



Micro Tray

INSTRUCTIONS FOR USE

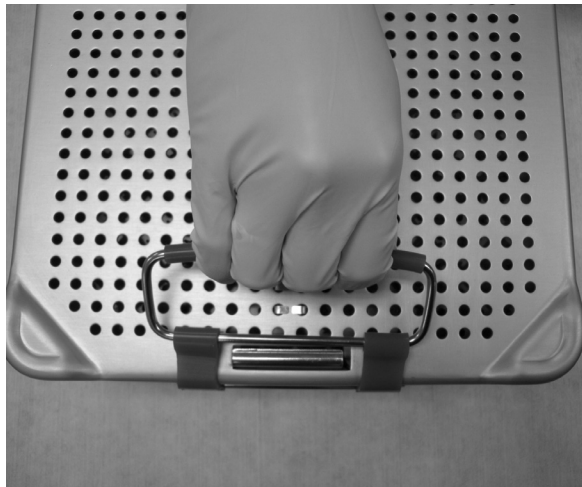


Figure 1

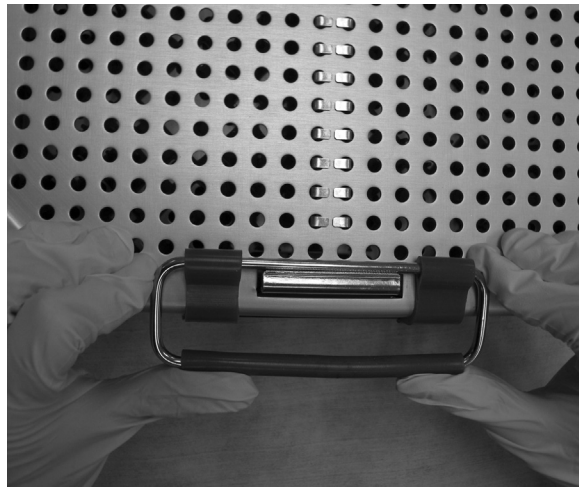


Figure 2

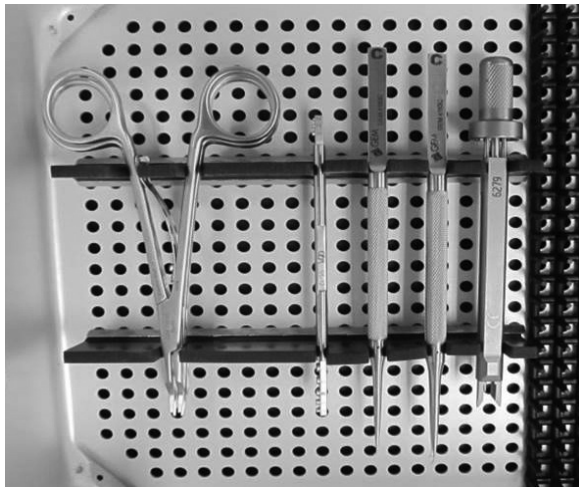


Figure 3

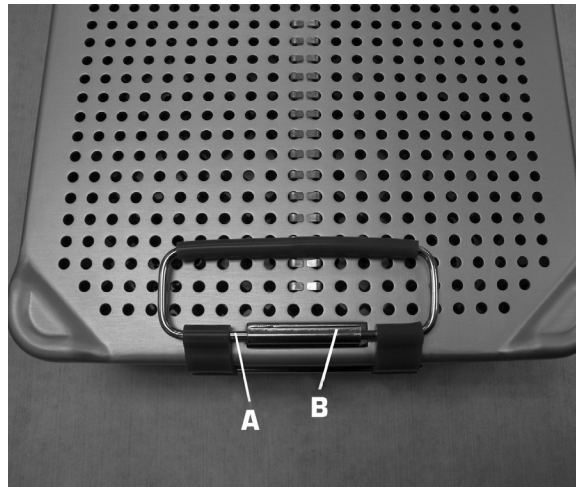


Figure 4

A
Metal Handle Bar

B
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 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 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. Tray versions are also available with silicone instrument holders for the GEM Microvascular Anastomotic COUPLER System and GEM MicroClip Appliers.

INDICATIONS FOR USE:

GEM MICRO TRAY Sterilization Trays organize, protect and transport 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.

CAUTIONS:

The tray has been validated for prevacuum steam sterilization only.

Always follow the manufacturer's instructions when sterilizing complex instruments requiring disassembly.

This device 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 (including all accessories) 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 USE:

Reprocessing:

Thoroughly clean and inspect the tray for damage prior to loading, wrapping and sterilization. Synovis Micro Companies Alliance recommends the use of a neutral pH (pH 6.0-8.0) enzymatic detergent for this purpose. The cleaning agent must be compatible with anodized aluminum. The use of solvents, abrasive cleaners, wire brushes or scouring pads may damage the finish.

Manual cleaning of soiled areas may be done using a cloth, sponge or soft brush. Pre-soaking the tray per the detergent manufacturer's instructions may be necessary for heavily soiled items. Always rinse the tray thoroughly with warm water and allow it to dry before loading, wrapping and sterilization.

After washing, 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.

To minimize physical damage, handle the tray with the same care used with any other surgical device.

Loading Wrapping and Sterilization:

After cleaning, drying and inspection prepare the tray for sterilization as follows:

1. Load the base and insert tray (if included) with instruments. (See Figure 3)
2. Place the insert tray into the base.
3. Secure the cover (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.

Validated Sterilization Cycle Parameters:

Prevacuum Steam: 132° C, 4 minutes

Drying: 45 minutes

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 1)

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

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)

Limits of Reuse:

The materials used in GEM MICRO TRAY Sterilization Trays may be sterilized for an indefinite number of cycles. The life of the tray is limited only by irreparable physical damage from mishandling. Always inspect the tray between uses.

SERVICE:

For Customer or Technical service, contact:

Phone: + 205.941.0111 or 1.800.510.3118 (U.S. only)

Fax: + 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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 Synovis Micro Companies Alliance, Inc. (a subsidiary of Baxter International Inc.),
439 Industrial Lane, Birmingham, AL 35211-4464 USA
(Tel) **+1 205.941.0111** (US Toll free) **1.800.510.3318** (Fax) **+1 205.941.1522** www.synovismicro.com

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