Guidance for Industry and FDA Staff

Medical Devices with Sharps Injury Prevention Features

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This document supersedes Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features (Antistick), 12/31/2002

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and FDA Staff

Medical Devices with Sharps Injury Prevention Features

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification submissions for medical devices that incorporate a sharps injury prevention feature (e.g., anti-needlestick feature). A sharps injury prevention feature is designed to protect the user from a sharps injury. Most medical devices that include sharps injury prevention features are either intravascular (IV) administration sets (21 CFR 880.5440), piston syringes (21 CFR 880.5860), or hypodermic single lumen needles (21 CFR 880.5570).

This guidance pertains only to the sharps injury prevention feature. It does not provide FDA's recommendations for the device itself. Therefore, you should also consult FDA guidance, if available, for the device, as in the examples below.

- Guidance on the Content of Premarket Notification 510(k) Submissions for Hypodermic Single Lumen Needles, http://www.fda.gov/cdrh/ode/odegr450.html
- Guidance on Intravascular Administrations Sets Premarket Notification Submissions [510K)] http://www.fda.gov/cdrh/ode/guidance/1189.html.
- Guidance On The Content Of Premarket Notification [510(K)] Submissions for Piston Syringes http://www.fda.gov/cdrh/ode/odegr821.html

Some sharps injury prevention features are incorporated as integrated components of finished devices. Others are marketed separately as accessories that are attached to a device by the user at the point of use, for example, a needle shield, marketed separately, which the user

attaches to a piston syringe before use. This guidance applies to both integrated sharps injury prevention features and accessories marketed separately.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center's Web page at http://www.fda.gov/cdrh/modact/leastburdensome.html.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Background

A manufacturer who intends to market a device of this generic type should conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87).

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87 and "**How to Prepare a 510(k) Submission**" on FDA Device Advice at http://www.fda.gov/cdrh/devadvice/314.html.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications**," http://www.fda.gov/cdrh/ode/parad510.html, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a guidance document addressing that device. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used. We recommend that you also include a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 21 CFR 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 11 for specific information that we recommend you include in labeling.)

Summary report

We recommend that the summary report contain:

Description of the device and its intended use
We recommend that you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. (Please refer to **Section 5. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[1]

[1] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

Description of device design
We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method
We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to **Section 6. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics
We recommend that you discuss the device characteristics that address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects
We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7-11** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[2] (See also 21 CFR 820.30, Subpart C - Design Controls under the Quality System Regulation.)

Reliance on standards
If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed, or

[2] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

- declaration of conformity to the standard.[3]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B)of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

4. Scope

The scope of this document is limited to medical devices that contain a sharps injury prevention feature. A medical device with a sharps injury prevention feature is a device designed with a component or attachment, either active or passive, that protects the user from a sharps injury.

This document does not address sharps containers or needle recapping devices. There is a separate FDA guidance document for sharps containers and needle destruction devices entitled **Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers**, http://www.fda.gov/cdrh/ode/895.pdf.

[3] See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

5. Device Design

Typically, devices with sharps injury prevention features are class II devices, subject to 21 CFR Part 820 Quality System Regulation, which include Design Controls. Design controls (21 CFR 820.30) are an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of the design an integral part of a device's development. As a result, deficiencies in design input requirements, and discrepancies between the proposed designs and requirements, may be discovered and corrected earlier in the development process. We believe design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use.

The design recommendations in Table 1 below are related to function and human factors engineering and are intended to help you address user needs for a device or feature intended to prevent sharps injuries.

Table 1. Design Recommendations for Sharps Injury Prevention Features

Type of Feature	Recommendation
All	The user should be able to easily tell whether the sharps injury prevention feature is activated.
All	Once activated, the sharps injury prevention feature cannot be deactivated and should remain protective through disposal.
Active (i.e., feature requires activation by the user)	It should be possible to activate the feature with a single-handed technique, allowing the user's hands to remain behind the exposed sharp.
Needle Shield	The shield should completely enclose the needle and prevent finger access when activated.
Retractable Sharp	The sharp should be fully retracted within the housing of the device.
Fixed Recessed Needle	The housing should extend beyond, i.e., fully cover the sharp and prevent finger access.
Colored Feature or Component	The use of color should achieve a specific purpose, (e.g., differentiate device models or sizes) and conform with user conventions, (e.g., orange hubs and needle covers for insulin syringes).

For more information about device design and human factors, see the guidance entitled, **Do It By Design - An Introduction to Human Factors in Medical Devices**, http://www.fda.gov/cdrh/humfac/doit.html and ANSI/AAMI HE48-1993: Human factors engineering guidelines and preferred practices for the design of medical devices.

6. Device Description

We recommend that you identify the device with a sharps injury prevention feature by regulation and product code. We also recommend that you provide information to show how the sharps injury prevention feature is similar to and different from other legally marketed devices by comparing:

- indications for use
- design features; e.g., materials, configurations, size
- specifications and dimensions
- materials, including chemical formulation
- any relevant voluntary standards.

We recommend that you include a side-by-side comparison of the information described below, whenever possible, in tabular format. We also recommend that you describe how any differences may affect the comparative safety and performance of the sharps injury prevention feature.

Material Composition

We recommend that you provide a complete listing of all device materials (trade name and chemical formula) used in fabricating the sharps injury prevention feature, and identify any metallic components. Metallic components may affect the safety of the device in an MRI environment. We also recommend that you identify any PVC plasticizers, bonding agents, or other additives (e.g., color additives, ink, dyes, markings, radiopaque materials) and provide their amounts.

It is helpful to present the information in the form of a listing, noting the component name followed by specific material identifier. We believe generic class alone (e.g., polyvinylchloride [PVC]) is not adequate because there are many formulations of material compositions.

Physical Specifications

When describing physical specifications, we recommend that you explain how the specifications below compare to unprotected hypodermic needles or deactivated sharps injury preventions features. We recommend that you indicate:

- dimensions such as inner diameter (ID), outer diameter (OD), height, length, width, thickness, gauge
- diameter of housing (for fixed recessed needle safety devices)
- cannula/needle tip configurations
- priming volume
- residual volume in injection access port or syringe
- connector type: e.g., Luer lock, slip fit,
- dimensions of other features
- the color of all components
- opacity of any components that could affect use (e.g., visualization of flashback or entry of needle into skin)
- markings and scales: color, type of scales, indicating whether they can be read under all conditions of use (e.g., when a needle shield is retracted before use when filling a syringe, inverted)
- any other unique physical features and specifications of the device.

Mechanical Specifications

When providing mechanical specifications, we recommend that you indicate the:

- strength of materials (tensile, flexural, elongation, etc.)
- strength of joints, bonds, connections, hinges, valves, locking mechanisms, etc.
- rigidity of safety shield or sheath
- puncture/reseal limits of septa.

Design Features

We recommend that you describe any similarities or differences between the features of your device and similar legally marketed device of the same type, which may affect safety and effectiveness. For example, we recommend that you compare a new syringe with a safety shield to a legally marketed syringe with a safety shield.

7. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of sharps injury prevention features addressed in this document. The information we recommend you include in your 510(k) to address these identified risks are given in this guidance document, as shown in the table below. We recommend that you conduct a risk analysis (before submitting your 510(k)) to identify any other risks specific to your device. The 510(k) should describe the risk analysis method and include the risk analysis and its results. If you elect to use an alternative approach to address a

particular risk identified in this document or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
Device malfunction	Section 8. Bench Testing
Adverse tissue reaction	Section 11. Biocompatibility
Infection	Section 9. Microbial Ingress Testing Section 10. Simulated Clinical Studies Section 12. Sterilization
Improper use	Section 13. Labeling

8. Bench Testing

We recommend that you conduct all testing under both a dry test condition and a wet environment simulating body fluids or fluids being administered. We recommend that you evaluate your device compared with a similar legally marketed device, using worst case simulated static and dynamic forces to the failure point of the component. We also recommend that you describe how you determined the worst case conditions used. We recommend your testing assess the:

- force to attach and detach connections
- force to activate and deactivate the safety feature(s)
- reaction force generated by the activation mechanism, if any (e.g., with a passive spring loaded feature, or an elastic component)
- number of activations to failure
- puncture resistance of shield or sheath, i.e., the force to failure (puncture)
- rate of fluid flow simulating extremes of pressure (e.g., the maximum force applied to the piston or maximum flow through an access port)
- accuracy of the dose administrated, if your device has atypical or unusual markings, e.g., inverted syringe markings.
- strength of joints, bonds, connections, hinges, valves, locking mechanisms, etc.

In addition to the above, we recommend you assess the tensile, flexural, and elongation strength of the materials. We also recommend you state the specifications and tolerances related to strength, pass/fail testing criteria, and the basis for the specification and criteria.

Where appropriate to your device's intended use or design, we also recommend that you follow ISO 594, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Equipment or equivalent measures in addition to the testing already described.

9. Microbial Ingress Tests

We recommend that you conduct microbial ingress testing of sharps injury prevention features that are needleless (i.e., needle-free).[4] For guidance on microbial ingress testing, see Guidance on Premarket Notifications for Intravascular Administration Sets, http://www.fda.gov/cdrh/ode/guidance/1189.html.

10. Simulated Clinical Use Testing

For devices that include sharps injury prevention features, we recommend that you conduct simulated clinical use testing and provide an analysis of the results from simulated clinical use testing and a summary of the results and conclusions. If your sharps injury prevention feature is currently legally marketed as a part of another device, you may identify that device in lieu of performing simulated clinical use testing.

Simulated use testing mimics actual clinical use by using patient substitutes (e.g., instructional models) rather than actual patients. Bench testing recommended in section 7 may also serve as part of simulated testing if done by health care professionals. The use of fruit as an instructional model may mimic a subcutaneous (SC) or intramuscular (IM) route of administration, but is not feasible simulation of IV administration. Simulated use testing helps:

- isolate problems with the device
- optimize the device design
- identify deficiencies in labeling
- evaluate the type of training needed for device users.

There are no standardized, validated methods to simulate clinical use of sharps injury prevention features. We recommend that you devise a protocol specific for your device. Whenever possible, protocols should be based on statistical considerations, such as sample size, response variables, pass/fail criteria, comprehensive report forms/questionnaires, proper

[4] Needleless Systems are those that allow repeated access to a patient's vascular system without the use of sharps. Fluid flow through the system may be uni or bi-directional, with the latter enabling the user to administer or withdraw fluids or medication. Needleless mechanisms generally include three types: pre-pierced septum and blunt cannula; valved connector (also called reflux valve); and capped Luer connector.

controls, and appropriate statistical test methods. The protocol should be comprehensive, in other words it should:

- state a clear objective
- include a determination of sample size
- explain how the number of evaluators was determined
- explain how evaluators were selected
- define terms and evaluation parameters used
- explain how the data will be analyzed.

Study Design

The evaluators should include a variety of health care professionals who routinely use the type of device you are testing. We believe a simulated clinical use study using experienced health care professional volunteers generally helps avoid learning curve artifacts. We recommend that the study also include observers who comment on the evaluators' adherence to protocol and their technique.

We recommend that you minimize bias by selecting a sufficient number of evaluators to each use a large enough sample of devices (such as 1/8 of the total number per evaluator) to allow them to gain familiarity with the device and thus provide objective opinions. The evaluators should have no conflicting financial interest in the device, but they may be compensated for their time. Studies conducted at more than one test site will decrease test bias.

The device should be tested under conditions that simulate the critical clinical variables (e.g., models to simulate patients, gloved hands, dry and wet fingers, one-handed technique).

You should make every effort to devise and execute the simulation properly. You should include all data points in the analysis. A deficient protocol or incomplete data is unlikely to provide sufficient information to support FDA's evaluation. If your protocol is deficient or your data incomplete, FDA may request additional simulated data.

Evaluator Training

We recommend that you instruct the evaluators on the study protocol, to ensure uniformity of technique, simulation of adherence to universal precautions, consistent observations, scoring, and evaluations, and complete data collection.

Report Forms

The evaluators should record the results of testing on report forms (i.e., evaluator questionnaires). Examples of report forms are available at Training for Development of

Innovative Technologies Project, http://www.tdict.org. There should be ample space for narrative comments in your report forms. We recommend that report forms contain:

- general introductory questions for tracking purposes, such as date, time periods, study site, evaluator's name
- characteristics and experience of the evaluator (e.g., left or right handed, size of hand according to a defined scale, gender, age, number of similar devices used/day, work environment)
- numbers and types of devices used by the evaluator
- graded ability of the user to perform the intended function of the device such as injection, administering fluid
- graded ability of the user to visualize important use factors, such as scales, flashback
- any required changes in usual technique, such as modifications of one-handed use
- ability to maintain aseptic technique while extracting the device from packaging, preparing, and using the device
- ease of activation of the safety feature, and resistance to unintended activation
- all adverse effects or problems encountered, whether it's device or user related, such as a sharps injury, multiple venipunctures required, safety feature failed to remain activated, line disconnection
- comparison of perceived or actual time required to use the safety device to the control/legally marketed device and impact upon user acceptance
- ability to detect activation of safety feature, and comments on associated problems with detection that may be encountered during actual clinical use
- opinion on extent of learning curve with use of device
- a general assessment of the comparative acceptability of the device, including its advantages and disadvantages
- space for any other comments or noteworthy observations.

Failed Tests

We recommend that you report all data, including any failed tests. If a test includes a failure, FDA recommends that you include a detailed explanation of the failure and steps taken to ensure that the failure has been corrected. If you redesign your device, FDA recommends that you repeat the simulated clinical use study and report its results, including any failed tests.

Sample Size Determination

A sample size can be based upon a confidence interval of an observed failure rate in a test run of "N" devices. Failure is defined as a needlestick injury or significant problem with the safety feature that may lead to an injury. The upper limit of the interval serves as the worst case approximation for the "true" failure rate of the new device.

The following tables, generated using STAT EXACT TURBO® statistical software, list the upper 95% and 99% confidence limits based on the binomial distribution for an observed failure of 0, 1, 2, or 3 devices in a test sample of 100, 200, and 500 devices.[5]

Upper Bound of 95% Confidence Limit

	Number of Devices Tested			
	100	**200**	**500**	**1000**
Failures				
0	3.6%	1.8%	0.7%	0.3%
1	5.4%	2.7%	1.1%	0.6%
2	6.9%	3.5%	1.4%	0.7%
3	8.3%	4.3%	1.7%	0.9%

Upper Bound of 99% Confidence Limit

	Number of Devices Tested			
Failures	**100**	**200**	**500**	**1000**
0	5.2%	2.6%	1.1%	0.5%
1	7.1%	3.6%	1.5%	0.7%
2	8.8%	4.5%	1.8%	0.9%
3	10.3%	5.3%	2.2%	1.1%

Because a confidence interval generally involves both the upper and lower limits, when dealing only with one limit the actual confidence levels become 97.5% and 99.5% for 95% and 99%, respectively, because the 5% and 1% differences are split equally between the two tails of the distribution curve.

Thus, for example, if there were no failures observed in a test run of 500 devices, we would be 97.5% confident that the true failure rate was no higher than 0.7% and 99.5% confident that it was no higher than 1.1%. If, on the other hand, there were two failures among 200 devices tested, the true failure rate could be as high as 3.5% (95% upper bound) or 4.5% (99% upper bound).

[5] C.R.C. Handbook of Tables for Probability and Statistics, 2nd Edition, William H. Beyer, Editor. 1982.

This model shows that smaller sample sizes increase the chance of accepting a device that has a potentially higher injury rate, even if no failures were reported. However, we recognize that sample sizes large enough to detect real differences in needlesticks rates are generally not feasible. We recommend that simulated use testing of devices with sharps injury prevention features include a sufficient number of devices to provide confidence in the performance of the device. FDA believes that for many devices with sharps safety features it is feasible to test 500 devices, which will enable detection of grossly defective devices at a 1% level (see previous confidence tables).

With a sample size of 500, a successful study should report zero failures of the protection feature. No test control device is needed for comparison of a sharps injury endpoint since the endpoint is predetermined as a 0% rate of injury, based on the confidence intervals described above.

FDA will consider alternative approaches to sample size determinations, when the proposed alternative is supported by an adequate scientific rationale.

11. Sterilization

FDA recommends that you provide sterilization information in accordance with the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA.** http://www.fda.gov/cdrh/ode/guidance/361.html. The device should be sterile with a sterility assurance level (SAL) of $1x10^{-6}$ using a sterilization cycle that has been validated in accordance with the Quality Systems Requirements (QSR). 21 CFR 820.30.

12. Biocompatibility

We recommend that you conduct biocompatibility testing for your device as described in the guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**, http://www.fda.gov/cdrh/g951.html. We recommend that you select tests that are appropriate for the duration and level of contact and submit your pass/fail criteria. We also recommend that you document the results in your design history as part of the QSR (21 CFR 820.30). If identical materials and identical material processing are used in a predicate device with the same type and duration of contact, you may identify the predicate device in lieu of performing biocompatibility testing.

13. Labeling

Labeling should provide sufficient detail to satisfy the requirements of 21CFR 807.87(e). The following information will assist you in meeting the requirements of 21 CFR Part 801.[6]

Intended Use

We recommend that the intended use clearly identify the therapeutic, preventative, or diagnostic use of the device and its use in the prevention of needlestick (sharps) injuries. Labeling should prominently indicate that the device with the sharps injury prevention feature is part of a system marketed by the submitter that is intended to be used with other devices or accessories as a part of that system.

Directions for Use

We recommend that your directions for use include instructions for:

- positioning the hands on the device at all times during use for safe operation
- aseptic technique, particularly when technique for using the device with the safety feature differs from the techniques for commonly used devices without the safety feature
- deactivating the device after use
- pre-decontamination procedures, such as pre-swabbing a septum
- safely transporting sharps
- disposing of a used device
- visualizing blood flashback.

We recommend that you include illustrations, pictures, posters, cards, and other visuals that may clarify and reinforce the directions for use.

We also recommend that your directions for use include instructions for determining with certainty that any active safety feature is activated. For example, if the safety feature is a active

[6] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a device is introduced into interstate commerce. In addition, final labeling for prescription devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

system, such as a stop mechanism, directions should instruct the user to listen for an audible click to ensure the mechanism has been activated.

Precautions

We recommend that labeling include any special limitations related to hand size or dexterity.

Warnings

We recommend that labeling warn that leakage of fluid may occur when disconnecting components.

Description of the Device

We recommend that the description include whether the device is:

- single use only, non-toxic, non-pyrogenic fluid path, where applicable
- sterile, if package is intact, undamaged, and protective caps are secure.

Accessories

In addition to the information above, we recommend that labeling for an accessory:

- identify the specific devices that are compatible with the accessory (e.g., trade names and/or models of syringes, device specifications)
- instructions for connecting the sharps injury prevention accessory to the device
- instructions for discarding used device.

Appendix I. Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
DAGID	Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
DEHP	Diethylhexylphthalate
DSMICA	Division of Small Manufacturers International and Consumer Assistance
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration
ID	Inner Diameter
ISO	International Organization for Standardization
IV	Intravascular
OD	Outer Diameter
ODE	Office of Device Evaluation