VersaPak™ Modular Instrument Tray

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CE

These instructions pertain to Class I devices

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symmetry surgical®

ENGLISH
VersaPak™

INSTRUCTIONS FOR USE

Intended Use
The VersaPak™ brand modular instrument tray is intended to conveniently organize, transport, and store reusable surgical instruments and medical devices between uses. The VersaPak™ tray is used in conjunction with FDA-cleared sterilization wraps or reusable rigid containment systems.

Indications for Use
VersaPak™ is a modular instrument tray designed to organize, transport, and store reusable surgical instruments and medical devices between uses. The user can customize the VersaPak™ tray with a wide variety of bracketry to hold an array of instrumentation. Brackets can be assembled with a standard screwdriver. Users also have the option to purchase preconfigured trays to hold specific instruments, such as components of Symmetry Surgical's Bookwalter® Retractor System and Greenberg® Universal Retractor System. The optional lid provides a means to secure the instruments during transportation. The tray is used in conjunction with FDA-cleared sterilization wraps or reusable rigid containment devices.

Product Description
Symmetry Surgical's VersaPak™ is a configurable instrument tray with modular bracketry to accommodate customer-specific instrument sets. The VersaPak™ tray is designed to conveniently organize surgical instruments during transport, sterilization, and storage between uses (see Figures 1-4).

- Trays are offered in ½, ¾, and full DIN footprints in 2", 3", and 4" heights with an optional lid (Figure 4) that easily secures to the base of the tray with low-profile latches.
- There are preconfigured VersaPak™ trays available with preassembled bracketry (Figure 2). These include the Bookwalter® Table Fixation VersaPak™, Bookwalter® Blades and Accessories VersaPak™, Bookwalter® Magrina VersaPak™, Greenberg® VersaPak™, McCulloch VersaPak™, Vesolock™ VersaPak™ Extended Length, and Vesolock™ VersaPak ™ Standard Length.
- The perforated tray permits sterilant permeation and drainage. Two sets of handles, located on the base and the lid of the device, improve accessibility and promote ease of use. The embossed feet and C-shaped guard on the device enhance stacking abilities. The broad selection of aluminum and silicone bracketry facilitates customization of trays.

Figure 1: VersaPak™ Assembly

Figure 2: Preconfigured

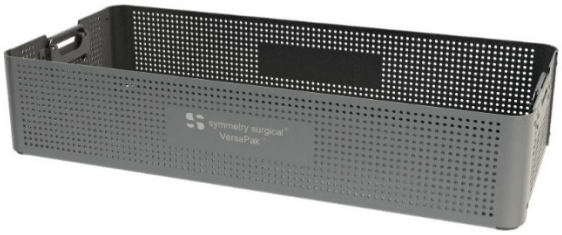

Figure 3: VersaPak™ Base

Figure 4: VersaPak™ Lid

WARNINGS AND PRECAUTIONS

The federal law restricts this device to sale by or on the order of a physician.

Warnings

- The VersaPak™ tray is provided NON-STERILE. Remove all transport packaging and properly clean and sterilize the device prior to each use.
- Read, follow, and keep these instructions for use. Persons using this product should have the requisite training, knowledge, and experience. Use product only in accordance with its intended use.
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged and get a new VersaPak™ tray.
- Replace any damaged components immediately with original replacement parts.
- Failure to remove detergent residue from reprocessing can affect the anodized aluminum finish.
- The VersaPak™ tray and its contents must not exceed 25 lbs (11.3 kg) or size-specific limiting weight restrictions as defined in Table 3 for proper sterilization.
- VersaPak™ bases are only to be used with approved VersaPak™ brackets.
- Do not cover more than 50% of the VersaPak™ floor holes with bracketry.
- **The VersaPak™ is NOT intended to be used to contain endoscopes during sterilization.**
- Failure to follow the manufacturer's instructions may result in irreparable damage to the device or in the device contents not being sterilized.

Precautions

- Use care when transporting the loaded, non-sterile tray, as aggressive handling or dropping of the tray can cause damage to the unit and instruments contained within.

INSPECTION

The product should be inspected prior to use. Check to confirm that the tray is clean before use and that the product functions correctly. Do not use if there is damage, evidence of corrosion, or if the tray is not operating properly.

The device should be inspected for damage prior to each use. Devices that show signs of damage should not be used. In addition to structural inspection, the following areas should be carefully assessed:

- Latch on the lid
- Handles on the lid and base
- Silicone brackets
- Screws

REPROCESSING INSTRUCTIONS

Remove all surgical instruments from the VersaPak™ tray prior to cleaning. Do not remove brackets from the VersaPak™ tray for cleaning or sterilization purposes.

Cleaning

Clean the VersaPak™ tray before first use and after each use according to the recommended directions in Symmetry Surgical IFU-204233. The VersaPak™ tray may be washed manually or in automated washers. Use an instrument cleaning detergent suitable for use with anodized aluminum. A detergent with excellent rinsing and controlled sudsing is recommended. Please consult your cleaning/detergent supplier for more information.

Copies of IFU #204233 are available by requesting from Symmetry Surgical Customer Service at: Phone: 1-800-251-3000
Email: customerservice@symmetrysurgical.com
Website: www.symmetrysurgical.com

Sterilization

The VersaPak™ tray can be used in either FDA-cleared sterilization wrap (double wrapped) or inside an FDA-cleared sterilization container. The VersaPak™ tray is made from aluminum, stainless steel, and silicone and are compatible with steam and ethylene oxide sterilization.

Follow the manufacturer's recommendations for sterilization for each instrument placed inside of the VersaPak™ during reprocessing.
Make certain that all external and internal surfaces of the product will be exposed to the sterilizing agent.

1. When sterilizing several products at the same time in a steam sterilizer, ensure that the maximum load capacity of the steam sterilizer specified by the manufacturer is not exceeded.
2. Clean and decontaminate instruments and devices per the manufacturer's instructions prior to sterilization. Disassemble instruments and devices as required per the manufacturer's instructions prior to sterilization.
3. Complex instruments (e.g. instruments with lumens and channels) should be prepared and sterilized according to the instrument manufacturer's instructions.
4. See Table 3 for recommended instrument weight per VersaPak™. Recommended weights are based upon limiting the total loaded container weight to approximately 25 lbs (11.3 kg) per ANSI/AAMI ST77:2013, Containment Devices for Reusable Medical Devices.
5. Instruments should be uniformly distributed across the VersaPak™. Ensure that instruments are properly loaded so that they do not contact or interfere with closing the lid or other instruments in the case. Hinged devices should be in an open position when placed in the VersaPak™.
6. **Do not** place device upside down in the sterilization chamber.
7. **Do not** use device outside of what is recommended in this IFU.

8. To achieve a sterility assurance level of 10^{-6}, Symmetry Surgical recommends the following sterilization parameters (see Table 1 & Table 2):

Table 1: Recommended Steam Sterilization Parameters

Recommended Steam Sterilization Parameters (Double Wrapped)			
Cycle Type	**Minimum Temperature**	**Minimum Exposure Time**	**Minimum Dry Time**
Pre-Vacuum	132°C-135°C 270°F-275°F	4 minutes	20 minutes
Gravity	121°C-123°C 250°F-253°F	55 minutes	20 minutes
	132°C-135°C 270°F-275°F	30 minutes	20 minutes

Table 2: Recommended EO Sterilization Parameters

Recommended Ethylene Oxide Sterilization Parameters (Double Wrapped)	
Preconditioning	None
Temperature	125°F -135°F / 52°C-57°C
Humidity	30-80% RH
Pre-Vacuum	22-26" HG
Humidity Dwell	30-45 minutes
Sterilant	10% EO/ 90% HCFC
Gas Concentration	600 ± 30 mg/L
Gas Dwell	2 hours minimum
Post Vacuum Cycle	22-26" HG (2 cycles)
Aeration	24 hours @ 110-130°F minimum

Failure to follow the manufacturer's instructions may result in irreparable damage to the device or in the device contents not being sterilized.

Reprocessing procedures recommended above have been validated. Do not use reprocessing procedures outside of what is recommended in this IFU.

WARNING Take proper precautions when removing the device from the sterilization chamber. When steam sterilized, the tray may be hot. Use proper precautions to prevent injury.

Secure lid to base of VersaPak™ and carry the device by the handles on the lid. If the device does not have a lid, carry the device by the handles on the base.

Modifications to the VersaPak™ made outside of what is recommended in this IFU may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

DISPOSAL/SERVICE Adhere to national regulations when disposing of or recycling the product, its components and its packaging. For service outside the United States, contact your local Symmetry Surgical representative. Inside the United States, call Symmetry Surgical Customer Service: 1-800-251-3000.

WARRANTY

Symmetry Surgical warrants that this medical device is free from defects in both materials and workmanship for one (1) year from the date of purchase. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof. Abuse or misuse of the product or failure to comply with the instructions for use shall void this warranty.**

DIRECTIONS FOR USE

The VersaPak™ base is available in the following sizes with the corresponding recommended maximum instrument load (Table 3):

Table 3: Recommended Maximum Instrument Load

Part Number	Size	Maximum Load (lbs)
50-8530	½ DIN 100mm	13
50-8532	Full DIN 100mm	22
50-8533	Full DIN 100mm	22
50-8534	Full DIN 100mm	22
50-8535	Full DIN 100mm	22
50-8536	¾ DIN 50mm	8
50-8537	½ DIN 50mm	8
50-8538	½ DIN 75mm	8
50-8539	¾ DIN 50mm	8
50-8540	¾ DIN 75mm	13
50-8541	¾ DIN 100mm	22
50-8543	Full DIN 50mm	8
50-8544	Full DIN 75mm	22
50-8545	Full DIN 100mm	22
50-8615	Full DIN 100mm	22
50-8616	Extended 50mm	22
50-8617	Extended 50mm	22

Customizable

The versatility of this device provides options for the customer to configure their own unique VersaPak™.

- Do **NOT** load more than the recommended amount of bracketry into a single VersaPak™.
  - Do **NOT** cover more than 50% of the VersaPak™ floor holes with bracketry.
- VersaPak™ bases are only compatible with VersaPak™ bracketry.
- Brackets can only be assembled in VersaPak™ bases, not lids.
- Bracket placement must ensure instruments provide uniform weight across the device for allowable air flow.
- For complete portfolio of VersaPak™ brackets and accessories, contact Symmetry Surgical Customer Service: Phone: 1-800-251-3000 or E-mail: customerservice@symmetrysurgical.com

Assembly Instructions for VersaPak™ brackets:

1. Remove bracket from packaging.
2. Visually inspect screws for burrs. Do not attempt to assemble stripped or burred screws.
3. Remove screw(s) from bracket channel with a standard Phillips head screwdriver.
4. Place bracket in desired location on the inside of the base of the device.
5. Line up the holes of the channel and nut with the holes on the floor of VersaPak™ base.
    a. Brackets can only be assembled to VersaPak™ bases, not lids.
6. Place screw through the VersaPak™ base into the channel and nut of the bracket.
7. Use a standard Phillips head screwdriver to attach the bracket.
8. Ensure screws are securely tightened onto VersaPak™ base.

Figure 5: Bracket Assembly

LABELING SYMBOLS

Symbol for Manufacturer; the name and address of the Manufacturer is next to this symbol

Caution-Consult accompanying documents

LOT Lot number or batch number

REF Catalog number

Consult instructions for use

EC REP European Representative

Rx ONLY

CE

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