



September 18, 2002

Dockets Managements Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically to www.fda.gov/dockets/ecomments

Re: Comments 21CFR §880, Medical Devices; Needle-Bearing Devices; Request for Comments and Information, (Docket No. 01P-020)

Dear Sir and Madam,

Medisystems Corporation is a leading U.S. supplier of Arterial Venous Fistula Needles for hemodialysis therapy and Pheresis Needles for plasma pheresis procedures. Medisystems produces a complete line of guarded designs for these blood access procedures. Over 50 million guarded needles per year is our current sales, so we have some experience in the area on which the FDA is seeking comment.

Hemodialysis, with a higher patient incidence of Hepatitis C and higher patient incidence growth of HIV, is a particularly high risk healthcare setting compared to most other medical treatment populations. Medisystems shares the FDA's concern for protection of healthcare workers from accidental needlesticks and other percutaneous injuries. Therefore, Medisystems is pleased to offer it's comments on the proposed document.

The HRG/SEIU petition requests that the FDA ban needle bearing devices that do not meet all of the criteria listed below. The criteria, with Medisystems' responses, are listed below.

- 1) HRG/SEIU Criterion- "It provides a barrier between the hands and needles after use."
Medisystems Comments- Upon removal from a hemodialysis patient, the sharp, contaminated needle tip comes dangerously close to the health care worker's ("HCW") fingers that must be used for hemostasis pressure, whether a safety guard is employed or not (see #2). For effective injury prevention in hemodialysis, a protective barrier must be placed not only between the hands and the needles *after use*, but more importantly between the fingers and the needle tip *before and during* activation of the guard. The protective barrier should also permit visualization of the needle during removal, so that accurate hemostasis pressure can be applied (Figure 1). Statistics show that the majority of percutaneous injuries are related to needle sharps removal and disposal processes¹. It is our experience that a protective barrier between the fingers and the needle tip before and during needle removal, dramatically reduces needlestick injuries².



Figure 1. Example of a protective barrier between the fingers used for hemostasis and the needle tip; safety guard is clear allowing visualization of the needle tip upon removal.



- 2) HRG/SEIU Criterion- "It allows or requires the worker's hands to remain behind the needle at all times."
Medisystems Comments- While this requirement may be appropriate for hypodermic type needles typically used for intra-muscular or venous injections, in hemodialysis this requirement would result in a high risk patient blood loss and HCW and patient blood exposure. The following factors, unique to hemodialysis patients, require the HCW's hands be in front of the needle in preparation to immediately apply hemostasis pressure: 1) hemodialysis patients have a surgically created vascular access that joins a major high flow artery to a vein. This access has blood flows up to 2,000 ml/min and pressures up to 100mmHg (or 10Xs more pressure and greater flow than a typical vein); 2) hemodialysis patients are highly anti-coagulated which results in prolonged post-treatment bleeding; and 3) hemodialysis vascular access is achieved via two large-gauge hollow-bore AV fistula needles (14-16ga), 3 times per week. Whether a needle guard is used or not, hemodialysis workers must place their fingers on the cannulation site, immediately in front of the needle tip—before the needle is removed. Once the needle is removed, hemostasis pressure is applied immediately to prevent blood loss and blood exposure. If this HRG/SEIU criterion were applied to hemodialysis, the risk of blood loss for patients and blood exposure for patients and caregivers would increase dramatically.
- 3) HRG/SEIU Criterion- "It is an integral part of the device."
Medisystems Comments- Medisystems agrees with this criterion.
- 4) HRG/SEIU Criterion- "It is in effect before disassembly, if any, and remains in effect after disposal."
Medisystems Comments- Medisystems agrees with this criterion, but believes that the criterion should also require that the safety guard, when engaged, prevents the HCW's fingers from entering the guard.

Even more importantly, in addition to the criterion outlined above, a guarded AV fistula needle should provide safety without compromising the basic design and purpose of the fistula needle itself. For over 20 years, fistula needles have been designed with an extremely short (rigid) hub, connected to flexible tubing. This short hub/flexible tube combination is critical to minimize lever forces, permit safe cannulation in a variety of locations, and allow visualization of the blood flashback upon needle insertion. Hemodialysis patients can have surgically placed accesses in varied body locations, and accesses can over time become misshapen due to thrombosis and scarring. Two fistula needles must be placed in one vascular access (on one arm) for Arterial and Venous flow. A fistula needle with a longer hub greatly increases the potential for damage to the vascular access, restricts the selection of cannulation sites, and increases the infiltration rate compromising patient comfort and safety. For these reasons, a guard should not modify the basic AV fistula needle design or increase the rigid hub length.

Thank you for the opportunity to comment and further protect front-line healthcare workers from needlesticks and other percutaneous injuries.

Sincerely,

A handwritten signature in cursive script that reads "Fred Swindler".

Fred Swindler
Medisystems Corporation
Vice President RA/QA

- 1) Occupational Safety and Health Administration. Needlestick Prevention. <http://www.osha.gov/SLTC/needlestick/Accessed> September, 2002.
- 2) McCleary J, Caldero K, Adams T. Guarded fistula needle reduces needlestick injuries in hemodialysis. *Nephrol News Issues*. 2002; 16(6):66-72.