



GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Coordinators:

Determine which products are to be evaluated and provide at least four or more test samples for each individual evaluating the product. (Each evaluator should have enough samples to disassemble and examine the design thoroughly.)

Set up a testing station for each type of device which allows testers to evaluate products in a simulated patient procedure. Provide training dummies (injection pads, oranges, etc.) as necessary.

Provide visual instructions and demonstrate proper use of each device.

Review the instructions and rating system with each evaluator.

Encourage each evaluator to comment on the sheets and prioritize the questions at the end of the evaluation. This will provide a useful decision making tool and will help alert you to specific areas of concern which may not have been covered by the questionnaire.

Evaluators:

Re-enact all steps of the intended or possible procedures performed with the device being tested.

Attempt to misuse the device and circumvent or disable the safety feature.

Answer each question, including the short answer section at the end. If you do not understand a question, please write comments directly on the sheets.

NOTE: The utility of these criteria is for initial screening of devices and **NOT** for clinical assessment/pilot testing. Certain assumptions have been made in the development of these forms based on information about currently available products. We recognize the likelihood that the ideal product may not exist. TDICT welcomes your comments on the use of these tools.

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© June 1993, revised August 1998 (Federal OSHA Instruction CPL 2-2.69, 11/27/01)

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SAFETY FEATURE EVALUATION FORM
SAFETY SYRINGES

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agreedisagree

During Use:

- | | | | | | | |
|--|---|---|---|---|---|-----|
| 1. The safety feature can be activated using a one-handed technique | 1 | 2 | 3 | 4 | 5 | N/A |
| 2. The safety feature does not obstruct vision of the tip of the sharp | 1 | 2 | 3 | 4 | 5 | N/A |
| 3. Use of this product requires you to use the safety feature | 1 | 2 | 3 | 4 | 5 | N/A |
| 4. This product does not require more time to use than a non-safety device | 1 | 2 | 3 | 4 | 5 | N/A |
| 5. The safety feature works well with a wide variety of hand sizes | 1 | 2 | 3 | 4 | 5 | N/A |
| 6. The device is easy to handle while wearing gloves | 1 | 2 | 3 | 4 | 5 | N/A |
| 7. This device does not interfere with uses that do not require a needle | 1 | 2 | 3 | 4 | 5 | N/A |
| 8. This device offers a good view of any aspirated fluid | 1 | 2 | 3 | 4 | 5 | N/A |
| 9. This device will work with all required syringe and needle sizes | 1 | 2 | 3 | 4 | 5 | N/A |
| 10. This device provides a better alternative to traditional recapping | 1 | 2 | 3 | 4 | 5 | N/A |

After Use:

- | | | | | | | |
|---|---|---|---|---|---|-----|
| 11. There is a clear and unmistakable change (audible or visible) that occurs when the
the safety feature is activated | 1 | 2 | 3 | 4 | 5 | N/A |
| 12. The safety feature operates reliably | 1 | 2 | 3 | 4 | 5 | N/A |
| 13. The exposed sharp is permanently blunted or covered after use and prior to disposal | 1 | 2 | 3 | 4 | 5 | N/A |
| 14. This device is no more difficult to process after use than non-safety devices | 1 | 2 | 3 | 4 | 5 | N/A |

Training:

- | | | | | | | |
|---|---|---|---|---|---|-----|
| 15. The user does not need extensive training for correct operation | 1 | 2 | 3 | 4 | 5 | N/A |
| 16. The design of the device suggests proper use | 1 | 2 | 3 | 4 | 5 | N/A |
| 17. It is not easy to skip a crucial step in proper use of the device | 1 | 2 | 3 | 4 | 5 | N/A |

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?