/77° F tap water.
Soak submerged instruments in enzyme cleaning soaking solution ¹ for 20 minutes.
Manually debride all exposed surfaces, lumens, and joints with soft brushes, in 25°C/77°F tap water /enzyme mixture ¹ until visible soil is removed.
Sonicate submerged items for 10 minutes in 25°C/77°F enzymatic cleaning solution ¹ at 40-50kHz.
Automated Cleaning :
Pre wash for 3 minutes in cold 25°C/77°F tap water, allow to drain for 115 seconds.
Wash 4 minute in warm 60°C/140°F water and Steris Prolystica™ 2X Concentrate Neutral Detergent , drain for 90 seconds.
Neutralize 2 minute in warm 60°C/140°F tap water and Prolystica ¹ , drain for 90 seconds.
Rinse for 2 minute in 70°C/158°F DI water, drain for 1.5 minutes.
Heated dry for 15 minutes at 110°C/230°F.

¹Note: Soaking solution 0.5 fl oz Prolystica 2X Enzymatic Pre Soak and Cleaner per gallon water

STERILIZATION:

Unless marked sterile and clearly labeled as such, the instruments described in this insert are provided non-sterile and must be sterilized prior to use. These instruments are recommended to be steam sterilized by the hospital using the following process parameters:

Method	Cycle	Temperature*	Exposure Time*
Steam	Pre-Vacuum	270F (132C)	6 Minutes

*Note: Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared, intact steam sterilization compatible wrap to maintain sterility. Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for the equipment. Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Never store instruments while they are still moist or wet from sterilization.

STORAGE:

The GSO surgical instruments should remain stored in a clean, dry area until ready for use. Always protect instruments during storage, especially from corrosive environments.

SURGICAL PROCEDURE:

Refer to Physician's Guide for detailed information.

PRODUCT COMPLAINTS: Any Health Care Professional (e.g. customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the GSO distributor. Further, if any instrument component ever malfunctions (i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any GSO product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from GSO is requested.

RETURNED GOODS POLICY:

For detailed information on the GSO return goods policy, please contact your GSO representative.

FURTHER INFORMATION: If further details for the use of this system are needed, please check with your GSO representative. If further information is needed or required, please see the address on this document.

WARRANTY:

GSO expressly warrants the fabrication of these instruments from material of one or more of the aforementioned materials. No other warranties, expressed, or implied are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.