

PEOPLE & OPINIONS



Count sheets: Where do we put them?

by Matt Smith, Healthmark Industries

Sterile processing departments commonly have a difficult time creating a process to determine proper placement of instrument count sheets. Although there have been no known cases of adverse patient incidents associated with a count sheet placed inside an instrument set, the issue of count sheet placement remains controversial. Hospitals may or may not be using medical grade paper or inks; many may be using regular printer paper, inks, and ribbons. Manufacturers of these products do not provide toxicity reports since they are not tested for the sterile environment.

In 2008, the AORN did issue recommendations advising against the placement of count sheets inside of instrument sets based on the potential that printer inks used on the count sheets might be toxic and could be transferred onto the instruments posing a threat to patient safety. This raised the issue of potential hazard to a high level of visibility. To date, no other U.S. industry group has issued recommendations for placement of count sheets.

In evaluating the risk, what we do know is that ink is a complex formulation composed of solvents, ligaments, dyes, resins, lubricants, solubilizers, surfactants, particulate matter, fluorescers, and other materials. The components of inks serve many purposes; the ink's carrier, chlorelas, and other additives control flow and thickness of the ink and its appearance when dry¹.

The general opinion that ink is non-toxic even if swallowed is a misconception. Although ink is in large part harmless when not consumed, ink can in fact be a health hazard when ingested. Certain inks, such as those used in printers (and even some found in common pens) can be harmful. Ingestion or inappropriate contact may cause severe headaches, skin irritation, or nervous system damage. These effects can be caused by solvents, or by pigment ingredients such as p-Anisidine, which helps create some inks' color and shine.¹

Three main components of ink pose environmental issues:

- Volatile organic compounds
- Heavy metals
- Non-renewable oils

Some regulatory bodies have set standards for the amount of heavy metals in ink. There is a trend toward using vegetable oils rather than petroleum oils in recent years in response to a demand for better environmental sustainability.

The standard is different, however, when it comes to the medical field, because ink can and does leach at times in sterilization sets.

To date none of the professional associations or regulatory entities has published any written document, standard, or recommendation regarding the product specifications for papers, toners, or inks for production of count sheets. Still the general consensus among healthcare professionals is that chemicals in the paper may pose a theoretical risk of reaction in some sensitized patients.

Since AORN's original stance in 2008, they conducted a detailed research study on the potential cytotoxicity of toner inks, the transference of the ink onto instruments during sterilization and the inherent risk factor. The results of this study appeared in the March *AORN Journal* vol. 89, No.3 page 521.

The summary of the results revealed that placing count sheets and printed labels inside of instrument sets during steam sterilization did not appear to generate any significant cytotoxicity and thus did not pose any immediate threat, however there was no guarantee that the practice was safe. AORN did state in the article that if placing a count sheet in an instrument set, the count sheet should be placed in a medical grade paper bag to prevent transfer of ink to instruments².

According to AORN's 2011 Recommended Practices for Selection and Use of Packaging Systems for Sterilization Recommendation (IV #3) - "Count Sheets should not be placed inside wrapped sets or rigid containers. Although there are no known reports of adverse events related to sterilized count sheets, there is no available research regarding the safety of toners and/or various papers



Ink transfer to instruments and containers. Images provided by Rose Seavey.

subjected to any sterilization method. Chemicals used in the manufacturer of paper and toner ink pose a theoretical risk of reaction in some sensitized individuals³."

Rose Seavey, from Healthcare Consulting believes count sheets have no place inside containers or wrapped items. She stated, "I worked at one hospital for 14 years and another for 13 years and we never put them inside. There is no real reason why they should be sterile. They just should accompany the set for quality control and identification reasons."

Seavey raises another issue to support her argument. "Besides the theoretical risks with chemical ink toner or paper, there are also concerns with shredding of the papers and the ink transfer onto the instruments or containers. Regarding the papers, we now use a lot of recycled papers which tend to shred and our MM departments tend to purchase the less expensive papers. Often times contracts regarding toners change and SPD is not notified."

If ink (or ink transfer) is a health issue, then the type of ink used is important. A standard exists regarding the use of pens used to write on peel pouches. Many SPD workers use felt-tip pens to write on packaging materials⁴. These pens should adhere to the ASTM D4236 standard, which first declares:

"Since 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."

The standard clarifies:

"Conforms to D-4236" on an art material label does NOT mean the product is "non-toxic." Rather, it means:

- The material has been evaluated by a toxicologist for acute and chronic toxicity;
- The label names the ingredients identified as presenting a chronic health hazard, if any.
- A product presenting a chronic health hazard comes with safe use instructions.

LHAMA, the federal Labeling of Hazardous Art Materials Act, governs hazard labeling nationally. Its intent is that art materials should be labeled to warn consumers of potential chronic (long-term or slow-emerging) hazards. LHAMA transformed ASTM D4236 from a voluntary standard into a mandatory rule.



Commercially available products for use with wrapped trays and closed containers were created to be compliant with AORN guidelines.*

LHAMA is enforced by the Consumer Product Safety Commission.

The following is a brief outline of the development of the LHAMA⁵:

On November 18, 1988, President Ronald Reagan signed into law the Labeling of Hazardous Art Materials Act (Public Law 100-695). This law requires that all art materials be reviewed to determine the potential for causing a chronic hazard and that appropriate warning labels be put on those art materials found to pose a chronic hazard. The term "art material" includes "any substance marketed or

represented by the producer or repackaged as suitable for use in any phase of the creation of any work of visual or graphic art of any medium." (15 U.S.C. 1277(b) (1)). The law applies to many children's toy products such as crayons, chalk, paint sets, modeling clay, coloring books, pencils, and any other products used by children to produce a work of visual or graphic art.

The "Labeling of Hazardous Art Materials Act⁵" (LHAMA) amended the Federal Hazardous Substances Act (FHSA) by adding Section 23 and designating the ASTM Standard Practice for Labeling Art Materials for Chronic Health Hazards (ASTM D-4236-88) as a regulation under Section 3(b) of the FHSA. The requirements of the LHAMA became effective on November 18, 1990. These requirements apply to art materials that are intended for use in the household or by children, which are initially introduced into interstate commerce on and after November 18, 1990.

The question CSSD employees should be asking is, "At a minimum, does the ink we are using for printing count sheets conform to D-4236?" If the answer is yes, there should be no issue with the ink, and the ink could be used to write on packaging or on paper for count sheets.

The question remains that if there is a possible risk, should there be changes made to sterilization processes? Nancy Chobin, RN, CBSPD, Sterile Processing University said, "Changing the current process would probably put the patient at more risk of danger. There is no evidence that the ink or paper

causes any injury to the patient. If it were a danger, I believe it would have already caused significant problems and we would know it to be a danger."

Chuck Hughes, General Manager, SPS-medical Supply Corp has done toxicity tests on paper and toner and states: "SPSmedical has provided a number of safety reports regarding cytotoxicity testing of both paper and toner ink provided to us by clients, after steam sterilizing their count sheets at our facility per their packaging and worst case sterilizing parameters. While we have no way of knowing how many variations of count sheets are in use or what other validation laboratories findings have been, we are pleased to report that all test samples we have tested year to date have proven safe for use under the test conditions they were exposed to."

This doesn't solve the problem of placement of count sheets in instrument sets, however. Hughes also mentions that there are concerns having seen some healthcare facilities use a large quantity of count sheets folded numerous times before placement in the instrument trays. "There is a concern that the extra barrier could trap air during sterilization," said Hughes.

It makes sense to avoid or at least minimize any physical contact between the count sheets and surgical instruments. It is the responsibility of each hospital to establish practical policies and procedures to address this issue while meeting their individual and unique needs. Many hospitals are placing the count sheets on the outside of containers and wrapped sets, which eliminates any such concerns. If count sheets must be placed inside, certain measures can be taken to minimize the direct contact of the count sheet with instruments and the likelihood of leaching of chemicals and inks. For example, count sheets can be folded in half or in thirds with the printed side in, and placed in a medical-grade paper bag. When using a sterilization container system the folded count sheet could be placed on the internal side between the container wall and the instrument basket. Alternatively, the folded sheets can be taped onto the outside of the rigid container handle or to the top of the wrapped tray.

Commercially available count sheet holders are very effective because the paper packaging is manufactured from cellulose material, which allows penetration of the sterilant.

In the end, each institution must determine for itself the best method for managing count sheets. Hopefully this article has helped to frame the complex issue for further consideration. **HPN**

Visit www.hpnonline.com/inside/2012-04/1204-PnP.html for references.

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If placing count sheets inside of an instrument set, the AORN recommends use of Medical Grade Paper Bags. An independent study was conducted to determine the suitability of placing count sheets in these bags. Following the same protocol as the AORN study, including the same ink, paper and printer, the study found that no ink transfer to instruments occurred, and the test for cytotoxicity was negative.*

*<http://www.healthmark.info/InstrumentCare/Paper-Products/Cytotoxicity.pdf>