

MC.001—Spinal 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 spinal surgical procedures involving all levels of the spine that will translate to live patient surgeries utilizing as minimal of an access incision as possible to still allow for the execution of a proper stabilization technique.

Methodology to Achieve Objective:

By utilizing fresh-frozen, embalmed, or embalmed and injected cadaver specimens, the sponsor will perform, teach, and/or perfect spinal surgeries by following as closely as possible the methodology utilized in live patient surgery. 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 the aforementioned consistency with live patient surgery. These include, but are not limited to minimal access to the cervical, thoracic, lumbar or sacrum spinal procedures, open access to the cervical, thoracic, lumbar and/or sacrum spinal procedures.

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

- General Surgical Instrumentation
 - Surgical Instrumentation and Implants Provided by Sponsor
 - C-arm Fluoroscopic Unit with Technician
 - Lead Aprons and Thyroid Shields
 - Surgical Microscope
 - Surgical Drill
 - Endoscopic Light Source
 - Electrosurgical Unit (Bovie)
 - Suction Source
 - PPEs (Gloves, Gowns, Masks with Shields, Caps, and Shoe Covers)
 - Other specialty items specified by sponsor or MERI
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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.

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.

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.