OP-marks™
SURGICAL SITE MARKERS

YES

January 23, 2009

To whom it may concern,

I would like to humbly offer a suggestion to your Survey Teams and The Joint Commission as an influential healthcare oversight entity. The comprehensive verbiage used to define the National Patient Safety Goals is very informative. I have, however, been unable to locate a Joint Commission statement related to the type of marking implement surgeons should use to pre-operatively identify and mark the correct surgical site.

As an OR Administrator and Consultant, I am frequently asked to clarify and develop policy to work around TJC requirements of a "permanent mark". As you know by now, a "permanent marker" in the operating room is generically and universally thought of as the Sharpie Brand pens traditionally used to label sterilized supply wrappers. While the Sharpie is the absolute gold standard for labeling instrument wrappers and sterilization tape, this indelible pen is classified as an art supply material that carries the ASTM-D4236 designation. This designation, according to ASTM, is standard practice for labeling a product where "knowledge about chronic health hazards is incomplete and warnings cannot cover all uses of any product, it is not possible for precautionary labeling to ensure completely safe use of an art product". This is not a resounding endorsement of a product used in an operating room setting.

When the mandate to mark certain surgical procedure sites was instituted by the JCAHO in 2004, the term "permanent marker" was not explicitly defined, and as a result the term proved ambiguous and ineffective. In response to the new regulations, a large number of facilities naturally and inexpensively converted their instrument-labeling markers to surgical site markers. Furthermore, some manufacturers are labeling their gentian violet skin markers as containing "permanent" ink in an attempt to comply with TJC mandates. This assertion is false and misleading. OP-marks, Inc. has and will continue to file formal complaints against all manufacturers that knowingly market their products with this unsubstantiated claim.

The idea of using a product not intended for human skin is contrary to the working tenets of conscientious operating room professionals. Furthermore, using that same marking pen/implement on the skin of multiple patients sans decontamination is well understood to be more than merely costly in the current environment of insurance reimbursement and mutating skin contaminants.

My firm, OP-Marks, Inc., has been preaching these ideas at AORN and other shows for the past 4+ years. We have never embraced the idea of a "permanent marker" knowing there is no FDA approved product that meets your defined requirement. The current definition used by TJC requiring the mark to be "sufficiently permanent to remain visible after prep and draping" is being wildly misinterpreted across the board. To this day, we continue to battle with Supply Chain personnel and hospital clinicians who are afraid to stray from TJC term "permanent", even though they may be putting themselves and their institutions at medico-legal risk by using non-approved marking devices on human skin in the surgical setting.

Operating Room Directors and Managers across the country need a clear and unambiguous definition of acceptable marking implements and protocol. Please help make the job of caring for patients a bit easier for the operating rooms of the country. A simple definition of acceptable marking implements that are safe, infection neutral, and consistent with TJC safety goals would solve countless issues and dramatically increase compliance with the site marking mandate.

Respectfully,

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