

SAMED Position on Company Representatives in Theatre

November 2017

SAMED is aware that medical device company representatives are being asked by healthcare professionals to enter the sterile field and assist with surgical procedures. Naturally this is a practice that may not be allowed to continue.

The [Medical Device Code of Ethical Marketing and Business Practice](#) strictly forbids this, as does the [CRICE \(Company representative in the Clinical Environment\) course](#). The primary reasons being that of not undermining patient safety, confidentiality and to mitigate against potential liability.

SAMED developed the CRICE course a number of years ago specifically to address this matter.

In accordance with the Code and CRICE, we draw your attention to the following in terms of the Company Representatives role.

The Company Representative:

- Must ensure that a discussion has taken place with the surgeon confirming that the surgeon has received patient consent for the company representative to be present
- May only enter an operating room/clinical environment in accordance with permission from appropriate members of the medical staff of the facility. Company representatives are expected to wear appropriate attire, as provided by/or approved by the facility. It remains the responsibility of the facility to provide appropriate clothing. However if this is not possible then the facility must provide authorization for the company representative to provide their own appropriate attire
- Should be prepared to advise on technical questions related to the assembly and operational performance of company products consistent with the labelling and instructions for use
- May not provide clinical diagnostic advice, surgical advice or recommend treatment, even as the result of a direct request from the surgeon, operating room staff, or any other healthcare professional
- When acting on behalf of one's company, company products may not be used and/or applied directly to a patient by the company representative even if they hold appropriate certification/licenses, as they are acting as a company representative and not a healthcare professional
- May not deliver patient care or perform medical services of any type, even if the company representative possesses an appropriate medical license/certification, as they are acting as a company representative and not a healthcare professional
- May not have any physical contact with the patient or any part of the patient during surgery or a clinical event and may not pass instruments directly to the surgeon / physician

The sole purpose of the company representative in the operating room/clinical environment is to provide expertise relating to the preparation, assembly and use of instrumentation, devices, or product information which must be facilitated by communicating with the appropriate healthcare professional performing the procedure.

It has been argued that facilities are understaffed and that this is one of the reasons why healthcare professionals are requesting company representatives to assist during a procedure. SAMED urges hospitals and healthcare professionals to review their staffing requirements and scheduling of cases to ensure that this situation no longer continues. This is a serious concern and we ask all SAMED members, hospitals and healthcare professionals to ensure that proper processes and systems are in place to prevent company representatives from entering the sterile field going forward.

For clarity when we refer to the sterile field we are referring to that area directly adjacent to the patient, where the healthcare professionals work. We are not referring to the periphery where the company representative gloved and gowned works to manage their products. Medical device companies must be held accountable for providing adequate training to the appropriate healthcare professional and theatre support staff.

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