



Standpunt NOV over aanwezigheid productspecialist firma medische hulpmiddelen in de OK

De NOV volgt de beleidslijn van de Eucomed (inmiddels opgegaan in [MedTech Europe](#)) en adviseert de ziekenhuizen/vakgroepen orthopedie deze ook te volgen (zie samenvatting in de bijlage onder).

Voor de NOV gelden de volgende uitgangspunten:

1. De ondersteuning van een functionaris vanuit een firma voor medische hulpmiddelen kan uitsluitend bestaan uit technische-/productassistentie.
2. Doel is te zorgen voor en vergemakkelijken van veilig en effectief gebruik van de medische technologieën van zijn of haar bedrijf op de OK; als technisch adviseur van het medisch team.
3. Het betreft een toevoeging en geen vervanging van bestaande capaciteit en/of expertise.
4. De industrie levert deze extra productkennis door - waar nodig - een gespecialiseerde functionaris met een specifieke medisch-technische competentie (bijv. productkennis in combinatie met verpleegkundige scholing) in te zetten voor advies tijdens de operatie.
5. Het betreft uitsluitend nieuwe/innovatieve technieken en/of complexe, zeldzame ingrepen (bijvoorbeeld bij revisies) en in het kader van training en opleiding waarbij technische ondersteuning gewenst is.
6. De betrokkenheid van die functionaris is product-gerelateerd en niet patiënt-gerelateerd.
7. De ondersteuning geldt voor de medisch specialist maar ook voor het overig OK personeel.
8. Deze functionaris komt bij voorkeur niet in het steriele veld.

Bijlage: Samenvatting

[Position paper on the Access to the Operating Room by Company Representatives \(2011\)](#)

Introduction

Representatives of medical device companies have traditionally been present as needed during perioperative 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 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.

Recommendations

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 nonHCP 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").