Does your flap **have flow?**

The FLOW COUPLER System consists of a FLOW COUPLER Device and a FLOW COUPLER Monitor. The FLOW COUPLER Monitor is a pulsed Doppler ultrasound system designed for the detection of blood flow in vessels. The FLOW COUPLER Device includes a 20MHz ultrasonic Doppler transducer (probe) attached to one of the FLOW COUPLER rings, and an external lead. The probe connects to the Monitor via the external lead and emits a pulsed ultrasonic signal. An audible signal of varying volume strength is produced when the probe detects flow.[1]

Ordering Information

Product #	Description
GEM1020M-2	FLOW COUPLER Monitor with power cord
GEM1003EXT-FC	External Lead, box of 4
GEM2760-HH	IntraOp Doppler, box of 4
GEM1020PS-2	Power Supply Kit

All persons using these devices should be knowledgeable in the use and handling of surgical instruments.

Distributed By

Features & Benefits[1-4]

- **Monitoring of the vessel will detect cessation of the flow almost immediately**
- **Allows for early intervention and may reduce re-explorations**
- **Rechargeable battery***
- **Touch screen**

Scan to hear blood flow

FLOW COUPLER Device

GEM
Global Excellence in Microsurgery
Synovis MCA

The FLOW COUPLER rings are made of high density polyethylene and surgical grade stainless steel pins. A protective cover and jaw assembly protect the rings and probe which allow for easy loading onto the Anastomotic Instrument. Both the protective cover and jaw assembly are disposable. Accessories to the FLOW COUPLER System include a reusable Anastomotic Instrument (surgical-grade stainless steel and titanium), a reusable Vessel Measuring Gauge (surgical-grade stainless steel), COUPLER Forceps (surgical-grade stainless steel), and a Sterilization Tray (anodized aluminum).[2]

Ordering Information

Microvascular Anastomotic COUPLER (MAC) Set

GEM2741CC	Complete Set 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

FLOW COUPLER Monitor

GEM1020M-2	FLOW COUPLER Monitor
GEM1020PS-2	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. Postoperatively, 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:
The FLOW COUPLER Device is not indicated for use in end-to-side anastomosis or for patients presenting conditions that would normally preclude microvascular repair with suture technique. Examples of such conditions include, but are not limited to: • Pre-existing or suspected peripheral vascular disease, • Ongoing irradiation of the area of reconstruction, • Clinical infection of the area of reconstruction, • Anticipated infection due to significant contamination of the area of reconstruction, • Friability of the vascular tissue due to sclerotic conditions, • Concurrent diabetes mellitus, or • Concurrent corticosteroid therapy. The FLOW COUPLER Device and System is contraindicated for use in the central circulatory. The FLOW COUPLER Monitor is not intended specially to diagnose, monitor or correct a defect of the heart or the central circulatory system.

Rx Only. For safe and proper use of this device, refer to full Instructions For Use.

Reference: 1. FLOW COUPLER Monitor IFU. Synovis Micro Companies Alliance, Inc. Birmingham, AL. **2.** GEM Flow Coupler Device and System IFU. Synovis Micro Companies Alliance, Inc. Birmingham, AL. **3.** Fujiwara RJT, Dibble JM, Larson SV, Pierce ML, Mehra S. Outcomes and reliability of the flow coupler in postoperative monitoring of head and neck free flaps. Laryngoscope. Apr 2018;128(4):812-817. doi:10.1002/lary.26944 **4.** Um GT, Chang J, Louie O, et al. Implantable Cook-Swartz Doppler probe versus Synovis Flow Coupler for the post-operative monitoring of free flap breast reconstruction. J Plast Reconstr Aesthet Surg. Jul 2014;67(7):960-6. doi:10.1016/j.bjps.2014.03.034

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