REAL LIFE CLAIMS: MANUFACTURER REPRESENTATIVES IN THE OPERATING ROOM

The Case of the Mismatched Screws

Insurance SERVICES

Introduction to the Case

As the technology for implanted medical devices (such as knee replacements) is continually enhanced, the sales representatives of device manufacturers have come to be seen as an asset to the implanting surgeon—even in the operating room. It makes sense. Often, these reps know more about the specific device than the surgeons themselves. Still, any time someone other than hospital staff attends a surgery—even if it's to the patient's benefit—determining who is liable in the event of a complication becomes a challenge.

Manufacturer representatives in the operating room are, in theory, legally protected due to the passive role they play during surgeries. However, with the costs of healthcare continuing to rise, and social inflation playing a role in healthcare-related litigation, medical manufacturer representatives are at risk of greater liability exposure as attorneys and patients increasingly attempt to navigate around these protections.

In the story below—based on an actual claim—you'll see through the eyes of a medical manufacturer representative as they assist a surgeon performing a knee replacement. We'll then provide some best practices to help protect all parties involved.

The Case of the Mismatched Screws

You get to the hospital early, ensuring you've double and triple checked that all the appropriate components are organized and ready for the surgeon to perform the knee replacement on Ms. Collins. You talk to the nurse about the implant and components on your cart to make it easy for the surgeon to follow the process according to the manufacturer's literature and your training.

"Better get scrubbed in. You're doing this today," the surgeon says as he enters the operating room. You know he's joking, but your eyes go a little wide at the idea of it. "Oh, I'm only joking," he says, "but you'll be around in case we need anything, right?"

"Of course," you say, "just like last time." You've worked with this surgeon several times before, and he always lets you know about the great progress the patients are making after their surgeries.

The process begins smoothly. As the nurse needs help locating the correct components, you hand her the appropriate screws from your cart. It's a well-choreographed procedure, until the surgeon pauses. "I don't think this one's going to work," he says, looking at one of the screws. "Hand me a six millimeter."

You don't think much of it, and the surgeon completes the procedure without issue. In fact, over the next several weeks, you help that same surgical team complete a handful of similar knee replacements.

It's then that you learn Ms. Collins will need to have another procedure done—the screws used for the knee replacement weren't the appropriate size. Pain following this type of operation is normal, but Ms. Collins experienced pain long past what is typical. When another physician looked at it, it became clear that the components were shifting.

Now, you're involved in a claim, and it's not entirely clear how much responsibility you had in the moment. After all, it's the surgeon's call on which components to use, right?

MITIGATING THE RISK

In most cases, the surgeon would be considered the "captain of the ship" in an operating room, meaning the manufacturer rep is merely a consultant. However, this doesn't necessarily apply across the board. It could depend on any precedence set by state or local rulings.

In addition, as medical device technology continues to evolve, drawing the line between technical instruction and medical decisions is also becoming increasingly blurred and can make liability even more complicated.

Fortunately, no matter what situation you find yourself in, there are steps you can take today to help minimize some of the risk.

Document Training

One of the first things to ensure is that, as a medical manufacturer rep, you receive the appropriate training for the devices you provide—especially if you're going to be present in the operating room. And, you must be able to prove it. Keep documentation for all trainings that have been completed.

Outline Expectations

Medical manufacturer reps can be an invaluable resource in the operating room, but both the rep and the surgical team should be clear on what the rep's involvement looks like. It should be made clear that any advice a rep gives is based on the manufacturer's approved usage of a device. As a general rule, manufacturer representatives should be available to offer informed and accurate instruction to surgeons in the operating room, but should be careful not to fall into the trap of making any pivotal medical decisions. These expectations should be as detailed as possible to ensure there's no question as to the separation of duties.

Get Redundant Confirmation

While in the operating room, reps should get confirmation from all parties who handle the equipment. For example, if the surgeon asks for a component, the rep can provide the surgical team with the correct component, but the surgical team should announce which component they are then handing to the surgeon, and the surgeon should announce which component they receive. It's a small thing that can save a lot of hassle down the road. Be sure to communicate these expectations prior to entering the operating room.

Double Check Components

It's essential to make sure that all components, including screws, are compatible with the original implant. Ask yourself, are these components manufactured for use with this implant by the manufacturer? It's a simple step that can make a big difference in managing your risk and liability exposure in the operating room.

Keep Records of Involvement in Operations

Reps should keep detailed records of what they were asked to do and how they responded in the operating room. Be sure these records adhere to the hospital's policy for privacy and HIPAA guidelines, and—if you must document the happenings after the procedure—be sure to document them immediately afterward. The longer you wait, the less reliable your memory will be.

Make Sure You're Covered

While the hospital or surgery center typically dictates what coverage and limits manufacturer representatives are required to have, it's always a good idea to review your policy with your insurance provider to ensure there are no gaps in your coverage. Typically, we do not recommend limits lower than $1 million/$3 million, including Incidental Medical Professional coverage.

For more information about how you can minimize your risk, and ensure you have adequate coverage, reach out to your VGM Insurance Services Account Manager, or contact us today at **info@vgminsurance.com** or **800-362-3363.**

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