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WHAT TYPE OF SKIN MARKER INK SHOULD BE USED ON PATIENTS? WHAT IS THE DIFFERENCE BETWEEN A SKIN MARKER AND A UTILITY MARKER?

According to the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) *Universal Protocol Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery*, a permanent marker should be used to mark the surgical site. Some surgeons may wish to use standard office supply ballpoint, felt tip, or "Sharpie®"-type pens to mark the surgical site.

The Association of periOperative Registered Nurses (AORN) does not recommend using such standard office-type pens to mark on patients' skin. Such devices may not utilize biocompatible inks. While they typically contain nontoxic inks that are considered to have no long-term toxicity effects with repeated incidental exposures (as per ASTM D4236); they technically are not approved for direct, intentional use on human skin. In particular, they are not classified as "non-tattooing" nor approved for contact with subdermal tissues, as can occur when the mark is made at or near an open surgical incision.

Therefore, a nontoxic, non-tattooing, skin marking medical device should be used on patients' skin. The skin marker should be sufficiently permanent to remain visible after the site is prepped. The skin marker should contain only non-toxic, biocompatible inks, such as gentian violet, methylene blue, and so on.

Skin markers are classified by the FDA as a Class 1 Medical Device and, as such, are not required to go through a 510(K) or premarket approval process. Class 1 Devices, however, must meet ISO10993 requirements and be listed with the US Food and Drug Administration (FDA).

When skin markers are purchased, manufacturers are required to provide the purchaser with information about the product. DeRoyal's Skin Markers are listed with the FDA and use FDA-approved gentian violet ink. DeRoyal's registration and listing can be found on the FDA web site under DeRoyal's name, product code FZZ, or by contacting the local DeRoyal representative.

It also is important to check the label on all markers since DeRoyal sells separate markers for use on skin versus those for utility use (i.e., for use on labels, plastics, metal, glass, or other objects). Health care personnel may mistakenly believe that because a marker is sterile, it is acceptable to use it on skin. This is not always the case. DeRoyal's utility markers are clearly labeled "Not intended for use on skin". Perioperative nurses should supply the surgeon or person marking the site with marking pens indicated for use on patient skin, such as the DeRoyal Skin Markers, which are specifically designed for such use.