

Position paper on the Access to the Operating Room by Company Representatives

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Position paper on the Access to the Operating Room by Company Representatives

Purpose

Medical technology companies are frequently requested to have a representative of the company (“**Company Representative**”) present during surgical or other medical procedures in order to train and educate, as well as support, medical personnel on the proper use of the companies’ technologies during such procedures.

In this Position Paper, MedTech Europe member companies set out the issues related to such Company Representative’s presence during a procedure—be it in the operating room as well as in other settings, such as cardiac catheterization laboratories or special procedure rooms (collectively, “**OR**”) – and express their common position and recommendations as to the legitimate purposes for such presence, the actions to be performed and safeguards to be applied.

This position and its recommendations are not intended to supplant or supersede national laws or regulations or professional codes, including company codes, that may impose more stringent requirements concerning a Company Representative’s presence in the OR.

For avoidance of doubt, this Position Paper is also not intended to address the legitimate cases in which Company Representatives are fully trained and licensed Healthcare Professionals (“HCPs”), whose services have been secured through a formal agreement between the institution and the Company, in compliance with all applicable laws, regulations and industry codes.

A sample company policy is added to this Position Paper in the Appendix, which serves as guidance only to individual member companies.

Background

Representatives of medical technology companies have traditionally been present as needed during peri-operative interventions, as well as pre- and post-operatively to observe, train and support medical personnel using their company’s products. Company Representatives may also enter the OR as part of the development of new products and procedures. Through their presence, companies and their representatives aim to collaborate with HCPs in delivering optimal patient care through safe and effective use of medical devices. MedTech Europe supports the approach that Company Representatives are present in the OR during medical procedures when (1) their presence contributes to the safe and effective use of the technologies; and (2) their actions are in line with the recommendations given below.

Interested Parties and Issues

Persons and entities affected by the presence or absence of Company Representatives in the OR range from the HCPs conducting the medical procedure (surgeons, nurses) and the patient, to the medical institution at which the procedure is performed and the Company Representative him- or herself. When Company Representatives are present in the OR, the institution, HCPs and the Company Representative need to consider the concepts of liability (either to the patient or amongst the various parties involved), and considerations relating to the protection of personal data and confidentiality. In approaching the issues relating to the presence of Company Representatives in the OR, *safety* is at the centre of all considerations: the safety of the patient (both in terms of medical devices being appropriately applied during the procedure and the safety of hospital staff), and finally the safety of the Company Representative him-, or herself.

Related considerations are therefore the *quality of the care* applied, meaning, that the Company Representative's presence should contribute not only to the safe but also the effective use of the medical device.

Recommendations for the Company Representative's Presence in the Operating Room

- 1. Compliance with Applicable Laws.** Companies should regularly check with regulatory authorities to be aware of regulatory requirements governing the presence of Company Representatives in the OR. MedTech Europe will assist such efforts by establishing a European database with information on such requirements.
- 2. Interaction with the Institution.** MedTech Europe recommends that a Company in all cases of OR presence by a Company Representative ensures that the institution does not object to such presence. To the extent an institution has established a protocol for visitors' (including Company Representatives') presence in the OR, this should be strictly adhered to. This includes any training and qualification requirements that may have been established. MedTech Europe recommends that these be in line with the limited role played by the Company Representative in the OR; not be unduly burdensome and take into consideration training and certifications the Company Representative may have obtained through his or her employer, or otherwise. In order to maintain high quality of training and justified reliance on company programs, member companies shall ensure that any company certification granted to a Company Representative be subject to renewal on a regular basis or as important changes occur in OR procedures.
- 3. Data Protection and Privacy.** The Company Representative being present in the OR may be incidentally exposed to personal data of patient(s) undertaking an OR procedure, for the sole purpose of facilitating the safe and effective use of its Company's medical technologies upon the Institution's instructions (the 'Purpose').

The Institution is responsible, as data controller for the Purpose, for any transparency obligations towards the patients, and where required, obtaining, a freely given, informed and explicit consent from the patient, as defined under applicable data protection laws, ahead of the procedure.

The Company Representative will treat all patient data he might be exposed to as strictly confidential, and will not disclose or make the data available to any third party (with the exception of the Company if required for the Purpose) or use it for any other purpose than the Purpose.

4. Further Conditions on OR Presence. MedTech Europe supports the application of “generic” requirements for Company Representatives’ presence in the OR, such as health requirements that would be applied to any other OR visitor, or behavioural restrictions, such as on the use of telephones, refraining from undertaking sales pitches during a procedure, rules regarding the taking of pictures and potential sharing on social media, submitting to orientation requirements or generally submitting to the orders of medical staff.

5. The Role of the Company Representative in the OR. The Company Representative’s role is to facilitate the safe and effective use of his or her company’s medical technologies in the OR. A Company Representative acts as an advisor to the medical team and his or her role is limited to verbal technical and imaging assistance related to the company’s product and based solely on approved product functions and aspects of such product. He or she must not engage in the practice of surgery, nursing or medical diagnostic or decision-making.

The presence in the OR of the Company Representative must not function as a substitute for preoperative training of the surgical team. Therefore, his or her function is restricted to the provision of technical advice and recommendations, even if he or she is requested to do otherwise. Even if the Company Representative has the requisite educational background, training and/or licensing, his or her role is not to replace assignments that are reserved to HCPs, nor to provide medical advice. The Company Representative’s activities must under no circumstances substitute for tasks that are reserved to HCPs.

In the OR, the Company Representative should generally be equipped with the adequate theatre uniform and instructed on how it should be worn. He or she should be introduced to the patient, when feasible, and to the surgical team, and his or her limited role explained. Ideally, the Company Representative should be clearly *visually* identified as a visiting non-HCP whenever possible.

The Company Representative shall be required to comply with the Hospital specific protocols and to make use of safety devices provided by the hospital, and will inform his/her Company about any deficiencies and/or absence of such devices and make use of the ones given to him/her by the Company. The Company shall, if necessary, provide its employees with all individual protection devices that are required for the safe performance of their duties.

Any post-operative reports or presentations prepared by the Company Representative should be compliant with local privacy rules.

Recommendations for Member Companies

MedTech Europe recommends that companies issue company policies on the presence of their Company Representatives in the OR, geared to and in compliance with applicable law and the rules or recommendations of national or regional regulatory authorities. In addition, companies should support their Company Representatives in meeting the requirements imposed on them by institutions.

Appendix

Sample Company Policy: Policy for Employees in EMEA Operating Rooms

[This Sample Policy is not binding. Form of implementation is subject to company discretion]

Purpose and Goals

Given the actual service philosophy and the strategic task of the company, namely, to be as close as possible to our clients, it is inevitable that company employees may enter operating rooms, cardiac catheterization laboratories or special procedure rooms (collectively “OR”) for business reasons during business time. This policy (“**Policy**”) governs the presence of employees inside the OR located within the EMEA region.

In order to protect as much as possible the patients, our collaborators and our employees as well as to limit the company’s risks wherever possible, this Policy must be strictly followed by every employee who enters an EMEA OR in connection with the company’s business.

Scope

Applicable to all employees, without exception unless otherwise excepted herein, who enters an OR as a representative of the company.

Policy

Before entering an OR as a representative of the company, each employee must undertake special training, which will train her/him about procedures and circumstances occurring inside OR. Furthermore, she/he will be introduced and trained concerning this Policy.

ID Badge

If possible, a duly issued certificate in an ID format shall be worn as a badge by company representative entering the OR.

Certification

The OR access certification ensures that employees holding such a certification are acquainted with practical situations that might occur during a visit to an OR. Applications for an OR access certification are sent to the Director of Training who assesses the needed standard according to the applicable country legislation. A record of training and the current status of the OR access certification will be kept in the personnel dossier of each employee receiving the certification. The OR access certification is valid for 3 years or as defined by applicable law, whichever is shorter.

The OR access certification shall be issued only if at least one of the following conditions has been met:

- Employee has undergone the official company OR training;
- Employee has attended an official external OR training given by a duly certified institution;
- Employee has completed a degree as a Healthcare Professional, such as a surgeon, OR nurse, OR technician, and the like. In such cases, the Country Manager responsible for such employee must issue a 1) duly signed confirmation of such educational degree and 2) confirms that under local law there is no special requirement to be fulfilled

- Employee who has been regularly entering OR for the last three years with no less than 5 times a month frequency. Provided, however, that the Country manager responsible for such employee issues a duly signed confirmation attesting to such fact.

Invitation

Before accessing the OR, Employees shall make sure to comply with all the applicable hospital policies and/or obtain an authorisation by the person in-charge of surgery.

Hospital policies & internal rules

Employees planning to enter an OR shall inform themselves actively and in advance including regarding internal guidelines with regards to clothes, shoes, hygiene, dosimeter, sterility, contagious diseases, hierarchies, confidentiality and the protection of personal data. These and other hospital internal procedures must be followed strictly. Employees should also seek confirmation from the person in-charge of the surgery that the patient has been notified of and consented to the fact that a company representative will be present in the OR.

Should an incident happen (e.g., contact with the patient's biological agents), the employee i) must report to the HCP and medical staff; ii) must get treated at the Hospital emergency and follow Hospital protocols; iii) must report to the Company's relevant department.

Limited role

Employees must not engage in the practice of surgery, nursing or medical diagnostic or decision-making.

Knowledge and information gathered

Each and every incidence, knowledge and information gathered in the OR shall be considered as confidential information towards any third party with the exception of the company. Company confirms that such confidential information shall be treated as confidential within the company and not given out to any third party, with the exception of official requests from competent authorities and/or judicial investigation.

The employee shall strictly observe confidentiality obligations undertaken and preserve the patient's privacy. Any post-operative reports prepared by the employee should be compliant with applicable data protection laws. Any report prepared by the employee shall be free from any information that could directly or indirectly identify, the patients, as defined under applicable data protection laws (i.e., "male, 40 years old" is acceptable; including the hospital number is not), unless the Company has a lawful basis (e.g. a legal obligation or legal ground) to record and process the personal data.

State of health

Before entering an OR, every employee must be reasonably sure that they are not carrying any contagious diseases that may be transmitted through their presence in the OR and, more generally, must enquire about any internal hospital procedures with respect to contagious disease. Where local laws require certain health follow-ups to be conducted, the employee and the company are expected to comply with such requirements. Failure to comply with such local requirements may lead to specific sanctions and escalation steps in accordance with each jurisdiction.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.