

Comments for Docket No. 01P-0120
Medical Devices; Needles-Bearing Devices

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Since 1991, ECRI has been at the forefront of evaluating needlestick prevention devices and bringing this unbiased information to hospitals. We have evaluated over 60 devices in 13 product groups. Some of those groups are syringes, catheters, lancets, blood collection devices, blood gas syringes, hemodialysis needles, and more.

From our first look at needlestick prevention devices in 1991 to the present time, there have been significant technological advances. Through this time suppliers and healthcare workers have been able to define some key design issues that are useful and ones that are not useful. However, one thing that has been made clear from talking with healthcare workers is that there is not one design that works best in every hospital. While some hospitals have success and lower needlestick injuries with a specific design, other hospitals may not have success with that same design. This must be kept in mind when creating criteria for devices.

ECRI believes that there needs to be a central location where all device related data on needlestick injuries is reported. This data should clearly indicate the device supplier and model name, and a description of how the needlestick injury occurred. With this information, hospitals and the FDA will have a reference for which designs contribute to needlestick injuries.

ECRI would be very interested in helping the FDA develop a performance standard for these devices. If the FDA were looking to contract out this work, ECRI would be a knowledgeable and well established choice. We would be interested in discussing this option. Also, we would like to be a part of any type of panel or committee that is created to discuss these issues. We also suggest reviewing our criteria and findings in our Sharps Safety and Needlestick Prevention Guide for information on which designs we found acceptable and how users felt about these devices.

We look forward to helping you in your efforts to reduce the risk of needlestick injuries in healthcare.

*Please contact Robyn Silberman at 610-825-6000 ext. 5209
with any questions or information.*

OIP-0120

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A NONPROFIT AGENCY

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