

Sales Representatives in the Operating Room

ABSTRACT: Medical device sales representatives offer a valuable service to health care providers. The information and expertise they convey helps providers stay abreast of the latest developments in medical technology. For this reason, sales representatives are frequently allowed in operating rooms (or the “OR”) as consultants during procedures that involve the medical devices they sell. Too frequently, however, sales representatives either provide the wrong kind of information during procedures or participate directly in procedures and the medical device companies they represent are implicated in products liability lawsuits filed by allegedly injured patients. In order to minimize the potential liability associated with having sales representatives in the OR, medical device companies need to be very clear regarding what sales representatives are and are not permitted to do and say in the OR. To that end, companies should have a clear and consistent written policy that outlines the expectations for its sales representatives. This checklist provides a number of things to consider when drafting such a policy.

- **Do you ensure that hospitals include language in patient consent forms regarding sales representatives’ activities?** A hospital is required to obtain patient consent in order to allow a sales representative to be present during a surgery or procedure in the OR. Device companies should work with hospitals to ensure that language regarding the presence of sales representatives in the OR is included in all consent forms.
- **Are your sales representatives required to observe or consult from an observation room when possible?** Sales representatives who observe or consult from an observation room decrease the risk of becoming too intimately involved in the procedure. If an observation room does not exist, sales representatives should endeavor to stay out of the sterile field, and if any physical assistance must be provided it should be rudimentary and mundane (such as handing an instrument to a nurse).
- **Do your sales representatives have the means to clearly, verbally and visually identify themselves as sales representatives as opposed to healthcare personnel?** In order to prevent any confusion as to the identity and function of your sales representatives, they should be identified clearly. For example, sales representatives may wear special badges or “scrubs” in colors that are different from those worn by the surgical staff. Some hospitals have their own policies regarding sales representatives’ identification, so be aware of such policies in advance of any visits.
- **Are your sales representatives required to follow the hospital’s instructions on aseptic techniques for washing and attire when they are needed in the OR?** Require strict adherence to hospital protocols and procedures on aseptic techniques for washing and attire.
- **Are your sales representatives required to minimize or eliminate all direct patient contact during the surgery or procedure?** Sales representatives should refrain from touching the patient during a clinical procedure or from touching anything that touches the patient, if possible. Any interactions should be with the physician, not the patient.
- **Are the sales representatives required to refrain from the practice of medicine?** Sales representatives should never do anything that could be construed as the practice of medicine. They should take care not to perform any act of surgery or offer opinions, judgments, or evaluations of any product or the techniques used. Such analysis is reserved for licensed physicians only, and courts may impose liability on a medical device company for the unauthorized practice of medicine should its sales representative perform such an analysis. In all cases, the physician should be directing the procedure and deference should be given to the physician on all accounts. Any advice or consultation in the OR by the sales representative should be limited to matters specifically related to the device.
- **Do your sales representatives offer demonstrations or training programs regarding a new device prior to the actual surgical procedure?** Sales representatives should offer appropriate demonstrations or training opportunities related to new devices prior to the procedure. This provides an opportunity for sales representatives to offer feedback as well as discuss and resolve any foreseeable concerns.

This article is not intended as legal advice and does not constitute legal advice. It does not create an attorney/client relationship and is intended to provide only general, educational, non-specific legal information. It is not intended to cover all the issues related to the topic discussed. The specific facts that apply to various situations may make the outcome different than would be initially anticipated. You should consult with an attorney familiar with the issues and laws of your state and country, if you have any legal questions or concerns.

- **When physicians or technicians ask the sales representatives questions, are their responses limited to precise factual information and do they coincide with the information in the labels and instructions that accompany the product?** Responses to questions about the product by healthcare personnel should be limited to the factual information provided in the labels and instructions that accompany the product. Sales representatives should never promote, suggest, or imply that a physician should act in a way not expressly stated on the device's label.
- **Are there clear instructions regarding what sales reps should do should an off-label use occur?** If an off-label use occurs, sales representatives should generally remove themselves from the operating room with a verbal statement that this use is not approved by the FDA. They should follow this up with a written statement to the physician that the use is not approved the FDA.
- **Is the sales representative required to inform the company of adverse incidents they observe?** Sales representatives should inform their employer of adverse incidents that are observed. This alerts the company to a potential report that may need to be filed with the FDA as well as a claim that may need to be made to the company's products liability insurance carrier.

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