

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

Introduction:

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

In the following paragraphs, Medtech Canada will provide clinically based principles to support health care organizations and medical technology representatives when resuming elective procedures. The following principles and considerations are intended to guide health care facilities, health care personnel and medical technology representatives as they adopt access policies that support safe re-entry of medical technology representatives into the health care facility. These considerations are not a substitute for guidance or requirements from local, provincial or federal government authorities.

Supported by:

- Canadian Association for Interventional Radiology (CAIR)
- Canadian Association of Interventional Cardiology (CAIC)

Medtech Canada has aligned with AdvaMed's position regarding the re-entry to health care facilities by medical technology representatives. The Advanced Medical Technology Association (AdvaMed), is a trade association based in the United States that acts as the common voice for companies producing medical devices, diagnostic products and digital health technologies.

1. Re-entry to All Areas of Hospitals and Other Health Care Facilities

Principle: Re-entry policies and guidelines applicable to visitors including medical technology representatives will follow local government requirements, will be based on current COVID-19 incidence rates and community risk, and will be adjusted accordingly. Physical distancing and safety requirements will be applicable equally to all, including staff, patients, patient visitors and medical technology representatives, in all areas of the facilities.

Considerations: To ensure the safety of staff, patients, patient visitors and medical technology representatives, facility policies addressing re-entry by medical technology representatives should account for the following:

- Medical technology representatives should work with facilities and health care providers to deliver services, information, and support remotely whenever possible.
- Medical technology representatives needing facility access for: a) servicing and/or maintenance of medical equipment; b) providing physical product support; c) clinical research activities and/or d) any other required technical support for medical equipment,

should follow the same physical distancing and access policies applicable to facility staff with access to the equipment.

- Medical technology representatives should ensure that if they physically access a facility, they are healthy, in particular they do not have a fever, a cough or shortness of breath, and have not been in contact with anyone diagnosed with COVID-19 in the last 14-days.
- Medical technology representatives entering all areas of the facility should take safety precautions in accordance with the Public Health Agency of Canada (PHAC)¹, Canadian Centre for Occupational Health & Safety², community recommendations, federal, provincial/territorial and/or local public health authority recommendations, regarding hand washing and face coverings, both to protect the representative and others in the facility.
- Facilities with videoconferencing capabilities in their operating rooms should work with medical technology representatives and clinicians to utilize virtual support in surgical cases where appropriate and requested by the health care facility staff and where remote attendance does not compromise patient safety or privacy.

2. Personal Protective Equipment (PPE)

Principle: The majority of hospitals and health care facilities are managing and providing appropriate PPE that meets applicable health and safety requirements to medical technology representatives accessing such facilities. This ensures that the PPE can be quality controlled by the facilities and to help prevent possible introduction of outside pathogens.

Considerations: Health care facility policies/directives addressing the supply and use of PPE should account for the following:

- Health care facilities should follow applicable government guidance and meet specified criteria required in order to resume elective surgeries and, should ensure the facility has a 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 technology representatives essential to an elective procedure.
- Proper respiratory protection (e.g., fit-tested N95 respirators with face shield or surgical N95 respirator) should be provided to all individuals, including medical technology representatives, who are present for aerosol-generating procedures for patients who are not confirmed negative for COVID-19 at the time of the procedure.
- PPE supplied by health care facilities for surgical and other invasive procedures should be appropriate for the procedure.

3. Clinical Research Activities

Principle: During the COVID-19 pandemic, it is important to ensure that clinical investigations for existing and new medical technologies can continue with minimal disruption whilst preserving the safety of the participants and the quality of the data generated through the investigations. The medical technology industry performs risk assessments as mandated by

¹ Public Health Agency of Canada: <https://www.canada.ca/en/public-health.html>

² Canadian Centre for Occupational Health & Safety: <https://www.ccohs.ca/>

national authorities' guidelines and implements mitigation measures to manage the COVID-19 pandemic while keeping the clinical investigations running and safe for all parties involved. This is done in close collaboration with investigators to limit the possibility of COVID-19 infection.

Considerations: Studies underway prior to the pandemic may have been halted temporarily, recruitment of participants may have been suspended or slowed due to the significant decrease in procedures, and patients may not be willing to continue participation or are missing follow-up visits due to lock-downs, etc. Potential changes to clinical investigation plans to complete these studies could include but are not limited to the following:

1. Adapting follow-up physical visits by the study participants (patients) to phone or virtual visits via telemedicine or alternative care sites. Alternative locations for imaging studies and laboratory tests may need to be considered;
2. Collecting data at a later stage when it is safe for patients to return for a physical visit and delaying and extending timelines for data collection;
3. Accounting for delayed study start and slow enrolment by amending study protocols and statistical analysis plans.

In addition to the above, on May 23rd, Health Canada published an Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19³ recognizing the need to facilitate such clinical research.

While central or remote monitoring of clinical studies may be an option for some studies, at some point, clinical research staff from medical technology companies may need to attend the facility to ensure the integrity of the study data. In these situations, PPE will be required as described above.

4. Professional Education, Product Training

Medtech companies are committed to continue to provide educational and technical support to Health Care Professionals (HCPs) utilizing the most current technologies and channels, thereby decreasing face to face interactions in order to reduce risks for both the health care facility staff as well as medical technology representatives.

Medtech Canada stresses the importance of the following when resuming professional education and product training activities:

- The Medtech Canada Code of Conduct needs to be adhered to at all times (Section 4 Company Conducted Product Training and Education⁴)
- Align with respective applicable and most recent Public Health guidelines;
- Reduce unnecessary travel. If travel is required, only essential industry personnel should be in attendance.

³ Health Canada Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19, <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs.html>

⁴ Medtech Canada Code of Conduct, https://cdn.ymaws.com/medtechcanada.org/resource/resmgr/code_of_conduct/2019_code_en_append.pdf

5. Digital First Approach

- Evaluate all digital channels prior to engaging in face to face interactions. e.g. live educational virtual sessions, live virtual events, video recorded sessions, case studies and web-based learning programs.
- Technical skills learning through augmented reality, virtual reality, alternative tissues/simulator, virtual preceptorships.

6. Company Provided Meals to Health Care Professionals During Company Sponsored Events

Medtech Canada has aligned with AdvaMed's position regarding the provision of meals at company led product training sessions. This has given rise to some concerns specifically related to the COVID-19 response. In order to properly consider and manage the provision of meals to HCPs during Company-conducted training and education programs that are held virtually, similar to AdvaMed, Medtech Canada recommends that Companies (as defined in the Medtech Canada Code of Conduct):

- Create a process to control meal ordering and delivery, addressing health and safety issues, in addition to ensuring that the meals are not used as an inappropriate inducement;
- Track attendance to ensure that only appropriate recipients of the training/education are receiving the meals; and
- Specify that no home delivery will be permitted.

7. Face to Face Interactions

It is paramount that all safety measures are in place prior to face-to-face interactions including: a) the utilization of physical distancing guidelines; b) the incorporation of the most recent Public Health guidelines; c) incorporation of the policies and processes established by individual health care facilities and; d) the use of appropriate and approved PPE provided by the health care facility that meets the facility's quality requirements.