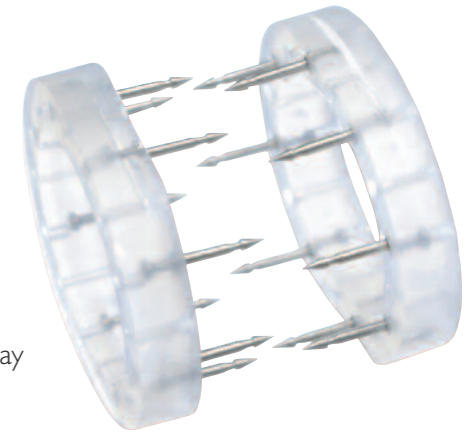


*The Synovis product portfolio includes COUPLER, FLOW COUPLER and GEM MicroClip. These products are used for joining small diameter vessels during autologous tissue breast reconstruction; sealing small blood vessels; in head, neck and hand procedures.*

## COUPLER™

### What is COUPLER?

The GEM (Global Excellence in Microsurgery) microvascular anastomotic COUPLER device and system has been specifically designed for use in the anastomosis of veins and arteries normally encountered in microsurgical procedures.



### Why use COUPLER?

The system provides a simple, fast yet safe way to perform microvascular anastomoses.

### Material

GEM COUPLER rings are made of high density polyethylene with surgical grade stainless steel pins, intended for use with veins and arteries having an outside diameter no smaller than 0.8mm and no larger than 4.3mm and a wall thickness of 0.5mm or less.



### Advantages over traditional suturing\*

- Time savings versus hand suturing which means reduced ischaemic time for flaps
- Less exposure to anaesthesia and less operating time
- Zero intraluminal foreign (suture) material which should decrease the rate of thrombosis
- Stents the anastomosis site preventing vessel collapse and assuring patency
- Anastomoses are 50% stronger than sutured anastomosis at four months (Spector et al 2006)
- Highly versatile enabling effective anastomosis of vessels with size discrepancy

### Evidence

Several large studies have documented the simplicity and dependability of this device in end-to-end and end-to-side anastomotic configurations, for use in various parts of the body.

\* References on file

## CONTENTS

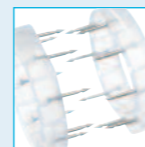
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## FLOW COUPLER®

### What is FLOW COUPLER?

The GEM FLOW COUPLER device and system is the marriage of two trusted technologies: The GEM COUPLER and a 20 MHz ultrasonic doppler. The FLOW COUPLER has been specifically designed for use in end-to-end anastomosis for the detection of blood flow in order to confirm vessel patency intra and post operatively at the anastomotic site.

### Why use FLOW COUPLER?

The system enables blood flow monitoring directly at the point of anastomosis. FLOW COUPLER offers audible early warning signals of reduced or slowing blood flow.

### Material

FLOW COUPLER rings are made of high-density polyethylene and surgical grade stainless steel pins with a Teflon coated doppler probe. FLOW COUPLER rings are available in 2mm, 2.5mm, 3mm, 3.5mm and 4mm sizes. The new improved second generation insulated silver coated copper coaxial lead is less sensitive to noise and signal interference.

### Advantages\*

- Single system combining mechanical anastomosis with doppler technology
- Early warning of flap ischaemia
- Potentially reducing failed flaps
- Greater signal accuracy of blood flow due to probe housing being integrated into COUPLER ring.

### Evidence

Several large studies have documented the simplicity and dependability of this device in end-to-end anastomotic configurations, in various parts of the body.

\*References on file



## MICROCLIP™

### What are MicroClips and SuperFine clips?

Our line of haemostatic MicroClips ensure a secure closure of even the most delicate vessels. GEM MicroClips and SuperFine titanium clips have a unique chevron shape and interlocking atraumatic teeth that prevent multi-directional slippage.



### Why use SuperFine Clips?

- GEM SuperFine MicroClips are great for side branch occlusions
- Ideal for restricted access areas in and around nerve tissue, where damage could occur through bipolar or harmonic scalpel use
- Less metal work in surgical site

## SUPERFINE™ MICROCLIP



### Material

MRI compatible pure, strong and malleable titanium.

### Advantages

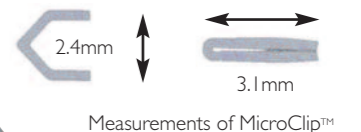
The GEM titanium, haemostatic SuperFine MicroClip is over 35% smaller than standard small hospital clips. The secure closure of the SuperFine MicroClip is formed by its chevron shape, creating a triangular design which ensures uniform closure.

SuperFine MicroClips are lined with diamond-shaped grooving that create interlocking teeth which enhance security and vessel closure while preventing multi-directional slippage.

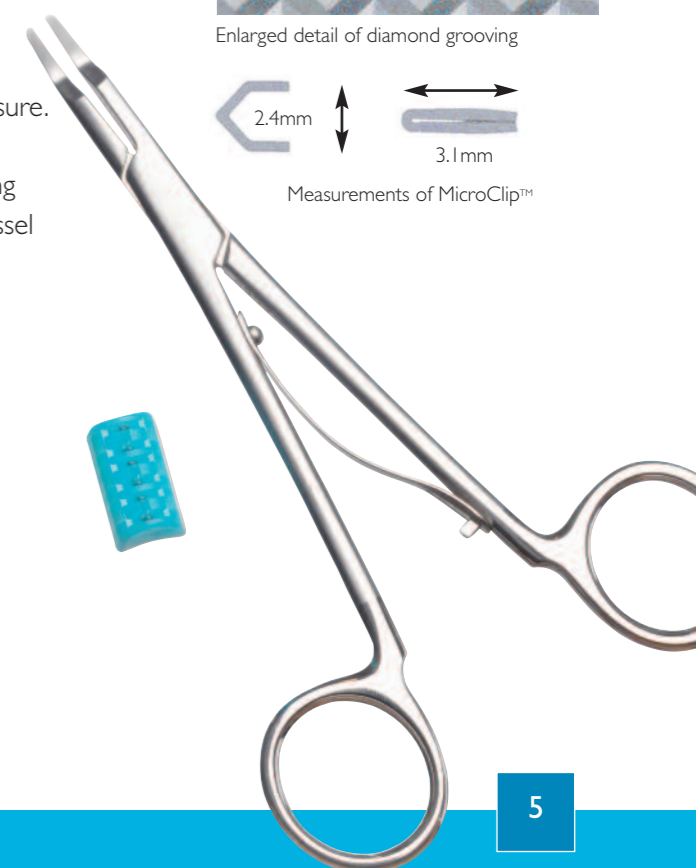
The World's smallest MicroClip!

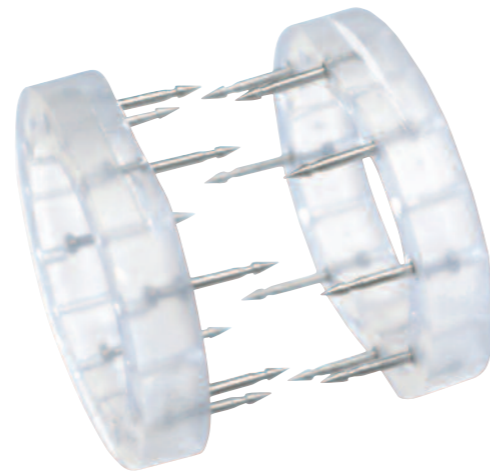


Enlarged detail of diamond grooving



Measurements of MicroClip™





**Evidence**

**Breast reconstruction with perforator flaps**

- The length of the procedure needs to be decreased, scars need to be improved and complications need to be decreased. With improvements in technology and technique, these goals can be realised.
- An anastomotic coupling device typically is used to connect the recipient and flap veins. The coupling device makes the anastomosis easier and faster; and has the additional benefit of stenting the vein open after the vessels are joined. **Robert J. Allen, M.D Et al**

**Lower extremity free flap reconstruction outcomes using venous coupler**

A retrospective review of 67 consecutive patients who underwent lower extremity microvascular reconstruction performed from August 2003 to September 2010 was performed.

- There were no intraoperative or perioperative complications involving the use of a microvascular anastomotic coupling device itself. It presents an important tool in the armamentarium for lower extremity microsurgical reconstruction. **Ducic, I., Brown, B., and Rao, S. Microsurgery. Volume 31, Number 5, July, 2011**

**Initially 50% stronger than sutured anastomoses at four months**

Strength of microvascular anastomoses: comparison between the unilink anastomotic system and sutures. **Gilbert RW, Ragnarsson R, Berggren A, Ostrup L. Microsurgery. 1989;10(1):40-6**

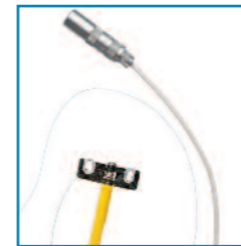
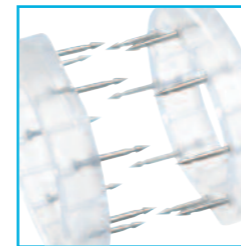
**COUPLER's are used in breast, lower limb and head and neck reconstruction**

1000 consecutive venous anastomoses using the microvascular anastomotic COUPLER in breast reconstruction.

**Schubert HM, Schoeller T, Wechselberger G. Plast Reconstr Surg. 2010 Nov; 126(5):1789**

Microvascular anastomotic COUPLER use in head and neck reconstruction.

**Frederick J.W. et al. Otolaryngology – head and neck surgery 149(1); 67-70**



**GEM COUPLER**

- GEM2750 1.0mm vessel range 0.8mm - 1.2mm box of 6
- GEM2751 1.5mm vessel range 1.3mm - 1.7mm box of 6
- GEM2752 2.0mm vessel range 1.8mm - 2.2mm box of 6
- GEM2753 2.5mm vessel range 2.2mm - 2.8mm box of 6
- GEM2754 3.0mm vessel range 2.7mm - 3.3mm box of 6
- GEM2755 3.5mm vessel range 3.2mm - 3.8mm box of 6
- GEM2756 4.0mm vessel range 3.7mm - 4.3mm box of 6
- GEM2750/I 1.0mm vessel range 0.8mm - 1.2mm single
- GEM2751/I 1.5mm vessel range 1.3mm - 1.7mm single
- GEM2752/I 2.0mm vessel range 1.8mm - 2.2mm single
- GEM2753/I 2.5mm vessel range 2.2mm - 2.8mm single
- GEM2754/I 3.0mm vessel range 2.7mm - 3.3mm single
- GEM2755/I 3.5mm vessel range 3.2mm - 3.8mm single
- GEM2756/I 4.0mm vessel range 3.7mm - 4.3mm single

**GEM2741CC**

- GEM2740 Reusable titanium tipped anastomotic instrument
- GEM2745 Anodised aluminium sterilisation/storage tray
- GEM2749 Stainless steel vessel measuring gauge
- GEM4183C COUPLER forceps, 18cm for everting vessel

**Complete Synovis set inc each of the following components:**

**GEM FLOW COUPLER**

- GEM1020M FLOW COUPLER monitor
- GEM1010UK UK power supply and cord
- GEM1003EXT-FC External lead
- GEM2760-HH Intraop doppler
- GEM2752-FC FLOW COUPLER 2.0mm
- GEM2753-FC FLOW COUPLER 2.5mm
- GEM2754-FC FLOW COUPLER 3.0mm
- GEM2755-FC FLOW COUPLER 3.5mm

**GEM MicroClip**

- GEM615-IG MicroClip applicator 15cm
- GEM620-IG MicroClip applicator 20cm
- GEM715-SF SuperFine MicroClip applicator 15cm
- GEM720-SF SuperFine MicroClip applicator 20cm
- GEM2431 MicroClip cartridges, 5 per box, 6 clips in each
- GEM1521 SuperFine MicroClip cartridges, 5 per box, 6 clips in each