INSTRUCTIONS FOR USE
eCLIPs™ Bifurcation Remodelling System

An *Evasc*™ Product

Manufacturer

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Device Description

The eCLIPs™ Bifurcation Remodelling System (Figure 1) is comprised of an eCLIPs™ Bifurcation Device (eCLIPs™ Device or Device); eCLIPs™ Hypotube; eCLIPs™ Sheath and eCLIPs™ Hub (not shown in Figure 1). The eCLIPs™ Device is made of a Nitinol frame with six radiopaque markers and provides an initial framework or scaffold at the opening of an aneurysm in support of embolic coiling and to provide an ancillary flow diverting effect.

The eCLIPs™ Hypotube is 0.36mm (0.014") guidewire compatible and is designed to deliver and detach the eCLIPs™ Device at the target location.

The eCLIPs™ Sheath is designed to protect the eCLIPs™ Device prior to use and creates an uninterrupted passage for the eCLIPs™ Device to be introduced into the eCLIPs™ Microcatheter.

The eCLIPs™ Hub assists with guidewire loading into the eCLIPs™ Hypotube for the purposes of navigation and implant placement.

The eCLIPs™ Bifurcation Remodelling System must be used with an eCLIPs™ Microcatheter (a 0.86mm (0.034")ID steerable neurovascular access catheter, manufactured by Evasc Medical Systems Corp.) and an eCLIPs™ Detacher (a detachment device, manufactured by Evasc Medical Systems Corp.)

Warning: Compatibility with other catheters has not been established.

The eCLIPs™ Bifurcation Remodelling System is available in the following size:

Unconstrained Device Diameter	3.6mm
Leaf Length/Overall Device Length	7.5mm/16.0mm
Recommended Anchoring Branch Vessel Diameter	2.00mm – 3.25mm*
Recommended Aneurysm Neck Length	≤ 6.0 mm
Recommended Aneurysm Neck Width	≤ 4.25 mm
eCLIPs™ Hypotube Overall Length	178cm
eCLIPs™ Hypotube Useable Length	170cm
eCLIPs™ Hypotube Crossing Profile Diameter	0.80mm (2.4F)

*11%–80% over-sizing

Indications for Use

The eCLIPs™ Bifurcation Remodelling System is indicated to provide support for embolic coils in the treatment of intracranial aneurysms arising from bifurcation branch artery diameters in the range of 2.0mm-3.25mm.

Contraindications

Use of the eCLIPs™ Bifurcation Remodelling System is only eligible to patients whom the following contraindications do not apply:

- Patients in whom antiplatelet/anticoagulation therapy is contraindicated.
- Patients in whom the angiography demonstrates the anatomy is not appropriate for endovascular treatment, due to severe intracranial vessel tortuosity or stenosis or inadequate iliac/femoral access, or intracranial vasospasm not responsive to medical therapy.
- Patients who have sensitivities or allergies to nickel or nickel titanium (Nitinol).
- Patients with a history of coagulation disorders.
- Patients in whom necessary medication administered during and/or after the procedure is contraindicated.
- Patients with lesions that cannot be crossed with a guidewire and/or a catheter is contraindicated.
- Patients with accessories and/or previously implanted devices that cannot be crossed with a guidewire and/or a catheter.

Recommended Accessories

In addition the eCLIPs™ Bifurcation Remodelling System, the following items are recommended:

- eCLIPs™ Microcatheter
- eCLIPs™ Detacher
- 0.36mm (0.014") max OD x 200cm min length steerable guidewire
- Standard microcatheter with distal tip ≤ 0.57mm (1.7F) for coiling
- Standard embolic coils
- Rotating haemostatic Y valves (RHV)

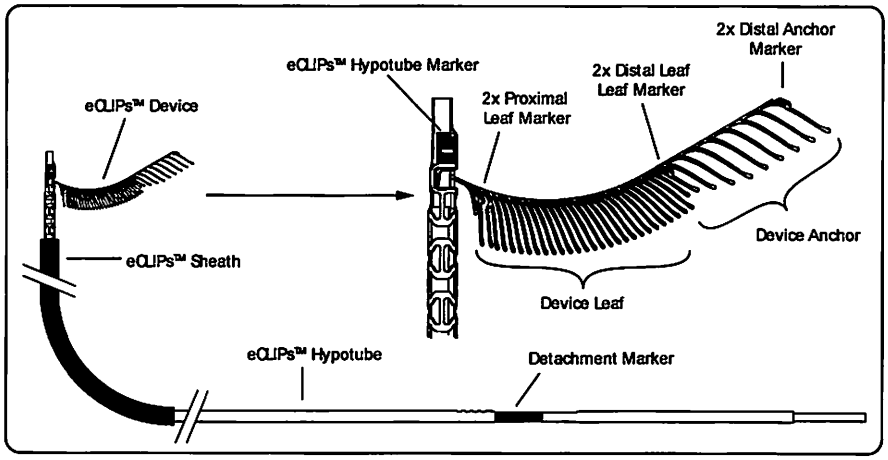

Figure 1

LABL-0043 Rev 7.03
Released: August 8, 2019

2019-08-08

Warnings

- This product should only be used by physicians trained in endovascular techniques and percutaneous transluminal neurovascular procedures.
- This product should only be used by physicians trained on all aspects of the eCLIPs™ Bifurcation Remodelling System and its recommended accessories as prescribed by Evasc Medical Systems Corp.
- The use of this product in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated could result in higher risk of thrombosis.
- Product is intended for single use only. Do not reuse and do not re-sterilize because the properties for re-use and re-sterilization have not been tested. After use, dispose in accordance with hospital and administrative and /or local government policy.
- If the eCLIPs™ Bifurcation Remodelling System packaging is opened and not used, the entire contents must be discarded.
- Product is sterile and is intended for use in a sterile field.
- High quality bi-planar fluoroscopy is recommended to be used with this product.
- It is recommended to confirm rotational orientation of the eCLIPs™ Device prior to detachment by taking multiple fluoroscopic images.
- Adverse events may occur without warning. Personnel competent in recognizing and treating adverse events of any severity should be on hand at all times.

Precautions

- Carefully read and understand all instructions prior to use of the eCLIPs™ Bifurcation Remodelling System.
- Store in a cool, dark and dry place
- The eCLIPs™ Bifurcation Remodelling System is not designed as a standalone device. This product is recommended for use with embolic coils.
- Do not use if packaging is breached.
- Do not use after 'Use by date'.
- Inspect all packaged components. Do not use if components are missing or damaged.
- Do not deploy or retract the eCLIPs™ Device from the eCLIPs™ Sheath when the eCLIPs™ Sheath is dry.
- Only advance and resheath the eCLIPs™ Device and eCLIPs™ Hypotube slowly and smoothly during delivery and deployment. Remove the eCLIPs™ Device completely if excessive friction is noted. If excessive friction is noted with a second eCLIPs™ Device, check the eCLIPs™ Microcatheter for damage.
- Do not resheath the eCLIPs™ Device Anchor more than 6 times.
- Do not resheath the entire eCLIPs™ Device more than 3 times.
- Do not torque, bend or pull the eCLIPs™ Hypotube proximal of the Detachment Marker with excessive force. eCLIPs™ Hypotube failure may occur as a result.
- Do not torque the eCLIPs™ Hypotube at any time. eCLIPs™ Hypotube failure may occur as a result.
- eCLIPs™ Device may not achieve full vessel apposition prior to detachment.
- The performance and safety of two or more overlapping eCLIPs™ devices or off-the-shelf devices has not been established.
- The ability of the eCLIPs™ Device to withstand balloon dilation has not been established.
- Use caution when crossing the implanted eCLIPs™ Device with guidewires and/or other accessories.
- Intermittent angiography is recommended to ensure no coil loops protrude into the vessel lumen.
- Do not use eCLIPs™ Hypotube for longer than 24 hours.

Packaging and Sterility

The eCLIPs™ Bifurcation Remodelling System is supplied sterile (sterilized using Ethylene Oxide). This product is enclosed in a peel-open pouch protected by a sealed carton. Each pouch contains one eCLIPs™ Bifurcation Device, one eCLIPs™ Hypotube and one eCLIPs™ Sheath packaged within a protective plastic dispensing hoop and one eCLIPs™ Hub attached to dispensing hoop card.

Product is sterile unless packaging is found to be broken or breached, or the 'use by' date' has passed. Discard and replace product if sterility has be compromised.

MR Information

Non-clinical testing demonstrates the eCLIPs™ Device to be MR Conditional. The eCLIPs™ Device can be safely scanned under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) or 3.0-Tesla (3.0T).
- Spatial gradient field of up to:
  - 5,720 G/cm (57.20 T/m) for 1.5T systems.
  - 2,860 G/cm (28.60 T/m) for 3.0T systems.
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 4.0 W/kg for 15 minutes of scanning at 1.5T.
  - 4.0 W/kg for 15 minutes of scanning at 3.0T.

In non-clinical testing with body coil excitation, the eCLIPs™ Device produced a temperature rise of less than 1.0°C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for:

- 15 minutes of scanning in a 1.5T Siemens Espree (MRC30732) MR scanner with SYNGO MR B17 software.
- 15 minutes of scanning in a 3.0T Siemens Trio (MRC20587) MR scanner with SYNGO MR A30 4VA30A software.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

In testing using a 3.0T system with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 0.3 cm from the implant.

Potential Complications and Adverse Events

Potential adverse events are similar for any interventional arterial implant procedure and include but may not be limited to the following:

- Allergic reaction including, but not limited to, contrast, Nitinol metal, and medications
- Arterial Dissection
- Arteriovenous fistula
- Arrhythmia
- Cerebral Ischemic Stroke or Ischemia
- Coil Migration
- Coma
- Death
- Device fracture
- Device migration or misplacement
- Device thrombosis or occlusion
- Embolism (air, tissue or thrombotic)
- Incomplete aneurysm occlusion
- Infection
- Hemorrhage or Hematoma at entry site
- Hypertension
- Hypotension
- Hydrocephalus
- Headache
- Intracerebral/intracranial Hemorrhage
- Mass effect
- Neurological deficits
- Parent artery stenosis
- Perforator occlusion
- Perforated aneurysm or aneurysm rupture
- Seizure
- Stroke
- Thromboembolism
- Transient ischemic attack (TIA)
- Vasospasm
- Vessel occlusion
- Vessel perforation
- Vision impairment

Preparation for Use

1. Gain vascular access according to standard practice.
2. Position the distal tip of a 2.0mm (6F) ID (min) sheath close to the target site.
3. Position fluoroscopic equipment such that the desired eCLIPs™ Device rotational orientation is achieved throughout the procedure.
   Note: It is recommended to use a second plane be used to confirm correct eCLIPs™ Device rotational orientation.
4. Following the Instructions for Use for the eCLIPs™ Microcatheter, navigate an eCLIPs™ Microcatheter 1.5-2.0cm distal of the aneurysm neck (as shown in Figure 2).

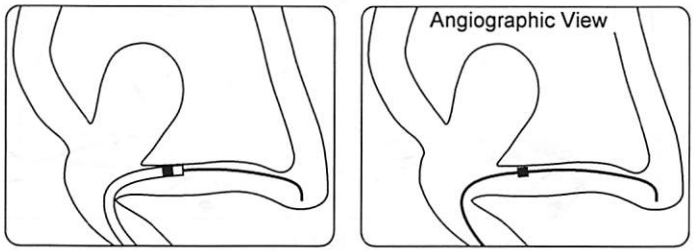

Figure 2

5. Remove all accessories from the eCLIPs™ Microcatheter once the microcatheter is in position.
6. Maintain continuous flush through the eCLIPs™ Microcatheter as per standard neurovascular practice.
7. Carefully inspect the eCLIPs™ Bifurcation Remodelling System pouch for damage that may have compromised product sterility. Discard and replace entire contents if sterility has been compromised.
8. Remove the dispensing hoop from the pouch and place the hoop in the sterile field.
9. Remove the eCLIPs™ Hypotube from the silicon stopper on the dispensing hoop. Grasp the end of the eCLIPs™ Hypotube and remove the eCLIPs™ Bifurcation Remodelling System.
10. Verify that the eCLIPs™ Device is completely inside the eCLIPs™ Sheath. Discard and replace product if the eCLIPs™ Device is found to be exposed.
    Note: Ensure that the eCLIPs™ Hypotube and eCLIPs™ Sheath are not kinked or damaged. Discard and replace if product is damaged.
11. Remove the eCLIPs™ Hub from the dispensing hoop card.
12. Attach the eCLIPs™ Hub to the proximal end of the eCLIPs™ Hypotube (as shown in Figure 3) and tighten the haemostatic grip.

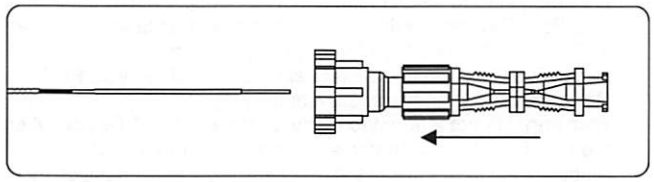

Figure 3

Note: Ensure that the eCLIPs™ Bifurcation Remodelling System is not kinked or damaged. Discard and replace if product is damaged.

13. Flush the eCLIPs™ Hypotube with sterile heparinised saline solution.
    Note: It is recommended to maintain a continuous flush through the eCLIPs™ Hypotube per standard endovascular practice.
14. Deploy the eCLIPs™ Device from the distal end of the eCLIPs™ Sheath and visually inspect that the eCLIPs™ Device for attachment to the eCLIPs™ Hypotube.
    Warning: Do not deploy or retract the eCLIPs™ Device from the eCLIPs™ Sheath when the eCLIPs™ Sheath is dry.
15. Insert a 0.36mm (0.014") guidewire into the eCLIPs™ Hypotube past the eCLIPs™ Device via the eCLIPs™ Hub. Position the tip of the guidewire approximately 5cm beyond the distal tip of the eCLIPs™ Hypotube. Ensure the guidewire remains on the outside of the device as shown in Figure 4 and the device remains fully deployed throughout guidewire loading.

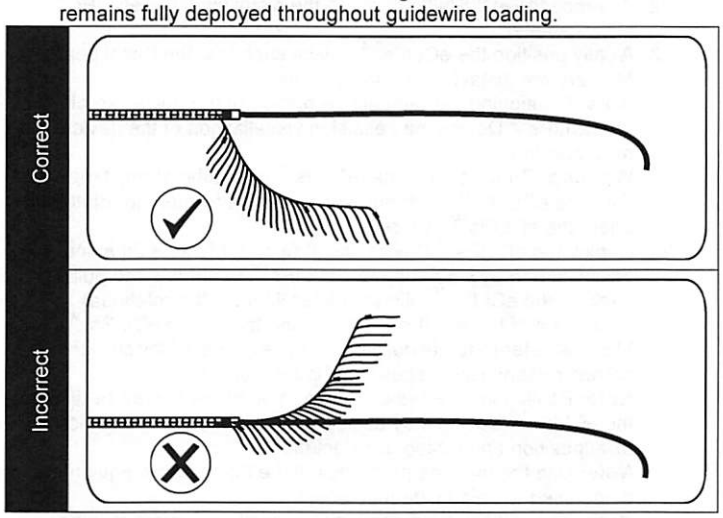

Figure 4

16. Submerge the eCLIPs™ Device in sterile heparinised saline solution, and fully resheath the eCLIPs™ Device and guidewire into the eCLIPs™ Sheath.
    Warning: Do not deploy or retract the eCLIPs™ Device from the eCLIPs™ Sheath when the eCLIPs™ Sheath is dry.

Delivery and Deployment

17. Advance the eCLIPs™ Sheath through the RHV of the eCLIPs™ Microcatheter hub until the eCLIPs™ Sheath is fully engaged. See Figure 5.

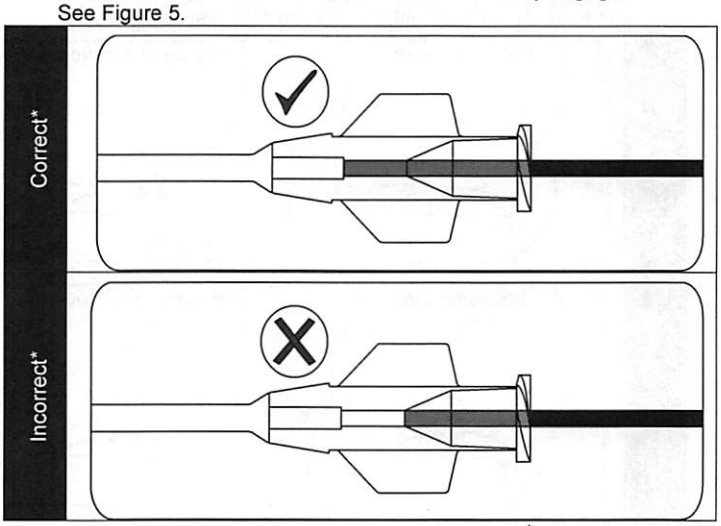

Figure 5 *RHV not shown for clarity

18. Close the RHV around the eCLIPs™ Sheath.
19. Advance the eCLIPs™ Bifurcation Remodelling System into the eCLIPs™ Microcatheter.
    Note: Ensure the eCLIPs™ Sheath does not become disengaged from the eCLIPs™ Microcatheter hub.
    Warning: If disengagement occurs and the eCLIPs™ Hypotube or eCLIPs™ Device becomes damaged, discard and replace the eCLIPs™ Bifurcation Remodelling System.
    Warning: If excessive force is felt, remove the eCLIPs™ Device completely. If excessive force is noted with a second eCLIPs™ Device, check the eCLIPs™ Microcatheter for damage.

20. Advance the eCLIPs™ Hypotube until the Detachment Marker reaches the end of the eCLIPs™ Sheath.
21. Remove the eCLIPs™ Sheath.
22. Advance the eCLIPs™ Device to the distal tip of the eCLIPs™ Microcatheter.
23. Axially position the eCLIPs™ Device such that the Distal Leaf Markers are distal to the aneurysm neck
    Note: Positioning the radiopaque portion of the guidewire distal of the eCLIPs™ Device may assist in visualization of the device axial position.
    Warning: Do not torque the eCLIPs™ Hypotube at any time. Only the eCLIPs™ Microcatheter should be torqued to rotationally orient the eCLIPs™ Device.
24. Deploy the eCLIPs™ Device Distal Anchor Markers 2mm into the vessel lumen by stabilizing the eCLIPs™ Hypotube and pulling back on the eCLIPs™ Microcatheter. Identify the rotational orientation of the eCLIPs™ Device and torque the eCLIPs™ Microcatheter to rotationally orient the eCLIPs™ Device within the correct rotation range shown in Figure 6 below.
    Note: Positioning the radiopaque portion of the guidewire distal of the eCLIPs™ Device may assist in visualization of the Device axial position and rotational orientation.
    Note: Use the bi-plane properties of the fluoroscopic equipment being used to help guide placement.
    Note: The eCLIPs™ Bifurcation Remodelling System may be resheathed by stabilizing the eCLIPs™ Hypotube and advancing the eCLIPs™ Microcatheter.
    Warning: Do not deploy the eCLIPs™ Device Distal Anchor Markers greater than 5 mm beyond the eCLIPs™ Microcatheter distal tip during rotational orientation,
    Warning: Do not resheath the eCLIPs™ Device Anchor more than 6 times.
    Warning: Do not torque the eCLIPs™ Hypotube. Only the eCLIPs™ Microcatheter should be torqued to rotationally orient the device.
    Warning: Do not torque the eCLIPs™ Microcatheter more than 1 turn in either direction unless a torque response is observed.

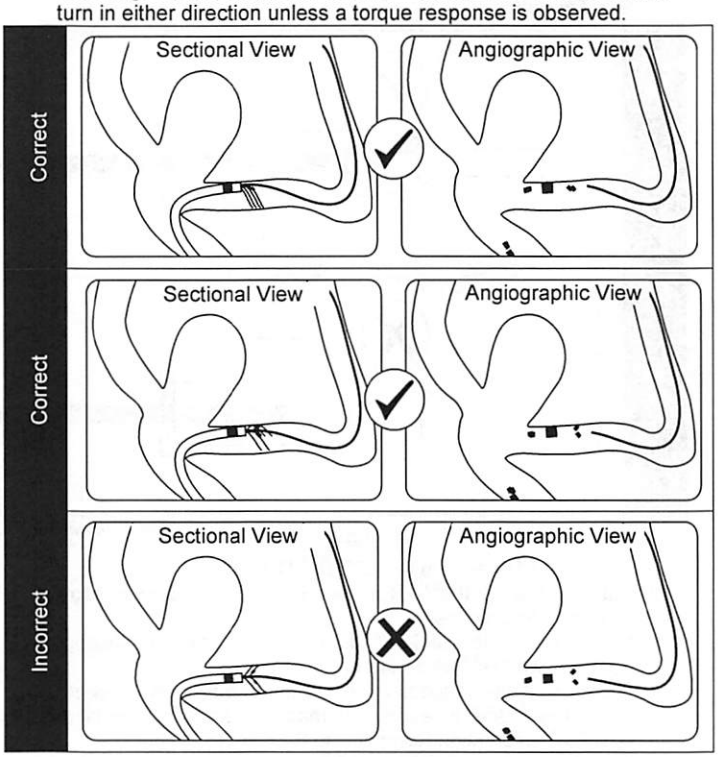

Figure 6

25. Deploy the remainder of the eCLIPs™ Device down the parent and/or trunk artery of the bifurcation site by stabilizing the eCLIPs™ Hypotube and pulling back on the eCLIPs™ Microcatheter. See Figure 7 below.
    Note: Position the eCLIPs™ Device and eCLIPs™ Hypotube in the parent artery such that the guidewire can access the second branch artery.
    Note: The eCLIPs™ Bifurcation Remodelling System may be resheathed prior to detachment if repositioning is required.
    Warning: Do not resheath the entire eCLIPs™ Device into the eCLIPs™ Microcatheter more than 3 times.
    Warning: Do not torque the eCLIPs™ Hypotube.

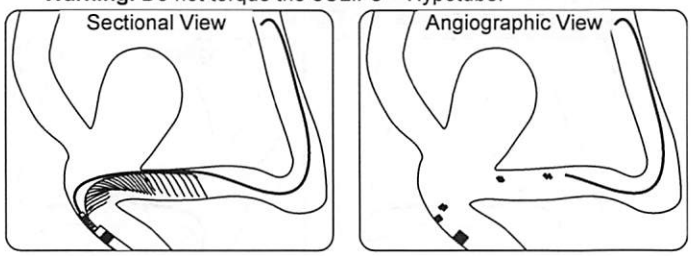

Figure 7

26. Maintaining the position of the eCLIPs™ Device and eCLIPs™ Hypotube, pull back on the guidewire until it falls into the parent and/or trunk artery.
27. Advance the guidewire down the 2nd branch of the bifurcation as shown in Figure 8 below.
    Note: Positioning the radiopaque portion of the guidewire distal of the aneurysm neck within the 2nd branch may assist in visualizing the device axial and rotational orientation and assist with tracking of the device into the 2nd branch.

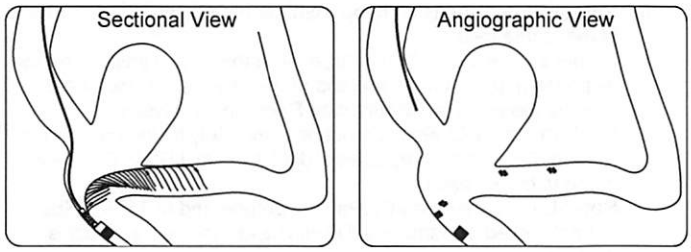

Figure 8

28. While maintaining the position of the eCLIPs™ Microcatheter, push on the eCLIPs™ Hypotube to advance the proximal end of the eCLIPs™ Device past the aneurysm neck until the Proximal Leaf Markers are distal to the aneurysm neck. Ensure the eCLIPs™ Device is in the correct rotational orientation as shown in Figure 9. Re-sheath and re-deploy as required.
    Note: The Proximal and Distal Leaf Markers of the eCLIPs™ Device should span the aneurysm neck.
    Warning: Do not attempt to resheath the eCLIPs™ Device when the eCLIPs™ Microcatheter is within the 2nd branch. If repositioning of the eCLIPs™ Device is required, reposition the eCLIPs™ Hypotube such that the eCLIPs™ Device Proximal Leaf Markers are within the parent and/or trunk artery before resheathing.

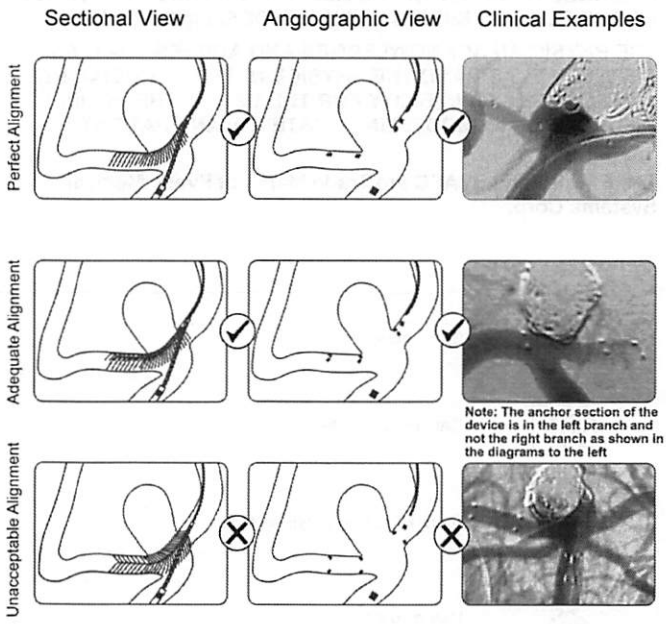

Figure 9

29. Position the distal tip of the eCLIPs™ Microcatheter 2-3mm proximal of the eCLIPs™ Hypotube distal tip.

Detachment

30. Carefully inspect the eCLIPs™ Detacher pouch for damage that may have compromised product sterility. Discard and replace product if sterility has be compromised.
31. Remove the eCLIPs™ Detacher and protective card as a single unit from the pouch and place the assembly in the sterile field.
32. Remove the eCLIPs™ Detacher from its protective card.
33. Inspect the eCLIPs™ Detacher for any visible damage. If visible damage is found, replace product.
34. Prior to eCLIPs™ Device detachment, secure the position of the eCLIPs™ Microcatheter and eCLIPs™ Hypotube by closing the guide catheter and eCLIPs™ Microcatheter RHVs.
    Note: Ensure that the eCLIPs™ Hypotube is not in compression prior to securement.
35. If they are attached, remove the eCLIPs™ Hub along with any accessories associated with a continuous flush of the eCLIPs™ Hypotube.
36. Place the Detachment Marker (black) within the slot of the eCLIPs™ Detacher as shown in Figure 10 and Figure 11.
    Note: The Detachment Marker (black) must be centered within Detacher Slot.

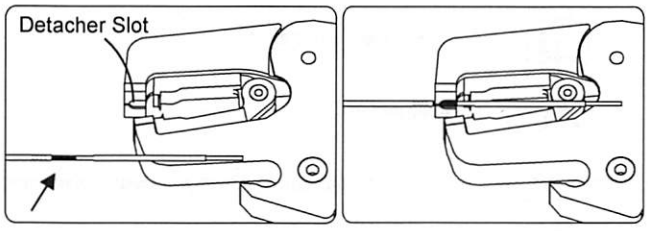

Figure 10 **Figure 11**

37. While stabilising the eCLIPs™ Hypotube, press the detachment handle (as shown in Figure 12) in a smooth and continuous motion until the handle reaches the end of travel.
    Note: Grip the detachment mechanism firmly throughout detachment.
    Note: Do not push or pull the eCLIPs™ Hypotube when the detacher is engaged.
    Note: Some resistance may be felt during the detachment process.
    Warning: If excessive force is felt, replace the eCLIPs™ Detacher and attempt detachment again.

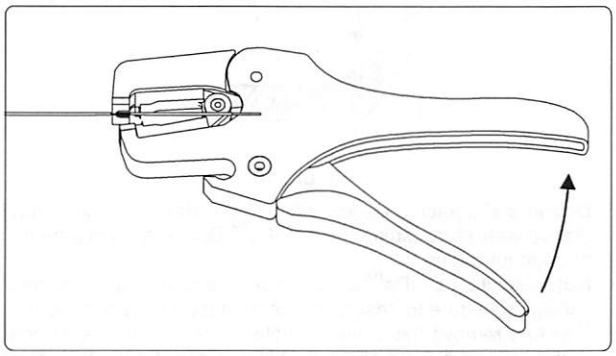

Figure 12

38. Release the detachment handle and remove the eCLIPs™ Detacher from the eCLIPs™ Hypotube.
39. While stabilizing the eCLIPs™ Hypotube, manually pull the Detachment Portion (Figure 13) approximately 5cm away from the eCLIPs™ Hypotube. This will detach the eCLIPs™ Device from the eCLIPs™ Hypotube. To confirm device detachment, push the Detachment Portion forward. The Detachment Wire should become visible as shown in Figure 14.
    Note: Some resistance may be felt during the detachment process.
    Note: If detachment is unsuccessful, see Secondary Detachment Instructions below.

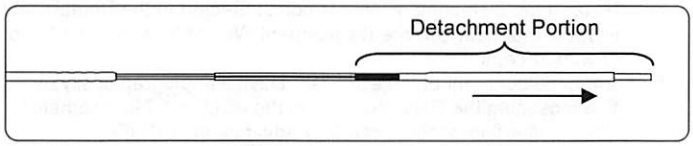

Figure 13

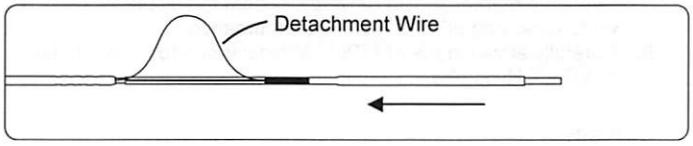

Figure 14

40. Verify detachment of the eCLIPs™ Device angiographically by first loosening the RHV attached to the eCLIPs™ Microcatheter. Then under fluoroscopy, carefully advance the eCLIPs™ Hypotube 2-3mm distal of the eCLIPs™ Device. The eCLIPs™ Hypotube marker should move away from the eCLIPs™ Device without causing eCLIPs™ Device disturbance.

Embolic Coiling after Device Implant

41. Carefully advance the eCLIPs™ Microcatheter to resheath the eCLIPs™ Hypotube.
42. Remove both the eCLIPs™ Microcatheter and eCLIPs™ Hypotube from the vasculature.
43. Insert and navigate a suitable embolic coiling catheter to the target site over an appropriate guidewire.
44. Use the guidewire and embolic coiling catheter to access the dome of the aneurysm through the architecture of the eCLIPs™ Device as shown in Figure 15.
    Note: Monitor eCLIPs™ Device marker positioning during device crossing to ensure device migration does not occur.

Warning: Do not use excessive force to penetrate the eCLIPs™ Device. If resistance is felt, reposition the guidewire and embolic coiling catheter and attempt access at a slightly different location.

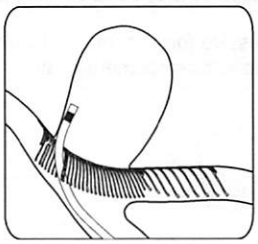

Figure 15

45. Deliver and detach coils according to standard practice. Verify that vessels surrounding the eCLIPs™ Device remain patent throughout coiling.
    Note: Monitor eCLIPs™ Device marker positioning throughout coiling procedure to ensure device migration does not occur.
46. Carefully remove the coiling catheter from the aneurysm dome.
47. Withdraw and discard all applicable accessories in accordance with hospital and administrative and /or local government policy.

Secondary Detachment Instructions

Perform the following steps only if detachment is unsuccessful using the eCLIPs™ Detacher:

1. Ensure the eCLIPs™ Microcatheter RHV is closed.
2. Remove the guidewire from the eCLIPs™ Hypotube.
3. Bend and break the eCLIPs™ Hypotube approximately 5cm distal of the Detachment Marker (black).
4. Pull the Detachment Portion section of the eCLIPs™ Hypotube proximally at least 10cm proximally to detach the eCLIPs™ Device.
   Note: If the Detachment Wire is not connected to the Detachment Portion, manually pull the Detachment Wire at least 5cm by hand or with forceps.
5. Verify detachment of the eCLIPs™ Device angiographically by first loosening the RHV attached to the eCLIPs™ Microcatheter. Then under fluoroscopy, carefully advance the eCLIPs™ Hypotube 2-3mm distal of the eCLIPs™ Device. The eCLIPs™ Hypotube marker should move away from the eCLIPs™ Device without causing eCLIPs™ Device disturbance.
6. Carefully advance the eCLIPs™ Microcatheter to resheath the eCLIPs™ Hypotube.

Warranty

Evasc Medical Devices Corp. ("Evasc") warrants that reasonable care has been used in the design and manufacture of the eCLIPs™ Bifurcation Remodelling System. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability, fitness for a particular purpose or use, durability and warranties arising from usage of trade and course of dealing. Evasc's obligation under this warranty is limited solely to the repair or replacement of the Product. No person has any authority to bind Evasc to any warranty or representation not expressly set out herein.

LIMITATION OF REMEDIES

UNDER NO CIRCUMSTANCES SHALL EVASC BE LIABLE FOR CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR SPECIAL DAMAGES DIRECTLY OF INDIRECTLY RELATING TO ANY USE OF THE ECLIPS™ BIFURCATION REMODELLING SYSTEM.

THE PHYSICIAN ACKNOWLEDGES AND AGREES THAT, AS BETWEEN EVASC AND THE PHYSICIAN, THE PHYSICIAN HAS THE SOLE RESPONSIBILITY FOR THE USE OF THE ECLIPS™ BIFURCATION REMODELLING SYSTEM IN ANY PATIENT.

TM: ECLIPS and EVASC are Trade Marks of Evasc Medical Systems Corp.

Symbols

LOT	Batch code
REF	Catalogue number
STERILE EO	Sterilized using ethylene oxide
	Use by date.
	Keep away from sunlight
	Keep dry
	Do not reuse
	Do not use if package is damaged
	Caution, consult accompanying documents
	Manufacturer
MR	Device is MR conditional
	Consult Instructions for Use
	Non-pyrogenic
EC REP	Authorised representative in the European Community
	Do not re-sterilize