

Policy Applies to

This policy is for medical supply company's technical representatives and supplier representatives ('representatives') invited to access a Mercy Hospital Dunedin facility, usually the perioperative environment, to provide technical support. It outlines the conditions of access including how the representative is invited, applying for access, protocols for entering and exiting the facility and the behaviours and rules necessary to maintain access approval.

Conduct

Representatives are expected to consistently maintain a high standard of ethical conduct and professionalism that complies with the current [Medical Technology Association NZ \(MTANZ\) code of practice](#).

Access to a Mercy Healthcare facility

A representative must first have been invited to attend an operating theatre by either a credentialed specialist (usually a surgeon or interventionist) or a Mercy Hospital team member with the intention that they provide theatre support/technical advice required during a patient's procedure. Following receipt of this invitation, initial information re Covid status must be stated clearly in a return email to the Theatre Manager, Mercy and or Manaaki. Covid status must be known prior to a representative's visit.

Where a medical practitioner invites a representative, a *Medical Company Representatives or Technical Support Persons in Mercy Operating Theatres Orientation, Induction & Confidentiality Agreement* must be completed prior to or at the time of the representative's first visit to the hospital. The medical practitioner takes full responsibility for the representative's (called an Invitee) performance and behavior as defined in the [By-Laws](#)

Where the medical representative has been invited by Mercy staff into the Theatre environment the Theatre CNM or their delegate is responsible for ensuring compliance with this policy.

Access is limited to the immediate patient care environment and is granted to people who are not employees or not credentialed, but who provide direct or indirect clinical care or support.

The appropriate Manager (Theatre or Manaaki) or their delegate is the authority that grants access for a specified period of time (e.g. in this case technical equipment assistance).

The representative agrees to participate in an induction at each hospital to which they have been granted access and working only towards their stated purpose.

In these circumstances, consent from the patient is not required (but may be provided) as the representative is regarded as being included in the perioperative team for the patient's procedure.

Note: Medical companies are responsible for ensuring their medical representatives/technical support employees have appropriate training in basic theatre etiquette before they are permitted to attend hospitals in person. Where possible, evidence of this should be detailed on the *Medical Company Representatives or Technical Support Persons in Mercy Operating Theatres Orientation, Induction & Confidentiality Agreement* form, for example the MTANZ/ Auckland District Health Board, Medical Representatives Workshop: 'Protocols and Aseptic Awareness for Operating Rooms training'.

Training of new company Representatives

Mercy Hospital acknowledges that from time to time, training of new company representatives (representative trainee) will be required. To facilitate this, the medical company must notify the hospital appropriate Theatre Manager in advance.

The following requirements apply:

- the representative trainee will have completed appropriate training in basic theatre etiquette prior to attending a theatre session and evidence of this should be detailed on the special circumstance application form
- the medical company trainer will be responsible at all times for the conduct of the trainee; and
- all representative trainees must complete the Mercy hospital familiarisation as detailed below.

Familiarisation to the hospital's perioperative environment

The Representative undertakes an induction appropriate to their special circumstances access and to meet the requirements of Health and Safety at Work legislation, as a minimum the *Medical Company Representatives or Technical Support Persons in Mercy Operating Theatres Orientation, Induction & Confidentiality Agreement*

The Theatre Manager or their nominee, is responsible for ensuring that the induction occurs and the following completed and signed records are retained:

- *Medical Company Representatives or Technical Support Persons in Mercy Operating Theatres Orientation, Induction & Confidentiality Agreement*

Note: optimally the familiarisation is planned prior to the representative (or trainee representative) requiring access to an operating theatre.

Pre-arranging visits

Representatives should notify the Theatre Manager(s) (or nominated person) by email or telephone that they (or an alternative person where this is necessary) have been invited to attend a procedure/s to support a medical practitioner. Ideally this should be at a minimum of 48 hours' notice.

Notification must include:

- The inviting Medical practitioner's name
- Date and time of visit
- Purpose of visit i.e. supporting medical practitioner, training, equipment evaluation, stock take
- Name, company and designation of the person attending

Under no circumstances are unsolicited visits by technical representatives and supplier representatives allowed. This may include, but is not limited to, presenting a medical specialist a new product without their prior knowledge or informing clinical staff where products are being evaluated

Protocol for entering hospital

All representatives must sign in and sign out when visiting a Mercy facility and wear the assigned visitor identification and their own company identification at all times and ensure both remain visible during the visit. Sign in occurs at the main entrance reception on arrival. Failure to comply with this procedure may mean that future admittance to the Mercy facility is denied.

The representative must wait in the reception area until access is given to perioperative by Reception. On entry to theatre they must check in with the Theatre Coordinator unless prior arrangements have been made with the Theatre Manager. Access to and continued presence in the perioperative environment is under the direction and oversight of either the credentialed specialist (surgeon or interventionist) or by a designated Mercy team member.

Protocol for entering the perioperative area

- The representative must change into full theatre attire: all jewellery removed, hair / beards fully covered and where required, shoe covers are worn
- It is expected that the representative will introduce themselves to all members of the operating team including the reason for their attendance, i.e. technical support
- A representative is required to confirm the equipment availability with the theatre staff prior to the patient's procedure commencing. This also needs to be visualised by theatre staff to ensure sterility (batch labels) and expiry date checks are completed before the procedure commences

- Strict infection prevention and control practices are to be maintained, including but not limited to appropriate [hand hygiene](#), protection of the sterile field and use of [personal protection equipment \(PPE\)](#).

In addition, the representative will observe the following requirements during their visit:

- Switch mobile phones to silent mode inside the operating theatre and refrain from making calls unless they are related to the patient's care and required by the medical practitioner or SCH. Phone calls should be made outside the operating theatre.
- Do not use laptops in theatres
- Do not bring food or drink into the perioperative environment
- Participate in team briefing (if present) and or [Time Out](#), identifying name, role and employer as required
- Keep conversation and noise to a minimum
- Follow all directions or requests of theatre staff e.g. emergency situations where may be required to leave immediately
- Leave the theatre immediately when assistance and support is no longer required / at the end of the procedure
- Where the representative has down time between procedures, they are required to wait in the theatre tearoom until theatre staff call them. It must be understood that the tea room is a staff rest area and not a suitable venue for business conversations
- In the event of an injury sustained during hospital visit, the Mercy Hospital will facilitate the completion of an incident form which will be followed up by Mercy's Health & Safety Coordinator

Company representatives / technical support persons are not permitted to

- Participate in direct patient care (e.g. positioning the patient)*
- Open or the checking of surgical items (instruments / consumable / implant) on to the sterile field
- Operate or move any theatre equipment owned by the facility * unless specifically requested to do so by a hospital staff member
- Take photographs / video or sound recordings on a personal phone, surgeon's phone, or other [insert facility] owned devices unless the invitee is demonstrating the use of new surgical camera/recording equipment e.g. laparoscopic stack, robotics
- Enter/observe any other operating theatre or areas during the visit
- Review other surgeon's theatre lists.
- Discuss / share any patient's personal health information, procedure, diagnosis or surgical pictures as per [Mercy Hospitals privacy policy](#)

- Use the staff tea room to promote products unless formally invited to do so by theatre manager.

** Irrespective of previous training or qualification e.g. registered nurse, registered anaesthetic technician, other healthcare worker*

Protocol for exiting hospital

- Inform the Theatre Manager (or the staff member in charge of the theatre the representative has accessed) that they are leaving the hospital
- Remove all theatre attire and dispose in the appropriate receptacles
- Sign out at the main entrance reception (where the representative signed in) and return any security access devices issued by the hospital
- Failure to return a security device may result in access rights being removed.

Complaints and escalation of concerns and event investigation

The representative agrees to raise any safety or other concerns promptly with the Theatre Manager or their nominee, to enable this to be promptly addressed. Where there is a risk of potential or actual harm, this should be done immediately.

Where there is an issue with, or a complaint regarding the representative's performance or behaviour, in the first instance this will be raised with the representative in a timely manner to enable an early resolution. Where this cannot be promptly resolved, the GM and the representative's employers should be notified

Where an adverse event occurs, the representative proactively participates in the investigation relevant to their role at the time.

Legislative requirements

- Health and Safety at Work Act 2015 and associated Regulations, Codes of Practice and WorkSafe guidelines
- All medical devices supplied by companies must have appropriate certification, Web Assisted Notification of Devices (WAND) in accordance of Ministry of Health statutory requirements.

Code of Conduct

- Company medical Representatives must comply with the [Medical Technology Association of New Zealand \(MTANZ\) Code of Practice guidelines](#)

References

- AORN eGuidelines Product Evaluation
- ADHB medical rep - Protocols and Aseptic Awareness for Operating Rooms

Appendices

- *Appendix 1: Medical Company Representatives or Technical Support Persons in Mercy Operating Theatres*
- *Orientation, Induction & Confidentiality Agreement Sept 2021*

[NZPSHA Member Criteria for Medical Representatives visiting hospitals under COVID-19 Alert Levels.](#)