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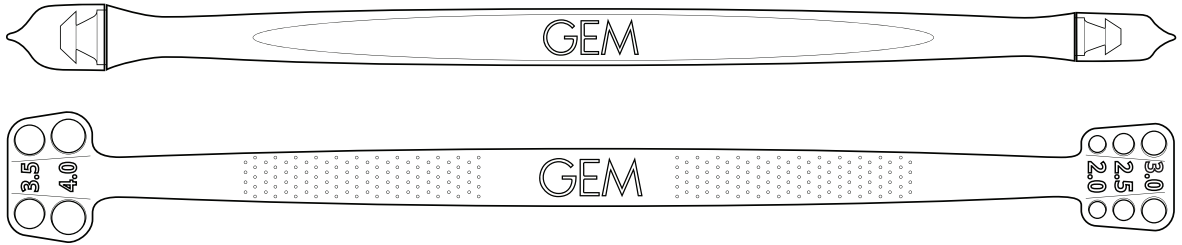
Global Excellence in Microsurgery

The VESSEL EVERTER System



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Symbols Glossary

Symbols are referenced from ISO 15223-1:2016 Medical Devices: Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements.

Additional symbols on the product labeling that are not required by the US FD&C Act:

Symbol	Title and Definition of Symbol
MADE IN THE U.S.A.	Made in the USA
ID	Manufacturer internal code
PN	Manufacturer part number
TN	Manufacturer tracking number

Symbols referenced on labeling: Symbol Glossary per US FD&C Act

Symbol	Title and Definition of Symbol	Reference Number
	Do not reuse; Indicates a medical device that is intended for use on a single patient during a single procedure.	5.4.2
STERILE EO	Sterilizing using Ethylene Oxide; Indicates a medical device that has been sterilized using Ethylene Oxide.	5.2.3
	Do not use if package is damaged or open. Indicated a medical device that should not be used if the package has been damaged or opened.	5.2.8
REF	Catalogue number; Indicated the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Use-by date; Indicates the date after which the medical device is not to be used.	5.1.4
LOT	Batch Code Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Consult the instructions for use for important information such as warnings and cautions.	5.4.4
LATEX	Not made with natural rubber latex. Indicates no presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	5.4.5
	Consult instructions for use	5.4.3
	Manufacturer	5.1.1
Rx Only	The product is a medical device and Federal Law (USA) restricts this device to sale by or on the order of a physician.	
CONTENT	Content	

DESCRIPTION:
The VESSEL EVERTER System is an accessory device designed to be used in conjunction with the GEM COUPLER System and GEM FLOW COUPLER System. The VESSEL EVERTER System comprises a VESSEL EVERTER and a SIZING GUIDE. The VESSEL EVERTER comprises a plastic handle with two silicone tips, one on each end. The SIZING GUIDE is a plastic instrument with holes for approximating vessel outer diameter in order to assist the surgeon in choosing an appropriate COUPLER size.

INDICATIONS FOR USE:
The VESSEL EVERTER System is indicated for use with the GEM Microvascular Anastomotic COUPLER and GEM FLOW COUPLER Device in the anastomosis of only arteries normally encountered in microsurgical procedures only in the peripheral vascular system. The VESSEL EVERTER System is indicated for use with COUPLER and FLOW COUPLER sizes from 2.0 to 4.0 mm.

INTENDED USE:
The VESSEL EVERTER System assists the surgeon in estimating the vessel outer diameter and everting the arterial vessel onto the COUPLER and FLOW COUPLER rings during peripheral vascular anastomoses.

CONTRAINDICATIONS:
Do not use with a 1.0 or 1.5 mm COUPLER.
Do not use in patients with known allergy to silicone.

WARNINGS:
Product is sterilized by Ethylene Oxide. Single-patient use only. Do not reuse. Reuse may increase the risk of unintended trauma or infection.
Do not re-sterilize. Re-sterilization may compromise the structural integrity of the part, which may increase the risk of unintended trauma or infection.
Do not use if package is open or damaged or device is damaged. Use of a damaged product or a product with damaged packaging may increase the risk of unintended trauma or infection.

CAUTIONS:
The use of the VESSEL EVERTER System is not required and has not been studied for venous anastomosis.

The VESSEL EVERTER may be used for up to 2 COUPLER/FLOW COUPLER anastomoses or 4 total vessel eversions per silicone tip. Overuse may lead to damage to the tip.

Rinse both end of the SIZING GUIDE and VESSEL EVERTER in heparinized saline prior to use. Failure to do so could lead to unintended trauma.

Rx Only Federal (USA) Law restricts this device to sale by or on the order of a physician.

Not made with natural rubber latex.

Recommended storage conditions between 4 - 40°C.

DIRECTIONS FOR USE:
PREPARATION

1. Inspect the EVERTER outer pouch packaging for damage, moisture, or any sign of contamination prior to opening. Do not use if these conditions are present or if the seals are not intact.
2. Peel the Poly-Tyvek outer pouch apart and aseptically transfer the inner pouch to the sterile field.
3. Peel the Poly-Tyvek inner pouch apart and remove the EVERTER and SIZING GUIDE. Inspect both devices for damage. Do not use if the device is damaged.
4. Rinse both ends of the SIZING GUIDE in heparinized saline prior to handing it to the surgeon.
5. Rinse both tips of the EVERTER in heparinized saline prior to handing it to the surgeon.

USE STEPS
After preparing the artery for end to end anastomosis per the COUPLER or FLOW COUPLER instructions for Use.

6. Use the SIZING GUIDE to estimate the outer diameter of each vessel end, by using forceps to pull the vessel through the SIZING GUIDE holes. Assess the vessel's inner lumen to ensure it appears satisfactory for coupling. See Figure 1.
7. Once a COUPLER or FLOW COUPLER has been selected and the first vessel end has been passed through the COUPLER or FLOW COUPLER ring, insert the desired size of EVERTER tip into the vessel lumen. See Figures 2 and 3.
8. Gently press the Everter until the tip is pierced by the COUPLER or FLOW COUPLER pins. See Figure 3.
9. Rock the EVERTER as needed to ensure the vessel wall and intimal lining are impaled upon each pin. See Figure 4.
10. Straighten the EVERTER and disengage it from the COUPLER or FLOW COUPLER. Check the COUPLER or FLOW COUPLER ring to ensure that both the vessel wall and intimal lining are fully impaled upon each pin.
11. Check the COUPLER or FLOW COUPLER ring and vessel for damage.
12. If the vessel is not fully everted, reapply the EVERTER or use microsurgical forceps to complete the eversion.
13. Repeat steps 7–11 for the other vessel end on the other COUPLER or FLOW COUPLER ring.
14. Complete the anastomosis per the COUPLER or FLOW COUPLER Instructions for Use.

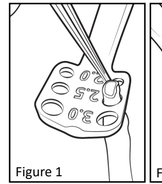


Figure 1

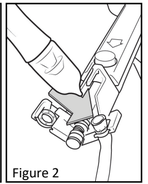


Figure 2

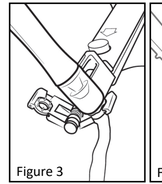


Figure 3

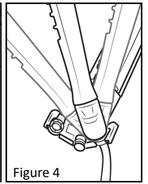
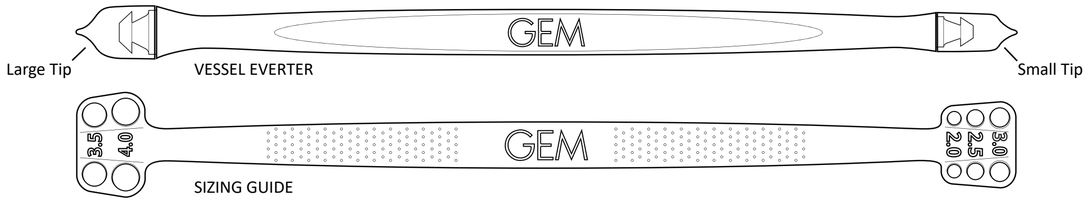


Figure 4



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Disclaimer of Warranty: Synovis Micro Companies Alliance, Inc., 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.

Synovis Micro Companies Alliance, Inc. (a subsidiary of Baxter International Inc.),
439 Industrial Lane, Birmingham, AL 35211-4464 USA.
(Tel) 205.941.0111 • 800.510.3318 • (Fax) 205.941.1522
www.synovismicro.com

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