Fibrant™ Instruments INSTRUCTIONS FOR USE

GENERAL INFORMATION

This document is intended to provide detailed instructions for processing reusable surgical instruments manufactured for Isto Biologics. Isto Biologics instruments are manufactured from various materials commonly used in reusable medical and surgical instruments, including stainless steel, aluminum, and polymers. The processes provided in these instructions are validated. Alternative methods of processing outside the scope of this document may be suitable for reprocessing. However, these processes must be validated by the user.

The Isto Biologics Fibrant Instruments are general surgical instruments for use in orthopaedic surgery. The instrument set is comprised of four awls for preparation of insertion sites for pedicle or other orthopedic screws, and a Graft Funnel system for the introduction of bone graft into operative sites in a patient. The instruments are provided in a tray that is suitable for their storage and sterilization, as detailed below.

Catalog Number	Description
IB-IA-5560 or TC-IA-5560	Awl for 5.5 / 6.0mm Screws
IB-IA-6570 or TC-IA-6570	Awl for 6.5 / 7.0mm Screws
IB-IA-7580 or TC-IA-7580	Awl for 7.5 / 8.0mm Screws
IB-IA-8590 or TC-IA-8590	Awl for 8.5 / 9.0mm Screws
IB-IB-6MM.1/2 or TC-IB-6MM.1/2	Graft Funnel System - 6mm
IB-IA-0000 or TC-IA-0000	Handle 1/4" Drive
IB-IT-0001*	Instrumentation Sterilization Tray

*Instrumentation Sterilization Tray is manufactured by SteriZign. Refer to SteriZign's instruction for use for additional information (Part No. 000101).

WARNINGS

Non-sterile.

- Instruments are provided non-sterile and must be cleaned and sterilized before use. The validated cleaning process is provided in the MANUAL CLEANING INSTRUCTIONS section of this document; and validated sterilization parameters are described in the STERILIZATION INSTRUCTIONS section of this document.
- Some instruments may have sharp edges. Care should be taken in handling such instruments to avoid injury to the user or patient.
- Staff should wear suitable protective clothing and equipment at all times. Special note should be taken of the instructions provided by the manufacturers of the cleaning agents used in the cleaning process.
- The surgeon should have a complete understanding of the surgical technique and of the function and limitations of each instrument.
- Surgeon should be cautious of the possibility of damaging soft or hard tissue during introduction, malleting or removal of instruments from the surgical site. Use should be guided by open or fluoroscopic visualization.

FIBRANT AWLS

The awls have a ¼" drive and are designed to be used with the handle. The awls are shaped to match the root dimensions of the screw and have a cutting feature that aids in the insertion of the awl. Each awl is labeled with the corresponding screw size and will fit down any introducer / cannula with greater than 8.5mm inner diameter. The awl will also tend to push bone laterally and as such will provide compaction of the bone to further aid fixation. The awl should be inserted so that the 3cm long tip of the awl is within the pedicle, with the end of the tip region at the pedicle surface.

The Fibrant awls are cannulated and may be used over a 1.4mm guide wire if desired. The shaft of the awl is laser marked at 1cm intervals and these marks may be used to reference the position, or changes to the position of the awl. Use should be guided by open or fluoroscopic visualization. The awls are also sized correctly to allow placement of the Fibrant Anchor.

FIBRANT GRAFT FUNNEL SYSTEM

The Fibrant Graft Funnel system comprises a 6mm inside diameter, 7mm outside diameter stainless steel tube. The handle is formed to have a funnel feature to facilitate introduction of graft material. The pusher is designed to push graft through and out of the tube. The graft funnel should be introduced into the patient with the pusher inserted to prevent any tissue being pushed up into the tube. The shaft of the funnel is laser marked at 1cm intervals and these marks may be used to reference the position, or changes to the position of the funnel. Use should be guided by open or fluoroscopic visualization. Graft material should be less than 6mm in diameter in order to be capable of being introduced by the system.

The Fibrant Graft Funnel system can be used to introduce Fibrant 6mm caliber Bullets. These are ideally introduced into the patient in their lyophilized state so that they may hydrate in situ.

CLEANING AND MAINTENANCE

All instruments must be free of packaging material and bio contaminants prior to sterilization. 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 those 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 protocols. Contaminated devices should be wiped clean of visible soil at the point of use prior to being transferred to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaning promptly after use per these provided instructions in order to ensure effective cleaning.

Instruments should be visually inspected for any damage between surgeries. Functionality of mating fits and of moving parts should also be checked between surgeries. The latch mechanisms on the Tray should be visually assessed between surgeries for functionality.

MANUAL CLEANING INSTRUCTIONS

Follow the instructions listed below prior to sterilization.

1. Rinse instrument thoroughly with running warm (35-40^{o}C) tap water for 1 minute. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from components. A syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas.
2. Soak instrument in Enzol® enzymatic cleaner solution (or equivalent pH neutral enzymatic cleaner) for a minimum of 10 minutes. Prepare the solution using the manufacturer's instructions. Fully immerse the instrument in the cleaner solution. After the soak, scrub the instrument in the soak solution with a soft bristle brush paying particular attention to hard-to-reach areas such as mated surfaces and lumens. A syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas.

3. Thoroughly rinse the instrument with running warm (35-40°C) tap water for 1 minute. While rinsing, a soft bristle brush, syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas.
4. Prepare an ultrasonic bath and sonicate the devices while immersed in the hospital approved cleaning solution (Enzol®) for 10 minutes. Follow the cleaner manufacturer's instructions for cleaner preparation.
5. Rinse instrument thoroughly with deionized or purified water for 1 minute. A soft bristle brush, syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas. Actuate all movable parts to fully irrigate all areas.
6. Visually inspect components for soil. Repeat the cleaning procedure, if necessary, until no visible soil remains on the instrument.
7. Perform a final rinse on the instrument using deionized water or purified water.
8. Dry the instrument using clean compressed air or a soft, lint-free, clean cloth.

STERILIZATION INSTRUCTIONS

Non-sterile instruments should be autoclave sterilized using the following validated cycle parameters.

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

Note: Sterilization parameters were validated using standard blue sterile wraps.

Cleaning and sterilization parameters were validated per FDA Guidance for Industry (March 17, 2015), Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, ANSI/AAMI/ISO 17665-1: 2006/(R)2013, ANSI/AAMI ST79:2017, *AAMI TIR12:2010 and AAMI TIR30:2011*. 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

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

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SteriZign Instrument Protection Trays

Instructions for Use

Indications for use

Identification

A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until it is used.

SteriZign Precision Technologies' Signatur Device Cassettes and Trays are used to organize, transport, store and protect surgical and other medical devices that are sterilized by a healthcare provider. Signatur Device Cassettes and Trays are intended to allow sterilization of the enclosed medical devices during pre-vacuum steam sterilization cycles. The Signatur Device Cassettes and Trays are not intended to maintain sterility on their own. SteriZign Signatur Device Cassettes and Trays have perforations and are intended to be used in conjunction with legally marketed, validated, FDA-cleared sterilization wrap.

Validated autoclave pre-vacuum sterilization cycle parameters:

- Temperature: 270°F (132°C)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- The total tray weight (tray, insert and instruments): 25 lbs.

Validated sizes of stainless-steel instrument lumens include:

- 1 each 1mm x 76 mm
- 1 each 1mm x 400 mm
- 1 each 2mm x 400 mm
- 1 each 3mm x 400 mm
- 1 each 5mm x 400 mm

Device description

SteriZign instrument protection trays (Signatur, Optimyz™ and Kustomyz™ models) are a required containment accessory for complex and delicate surgical instruments and accessories during the sterilization process and subsequent storage and transport. The trays are provided in various sizes of the same basic configuration: a rectangular base with a cover. The trays have perforations designed specifically to allow sterilant penetration. They are constructed with additional silicone brackets in the base and/or cover to provide enhanced organization, stabilization and protection for the instruments and devices within the tray.

Limitations for use

1) The life of the system is limited only by irreparable physical damage from mishandling. Always inspect the system before each use for wear and damage. Discontinue use if there are visible signs of damage; i.e., flaking, cracking, fading, or sharp edges. Always inspect the system between uses, and repair or replace tray components as necessary. Use only SteriZign original equipment replacement parts. Use of non-SteriZign parts may cause the system to not perform as intended.

2) DO NOT OVERLOAD TRAYS. The total weight of a tray (e.g. tray, insert and instruments) should never exceed 25 lbs.

3) This system must be used in conjunction with a legally marketed, FDA cleared sterilization wrap in order to maintain sterility of the contents. Always follow the wrap manufacturer's instructions when using sterilization wrap. KIMGUARD® ONE STEP® Sterilization Wrap was used during validation of SteriZign sterilization and drying cycle parameters.

4) Instrument lumens validated for sterilization in the Signatur cassettes and trays are limited to:

    - 1 each 1mm x 76 mm
    - 1 each 1mm x 400 mm
    - 1 each 2mm x 400 mm
    - 1 each 3mm x 400 mm
    - 1 each 5mm x 400 mm

5) Complex instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions.

Warnings

SteriZign™ Instrument Protection Tray systems are made with anodized aluminum. A neutral pH (6.0-8.5) detergent that is compatible with anodized aluminum must be used to avoid damaging the finish. A detergent with a highly acidic or highly alkaline pH could permanently damage the finish of the tray and metal components. The use of solvents, abrasive cleaners, wire brushes or scouring pads may also damage the finish.

IMPORTANT: Clean and visually inspect each tray according to the SteriZign instructions for use, before placing it back into service. SteriZign trays should be visually clean; if soil is seen, re-clean and re-inspect before placing back into service.

Point of Use

Always use proper PPE (gloves, face shield, gown, etc., per your facility protocols) while cleaning soiled or contaminated SteriZign trays.

Cleaning

Automated washer:

SteriZign Instrument Protection Systems are validated for the automatic wash system cycle in Table 1 below.

Table 1: Instrument and Utensil Cycle

Phase		Time	Temperature
Pre-wash		2 minutes	Cold tap water (nominal temperature < 21°C or < 70°F)
Wash	Stage 1	1 minute	122°F (50°C)
	Stage 2	2 minutes	150°F (65.6°C)
Rinse		15 seconds	Hot tap water (nominal temperature 43 - 66°C or 110-150°F)
Thermal Rinse		1 minute	194°F (90°C)
Dry		5 minutes 30 seconds	N/A

In addition, the following guidance must be followed:

1) User should follow washer equipment manufacturer's recommended service and maintenance practices.

2) Detergents should be calibrated according to automated washer manufacturer's instructions.

3) Instrument or utensil cycles are acceptable only if the above automated wash cycle parameters are used.

4) Tray hinges should be in the open position when loading into automated washers.

5) Tray lid should be removed and loaded upright to allow for proper drainage.

6) Instrument trays should not be stacked.

7) Inserts should be removed and loaded separately onto washer rack.

8) Trays should be positioned open for proper exposure to washing detergents and rinsing.

9) Tray contents should be loaded and processed according to manufacturers' instructions.

Disinfection

SteriZign Signatur trays are intended to be terminally sterilized.

Maintenance and Inspection

SteriZign Instrument Protection Trays must be inspected after each use for the following signs of mechanical, functional, or surface finish failure:

- Corrosion
- Rust
- Peeling
- Discoloration
- Cracks
- Flaking
- Sharp edges
- Broken or non-working latches
- Missing or torn silicone inserts
- Loose bracket holder

Parts of the SteriZign Signatur Instrument Protection Tray include:

1) Base
2) Lid
3) Handles
4) Latches
5) Inserts
6) Insert leveling bracket
7) Aluminum bar holder
8) Silicone bracket
9) Silicone finger mat
10) Mat bracket