

### MC.003—Vascular and Endovascular Procedures

#### **Scientific Merit for Achievement:**

The cadaveric specimens provide an opportunity for learners to have hands-on practice and testing with human anatomy. The learners may receive training via three or more ways such as simulation, live animal and NAM. Each of these training modalities provides a different perspective to the overall procedure. Overall, the NAM portion of the training is pivotal for the completeness of the learning process.

#### **Objective:**

To perform, teach, and/or perfect various vascular and/or endovascular procedures (open and/or less invasive), involving all areas of the vascular system, and to include those of the heart and brain that will translate to live patient surgeries. These surgeries are typically practiced in the fields of medicine to include but are not limited to the specialties of vascular surgery, general surgery, cardio surgery, interventional neuroradiology surgery, neurosurgery and other qualified professionals or educators relevant to the specialties.

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#### **Methodology to Achieve Objective:**

By utilizing fresh-frozen, embalmed, or embalmed and injected cadaver specimens, the sponsor will perform, teach, and/or perfect surgeries of the vascular system, the heart, and the brain. The utmost care will be taken to make the most minimal incision possible to preserve any future potential for research and education, and to maintain aforementioned consistency with live patient surgery. The specimen may be flushed beforehand to remove some of the remaining thrombi in the vessels. In addition, the specimen may also be perfused during the procedure to simulate flow. Synthetic replicators, flow models and/or simulators may also be used with or without specimens. These procedures can include but are not limited to:

Vascular and Endovascular surgeries such as:

- Endovascular or open repair of abdominal aortic aneurysms, thoracic aortic aneurysms, thoracoabdominal aneurysms that can include stenting or grafting
- Open surgical reconstructions and balloon angioplasty and stenting in all vascular areas
- Carotid endarterectomy and carotid artery stenting
- Bypass surgery and endovascular therapy for peripheral artery disease
- Endovascular and open surgical treatment for peripheral artery aneurysms
- Endovascular surgical interventions such as angioplasty and stenting in all vascular areas
- Varicose vein therapies
- Endovascular and open surgical reconstruction for deep vein occlusions
- Hemodialysis access
- Treatment of vascular malformations

Cardio surgeries such as:

- Aortic root surgery
- Cardiac catheterization
- Cardiac ablation
- Coronary bypass and/ or repair surgeries

- Heart valve surgeries
- Minimally invasive heart and/ or open-heart surgeries
- Transcatheter aortic valve replacement (TVAR)
- Pacemaker surgeries
- Ventricular assist device

Neurosurgeries, interventional neuroradiology surgeries, such as:

- Arteriovenous malformations (AVM)
- Brain aneurysm surgeries
- Carotid angioplasty and stenting
- Carotid artery stenosis
- Carotid endarterectomy
- Cavernous malformations
- Stroke prevention or repair
- Vertebral or basilar stenosis
- Brain tumor surgeries

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**Equipment, Supplies, and/or Instrumentation Potentially Required for Methodology:**

- General Surgical Instrumentation
- Surgical Instrumentation, Catheters, Implants, Guide wires Provided by Sponsor
- C-arm Fluoroscopic Unit with Technician if Requested
- Lead Aprons and Thyroid Shields
- Contrast Medium
- Vascular pump or pressure bag
- Suction Source
- PPEs (Gloves, Gowns, Masks with Shields, Caps, and Shoe Covers)
- Other specialty items specified by sponsor.

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**Qualified Learners/Participants:**

These individuals shall include board certified physicians, resident physicians, physician assistants, nurses, and other medical and non-medical learners/participants. Typically, the students are of the same specialties and of the same position in the medical/surgical field, field of study or the medical device industry.

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**Sponsors Approved in Utilization of Curriculum:**

- Category “A”-Sponsors shall mean medical device companies, professional societies, and federal, state or local government agencies.
- Category “B”-Independent board-certified physicians, healthcare professionals and others shall be subject to MERI’s Sponsor Application process.

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**Faculty Approved for Instruction of Curriculum:**

1) Client Sponsored Event:

Credentials review of Sponsor's faculty and other teaching specialists is exempt from MERI'S Academic Review Board review. However, MERI expects that normally maintained faculty, teaching specialists, and Sponsor representatives are educated and trained in the content outlined in the curriculum and have other demonstrated competencies within the specific discipline or field of study to instruct learners so they maintain and improve the quality of medical care by enhancing professional skills. A fully executed "Sponsor Agreement" between MERI and outside organizations shall serve as assurance of faculty competency.

2) MERI Sponsored Event

a) None at this time.

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**Escorted by MERI Personnel or Non-Escorted:**

- Category "A"-Sponsors as listed in "Sponsor Approved for Utilization of Curriculum" are approved to utilize MERI services both escorted and non-escorted.
- Category "B"-Sponsors as listed in "Sponsors Approved for Utilization of Curriculum" are subject to utilization of escorted and/or non-escorted services through MERI's "Sponsor Application" process.