Re-entry Guidance for Health Care Facilities and Medical Device Representatives

Presented by
American Hospital Association
Association of periOperative Registered Nurses
Advanced Medical Technology Association (AdvaMed)

Supported by
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American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Association of Gynecologic Laparoscopists
American Association of Nurse Anesthetists
American Burn Association
American College of Chest Physicians
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Society for Cardiovascular Angiography and Interventions
Society of Interventional Oncology
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Wound Ostomy and Continence Nurses Society

Introduction:

In response to the COVID-19 pandemic, hospitals and surgical facilities nationwide paused elective surgical procedures and other nonemergent and nonessential services, limiting physical access to facilities for nonessential health care personnel, patient visitors, and medical device representatives.

On April 17, the American College of Surgeons, the American Hospital Association, the Association of periOperative Registered Nurses (AORN), and the American Society of Anesthesiologists issued a ***Roadmap for Resuming Elective Surgery***. That joint statement provides key principles and considerations to guide health care professionals and organizations regarding when and how to resume elective surgeries safely, and includes a recommendation for facilities to account for medical device representatives in their consideration of case scheduling and prioritization as facilities begin to resume elective surgeries and other invasive procedures.

Since the issuance of the ***Roadmap for Resuming Elective Surgery***, AORN and the AHA have further collaborated with AdvaMed to provide these clinically based recommendations to support health care organizations and medical device representatives when resuming elective procedures. The following principles and considerations are intended to guide facilities, health care personnel and medical device representatives as they adopt access policies that support safe reentry of medical device representatives

into the facility. These considerations are not a substitute for guidance or requirements from state or federal government authorities.

1. All Areas of Hospitals and other Health Care Facilities

Principle: Facility social distancing and safety policies applicable to staff, patients and patient visitors should apply equally to medical device representatives in all areas of the facility. Facility access policies for all visitors will fluctuate and should vary based on the current COVID-19 incidence rates and activity in the immediate community.

Considerations: Facility policies for medical device representatives in all areas should account for the following:

- Medical device representatives should work with facilities and providers to deliver services, information, and support remotely whenever possible.
- Medical device representatives needing facility access for servicing medical equipment should follow the same social distancing and access policies applicable to staff with access to the equipment.
- Medical device representatives entering all areas of the facility should take safety precautions in accordance with Centers for Disease Control and Prevention (CDC) community recommendations,[1] and state and/or local public health recommendations, regarding hand washing and face coverings, both to protect the individual and others in the facility.

2. COVID-19 Testing and Screening

Principle: Facility testing policies for medical device representatives entering both restricted and non-restricted areas should follow current Centers for Disease Control and Prevention (CDC) priority recommendations for COVID-19 testing.[2] Medical device representatives entering all areas should be screened for symptoms (fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat) in the same manner as staff, patients and patient visitors.

Considerations: Requirements for medical device representatives to present negative test results (whether once or on an ongoing basis) are inconsistent with current CDC recommendations concerning testing priorities for health care workers and patients. Any required testing of asymptomatic individuals should only be consistent with and in accordance with applicable state and local health authority guidance.

3. Elective Surgical Procedures and Personal Protective Equipment

Principle: In accordance with the joint recommendations in the ***Roadmap to Resuming Elective Surgery***,[3] health care facilities should not resume elective surgeries until the facility has proper inventory of non-crisis level equipment and supplies, including PPE. Surgical case scheduling and prioritization policies should account for proper inventory of PPE, including PPE for any medical device representatives essential to an elective procedure.

Considerations: Facilities should provide proper PPE to medical device representatives deemed essential to any surgical or other invasive procedure. PPE for surgical and other invasive procedures should be appropriate to the procedure and provided by the health care facility to prevent the possible introduction of outside contaminants.

- Facility PPE policies should be in accordance with the considerations outlined in the ***Roadmap to Resuming Elective Surgery***.

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[1] Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission

[2] Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)

[3] Roadmap for Resuming Elective Surgery after COVID-19

- PPE that is managed and supplied by the facility can be quality-controlled by the facility in contrast to PPE brought in from outside the facility.
- Facilities with videoconferencing capabilities in their operating rooms should work with medical device representatives and clinicians to utilize virtual support in surgical cases where remote attendance does not compromise patient safety or privacy.
- Proper respiratory protection (e.g., fit-tested N95 respirators with face shield or surgical N95 respirator) should be provided to all individuals, including medical device representatives, who are present for aerosol-generating procedures for patients who are not confirmed negative for COVID-19 at the time of the procedure.[4]

4. Crisis-Level Emergency Surgical Procedures and Personal Protective Equipment

Principle: Facilities operating in crisis level may require medical device representatives essential to emergency surgical and other invasive procedures to provide their own PPE if the facility is in short supply to the extent this practice is consistent with applicable federal and state requirements.

Considerations: Medical device representatives and facilities should follow CDC and FDA guidance regarding use and decontamination of any such PPE, whether supplied by the facility or by a medical device representative. Protective equipment that is worn in the operating room serves two functions – protection of the wearer and protection of the environment. Re-aerosolization of contaminants on reused masks and respirators can be the source of sterile field contamination. To contain re-aerosolized particles, the facility should provide a surgical mask or other covering to be worn on top of any respirator a medical device representative has brought in from outside the facility.

- Facility PPE policies should be in accordance with CDC guidance for conserving PPE[5] and infection control.[6]
- Proper respiratory protection (e.g., fit-tested N95 respirator with face shield or surgical N95 respirator) should be worn by all individuals, including medical device representatives, who are present for aerosol-generating procedures for patients who are not confirmed negative for COVID-19 at the time of the procedure.[7]
- PPE that is used in the operating room should be effective in serving both functions of protective equipment – protecting both the wearer and the environment.[8]

5. Training and Education regarding COVID-19 Safety and Precautions

Principle: Medical device representatives should have an understanding of CDC infection prevention recommendations for COVID-19, FDA guidance for PPE, CDC guidance for PPE donning and doffing,[9] and facility policy related to COVID-19 safety principles.

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[4] Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings

[5] Strategies to Optimize the Supply of PPE and Equipment

[6] Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings

[7] Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings

[8] AORN Guideline for transmission-based precautions. In: ***Guidelines for Perioperative Practice***. Denver, CO: AORN, Inc; 2018. e133-e172; AORN Guideline for Transmission-Based Precautions. In: ***Guidelines for Perioperative Practice***. Denver, CO: AORN, Inc

[9] Using Personal Protective Equipment (PPE)