



*Association of periOperative Registered Nurses*

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Dockets Management (HFA – 305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm 1061  
Rockville, MD 20852

To Whom It May Concern:

AORN is submitting comments on the propose rule for: Medical Devices; Needle-Bearing Devices 21 CFT Parts 880, Docket No 01P-0120, RIN 0910-ZA20. AORN is a voluntary organization of professional registered nurses concerned with the care of patients undergoing surgical or other invasive procedures. AORN represents more than 40,000 registered nurses who facilitate the management, teaching, and practice of perioperative nursing. AORN is submitting comments on the proposed rule regarding the banning of IV catheter, Blood collection device and blood collection needle sets as well as the proposed performance standard. While AORN fully supports safe practices that prevent percutaneous injuries to all health care personnel, careful consideration is needed regarding a ban of certain sharps devices for the following reasons:

1. Currently there are not enough needleless systems or safety devices available in the market to meet the demand. Due to the increased demand as hospitals convert to sharps safety devices the vendors are running out of the new safety products creating backorder problems.
2. Some of the engineered devices are not safe, practical, or economical for use in the operating room. Disposable retracting scalpels, for example, break easily when used on fibrous tissue encountered in orthopedic surgery. This actually increases the risk of injury to the surgical team as well as the patient. Often surgeons use the blunt end of the scalpel for blunt dissection and the plastic retractable scalpels do not work for this type of dissection. Some of the retracting scalpels don't stay sharp as long as traditional knife blades and long cases require frequent changes of knife blades. The cost of using the retracting knife blades accompanied with the inadequate performance and perceived increase risk of injury has resulted in poor acceptance of this product. While this particular item is not listed in the petition it is an example of the current state of technology. While this presumably will continue to improve it would be deleterious to a surgical procedure to ban any products until there are replacements that are accepted by the clinicians.
3. The new safety devices and needleless systems are not always compatible with current products used in the operating room.
4. There are times when a needleless system or safety devices are not appropriate for the given clinical situation. For example, one of the items mentioned in the petition, IV catheters are routinely used in the operating room. It is often very difficult to start an IV on critically ill surgical or trauma patients due to their serious condition. There is no time more important for the clinician to have immediate access to effective and efficient technology for starting the IV than when a patient is in critical condition and seconds count. It would be unethical to have a ban on products that may save a patient's life. In fact the Occupational Safety and Health Administration standards require in its bloodborne pathogen standard that alternative "safety" devices be used when appropriate. There needs to be some clinical discretion based on the situation at hand and patient's need regarding the device used for a particular procedure.

AORN supports the use of safety devices already on the market to reduce percutaneous injury and promotes the development of new safety devices. To ban certain devices would not be in the best interest of either the patient or the health care worker. Until technology is compatible and the supply is reliable health care professionals and organizations should continue to put pressure on manufacturer's to develop safe and compatible systems.

Respectfully submitted by,

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President, AORN

and

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