



# LabNotes<sup>†</sup>

Volume10 No.1, Fall 2001

A Newsletter  
from BD  
Vacutainer  
Systems,  
*Preanalytical  
Solutions*

On November 6, 2000, President Clinton signed the Federal Needlestick Safety and Prevention Act into law. This new law stipulates that when safety-engineered sharps devices are available with built-in safety features that help reduce the risk of occupational exposure to patients' bodily fluids, healthcare facilities must evaluate and implement, where appropriate, the use of these devices. This law\* will ensure that healthcare workers have access to safety-engineered sharps devices that can provide added protection against potential infection with HIV/AIDS, hepatitis B and hepatitis C.

\*The Needlestick Safety and Prevention Act serves to reinforce the Occupational Safety & Health Administration (OSHA) Bloodborne Pathogen Directive issued on November 5, 1999. Complete compliance to the law was initially required by April 18, 2001, however healthcare facilities were given an extension until August 2001 to be in compliance.

## The Needlestick Safety and Prevention Act What Does It Require?

By Gina Pugliese, R.N., M.S. (Premier Safety Institute, Premier, Inc.) and Jane Perry M.A. (International Health Care Worker Safety Center, University of Virginia)

The Needlestick Safety and Prevention Act authorizes federal OSHA to revise the 1991 Bloodborne Pathogens Standard (29 CFR 1910.1030) to include safety-engineered sharps devices.

### Provisions of the new law:

- Requires healthcare employers to provide safety-engineered sharps devices and needleless systems to employees to reduce the risk of occupational exposure to HIV, hepatitis C and other bloodborne diseases.
- Expands the definition of "engineering controls" to include devices with engineered sharps injury protection.
- Requires that exposure control plans document consideration and implementation of safer medical devices designed to eliminate or minimize occupational exposure. Plans must be reviewed and updated at least annually.
- Requires each healthcare facility to maintain a sharps injury log with detailed information on percutaneous injuries (including type and brand of device involved in exposure incident, department where exposure

occurred and an explanation of how it occurred).

- Requires employers to solicit input from non-managerial (e.g., frontline) healthcare workers when identifying, evaluating and selecting safety-engineered sharp devices, and to document this process in the exposure control plan.

### Frequently Asked Questions:

#### Which healthcare facilities are covered by the new law?

The new federal law and the revised Bloodborne Pathogens Standard apply to any facility under federal OSHA where employees may be exposed to blood or other potentially infectious material, such as hospitals, long-term care facilities, and clinical laboratories. The law and revised standard do not cover public (state and municipal) facilities in federal OSHA states. (Note, however, that of the 27 states that are under federal OSHA, seven — Georgia, Maine, Massachusetts, New Hampshire, Ohio, Texas and West Virginia — have passed needle safety laws covering public health care settings.)

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### What's New About Access/EPINet™?

The EPINet™ system is now available for the easy-to-use Microsoft Access platform. Features include:

- Windows-based, user-friendly software with point-and-click capability
- Is a method of compliance with new OSHA guidelines
- Database software that uses Microsoft Access® format to provide much greater power for analyzing data
- Customized reporting feature allows for more in-depth analysis
- Ability to generate Single Incident Reports and Injury Logs
- Ability to export data to Excel or Access formats, or reports to Word or Excel formats
- Easy to use graphing feature
- New feature allows reporting for a number of non-hospital types of facilities
- Institution specific questions can be added to the program

### Does implementing the Access/EPINet™ system automatically make my institution part of an EPINet system network?

No. The Access/EPINet™ system is a stand-alone computer program. Although the consistency of reporting for those

using the Access/EPINet™ system program does allow data sharing and comparing (apples to apples), installing the program does not put you "on line". However, many groups start EPINet system networks by working through regional APIC chapters, GPOs, or integrated networks, which need to be organized at the hospital level. This approach helps institutions maintain privacy and control over data, but enables data sharing in a controlled environment.

### How does the Access/EPINet™ system enable healthcare providers to meet OSHA requirements?

OSHA's Prevention of Occupational Exposures to Bloodborne Pathogens mandates safe handling practices for sharps medical devices, and requires record keeping for adverse blood and body fluid contacts. New federal regulation includes specific record keeping requirements. The Access/EPINet™ system questionnaires and reports meet these requirements.

To order the EPINet system, call (800) 647-5513, or visit [www.bd.com/safety/epinet](http://www.bd.com/safety/epinet). Use the password **FIRST IN SAFETY** at either location to obtain a free copy of the software during this introductory period.

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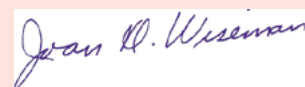
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# LabNotes

Our focus at *LabNotes* is to provide to the clinical laboratory, information to improve patient and healthcare worker safety. The operative word is SAFETY — patient safety, healthcare worker safety and safety in all facets of the laboratory.

In my role as editor of *LabNotes*, I have a deep well of laboratory experience from which to draw. This includes many years in the hospital laboratory prior to getting into industry. To say I've witnessed a lot of change in the last 50 years is an understatement, but change is the essence of progress. So it is particularly noteworthy that this issue of *LabNotes* focuses on recently written state laws and the Federal Needlestick Safety and Prevention Act. These laws mandate compliance on the part of healthcare facilities and their caregivers to help prevent occurrence of sharps injuries.

By now you should be into the implementation phase of your compliance activities. We hope you find the information in *LabNotes* relevant and useful in your goals to reduce sharps injuries and promote patient and healthcare worker safety.



Joan Wiseman, MT(ASCP)CT  
Editor

## What are the requirements for facilities in states with their own OSHA plans?

States with state OSHA plans (there are 23) must have regulations that are "at least as effective" (that is, at least as protective) as those of federal OSHA.

## How does the new federal law apply in states that have passed needle safety laws?

Seventeen states have passed needle safety legislation. The elements of the new federal law that are also part of many state laws include: (1) required evaluation and implementation, where appropriate, of sharps injury prevention devices; (2) a written exposure control plan that is updated annually to reflect consideration and use of safety-engineered devices; (3) a sharps injury log with detailed information on the type and brand of device and description of the incident; and (4) involvement of frontline workers in selection, evaluation and implementation of safety-engineered devices.

If a state needle safety law has requirements above and beyond what the federal law requires, then the additional state requirements must be followed. (For instance, some states require health care facilities to report needlestick injury data to a state agency.) If a state needle safety law is less protective than the federal law, the federal law's requirements must be followed.

## What effect does the new law have on OSHA's November 1999 compliance directive (CPL 202.44D) for the Bloodborne Pathogens Standard?

In drafting the federal Needlestick Safety and Prevention Act, legislators relied on the language and overall content of the compliance directive regarding requirements for the use of safety-engineered devices. The new law provides legislative authority for OSHA's current enforcement emphasis on the use of safety-engineered devices as a primary engineering control to prevent occupational exposures to bloodborne pathogens. In addition to mandating the evaluation and implementation, where appropriate,

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of safety-engineered devices, OSHA's compliance directive provides guidance on a number of other issues, such as updated requirements for post-exposure follow-up that include hepatitis C virus. (The revised compliance directive and additional compliance information and training resources are available on OSHA's web site: [www.osha-slc.gov/SLTC/needlestick/compliance.html](http://www.osha-slc.gov/SLTC/needlestick/compliance.html).)

## Does OSHA require safety-engineered devices now?

Use of sharps with safety-engineered sharps injury protection is now required. OSHA has the authority under the Bloodborne Pathogens Standard to require the use of engineering controls, such as safety-engineered devices, to reduce risk to workers. OSHA clarified its position in November 1999 with the revised compliance directive, and outlined the requirements and enforcement procedures for implementation of sharps injury prevention devices. Since November 1999, OSHA has cited healthcare facilities for failure to use safety-engineered devices. In determining a facility's compliance with the standard, however, OSHA has considered, among other factors, evidence of adoption of safety-engineered devices and whether the exposure control plan includes on-going selection, evaluation, and implementation of such devices, with a timeline for implementation.

The federal Needlestick Safety and Prevention Act does not change the current enforcement activities of OSHA, but rather gives a legislative mandate for OSHA's requirement that health care employers provide their employees with safety-engineered sharp devices.

## Will OSHA be stepping up its enforcement of the standard?

OSHA has already started conducting more inspections of health care facilities. During inspections, compliance with all occupational safety and health requirements is reviewed, including the Bloodborne Pathogens Standard. The increase in inspections is part of

a recent initiative that included a letter sent to 2,600 health care facilities that had the highest average illness and injury rates, announcing that OSHA would be conducting targeted inspections. The major source for OSHA inspections of health care facilities, however, will still be employee complaints. Thus, it will be important to adhere to the requirement that frontline workers' input be included in the development and implementation of a sharps injury program, in order to assure that their needs and safety concerns are being met.

## What should our facility do now?

- **Collect exposure data, using a system** such as EPINet. This data is

**The federal Needlestick Safety and Prevention Law does not change the current enforcement activities of OSHA, but rather gives a legislative mandate for OSHA's requirement that health care employers provide their employees with safety-engineered sharps devices.**

essential to understanding where exposures are occurring in a facility, and what interventions, including "safer devices", are necessary to prevent them. If your facility already has a system in place for tracking sharp-object injuries and blood and body fluid exposures, make sure the forms solicit information on the following: type and brand of device causing the injury, department where the exposure occurred, and an explanation of how the incident occurred. The new federal law requires that this information be collected. (The latest Microsoft® Access version of the EPINet system includes all this information on its data collection forms.)

- **Establish a sharps task force.** Each facility should have a multidisciplinary task force and assigned leader to coordinate the sharps injury prevention program. The task force

should include both managerial and non-managerial (frontline) workers to assist with the development or revision of a plan for selection, evaluation and implementation of safety-engineered devices. Consider such devices as one component of an overall sharps injury prevention program that includes management commitment to worker safety, education and training on the use of safety-engineered devices, strategies to encourage compliance, and ongoing evaluation of the effectiveness of such devices in reducing the risk of injury from contaminated sharps.

- **Revise the exposure control plan.** The exposure control plan should be revised to include the plan and timetable for evaluating and implementing, where appropriate, safety-engineered devices in all device categories with potential for bloodborne pathogen exposure. The involvement of frontline workers in the device selection process should be documented in the plan.
- **Select and evaluate devices.** The new law does not recommend specific devices, but requires employers to conduct their own evaluations of available safety-engineered devices. At present, there are relatively few studies documenting the efficacy of specific devices. Therefore, hospitals must select devices to evaluate based on a consideration of their own needs and requirements. If your facility has group purchasing contracts, start by reviewing the safety-engineered devices that are currently under contract. Note, however, that health care facilities must evaluate any safety-engineered device they believe is appropriate for their specific needs, regardless of whether it is covered by a group purchasing contract.
- **Implement safety-engineered devices.** When evaluation is complete, devices should be implemented promptly after appropriate education and training on the use of the device.

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## LabNotes Best Practice

### Question 1: When did the new OSHA safety regulations go into affect?

President Clinton signed the original document in November, 2000 and healthcare facilities were required to be in compliance with the new regulations by August 2001. All healthcare facilities, including hospitals, alternate site facilities and clinical laboratories need to comply with the regulations.

### Question 2: What products are affected by the new OSHA safety regulations?

The new regulations are designed to help protect healthcare workers from accidental exposure to blood or other potential infectious material. This means that healthcare facilities need to provide their employees with "safer medical devices". In terms of blood collection, this would mean using safety-engineered blood collection needles. However, blood collection tubes also need to be safer, and it is suggested that facilities use a plastic blood collection tubes instead of glass, which can break and injure an employee.

### Question 3: What is the best method for transferring blood from a syringe into a blood collection tube?

Whenever possible, it is suggested that blood be drawn directly into an evacuated tube. However, if it is necessary to use a syringe and then transfer the blood from it into a tube, a needleless device is recommended. NCCLS<sup>(1)</sup> suggests using a safety shielded syringe or a device designed to allow blood transfer from a syringe to a tube. Such a device is the BD Blood Transfer Device, which is specifically designed to transfer blood from a syringe into an evacuated tube or blood culture bottle. However, if a needle is still required to transfer blood from the syringe, the tube must not be held with the hand.

1. NCCLS "Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Fourth Edition," H3-A4, Vol. 18 No. 7, June 1998.



# Safety Message from BD

**BD** is fully committed to healthcare worker safety, offering the broadest array of safety-engineered devices in the industry. The following is a letter concerning compliance to the new Federal Needlestick Safety and Prevention Act. The new law stipulates that whenever safety-engineered sharps devices are available to reduce that risk of sharps injuries, they must be evaluated and implemented, where appropriate, in healthcare facilities. Please note that since this letter was written the compliance date changed to August 2001.

## Impact of Federal Law

On November 6, 2000, President Clinton signed the Federal Needlestick Safety and Prevention Act into Law. This new law stipulates that when safety-engineered sharps devices are available with built-in safety features that help reduce the risk of occupational exposure to patients' bodily fluids, healthcare facilities must evaluate and implement, where appropriate, the use of these devices. As a result of this law, we anticipate a substantial increase in customer demand for safety-engineered devices.

BD recognizes that medical professionals and healthcare facilities decide what types of medical devices are appropriate for various medical procedures and patient care situations. However, the language and intent of the new federal law now require healthcare facilities in the US to evaluate and use safety-engineered devices wherever feasible. We have been working closely with our customers to assist them in meeting the new requirements.

Among the steps required for compliance is completion of an Exposure Control Plan. This plan must now specifically include evaluation of safety-engineered sharps devices with participation of non-managerial direct healthcare workers, and implementation of the most effective safety-engineered devices when they are commercially available and do not interfere with patient safety or the success of a medical procedure. Based on the very broad range of needle-based medical devices, hospitals and other healthcare facilities will need to develop their own policies and protocols governing the selection and appropriate use of these devices. BD is prepared to assist with any or all of these compliance-related activities, including inservice training for your employees on use of safety-engineered sharps devices.



**BD is prepared to assist with any or all of these compliance-related activities, including inservice training for your employees on the use of safety-engineered sharps devices.**

## BD's Transition Plan

Consistent with our customers' compliance requirements and timing, BD continues to expand the supply of safety-engineered devices while scaling back production of conventional sharps devices accordingly. BD will focus initially on the highest volume application areas where the potential user benefits are greatest. These include infusion therapy (IV catheters), blood collection (needles and winged sets), and injection (syringes and needles). As described below, our steps will vary based on the medical procedures performed with these devices. BD also plans similar measures for other, lower volume sharps product categories.

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**For IV catheters**, BD continues to assist our customers in the already-rapid transition from conventional to safety-engineered designs. There is currently an ample supply of safety-engineered IV catheters available from BD and other manufacturers. We are working to ensure that a sufficient supply of safety-engineered catheters is available for all BD IV catheter users, and production of conventional catheters will be scaled back accordingly.

**For needles and winged needle sets used to collect blood**, BD will pursue the same steps as noted above for IV catheters, assisting customers in their transition to safety-engineered designs, and scaling back production of conventional devices accordingly. We will also continue to sell conventional blood collection needles, because some hospitals utilize these needles in conjunction with safety needle holders. As with IV catheters, there is an ample supply of safety-engineered needles and winged sets for blood collection available from BD and other manufacturers, and we do not anticipate any restrictions in supplying all our customers with safety-engineered designs by the compliance date.

**For syringes and needles**, BD recognizes that the majority (approximately 70%) of applications for these devices in hospitals do not involve direct percutaneous injection and therefore do not require a sharp needle. Conventional syringes used without needles (or used with blunt plastic cannulas for IV administration) are not sharps devices and pose no risk of needlestick injury. Conventional syringes and needles used in non-patient applications (such as medication preparation in the hospital pharmacy) pose no risk of bodily fluid exposure. Conventional syringes and needles will continue to be available for these and other medically necessary applications. A broad range of safety-engineered syringes, blood collection sets, needles and needleless devices including the BD Blood Transfer Device is available from BD and other manufacturers for procedures requiring percutaneous injection. Manufacturing capacity throughout the industry is currently not sufficient to supply all US hospitals with these devices, but is being scaled up rapidly.

## BD's Commitment to Sharps Safety

Over the past 12 years BD invested over \$500 million to develop the industry's broadest array of highly effective safety-engineered devices, across the full range of sharps product categories. We also funded the development of national safety training programs in conjunction with professional associations, and we provided unrestricted grants for the development of surveillance systems that enable hospitals to accurately report and track their sharps injury rates.

These efforts are part of a continuous commitment by BD to help you provide a safer work environment for your employees. BD is ready to assist your organization to understand and comply with the recently enacted legislation, and to complete the transition from conventional to safety-engineered sharps devices wherever feasible. Please distribute this communication in your facility. If you have any questions about this communication or need assistance, please contact your local BD sales consultant, or contact us toll free at 1.888.383.0118.

Thank you.

*\*For additional information on BD compliance-related services including inservice training, call the toll free number referenced above.*

# EPINet™ Exposure Surveillance Software Provides Standardized Methods for Recording Injuries

Now Available Access/EPINet™

**O**SHA estimates that 5.6 million workers in the health care industry and related occupations are at risk of occupational exposure to bloodborne pathogens. These pathogens include human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and others. Any worker handling sharp devices or equipment such as scalpels, sutures, hypodermic needles, blood collection devices, or phlebotomy devices is at risk. Needlestick injuries and other sharps-related injuries that result in occupational bloodborne pathogens exposure continue to be an important public health concern.

## Historical Overview

In 1988, Janine Jagger, M.P.H., Ph.D., a pioneer researcher on the causes and prevention of occupationally transmitted bloodborne pathogens, published a landmark report in the *New England Journal of Medicine*. Her research was the first epidemiological study identifying characteristics of medical devices associated with needlestick injuries and the transmission of HIV, HBV, and HCV among health care workers. It has been recognized as a major force in promoting the development of a new generation of medical devices designed to reduce percutaneous injuries and blood exposures.

Four years later, Dr. Jagger and her colleagues at the University of Virginia, supported by Becton Dickinson and Company, translated these research findings into a standardized needlestick and blood exposure surveillance system, the Exposure Prevention Information Network (EPINet). The International Health Care Worker Safety Center at the University of Virginia Health System was established to conduct further epidemiological research under the direction of Dr. Jagger, and to provide technical assistance to health care institutions using the EPINet exposure surveillance software. The Center utilizes nationally representative EPINet software data to accelerate development and dissemination of safety technology.

Since its release in 1992, EPINet software has been widely distributed in the United States and abroad, resulting in a massive increase in information on the causes and prevention of needlesticks and adverse blood exposures. In 1999, a Windows-based version of EPINet™ software (EPINet for Windows) was introduced to make it easier to use and to incorporate questions required in California. The recently introduced Access version of EPINet

(Access/EPINet) incorporates the latest OSHA reporting recommendations for compliance with the recently enacted federal needlestick legislation.

The International Health Care Worker Safety Center also formed partnerships with health industry manufacturers in order to achieve the goal of a safer health care workplace in which the risk of exposure to HIV and other bloodborne pathogens is reduced. Corporate partners include B. Braun Medical, Becton Dickinson and Company, Bio-Plexus, Inc., Johnson & Johnson Medical, Inc., Kimberly-Clark Corporation, Zerowet Splashield, Inc., New Medical Technology and others.

Dr. Jagger and a team of her colleagues are the inventors of six patented safety-engineered needle devices, and were honored with the Distinguished Inventor Award of 1988 by Intellectual Property Owners, Inc.

The Centers for Disease Control and Prevention (CDC) presented results of a study estimating the annual number of percutaneous injuries (PI) to U.S. hospital-based health care workers at a conference in March 2000. The estimates were based on combined data from two sources: the CDC's National Surveillance System for Hospital Health Care Workers (NaSH) database, and the Exposure Prevention Information Network (EPINet) database coordinated by the International Health Care Worker Safety Center (IHCWSC) at the University of Virginia.

The CDC estimates that 384,325 PIs are sustained by health care workers in hospitals annually. The CDC did not include an estimate for health care workers outside of hospital settings, which could as much as double the estimate. The underreporting rate used in the CDC study, 56.58%, was based on survey data from NaSH hospitals.

The CDC estimate was based on 1997 and 1998 data from 15 NaSH hospitals, and 1997 data from 45 EPINet hospitals. Because the EPINet and NaSH networks use similar data collection instruments, it was possible to combine the two data sources. EPINet hospitals tend to be smaller than NaSH hospitals—the average number of beds is 315, compared to 592 for NaSH hospitals—and are concentrated in the southeast and northwest, whereas NaSH hospitals are more scattered regionally, with a number located in the northeast.

The report was presented by Adelisa Panlilio, M.D., and colleagues at the International Conference on Nosocomial and Healthcare-Associated Infections, held in Atlanta in

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The recently introduced Access version of EPINet (Access/EPINet) incorporates the latest OSHA reporting recommendations for compliance with the recently enacted federal needlestick legislation.

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March 2000. Dr. Panlilio, a medical epidemiologist with the CDC's Hospital Infections Program, commented: "We're hoping that by combining the two data sets and our different hospitals that participate in them, we may get a more representative picture [of needlesticks nationally]."

The risk of infection following a single HIV, HBV, or HCV-contaminated needlestick or sharp object instrument injury is:

|     |            |
|-----|------------|
| HIV | 0.3%       |
| HBV | 6% – 30%   |
| HCV | .4% – 1.8% |

The consequences of occupational exposure to bloodborne pathogens are not only infections. Each year, thousands of health care workers are affected by psychological trauma during months of waiting for notification of serological results. Other personal consequences can include postponement of childbearing, altering sexual practices, side effects of prophylactic drugs, infection, chronic disabilities, loss of employment, denial of worker compensation claims, liver transplant, and premature death.

## What is the EPINet system?

EPINet (Exposure Prevention Information Network) is exposure surveillance software that provides hospitals and other health care settings with standardized methods for recording percutaneous injuries and blood and body fluid contacts. It was initially created to assist hospitals in complying with the OSHA record keeping requirements of the December 1991 Bloodborne Pathogens Standard. New Access/EPINet software incorporates questions and reports in compliance with new OSHA guidelines.

Hospitals can use the EPINet system to compare and share information and identify successful prevention measures. The latest EPINet system includes Summary Reports and Injury/Exposure Logs for both Needlestick and Sharp Object Injuries and Blood and Body Fluid Exposures as well as software for entering, accessing, and analyzing the data from the forms. EPINet system provides specific identification of the devices and products associated with exposures and the mechanisms by which the exposures occurred. This information allows hospitals to target high-risk devices and products and to evaluate the efficacy of new technology designed to prevent needlesticks and other exposures.

Since its introduction in 1992, more than 1,500 hospitals in the U.S. acquired it for use, as well as countries, including Canada, Italy, Australia, Spain, Japan, and Brazil.

## What can you do with the EPINet system?

- Target high-risk devices and procedures for intervention.
- Identify injuries that may be prevented with safety-engineered medical devices.
- Share and compare information and successful prevention measures with other institutions.
- Evaluate the efficacy of new devices designed to help prevent injuries.
- Analyze injury frequencies by job, device, and procedure.
- Prepare monthly, quarterly, and annual exposure reports.

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# The BD™ Vacutainer™ Eclipse™ Blood Collection Needle

Safety-Engineered Product Requires No Change of Technique

The BD Vacutainer™ Eclipse™ blood collection needle features a unique, fully-integrated shielding device to help protect health care workers from accidental injury.



"Our goal at BD is to deliver the highest quality patient care, while also protecting the doctors, nurses and technicians who use

our products to care for others every day," said Richard Brajer, President, BD Clinical Laboratory Solutions. The BD Eclipse blood collection needle not only delivers advanced protection technology for health care workers, it includes the proven quality and performance of the BD Vacutainer™ PrecisionGlide™ needle and is compatible with all the products in the Vacutainer Brand sample collection system.

The BD Eclipse Safety Shield is attached directly to a standard blood collection needle and already aligned with the bevel of the needle, so no extra assembly or adjustment is required by the user. The intuitive design of the advanced protection technology means there is no need to change the standard, one-handed venipuncture technique when using the Eclipse needle. The procedure remains familiar and the user's other hand is free to apply pressure to the patient's puncture site. The Eclipse shield is activated immediately after the needle is removed from the vein. When the thumb pushes forward on the shield, an audible click indicates that the safety shield is locked in place. The BD Eclipse shield has minimal impact on waste disposal.

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