LeMaitre® VASCULAR

TRIVEX® Sterilization Tray

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Instructions for Use - English

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(Model Number 7205683)
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Rx only NON STERILE

Instructions for Use/Intended use
The LeMaitre TRIVEX® Sterilization Tray is intended for the protection, organization and the delivery to the surgical field of surgical instruments and/or other medical devices. The TRIVEX Sterilization Tray is not designed to maintain sterility by itself. It is designed to facilitate the sterilization process when used in conjunction with a wrapping material (FDA cleared sterilization wrap) or a specified filtered sterilization container system. Wrapping materials and sterilization containers are designed to allow air removal, steam penetration/evacuation (drying) and maintain the sterility of the internal components.

Recommendations for Care, Cleaning and Sterilization Tray

Both physical and chemical (detergent) processes may be necessary to clean soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris; therefore, a careful manual cleaning of each item with a soft sponge or cloth is essential for maximum decontamination. For difficult access areas, a clean soft bristled brush is recommended. Once the items have been cleaned, they should be thoroughly rinsed with clean water to remove any detergent or chemical residue before sterilization. LeMaitre Vascular recommends the use of a mild enzymatic detergent with a near neutral pH. Do not use solvents, abrasive cleaners, metal brushes or abrasive pads. Tray may be placed in mechanical cleaning equipment. Always inspect for cleanliness or damage before use. Make sure all latches and handles are secure and in working order. Do not overload trays. Balance contents uniformly within the container and arrange to allow steam to come in contact with all objects in the container. LeMaitre Vascular recommends that the tray be processed according to the sterilization wrap or filtered container manufacturers instructions prior to sterilization to maintain sterility of internal components/items and for proper aseptic presentation to the surgical field.

For steam autoclaves, the manufacturer has verified product performance in the following cycles. Testing was done with common surgical appliances such as reamers, drills, hammers, rasps, drivers, chisels, awls, handpieces, rongeurs, blades and bits, including short lumened devices.

Complex instruments may require disassembly and extended sterilization times. Always follow instrument manufacturer instructions if their sterilization or drying recommendations exceed these guidelines.

1. Prevacuum Sterilizer
Wrapped cases, trays and instruments, or cases, trays and instruments should be exposed to 132° C to 135° C (270° F to 275° F) for at least four minutes. Dry for 20 to 40 minutes.

2. Gravity Displacement Sterilizer
Wrapped trays and instruments should be exposed to 132° C to 135° C (270° F to 275° F) for at least 30 minutes, or 121° C to 123° C (250° F to 254° F) for at least 55 minutes. Dry for 20 to 50 minutes.

Variables that may affect drying times include: loading density of the case/tray, instrument configuration, total contents of the sterilizer, steam quality, equipment maintenance and others.

3. Ethylene Oxide Sterilization
The TRIVEX Sterilization Tray has been validated for Ethylene Oxide Sterilization using 10/90 cycle (10%EO/90%HCFC). A minimum two hour exposure cycle at 52° C to 57° C (125° F to 135º F) is required. Validation testing was done with common surgical appliances, scopes and scope accessories, including stainless steel lumened devices up to 8 1/2 inches. Complex instruments may require disassembly and extended sterilization times. Always follow instrument manufacturer instructions if their sterilization recommendations exceed these guidelines. Always follow instrument manufacturer instructions regarding use in Ethylene Oxide systems. Trays have been shown to be within acceptable residual ranges after degassing for 12 hours.

4. Filtered Sterilization Container Systems
The TRIVEX Sterilziation Tray has been validated for placement inside Ultra Container, Genesis and Aesculap filtered sterilization container systems and exposed to 132º C to 135º C (270º F to 275º F) for at least four minutes for prevacuum sterilizers only. Systems have not been validated for use in filtered sterilization containers in gravity displacement sterilizers and should not be used in such a system.

Follow the recommendations of the manufacturer of the filtered sterilization containers for the proper placement and use of cases and trays inside the container.

Contraindications
The TRIVEX Sterilization Tray has NOT been validated for use with flexible endoscopes, or devices with lumens or working channels longer than 4 inches (3mm ID). Always refer to instrument manufacturer instructions.

The TRIVEX Sterilization Tray has NOT been validated for ETO sterilization of devices with lumens or working channels longer than 8 1/2 inches (1.5mm ID). Always refer to instrument manufacturer instructions.

Stacking trays and overloading of the units will adversely affect sterilization and drying effectiveness.

DO NOT STACK cases and trays in autoclave chamber.

Notice:
1. DO NOT load cases into sterilizer on sides or upside down with lid side on the shelf or cart. Load cases on cart or shelf, so that the lid is always facing upward. This will allow for proper drying. The TRIVEX Sterilization Tray is designed to drain in this position.
2. After the autoclave door is opened, all cases must be allowed to cool thoroughly. Place trays on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the tray is not allowed to cool properly.
3. If condensation is observed, check to ensure steps 1 and 2 were followed. In addition, verify that the steam, which is being used for sterilization processing, has a quality of more than 97%. Also confirm that the sterilizers have been inspected for routine maintenance in accordance with manufacturer recommendations.
4. Silicone mat accessories should be placed in alignment with perforations in cases or trays so that sterilant pathways are not obstructed.
5. Only use internal baskets, trays, mats, or accessories that have been designed and tested for use in ETO processes. The TRIVEX Sterilization Tray and mat are made from metal, Radel®-R or silicone and meet this requirement.

The following table provides guidance on maximum loads. Do not overload delivery systems, and always follow AAMI, OSHA and hospital standards for maximum loading. Follow instrument manufacturers instructions for use.

Tray Size	Maximum Total Weight
Full Size Case (~ 9 x 19 x 4 in.)	22 lb. (9 Kg)

Limited Product Warranty; Limitation of Remedies
LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. LeMaitre Vascular makes no representation regarding the suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.
IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.
A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

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