



***Access to the Operating Room For  
Medical Device Company Representatives***

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

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## Purpose

Medical Device 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.<sup>1</sup> In this Position Paper, Eucomed 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.

The positions expressed and recommendations made here 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.

A sample company policy is added to this Position Paper in [Appendix I](#) which policy serves as guidance only to individual member companies.

## Background

Representatives of medical device 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

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<sup>1</sup> It should be noted that in some cases Company Representatives may be fully trained and licensed Healthcare Professionals, whose services have been secured through a formal, transparent and compliant agreement between the institution in connection with a procedure. Such cases are not covered by this Position Paper or the definition of Company Representative as used herein.

representatives aim to collaborate with Healthcare Professionals (“HCPs”) in delivering optimal patient care through safe and effective use of medical devices. Eucomed supports the approach that Company Representatives are present in the OR during medical procedures for as long as (1) their presence is needed for 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. While the issues for the institution, HCPs and the Company Representative generally emanate from the concept of liability (either to the patient or amongst the various parties involved), for the patient, in addition, issues relating to privacy may prevail.

In approaching the issues relating to the presence of Company Representatives in the OR, *safety* is at the center of all considerations: the safety of the patient (both in terms of medical devices being appropriately chosen and applied during the procedure as well as preventing interference by the Company Representative’s presence), the safety of hospital staff (again by preventing undue interference by the company representative), 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 OR

- 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. Eucomed will assist such efforts by establishing a European database with information on such requirements.
- 2. Interaction with the Institution.** Eucomed recommends that a Company in all cases of OR presence by a Company Representative ensures that the institution does not object to such presence. It may be advisable to keep written records of such non-objections, such as in the form of an actual written consent or a written record/summary of conversations regarding the issue. 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.

Eucomed 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 at least every three years or as important changes occur in OR procedures.

- 3. Patient's Notification.** The Institution should in each case provide notification to the patient ahead of the procedure that visitors may be present in the OR and, upon request, document and/or certify this to the Company Representative.
- 4. Further Conditions on OR Presence.** Eucomed 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 behavioral restrictions, such as on the use of telephones, refraining from undertaking sales pitches during a procedure, rules regarding the taking of pictures, 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 ensure and facilitate the safe and effective use of his or her company's medical technologies in the OR. A Company Representative is an advisor to the medical team and his or her role is limited to verbal technical or laser pointing 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 decision-making and must not touch the patient for purposes of medical care nor touch instruments or the patient for purposes of applying medical care. He or she may perform calibration and/or synchronization to adjust or program devices (*e.g.*, pacemakers, laser technicians), but only under the supervision of the HCP.

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.

If a true emergency occurs during the procedure, as determined solely by the HCP in charge, the Company Representative may render support to the best of his or her ability and in strict accordance with the HCP's instructions. In such situations, companies should consider

appropriate indemnification for Company Representatives for liabilities arising out of such situations.

In the OR, the Company Representative should generally be equipped with the adequate theater 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, for example by a particular badge or differently colored gown.

Any post-operative reports prepared by the Company Representative should strictly observe confidentiality obligations undertaken and preserve the patient's privacy. The Company Representative should always refer to the patient with non-identifiable terms (*i.e.*, "male, 40 years old").

## Recommendations for Member Companies.

Eucomed 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.

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# Appendix I

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## 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 operation theaters for business reasons during business time. This policy ("**Policy**") governs the presence of employees inside the operation theaters 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 operation theater in connection with the company's business.

### **Scope**

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

### **Policy**

Before entering an operation theater as a representative of the company, each employee must undertake special training, which will train her/him about procedures and circumstances occurring inside operation theaters. 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 each employee and company representative entering the operation theater.

As an exception and only in cases of urgent necessity, employees who were unable to have undergone the special training may enter the operation theater if her/his assistance is strictly passive, remains outside the sterile zone and she/he is accompanied by a company colleague who is duly certified under the special training herself/himself.

## 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

Employees shall enter an OR only upon invitation of the responsible person at the facility and with the consent of the person in-charge of surgery.

## Hospital policies & internal rules

Employees planning to enter an operation theater shall inform themselves actively and in advance including regarding internal guidelines with regards to clothes, shoes, hygiene, dosimeter, sterility, contagious diseases and hierarchies. These and other hospital internal procedures must be followed strictly. Employees must also remind the person in-charge of surgery regarding notification of the patient that a visitor will be present in the OR.

## No active role

Under no circumstances are employees allowed to play an active role in the OR. It is prohibited to touch the patient or anything in direct contact with the patient. The operating surgeon and the operation team have to be informed by the employee about this restriction in advance.

## Emergencies

In case the responsible surgeon declares a situation as an emergency, employees at the request of the authority in charge, may render support to their best knowledge in accordance to the request and provided the employee does not carry contagious diseases that could be transmitted through the type



of support requested. In such emergencies cases, the company will support, protect and indemnify its employees for every liability arising out of such a situation.

## **Knowledge and information gathered**

Each and every incidence, knowledge and information gathered in the operation theater 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.

## **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.