

## Letter to AORN, 10 May 06

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Dear Ms. Dunbar and Ms. Girard,

I was recently at the AORN Convention in Washington, D.C., representing my company, OP-marks, Inc., which sells products specifically designed for surgical site marking. In talking with different nurses from across the country, I was amazed at how much confusion and misinformation still surrounds the subject of site marking. I would like to offer a number of comments, if you are interested.

1) What marking system to use. Roughly 4 out of 10 of the nurses I talked to said their hospitals were using the "YES" system while another 4 out of 10 were using the initialing system. The remaining 2 out of 10 were still using markings such as "X", arrows, "correct site", etc., in spite of extensive efforts to get everyone on at least the same two pages.

The upside of this is that we have honed down an array of different site marking styles to the point that we now have two main categories. The downside is that we now have two main categories. And neither is proving to be entirely adequate when used as a stand-alone system of marking.

Among those nurses whose hospitals were using the "YES" system, there was a discernible sense of annoyance with the fact that they were all too often being "stuck" with the job of marking patients for surgery, and that the operating surgeons were not always fully engaged in the process of site marking (as they must be). Conversely, among those nurses whose hospitals were using the initialing system, there was an almost universal shrug and reply to the effect that site marking was "the surgeon's problem". Obviously, these nurses were not being fully engaged in the marking process either (as they must be). When used alone, each of these systems therefore has a tendency to disengaging a key element of the surgical team from the site marking process (see attached Figure 1).

I realize that no one wants to hear this (because it involves yet another change, and yet another thing to do), but the only marking system that truly makes sense, and that truly engages every member of the operating team, is a hybrid of the above two systems: the co-signed Universal "YES". With such a system, any patient, in any part of the country, would be marked for surgery in the same universal way, regardless of which hospital they walked into. Some might argue that it would be an added complication. In reality, it would be an immense simplification.

(I've heard the arguments that different institutions face different site marking "realities" and must be given leeway in marking their patients for surgery (translation: we don't want to change what we're already doing; it seems to be working OK for us"). This is nonsense. There is absolutely no reason why everyone in the country cannot be on the same page when it comes to marking patients for surgery.)

(Like it or not, the pre-operative nurse assumes a certain degree of responsibility for site marking, whether he or she actually makes any mark at all. Would it not be better to actively engage that nurse in the marking process rather than having them falsely believe that it was "somebody else's problem"? Likewise, the operating surgeon is absolutely obligated to be involved in the marking of each and every patient they operate on (again, whether they like it or not). The hybrid system, would actively engage both in a way that the current systems usually fail to do.)

(I fully understand that the laws of a number of states preclude the nurses in those states from directly marking patients for surgery. This does not mean that the pre-operative nurse cannot instruct the patient (or the patient's guardian) on marking the "YES" themselves in the appropriate area and in the appropriate manner.)

Wrong site surgery will never be completely eradicated, regardless of how good we are at site marking patients. But until every patient in every hospital of the country is marked in the same exact way (a truly universal protocol, not a "sort of" universal protocol), mistakes will continue to be made that potentially could have been avoided. AORN has finally taken a leadership role in clarifying how we site mark patients for surgery. I implore you to finish the job and get the entire country on the same page.

(This is admittedly a self serving comment, since our company sells a universal "YES" stamp, but I strongly feel that the "YES" should be uniform and professional in appearance, not hand-written. I am a Plastic Surgeon and I know

that if I put a sloppy dressing on after surgery, the patient can and will get the impression that they've had sloppy surgery as well. The same holds true for "YES" markings. Hand written "YES" marks have little or no uniformity and typically look unprofessional in appearance. Even a cleanly stenciled circle encompassing a handwritten "YES" would be a far preferable alternative.)

2) What type of ink to use? I have written to the Joint Commission about this before, and I will bring it up with you again because a lot of institutions are still using permanent markers, ball point pens, and art markers to mark patients for surgery. There is no such thing as an indelible ink that is medico-legally approved for direct use on human skin. Furthermore, even though "non toxic" inks are considered to be safe for incidental skin exposure (they are ASTM D4236 approved for use as art materials, meaning that they have no long-term toxicity effects with repeated exposures), they technically are not approved for intentional use on human skin. And they are certainly not approved for use at or near an open surgical incision. Since indelible inks are capable of inducing significant inflammatory responses upon coming into contact with dermal and subdermal dermal tissues (see attached article by Granick, et. al.), their use could be attributed in a court of law to virtually any wound complication (whether related or not). On the basis of the medico-legal implications alone, it is clearly imprudent to be marking surgical patients with anything other than FDA approved substances (gentian violet, methylene blue, etc.).

(Indelible inks make better marks on skin because they contain solvents that cut through the outer oily layer on the skin, allowing better penetration of the ink into the epidermis. The same effect can be achieved when using "FDA approved" inks (which are water-based) by degreasing the skin first with an alcohol wipe, and then marking.)

(Some day in the not too distant future, a lawyer is going to bring a suit for a run-of-the-mill surgical wound complication, during which time he or she is going to dramatically wave around a Sharpie and say "You mean to tell me that you used this marker on my client's skin in preparation for surgery? Did the Sharpie people say it was OK to do this? Directly on human skin? Next to an open surgical wound?!?" The defendants might as well start writing out a check (not a big one, granted, but a check nonetheless), and the courts might as well get ready for the flood of frivolous law suits that will follow.)

3) Is it smart to reuse marking devices? The "Sterility of Surgical Site Marking" article by Conen, et.al., is often mistakenly used as "proof" that there is no reason to be concerned about re-using markers. It is not. Furthermore, quoting the fact that there is currently no evidence that a used marker leads to any increased incidence in surgical site infection in the patients on which it is subsequently used is taking a very myopic view of the infectious disease aspects of re-using marking devices, to say the least.

Surgical markers most commonly contain gentian violet ink, that in itself also contains alcohol as a drying agent. Both substances are effective antiseptic agents, and it is not surprising that cultures of contaminated tips do not show any growth of bacteria. Additionally, the marked skin is going to be prepped with yet another antiseptic agent prior to surgery. The findings of the Conen article are therefore very unsurprising.

All of this, however, ignores the fact that the marker barrel itself is a very effective vector for the transmission of undesirable pathogens throughout the entire surgical milieu. Pathogens can easily survive for months on inert surfaces. In addition, the smoother the surface (such as the barrel of a marking pen), the more efficiently the pathogen will be transmitted to its next destination. So even though hands are being washed appropriately in between patient contacts, if a contaminated pen is then handled for subsequent use, cross contamination can and will occur. This is not going to contribute directly to immediate surgical site infections (because of the reasons just mentioned). Rather, it will contribute to a more insidious spread of pathogens throughout the entire surgical milieu. We have learned not to "reuse" stethoscopes on multiple patients (without cleaning the head first with an alcohol swab in between uses). If surgeon's and nurses feel compelled to re-use marking pens on multiple patients, at least get them to wipe the pens off with alcohol swabs in between uses.

(From my own experience, I know that it is against human nature to throw away a perfectly good, full sized marking pen after making only one mark with it. Psychologically, it seems too wasteful. So the pen invariably ends up in a pocket or a drawer, only to be used over and over again. That is the very reason that we made all of our marking products single use only with proof-of-use packaging. We also designed them to look disposable so that people would actually dispose of them).

All of this, however, ignores the fact that the marker barrel itself serves as an excellent vector for the transmission of undesirable pathogens throughout the entire surgical milieu. Pathogens can easily survive for months on smooth, inert surfaces (see attached article by Weinstein). Furthermore, the smoother the surface, the higher the transmission rate to a new human contact. While the clinical significance of this cross-contamination is yet to be defined clearly, it is not hard to envision the spread of MRSA and other pathogens throughout the surgical environment if marking devices are being reused, because the marker will re-innoculate even an adequately washed hand. Such a practice would not be expected to result in an increase in the absolute number of surgical site infections. Rather, it would result in a change in the spectrum of pathogens seen in those infections. And if just one surgical site infection is

converted from a run-of-the-mill Staph infection to a MRSA infection due to this practice, it is one case too many.

(MRSA is becoming ubiquitous both inside and outside of the hospital. I tell clinicians that if they truly believe that re-using surgical markers is an acceptable practice given the current environment (and many do), then they should be honest with their patients about it. Look them straight in the eye and tell them: "we're going to mark you with this dirty marker that's been used on other patients; but there's no problem with it, as far as we know." Even without the benefit of medical training, most patients will stare back incredulously and ask "you're going to do what?!?")

From my own experience (I'm a Plastic Surgeon), I know that it is psychologically difficult to throw away a perfectly good, full-sized skin marker after making only one mark with it. It seems too wasteful, so the marker invariably ends up back in a pocket or back in a drawer, where it will be used over and over again. That is why we designed all of our marking products to be single-use only with proof-of-use packaging. We also designed them to look disposable (such as our mini-markers) so people would indeed dispose of them).

Despite everyone's efforts to date, the incidence of wrong site surgery continues to rise. Clearly, we're not doing it right yet. I truly believe that AORN is the only organization in the country that is capable of getting everyone on the same page, and eventually getting it right, once and for all. And I hope that the above comments will be of some help to you in your efforts to do so. I applaud those efforts, and I thank you for your attention to my ramblings.

Yours truly,  
Stephen Lober, M.D.