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*A nonprofit corporation of*

The Sisters of Charity  
of St. Augustine Health System *and* **UniversityHospitals  
HealthSystem**

**Surgical Services Information and Protocol Packet  
For – Representatives / Visitors in the  
Operating Room**

# PRODUCT REPRESENTATIVES IN THE O.R.

## PURPOSE

- A. To establish and define guidelines for Product Representatives or Visitors entering the Operating Room and associated office areas/patient care areas.
- B. To insure reasonable control and identification of Product Representatives while in the surgical pavilion.
- C. To minimize interruptions to patient care and staff/physician productivity through management of vendor-related access.
- D. To establish a process to safeguard MMC property and personnel and provide for patient confidentiality.

## ACCESS CRITERIA

Product Representatives will be permitted access to the Operating Room in accordance with the following guidelines:

- A. To introduce and trial new products, devices and equipment:
  - 1. Product Representatives may access the Operating Room to introduce an approved product, device, or piece of equipment for evaluation or formal clinical trial.
  - 2. All new products, devices, and equipment being considered for evaluation or a formal clinical trial must be pre-approved by the New Products Committee, or High Tech, High Cost Administrative Committee.
- B. To support an existing/approved product, device, or piece of equipment:
  - 1. Product Representatives may function as a resource to the surgeon or the nursing staff regarding their respective product, device, or piece of equipment, however the Product Representatives may not scrub in or participate in the surgical procedure.
  - 2. Product Representatives may visually and audibly verify an item with the surgeon; however they may not open any item and place it on the sterile field, or otherwise perform the duties of the circulator.

## ACCESS PROCEDURE/GUIDELINES

- A. Product Representatives may access the Operating Room upon the formal request of the Attending Surgeon, Anesthesiologist, Director of Surgical Services, Nurse Manager, or Team Leader.
- B. When the surgeon requests a trial of an **unapproved** product, an advanced notice of **one (1) month** is required in order to provide the medical center with sufficient time to meet with the associated Product Representative to discuss clinical, financial, and administrative specifics.

- C. Notification must include the Representative's name, company, the date and time of the procedure, requesting sponsor, a description of the product, and reason for the visit.
- D. If the Surgeon did not initiate the request, the Surgeon should be notified and approve the visit prior to the operation.
- E. The Director of Surgical Services will contact the requesting sponsor if Product Representative access is deemed inappropriate.
- F. All vendors must report to MMC Purchasing Department or the Security Department where they will be required to sign-in the Purchasing Visitor's Log and to pick up their visitor badge.
- G. Prior to entering the surgical pavilion, all Product Representatives must report to the O.R. Control Desk to obtain a set of scrubs, and sign-in in the Surgical Visitor's Log Book. Required information includes:
  - 1. Vendor Name
  - 2. Company
  - 3. Sponsor (surgeon/nurse manager, etc.)
  - 4. Reason for the visit/product
  - 5. Date
  - 6. Time in
  - 7. Time out
- H. The Visitors Badge is valid for the date indicated and may not be used for subsequent visits, and must be returned to Security or Materials Management.
- I. No presentations or product trails are permitted without prior approval.
- J. After obtaining scrub attire and signing in, Product Representatives should proceed directly to the appropriate operating room or remain in the O.R. Staff Lunchroom if the case not yet begun.
- K. Product Representatives are not permitted in the Physician's Lounge or Physician's Dressing Rooms. Permission is granted to enter the Physician's Dressing Rooms only to get scrubs and then you must enter the Employee Dressing Room to change. Please keep valuable personal items with you.
- L. To insure patient privacy, the patient must be fully draped before Product Representatives are permitted in the Operating Room.
- M. Product Representatives must have their Visitors Badge worn visibly on their scrub apparel at all times.
- N. Brief cases, satchels, bags, etc. are not to be carried into the O.R. suite.
- O. Vendors are not permitted to be in the Scheduling Office, nor take or review a surgery schedule.
- P. Vendors are not permitted behind the Main Control Desk.
- Q. Vendors may not take any documents (including patient labels) that contain any patient-specific information, including name, social security number, or medical records number.

- R. Product Representatives are not permitted to distribute or post any type of hand printed or handwritten invitations, advertisements, signs, or promotional materials unless pre-approved by the Director of Surgical Services.
- S. Product Representatives must remain in their assigned surgical suite. They are not permitted to move freely among the various rooms.
- T. Prior to initial entrance into the Operating Room, Product Representatives must be suitably attired in surgical scrubs with associated mask and hat in accordance with the Operating Room dress code.
- U. Prior to first access to the O.R., Product Representatives must provide the following health information:
  - 1. A TB skin test read as negative.
  - 2. If skin test is positive the vendor must provide the results of a follow-up chest x-ray.

\*Annual renewals are expected.

- V. Product Representatives must complete MMC's Surgical Services Information and Protocol Packet. ~~(A score of 100% is required for admittance into the surgical pavilion.)~~ Assessment forms may be obtained in the Surgery Office or online at [www.thequalityhospital.com](http://www.thequalityhospital.com).
- W. Product Representatives must have a scheduled appointment prior to coming to the Operating Room. No "drop-in" visits will be permitted.
- X. ~~Upon completion of the Surgical Services Information and Protocol packet, each Product Representative must sign an attestation form stating that they have received and read the "Product Representative in the Operating Room" policy and agree to accept the guidelines and conditions therein.~~
- Y. Financial and administrative arrangements for any product(s) brought into the operating room (supplies, equipment, implants) must be discussed with and approved by the Director of Surgical Services prior to the start of the procedure. Invoices submitted without prior agreement and approval will not be honored.
- Z. Product Representatives are invited guests and as such, non-compliance with any portions of this policy may result in immediate removal from the Operating Room and termination of sales and marketing privileges.
- AA. Product Representatives may not take home the facility scrubs.
- BB. ~~Product Representatives are invited guests and as such non-compliance with the policies of Mercy Medical Center and the Operating Room may result in immediate removal from the operative suite and termination of sales and marketing privileges.~~