



FLOW COUPLER Device



Does your flap have flow?

The GEM Microvascular Anastomotic **FLOW COUPLER** Device and System have been specifically designed for microvascular anastomosis and blood flow detection.

The COUPLER combined with a 20 MHz Doppler confirms vessel patency intra- and postoperatively at the anastomotic site.

Advantages of the **FLOW COUPLER**

Early Intervention

- Monitoring of the outflow vein of the flap will detect cessation of venous flow almost immediately
- Interruption of arterial flow will cause a near-immediate loss of the venous Doppler signal
- Venous monitoring helps detect venous thrombosis and simultaneously serves as a monitor of arterial flow of adjacent vessels

Auditory Feedback

- Loss of an audible signal alerts staff that a potential problem with perfusion exists

Safety and Efficiency

FLOW COUPLER may:

- Reduce unnecessary re-explorations
- Increase flap salvage rates
- Minimize flap loss

Rapid Detection

- Timing of presentation of flap compromise is a significant predictor in flap salvage rates
- Intensive monitoring in the initial postoperative period by the clinician leads to early re-exploration and more likely flap salvage

Rx Only. For safe and proper use of the device, please refer to full Instructions for Use.
See Indications and Important Risk Information on page 2.

FLOW COUPLER Device

GEM
Global Excellence in Microsurgery



The GEM Microvascular Anastomotic COUPLER System consists of a reusable Anastomotic Instrument, reusable COUPLER Forceps, and a reusable Double-Ended Vessel Measuring Gauge. The **FLOW COUPLER** System components are sterile, intended for single-patient use only, and are available in five sizes.

Ordering Information

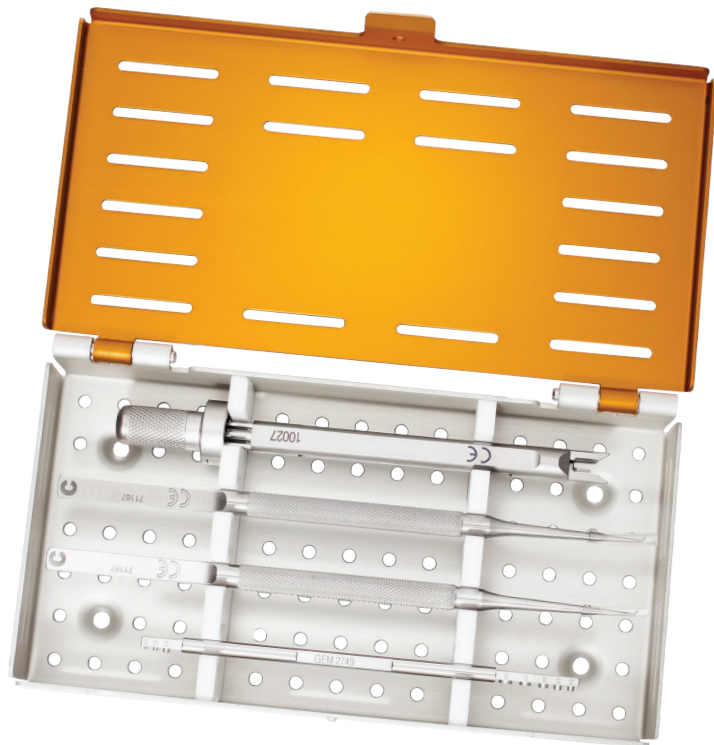
Microvascular Anastomotic COUPLER (MAC) System

- GEM2741CC** Complete System includes the following components:
- GEM2740** Reusable, Titanium Anastomotic Instrument
- GEM2745** Anodized Aluminum Sterilization Tray
- GEM2749** Non-Glare Stainless Steel Double-Ended Vessel Measuring Gauge
- GEM4183C** COUPLER Forceps (2), 18cm – For everting the vessel over the pins

GEM **FLOW COUPLER** – Available in Single Units

- GEM2752 - FC** 2.0 mm FLOW COUPLER
- GEM2753 - FC** 2.5 mm FLOW COUPLER
- GEM2754 - FC** 3.0 mm FLOW COUPLER
- GEM2755 - FC** 3.5 mm FLOW COUPLER
- GEM2756 - FC** 4.0 mm FLOW COUPLER

- GEM1020M** FLOW COUPLER Monitor
- GEM1010US** Power Supply & Cord
- GEM1003EXT - FC** External Lead (Box of 4)



INDICATIONS FOR USE:

The FLOW COUPLER Device is a single use, implantable device that is intended to be used in the end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. The FLOW COUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-fit onto one of the rings. When the FLOW COUPLER Device is used in conjunction with the FLOW COUPLER Monitor, the FLOW COUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site. Post-operatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW COUPLER Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively.

CONTRAINDICATIONS FOR USE:

The FLOW COUPLER Device is not indicated for use in end-to-side anastomosis or for patients presenting conditions that would normally preclude the microvascular repair with suture technique.

Synovis Micro Companies Alliance

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