GEM
Global Excellence in Microsurgery

Micro Tray Max

Instructions for Use

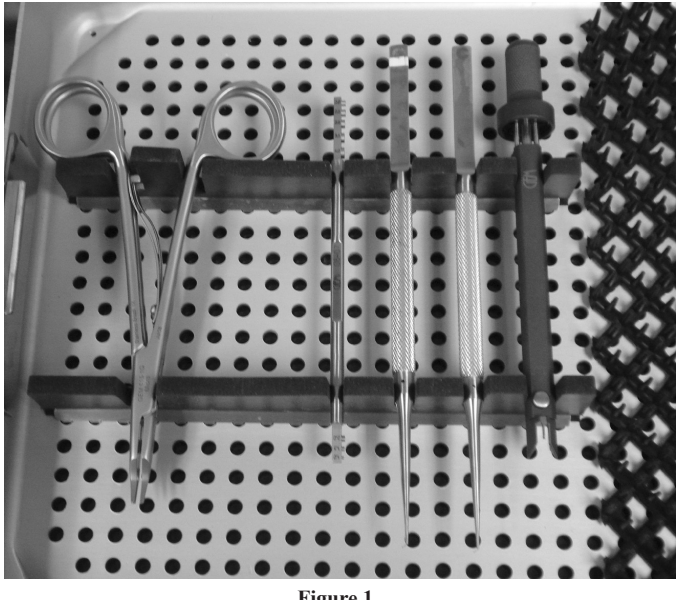

Figure 1

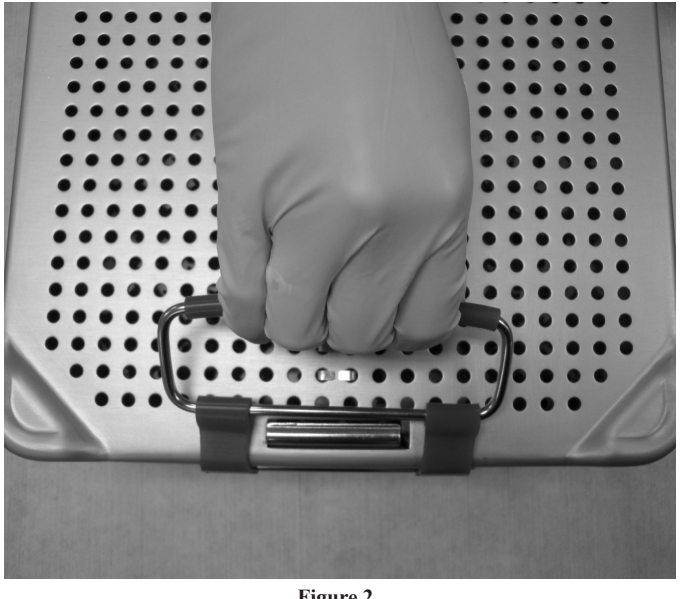

Figure 2

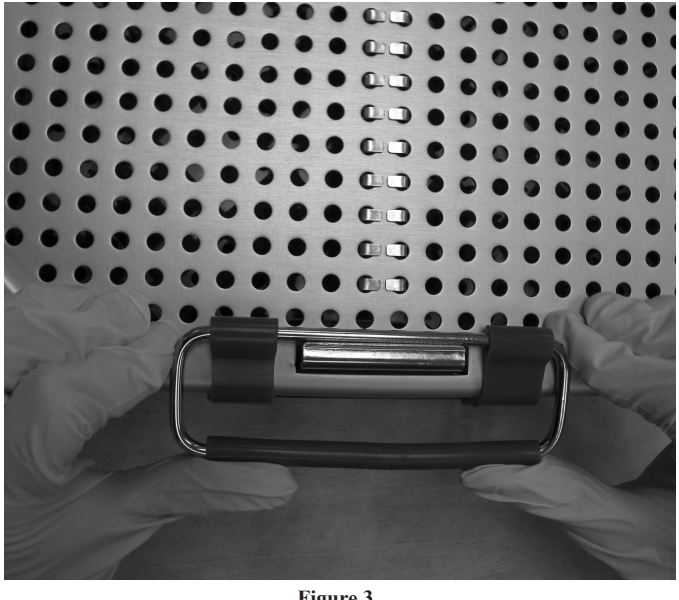

Figure 3

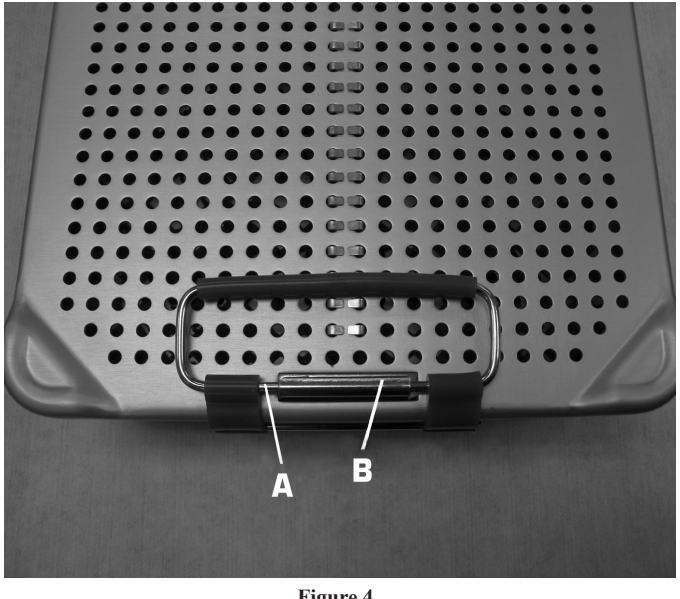

Figure 4

A	**B**
Metal Handle Bar	Metal Hook

SYMBOL GLOSSARY PER US FD&C ACT:

Standard	Symbol	Symbol Title	Symbol Meaning	Symbol Number
ISO-15223-1*		Manufacturer	Manufacturer	5.1.1
ISO-15223-1		Batch code	Lot number	5.1.5
ISO-15223-1		Catalogue number	Catalogue number	5.1.6
ISO-15223-1		Non-sterile	Indicates a medical device that has not been subjected to a sterilization process	5.2.7
ISO-15223-1		Consult instructions for use	Consult instructions for use	5.4.3
ISO-15223-1		Caution	Attention, consult accompanying documents	5.4.4

*ISO 15223-1 Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied- Part 1: General Requirements.

Additional symbols and graphics on the product labeling that are not derived from standards:

Symbol	Symbol Description
	Made in the USA
	Manufacturer part number
	Content

DESCRIPTION:

The GEM Micro Tray MAX System consists of a reusable Anastomotic Instrument* (surgical-grade stainless steel, titanium and hard-coat anodized aluminum), reusable COUPLER Forceps* (surgical-grade stainless steel), a reusable Double-Ended Vessel Measuring Gauge* (surgical-grade stainless steel), 2 MircoClip Appliers* (Surgical grade stainless steel) and a Micro Tray Sterilization Tray (anodized aluminum).

The GEM Micro Tray Sterilization Tray is a multi-use device designed to organize, protect and transport medical instruments during prevacuum steam sterilization and subsequent storage. The sterilization trays consist of an anodized aluminum base and cover with handles and latches. The trays are available in single tier or double tier with insert and contain silicone finger mats to hold instruments in place. The base, cover and inserts are highly perforated to facilitate steam sterilant penetration.

**Refer to individual device IFUs.*

INDICATIONS FOR USE:

The GEM Micro Tray MAX System contains instruments indicated for use with the GEM Microvascular Anastomotic COUPLER device and GEM MicroClips. The Micro Tray organizes, protects and transports medical instruments during prevacuum steam sterilization and subsequent storage.

Sterilization trays do not maintain sterility unless used in conjunction with a sterilization wrap that is legally marketed and cleared by the FDA or other appropriate regulatory authority. This device has not been validated for sterilization of instruments that are porous or have lumens.

WARNINGS:

- The Anastomotic Instrument, Vessel Measuring Gauge, COUPLER Forceps, and MicroClip Appliers **must be sterilized prior to use**.
- The Anastomotic Instrument, Vessel Measuring Gauge, COUPLER Forceps, and Sterilization Tray should be thoroughly inspected before use. Instruments that are damaged and/or in need of repair should not be used.

CAUTIONS:

- The system has been validated for prevacuum steam sterilization only.
- For instruments not supplied in this system, always follow the manufacturer's instructions when sterilizing complex instruments requiring disassembly.
- The Micro Tray has not been validated for sterilization of instruments that are porous or have lumens.
- Instruments with hinges should have the hinges in the open position during sterilization.
- Total weight of the tray and its contents must not exceed 25 lbs.
- The cover must be securely latched to the base during handling, wrapping and sterilization.
- Only a legally marketed and cleared sterilization wrap should be used.
- Do not stack trays during sterilization. Allow adequate room on all sides to ensure proper sterilization and drying.
- The use of nonabsorbent tray liners can cause condensate to pool.
- "Wet-packs" must be considered non-sterile and must be re-sterilized. Always inspect the tray for evidence of moisture upon completion of the sterilization/drying cycle.

INSTRUCTIONS FOR REPROCESSING USE:

Limitations on reprocessing	
The system may be sterilized for an indefinite number of cycles. Always inspect the GEM Instruments and the tray between uses - the life of the devices is limited only by irreparable physical damage from mishandling.	
Instructions	
Point of use:	Rinse all instruments with water after use.
Preparation for cleaning:	**CAUTION:** Use of a cleaner with a pH greater than 10 will remove the anodized layer of the aluminum devices, such as the Anastomotic Instrument and the Sterilization Tray. The use of solvents, abrasive cleaners, wire brushes or scouring pads may damage the finish. 1. Pre-soaking the tray per the detergent manufacturer's instructions may be necessary for heavily soiled items. 2. Using a neutral (pH 7-10) detergent, wash each tool clean of all blood and debris after every use. Scrub each tool with a soft brush. Pay particular attention to areas where debris can accumulate. 3. Avoid use of any harsh material that can scratch or mar the surface of the instruments or tray. 4. Rinse the instruments thoroughly with running water. Apply a fine jet stream through the hole in the Anastomotic Instrument knob end and press the release button while rinsing to ensure that all surfaces of the instrument are cleaned. For Clip Appliers disengage the middle spring and open the handle completely for cleaning and sterilization.

Cleaning: Manual	Place the instruments in an ultrasonic cleaner utilizing a neutral (pH 7-10) cleaning solution and clean ultrasonically for 15 minutes. Rinse the Anastomotic Instrument thoroughly again, applying a fine jet stream of water through the hole in the Anastomotic Instrument knob end. For the tray, manual cleaning of soiled areas may be done using a cloth, sponge or soft brush and neutral detergent. Always rinse the tray thoroughly with warm water and allow it to dry before loading, wrapping and sterilization.
Cleaning: Automated	Place the tray and instruments individually on the rack of an automated washer and clean at a temperature of 45º–55º C, with a neutral (pH 7-10) cleaning solution for at least 10 minutes.
Disinfection:	(Optional) Using an automated washing machine, thermally disinfect the Instrument at a temperature of 90º–95º C, for a minimum of 5 minutes.
Drying:	Following cleaning by either manual or automated cleaning methods ensure instruments and tray are fully dry. Do not exceed 100º C for 30 minutes.

Maintenance, Inspection and Testing:	• Ensure that all visible debris is removed to assure the continued quality of the instruments. • Lubricate the cleaned Anastomotic Instrument (including knob) with a water-soluble lubricant prior to sterilization. • CAUTION: Failure to clean and lubricate the Anastomotic Instrument as directed may result in instrument failure. • Inspect the tray for damaged, loose or missing parts. Always ensure all latches and handles are secured and working properly. Do not use if damaged.
Loading the Tray:	1. Load the base and insert tray (if double tier) with instruments. Place the GEM Instruments into the designated silicone bar slots. (See Figure 1) 2. If a double tier tray, place the insert tray into the base. 3. Secure the cover to the base by using the latches and ensuring the metal handle bar rests against the hook (see “Using the Latches”). 4. Fold the handles inward (against the cover). 5. Wrap for Sterilization. Always follow the manufacturer’s instruction when using a sterilization wrap.

<table>
<tr><td>Sterilization:</td><td>PREVAC AUTOCLAVES
Temperature Recommended Exposure Time
(not Total Cycle Time)<table><tr><td>270°F - 273°F</td><td>4-5 minutes (wrapped)</td></tr><tr><td>132°C - 134°C</td><td>4-5 minutes (wrapped)</td></tr><tr><td>Drying</td><td>45 minutes</td></tr></table>NOTE: It is recommended that each institution establish the efficacy of its sterilization procedure.</td></tr>
<tr><td>Storage:</td><td>Recommended storage at controlled room temperature 20-25°C (68-77°F).</td></tr>
</table>

INSTRUCTIONS FOR MAX TRAY USE:

Using the Latches:

The tray is latched securely when the metal handle bar rests completely under the metal hook at each end of the tray. The latch straps simply keep the bar in place. Once latched, the handles should be rotated inward (against the cover) prior to wrapping.

Unlatching

To unlatch, stretch the straps toward the middle of the tray until the bar comes free from beneath the hook. This can be done in two ways:

Method 1: Grasp both handles and pull inward, either together or one-at-a-time. (see Figure 2).

Method 2: Rotate each handle outward as far as it will go, then push toward the middle of the tray. (see Figure 3).

Once unlatched, the cover may be lifted straight up off the base.

Latching

Either method may be reversed to secure the latches. When securing the latches, be certain the metal handle bar is completely under the metal hook. (see Figure 4)

SERVICE:

For Customer or Technical service, contact:

Phone: +1 205.941.0111 or 1.800.510.3318 (U.S. only)

Fax: +1 205.941.1522

Website: synovismicro.com

WARRANTY:

All metal parts are warranted for two (2) years from the date of purchase against any defects affecting function or usability when used in accordance with the “Instructions for Use” provided. Cosmetic damage from routine handling, damage resulting from abuse or mishandling, or damage resulting from the use of cleaning or sterilization methods incompatible with anodized aluminum is not covered under warranty. All non-metal parts, including latch parts, are warranted for the useful life of the system (see “Limits of Reuse” section for details).

DISCLAIMER OF WARRANTIES

Synovis Micro Companies Alliance, Inc., (SMCA), a subsidiary of Baxter International Inc., warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. Since SMCA has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after it leaves its possession, SMCA does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. SMCA will replace any device which is defective at the time of shipment. No representative of SMCA may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

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MS-0722775/C
2022-11-17