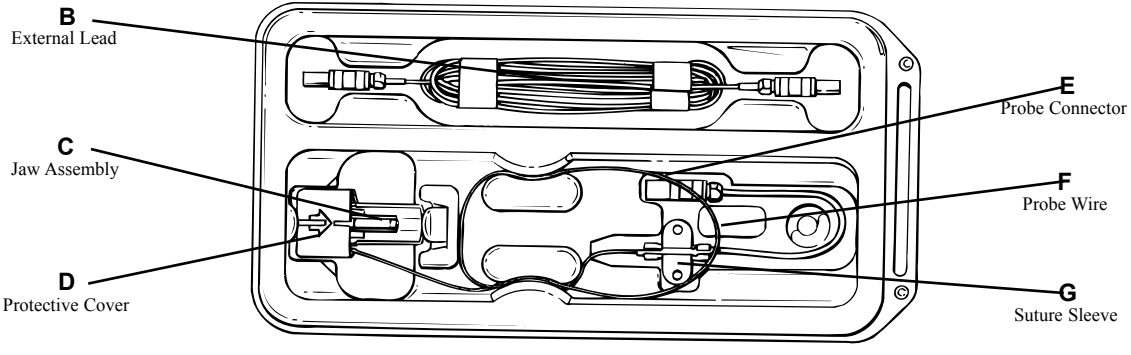
GEM™
Global Excellence in Microsurgery

Synovis®
Micro Companies Alliance, Inc.

GEM™ FlowCOUPLER®
Device and System

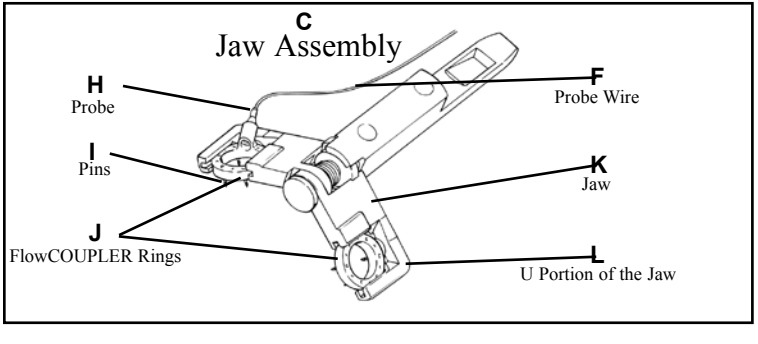
A

FlowCOUPLER Device



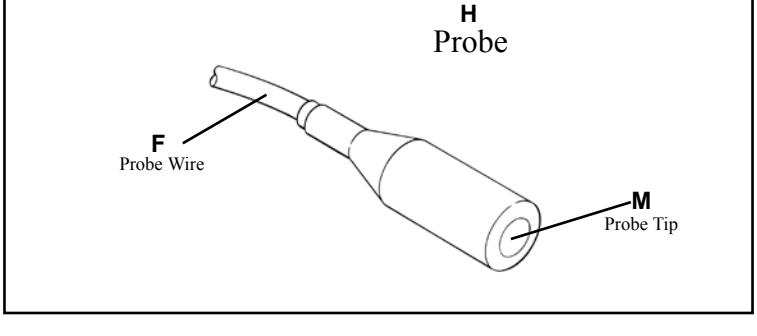
C

Jaw Assembly



H

Probe



A
FlowCOUPLER Device

B
External Lead

C
Jaw Assembly

D
Protective Cover

E
Probe Connector

F
Probe Wire

G
Suture Sleeve

H
Probe

I
Pins

J
FlowCOUPLER Rings

K
Jaw

L
U Portion of the Jaw

M
Probe Tip

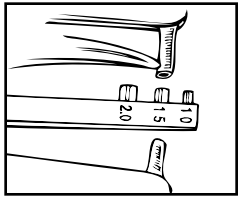
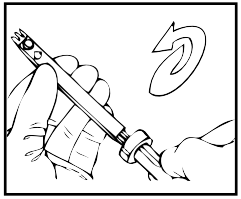


Figure 1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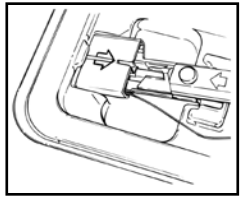
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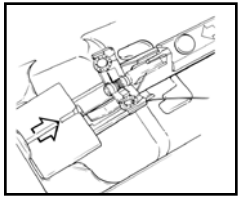
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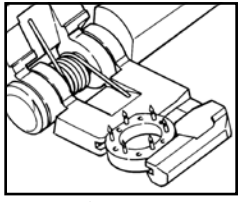
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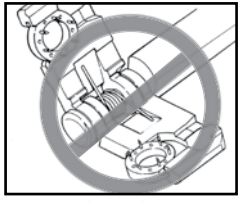
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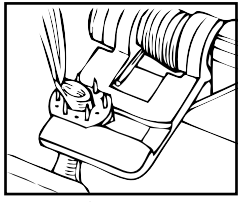
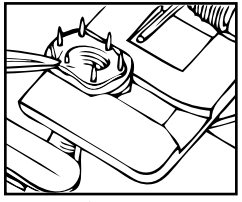


Figure 6


Figure 7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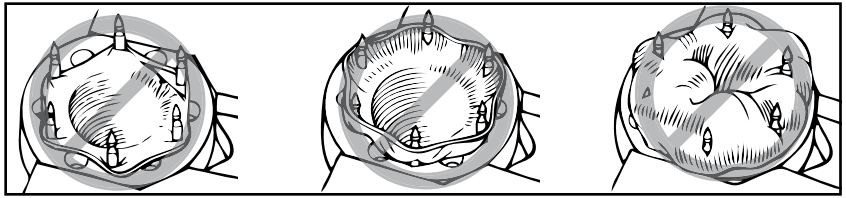


Figure 9

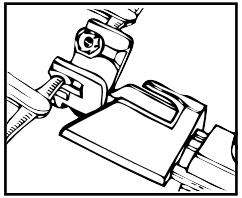
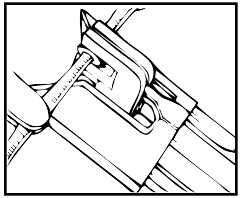


Figure 10



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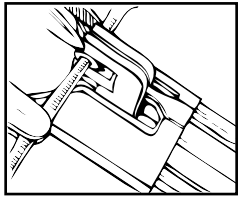

Figure 12

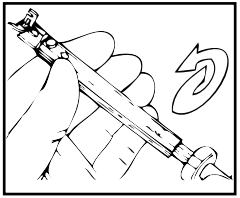

Figure 13

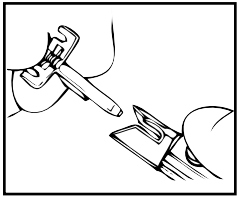

Figure 14

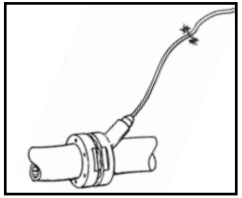

Figure 15

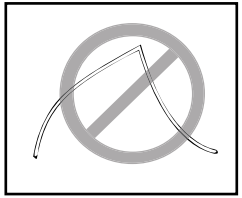

Figure 16

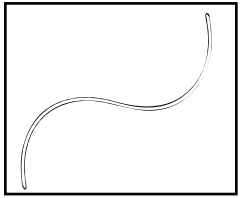

Figure 17

SYMBOL DEFINITIONS:

The following symbols and definitions pertain only to the GEM FlowCOUPLER Device:


Size of the GEM FlowCOUPLER Device
(inner diameter of the FlowCOUPLER rings)


Consult instructions for use


Do not reuse


Use by Date

STERILE EO
Sterilized using ethylene oxide


Do not use if the product sterilization barrier or its packaging is compromised.

The following symbols and definitions pertain to the GEM FlowCOUPLER Device and System:


Attention, consult accompanying documents.


This product and package do not contain natural rubber latex

MADE IN THE U.S.A.
Made in the U.S.A.

CONTENT
Content

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


Type CF Applied Part


RF Transmitter

Direct current

REF
Catalog number

LOT
Lot number

PN
Part number

TN
Tracking number


Manufacturer

DESCRIPTION:

The Synovis MCA GEM™ FlowCOUPLER® Device and System have been specifically designed for use in end-to-end anastomosis of blood vessels and the detection of blood flow at the anastomotic site. On an as needed basis, blood flow can be detected for up to 7 days.

The FlowCOUPLER System consists of a FlowCOUPLER Device and a FlowCOUPLER Monitor. The FlowCOUPLER Device includes a 20MHz ultrasonic Doppler transducer (probe) attached to one of the FlowCOUPLER rings, and an external lead. The FlowCOUPLER 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 FlowCOUPLER 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).

INDICATIONS FOR USE:

The FlowCOUPLER 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 FlowCOUPLER 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 FlowCOUPLER Device is used in conjunction with the FlowCOUPLER Monitor, the FlowCOUPLER 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 FlowCOUPLER Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively.

CONTRAINDICATIONS:

The FlowCOUPLER 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 FlowCOUPLER Device and System is contraindicated for use in the central circulatory system.

WARNINGS:

- Failure to use the Vessel Measuring Gauge to approximate the vessel size could result in using a FlowCOUPLER of an inappropriate size. Using a ring too large for the vessel may result in stressing or tearing of the vessel wall and a compromised anastomosis. Using a ring too small for the vessel may unduly constrict the vessel and lead to thrombosis or ring separation.
- Failure to squeeze the FlowCOUPLER jaws with a hemostat or similar instrument prior to ejection of the joined rings may result in an inadequate friction fit and possible ring separation. **Inspect the anastomotic site** to ensure that the anastomosis has been satisfactorily completed.
- The FlowCOUPLER is supplied sterile and is single use only. **Do not resterilize or reuse** the FlowCOUPLER.
- Do not use the FlowCOUPLER if the package appears to be damaged or compromised.
- Safe use of the FlowCOUPLER for the anastomosis of tubular structures other than veins and arteries has not been established.
- Safe use of the FlowCOUPLER for the anastomosis of growing vessels in children or adolescents has not been established. Not intended for fetal use.
- Safe use of the probe portion of the FlowCOUPLER during MRI procedures has not been established. Therefore the probe should be removed prior to a MRI procedure.
- Security of an anastomosis utilizing FlowCOUPLERs that have been approximated, reopened, and then reapproximated has not been demonstrated. When reapproximation of the anastomosis is desired, the vessel should be removed from each ring and a new FlowCOUPLER utilized.
- Ensure that suture sleeve and connectors are not implanted.
- The Anastomotic Instrument, Vessel Measuring Gauge, COUPLER Forceps, and Sterilization Tray **must be sterilized prior to use.**
- The Anastomotic Instrument, Vessel Measuring Gauge, COUPLER Forceps, and Sterilization Tray should be thoroughly inspected before use. Instruments that are damaged and/or in need of repair should not be used.

CAUTIONS:

- Use of the FlowCOUPLER involves potential risks normally associated with any implanted device, e.g., infection, perforation, or laceration of vessels, erosion, implant rejection, or device dislodgement/migration.
- The angle of the probe wire relative to the flap will be influenced by the orientation of the Anastomotic Instrument during formation of the anastomosis. To avoid unwanted kinking or twisting of the vessel during positioning of the flap-which may result in poor flap perfusion-care should be taken to establish the desired angle of the probe wire relative to the flap and to adjust the Anastomotic Instrument accordingly prior to starting the anastomosis.
- Should a probe be prematurely removed from the probe-holder, do not attempt to re-insert the probe into the probe-holder. Instead remove rings and implant a new FlowCOUPLER Device.
- **Probe wire is delicate. The use of crushing forceps may damage the probe wire.**
- **Use caution when manipulating the probe wire. Sharp bends may cause damage to the probe wire.**
- **The use of clamps on the external lead wire may damage the external lead.**
- The probe is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively.
- Avoid excessive force to remove the probe from the patient, which may cause injury to the blood vessel. If the probe can not be removed using gentle traction, the probe should be surgically removed. **Do not cut the probe wire.**
- Assure that the probe is attached to the probe wire upon removal of the probe. If not, surgical removal of the probe is required.
- The FlowCOUPLER should only be used with the GEM FlowCOUPLER Monitor.
- During the use of all ultrasound devices, the operator should minimize the exposure of ultrasound energy to the patient using the principle of ALARA (As Low As Reasonably Achievable).

INSTRUCTIONS FOR USE:

These *Instructions for Use* are designed for proper use of this device. They are not intended to serve as a reference to surgical technique, to supersede institutional protocols or professional clinical judgment regarding patient care.

It is the responsibility of the clinician to inform the patient that he/she is the recipient of permanent implants which contain metal components (surgical-grade stainless steel pins). The FlowCOUPLERs have been evaluated with a 1.5 Tesla magnetic field and no change in displacement was observed in each of three orthogonal planes.[1] The stainless steel pins in the FlowCOUPLERs are nominally nonferromagnetic. However, the US Food and Drug Administration (FDA) has made recommendations for any medical device implanted which have metallic components to include:

- Documentation in the official medical record of the identity of the implant (manufacturer, model number, lot and serial numbers, and identifying marks, if any).
- Documentation of the technique and results of any magnetic testing performed on the implant or that no such testing was done.
- Patient education regarding the particular implant and recommendation for identifying medical alert card, bracelet, or necklace characterizing the implanted device.[2]

END-TO-END ANASTOMOSIS:
Using conventional microsurgical technique, mobilize a minimum of 1 cm of each vessel end. Using vascular clamps, clamp off the vessel(s) and irrigate the vessel openings. The FlowCOUPLER requires a greater amount of free vessel within the clamps than a conventional suture repair.

1. After gentle dilation, estimate the **outer** diameter of each vessel using the Vessel Measuring Gauge. The circular guides on the gauge **should not** be placed inside the vessel lumen (See Figure 1). If there is a size discrepancy between the two vessels, use the measurement of the smaller vessel to choose the appropriate FlowCOUPLER. The degree of vessel spasm and the elasticity of the vessel should be considered when choosing the FlowCOUPLER size to be used.
2. Select the appropriate size FlowCOUPLER. Both vessel ends should be approximately the same size as the inside diameter of the FlowCOUPLER being selected.
3. Remove the lid from the outer tray and aseptically remove the inner tray; the inner tray may be placed in the sterile field. Inspect the inner tray. Do not use if the inner tray is damaged or if the seals are not intact. Remove the lid from the inner tray.
4. Turn the Anastomotic Instrument knob fully counterclockwise, and then insert the FlowCOUPLER onto the Anastomotic Instrument while FlowCOUPLER is still in tray. **The matching indicator arrows on the FlowCOUPLER and the Anastomotic Instrument should be pointing toward each other when loading** (See Figures 2 & 3). **Ensure that an audible click is heard for proper loading.**
5. Remove FlowCOUPLER from tray and protective cover, being careful not to pull the wire (See Figure 4).
6. Verify probe function by connecting probe to Monitor and irrigating attached probe tip with sterile saline. (Refer to the Flow Detection section of these Instructions for Use for proper connection instructions.) An audible signal from the Monitor verifies proper function of the device. If no signal is identified, refer to the Troubleshooting section of these Instructions for Use.
7. Visually inspect to see that both rings are seated at the bottom of the U portion of the jaw and the pins are not bent (See Figures 5a & 5b). If pins are bent, do not attempt to straighten. Instead use a new FlowCOUPLER Device.

NOTE: To avoid unwanted kinking or twisting of the vessel during positioning of the flap, care should be taken to establish the desired angle of the probe wire relative to the flap and to adjust the Anastomotic Instrument accordingly prior to starting the anastomosis.

8. Place the Anastomotic Instrument perpendicular to the vessel(s), with the FlowCOUPLER jaw assembly near the two vessel ends. Pull one vessel end through one of the FlowCOUPLER rings using microsurgical forceps (See Figure 6). Care should be taken to avoid twisting of the vessel.
9. Take a bite of approximately one to two pin diameters of the vessel wall and intimal lining, evert 90 degrees and impale onto one pin. Proceeding in a triangular fashion, impale the vessel firmly upon every other pin, completing three pins (See Figure 7). Complete vessel placement on the ring by impaling the vessel upon the remaining three intermediate pins (See Figure 8). Ensure that both the vessel wall and the intimal layer are fully impaled upon each pin to reduce the risk of thrombosis. Should the vessel wall tear during impalement, remove the vessel, trim the end, and repeat the procedure. For examples of improper impalement of the vessel see Figure 9.
10. Repeat Steps 8 and 9 to impale the other vessel end upon the second FlowCOUPLER ring.
11. When both vessel ends have been suitably impaled, visually inspect to ensure that both rings are seated at the bottom of the U portion of the jaw and the pins are not bent (See Figures 5a & 5b). Bring the rings together (See Figures 10 & 11) by turning the Anastomotic Instrument knob clockwise.
12. **Prior to ejecting the joined rings, gently squeeze the end of the apposed jaws with a small hemostat** (See Figure 12) **to ensure ring approximation and a tight friction fit.** Turn the Anastomotic Instrument knob further clockwise to eject the joined rings.
13. Check the anastomosis under the operating microscope before opening the vascular clamps. Remove the clamps and **inspect the anastomotic site to ensure that the anastomosis has been satisfactorily completed** (patent vessel without leakage).
14. To remove the jaw assembly turn the Anastomotic Instrument knob fully counterclockwise (See Figure 13). Press the release button, located near the arrow on the Anastomotic Instrument, and remove the jaw assembly (See Figure 14).
15. Rinse the Anastomotic Instrument with water after use.

FLOW DETECTION:
Prior to closure of the surgical site verify detection of blood flow.

1. Temporarily secure the probe wire to the skin to prevent the weight of the metal connectors from pulling on the probe.
2. Join the probe connector to either end of the external lead. Attach the other end of the external lead to the FlowCOUPLER Monitor.
3. Turn on the FlowCOUPLER Monitor.

NOTE: The FlowCOUPLER Monitor can be powered by batteries (8 AA) or with the external power supply. If the low battery light illuminates, either replace all 8 batteries or use power supply.

NOTE: For further instructions, refer to the GEM FlowCOUPLER Monitor Instructions for Use.

4. Select appropriate channel on FlowCOUPLER Monitor and listen for blood flow. Adjust volume as needed. If a strong audible signal is not identified, irrigate the site where the probe tip meets the vessel with saline. During irrigation, an audible signal from the monitor verifies proper function of the device.

NOTE: Do not attempt to adjust probe location.

5. When routing wire away from the anastomotic site, a loose suture may be placed around the wire to ensure that it does not affect the orientation of the joined FlowCOUPLER rings. Optimal wire position would be aligned with probe tip. (see Figure 15) Do not bend probe wire at a sharp angle. (see Figure 16) See Figure 17 for an example of proper probe wire angle. Carefully position the probe wire to leave enough wire length in the wound, providing slack to assure there is no tension on the anastomosis.
6. Once satisfied with wire placement, use a tack suture on the probe wire at the wound margin (5-0 or similar). Secure the suture sleeve to the skin (suture, tape or staple). Ensure adequate slack in the wire.
7. Following verification of probe function and wire placement, close the incision using standard techniques. Cover exposed probe wire with medical dressing.
8. On an as needed basis, blood flow can be detected for up to 7 days. The probe is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively.
9. When monitor is not being used to detect flow, external lead may be disconnected from the probe by pulling probe connectors apart.

NOTE: Ischemia or reperfusion rate may delay or affect the initial Doppler signal.

NOTE: If blood flow is not detected with the Monitor post-operatively, rely on clinical indications for patient status.

NOTE: Doppler signal may vary during monitoring period.

10. To remove the probe, first detach the suture sleeve and wire from the skin (remove suture, tape or staple). Remove the probe by applying gentle traction to the wire while applying counter pressure externally at the site of incision until the probe is extracted. Inspect to ensure that probe tip is fully intact. If probe is not present, surgical removal is required.

Devices: Anastomotic Instrument, Vessel Measuring Gauge, COUPLER Forceps, and Sterilization Tray.

SPECIAL INSTRUCTIONS

WARNINGS

- The Anastomotic Instrument, Vessel Measuring Gauge, COUPLER Forceps, and Sterilization Tray are supplied non-sterile and must be sterilized prior to use
- The Anastomotic Instrument, Vessel Measuring Gauge, COUPLER Forceps, and Sterilization Tray should be thoroughly inspected before use. Instruments that are damaged and/or in need of repair should not be used.

LIMITATIONS ON REPROCESSING

No particular limitations

INSTRUCTIONS	
Point of use:	Rinse all instruments with water after use.
Preparation for cleaning:	1. Using a neutral (pH 7-10) detergent, wash each tool clean of all blood and debris after every use. Scrub each tool with a soft brush. Pay particular attention to areas where debris can accumulate. CAUTION: Use of a cleaner with a pH greater than 10 will remove the anodized layer of the Anastomotic Instrument and the Sterilization Tray. 2. Avoid use of any harsh material that can scratch or mar the surface of the instruments 3. Rinse the instruments thoroughly with running water. Apply a fine jet stream through the hole in the Anastomotic Instrument knob end and press the release button while rinsing to ensure that all surfaces of the instrument are cleaned.
Cleaning: Automated	Using an automated washing machine, clean at a temperature of 45º – 55º C, with a neutral (pH 7-10) cleaning solution for at least 10 minutes.
Cleaning: Manual	Place the instruments in an ultrasonic cleaner utilizing a neutral (pH 7-10) cleaning solution and clean ultrasonically for 15 minutes. Rinse the Anastomotic Instrument thoroughly again, applying a fine jet stream of water through the hole in the Anastomotic Instrument knob end.
Disinfection:	(Optional) Using an automated washing machine, thermally disinfect the Instrument at a temperature of 90º - 95º C, for a minimum of 5 minutes.
Drying:	Following cleaning by either manual or automated cleaning methods ensure instruments are fully dry. Do not exceed 100º C for 30 minutes.
Maintenance, Inspection and Testing:	• Ensure that all visible debris is removed to assure the continued quality of the instruments. • Lubricate the cleaned Anastomotic Instrument (including knob) with a water-soluble lubricant prior to sterilization. Failure to clean and lubricate the Anastomotic Instrument as directed may result in instrument failure.
Packaging:	Package the instruments using the appropriate method for the sterilization cycle chosen.
Sterilization:	GRAVITY AUTOCLAVES Temperature: Recommended Exposure Time (not Total Cycle Time) 250°F (121°C): 15 minutes (wrapped or nonwrapped) 270°F (132°C): 3 minutes (nonwrapped)/10 minutes (wrapped) PREVAC AUTOCLAVES Temperature: Recommended Exposure Time (not Total Cycle Time) 270°F -273°F (132°C - 134°C): 3-5 minutes (nonwrapped)/4-5 minutes (wrapped) NOTE: It is recommended that each institution establish the efficacy of its sterilization procedure.
Storage	Recommended storage at controlled room temperature 20-25°C (68-77°F).

PROBE TROUBLESHOOTING GUIDE

SYMPTOMS	POSSIBLE PROBLEMS	SOLUTION
No sound output Intra-operatively	No moisture contact	Site irrigation
		Verify no vessel stricture
		Check blood flow (vein and artery)
		Massage blood vessel to increase blood pressure
		Wait until blood flow can be seen and heard
		Ischemia or reperfusion rate may delay or affect the initial Doppler signal. Check with hand held probe.
	No power	Check all connections: • Probe Connector to External Lead • External Lead to Monitor
	External Lead is not functioning	Replace External Lead
	Probe is not functioning	Rely on clinical indications for patient status.
No sound output Post-operatively	No power	Check all connections: • Probe Connector to External Lead • External Lead to Monitor
	External Lead is not functioning	Replace External Lead
	Probe may have lost contact with vessel	Rely on clinical indications for patient status.
	Probe is not functioning	Rely on clinical indications for patient status.

MONITOR TROUBLESHOOTING GUIDE

SYMPTOMS	POSSIBLE PROBLEM	SOLUTION
No sound output	No power	Verify Monitor power is on
	No power	Check all connections: • Probe Connector to External Lead • External Lead to Monitor • Monitor to AC Power Supply • AC Power Supply to Power Cord • Power Cord to outlet
	Volume is too low	Adjust volume using Volume Increase switch
	Wrong channel is being used	Verify the correct channel is illuminated
	Batteries are dead	Replace batteries or use external power supply
	Monitor not functioning	Connect a different Monitor
	Monitor not functioning	Contact Synovis Micro Companies Alliance
Weak sound output	Weak batteries (low battery indicator is illuminated)	Replace batteries or use external power supply
	Volume is too low	Adjust volume using Volume Increase switch
	Monitor not functioning	Connect a different Monitor
	Monitor not functioning	Contact Synovis Micro Companies Alliance

SERVICE:

For Customer or Technical service, contact:

Phone: + 205.941.0111 or 1.800.510.3318

Fax: + 205.941.1522

Website: synovismicro.com

DISCLAIMER OF WARRANTIES:

Synovis Micro Companies Alliance, Inc., (SMCA), a subsidiary of Synovis Life Technologies, 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

REFERENCES:

1. DeLacure M and Wang H: Magnetic Resonance Imaging Assessment of a Microvascular Anastomotic Device for Ferromagnetism. Journal of Reconstructive Microsurgery 13:8, 1997.

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