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Medical company representatives or technical support persons in the operating theatre policy

This policy is for medical supply company's technical representatives and supplier representatives ('representatives') invited to access a Southern Cross Healthcare (SCH) 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 Southern Cross Healthcare facility

A representative must first have been **invited** to attend an operating theatre by either a credentialed medical practitioner (usually a surgeon or interventionist) or a SCH team member with the intention that they provide theatre support/technical advice required during a patient's procedure.

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 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, for example the *MTANZ/Auckland District Health Board, Medical Representatives Workshop: 'Protocols and Aseptic Awareness for Operating Rooms training'*.

Training of new company representatives

SCH 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 Theatre Manager in advance.

The following requirements apply

- the representative trainee will have completed and provided evidence of appropriate training in basic theatre etiquette prior to attending a theatre session
- the medical company trainer will be responsible at all times for the conduct of the trainee; and

- all representative trainees must complete the SCH hospital familiarisation as detailed below.

Familiarisation to the hospital's perioperative environment

The Representative undertakes an induction and to meet the requirements of Health and Safety at Work legislation. 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 Representative Access to Operating Theatre Declaration Form](#)
- Health and Safety Induction Checklist

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 (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 within 48 hours.

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 SCH facility and wear the assigned visitor identification and their own company identification at all times and so 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 SCH facility is denied.

The representative must wait in the reception area until access is given to perioperative environment [local processes]. This will usually include a SCH staff member escort 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 medical practitioner (surgeon or interventionist) or by a designated SCH team member.

Protocol for entering the perioperative area

- The representative must change into full theatre attire: all jewelry 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, ie 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 [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 [facility] [SafeHub Event Form](#) will be completed and will be followed up by the HS Advisor

Representatives 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 [privacy act policy](#)
- Use the staff tea room to promote products or undertake other business unless formally invited to do so by theatre manager or
- Undertake other non SCH business

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

Protocol for exiting the 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 investigations

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 and if indicated inform the SCH national procurement team.

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.](#)



Attachment Medical Company Representative Access To Operating Theatre Declaration Form 10 08 2021 (1)

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