

Finding REAL Solutions



Helping all people
live healthy lives

Protecting healthcare workers
and patients around the world

BD Eclipse™ Bifurcated Needle



Introducing the **BD Eclipse™ Bifurcated Needle**

A safety-engineered needle for smallpox vaccinations approved by clinicians

Since the terrorist attacks on the World Trade Center in New York City on September 11, 2001, the United States and other countries around the world have increased their bioterrorism preparedness programs. One possible threat includes the smallpox virus. If used as a biological weapon, today's highly mobile global population is extremely susceptible to a sudden outbreak of this disease. Due to the cessation of smallpox vaccinations following the disease's eradication in 1981, the establishment of emergency stockpiles of the smallpox vaccine, associated injection devices, and healthcare worker training programs have been instituted as a part of biosecurity preparedness.

In an effort to enhance the preparedness of healthcare institutions around the world, BD has developed the BD Eclipse™ Bifurcated Needle. The BD Eclipse Bifurcated Needle incorporates the proven designs of the BD Eclipse™ Injection Needle and the BD™ Bifurcated Needle, providing a highly efficient safety-engineered device — one that delivers the vaccine while helping prevent accidental needlesticks. Unique features make it the medical device of choice for either large-scale immunization campaigns or emergency responses.

Safety features help protect healthcare workers:

- BD Eclipse safety shield helps to prevent accidental contact with needle tip which may contain residual vaccine
- Plastic holder designed to promote a safe distance between healthcare worker's hand and vaccine
- Activation of safety shield immediately following vaccination with no negative impact to healthcare worker or patient
- Audible click indicates safety activation
- BD Bifurcated Needle remains inside locked safety cover
- Textured pad keeps worker's finger safely behind the needle
- OSHA¹ compliant technology platform

Designed for performance:

- Accurate dose delivery between bifurcated needle tines²
- Engineered to provide performance equivalent to device used by WHO's Global Smallpox Eradication Programme

Easy to use:

- Single-handed activation
- Intuitive assembly and use
- Single-use
- Minimal change in technique
- Double locking system
- Designed for easy disposal in BD™ Sharps Containers
- Package design facilitates cross-distribution with vaccine

High-quality design:

- Integrated needle/hub design based on clinician approved BD technologies³
- Non-toxic components
- Five-year shelf life
- Stainless steel needle with plastic needle shield
- Packaging maintains sterility and prevents contamination

Certificates and market clearances:

- US: 510k, Food & Drug Administration (FDA)⁴
- Europe: CE-mark

¹ The mission of the U.S. Occupational Safety and Health Administration (OSHA) is to save lives, prevent injuries and protect the health of America's workers. OSHA and its state partners have approximately 2100 inspectors, plus complaint discrimination investigators, engineers, physicians, educators, standards writers, and other technical and support personnel spread over more than 200 offices throughout the U.S. This staff establishes protective standards and enforces those standards, with the objective of protecting all working men and women in the U.S.

² Data on file.

³ BD Eclipse™ Injection Needle and BD™ Bifurcated Needle.

⁴ 510(K) No: K032528 (special)

Needle Preparation & Instructions for Use:

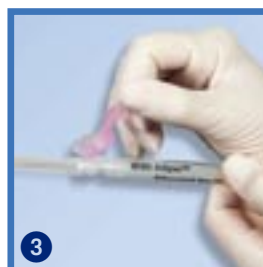
Vaccination Guidelines:⁵



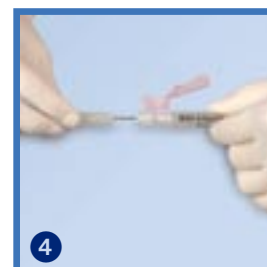
1 Peel apart the package and remove the holder.



2 Attach the holder to the bifurcated needle by firmly seating the needle on the holder with a push and a clockwise twist.



3 Once the needle is firmly attached to the holder, pull back on the pink safety cover toward the holder and away from the needle.



4 Grasp the holder with one hand, and with the other hand remove the clear needle shield by pulling straight off.

Vial Administration:



5 Remove seal from vial. Gloves should be worn.
– Place BD Eclipse™ Bifurcated Needle into vial of reconstituted vaccine.



– On withdrawal, a droplet of vaccine is contained between tines. The droplet will contain the recommended dosage of vaccine, and its presence within the prongs of the needle should be confirmed visually.

Skin Application and Safety Activation:



6 Apply vaccine according to institutional guidelines or vaccine manufacturer instructions.⁵



7 Immediately activate pink safety cover as follows:
– Using the same hand, center thumb or forefinger on the finger pad area of the pink safety cover.
– Push the pink safety cover forward toward the needle until you hear and/or feel it lock.
– Visually confirm that the needle tip is covered.



8 **Discard immediately in an approved sharps container.**
– Apply appropriate dressing.

Visit us at: www.bd.com/immunization/biodefense

⁵ Vaccination guidelines adapted from WHO, CDC and ACIP/Advisory Committee on Immunization Practices. Always administer vaccine according to instructions of vaccine manufacturer and/or recognized clinical authority.



BD Eclipse™ Bifurcated Needle

Product Specifications

- **Dose Delivery:** Equivalent to device used in WHO Smallpox Eradication Programme.
- **Cannula Size:** 0.038 inch/.965 mm diameter, solid type 305 stainless steel
- **Total Length:** 5.1 inches / 12.9 cm
- **Major Components:**
 - ✓ Stainless Steel Cannula
 - ✓ Polypropylene Needle Shield
 - ✓ Convenient Combo Package
- **Shelf Carton Size:** 50 units
- **Minimum Order Quantity:** 6 shelf cartons (300 units)

Available Product Reference* Numbers:

301798	CE	BD Eclipse™ Bifurcated Needle 50 Combo-packs
301799		BD Eclipse™ Bifurcated Needle 50 Combo-packs



BD™ Waste Disposal Solutions
www.bd.com/sharps

Finding REAL Solutions

Facts About Smallpox

Smallpox infection was eradicated from the world in 1977. Smallpox is caused by the variola virus. The incubation period is about 12 days (range: 7 to 17 days) following exposure. Initial symptoms include high fever, fatigue, and head and back aches. A characteristic rash, most prominent on the face, arms, and legs, follows in 2-3 days. The rash starts with flat red lesions that evolve at the same rate. Lesions become pus-filled and begin to crust early in the second week. Scabs develop and then separate and fall off after about 3-4 weeks. The majority of patients with smallpox recover, but death occurs in up to 30% of cases.

Smallpox is spread from one person to another by infected saliva droplets that expose a susceptible person having face-to-face contact with the ill person. Persons with smallpox are most infectious during the first week of illness, because that is when the largest amount of virus is present in saliva. However, some risk of transmission lasts until all scabs have fallen off.

In people exposed to smallpox, the vaccine can lessen the severity of, or even prevent illness, if given within a few days after exposure. Vaccine against smallpox contains another live virus called vaccinia. The vaccine does not contain the smallpox virus. There is no proven treatment for smallpox, but research to evaluate new antiviral agents is ongoing. Patients with smallpox can benefit from supportive therapy (intravenous fluids, medicine to control fever or pain, etc.) and antibiotics for any secondary bacterial infections that may occur.

References:

1. Fenner F, Henderson DA, Arita I, Jezek Z, Ladnyi ID, Smallpox and its eradication. Geneva, Switzerland: World Health Organization, 1988.
2. Henderson DA, Inglesby TV, Bartlett JG, et al. for the Working Group on Civilian Biodefense. Smallpox as a biological weapon: medical and public health management. *JAMA* 1999; 281:2127-37
3. Centers for Disease Control and Prevention. Recommendations for using smallpox vaccine in a pre-event vaccination program: supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR* 2003;52(No. RR-7)

Making a World of Difference

BD (Becton, Dickinson and Company) is a medical technology company, which has served healthcare institutions, life science researchers, clinical laboratories, industry, and the general public for over 100 years. This experience has kept us at the forefront of discovery and innovation. It has also helped to put dynamic products in the BD pipeline that are eagerly awaited by the government, the armed forces, and the entire healthcare industry.

We manufacture and sell a broad continuum of medical supplies and devices, laboratory equipment, and diagnostic products. Through these products, we broadly serve the world in many important ways. Our goal is to eliminate unnecessary suffering and death from disease, and in so doing, become one of the greatest healthcare companies in the world.



1 Becton Drive MC204
Franklin Lakes, NJ 07417
tel: 201.847.6800
fax: 201.847.4845

30 Tuas Avenue 2
Singapore 639461
tel: 65.6861.0633
fax: 65.6860.1593

Denderstraat 24 B-9320
Erembodegem Aalst
Belgium
tel: 32.53.720211
fax: 32.53.720200

Carretera General San Martin 16500
Sitio 33, Colina
Santiago, Chile
tel: 562.460.0380
fax: 562.460.0306

Unit 401-403, 318 Pidemco Tower
318 Fuzhou Road
Shanghai, People's Republic of China
tel: 86.21.6391.2678
fax: 86.21.6391.2698

Signature Towers B, 6th Floor
South City I, Gurgaon 122001
Haryana, India
tel: 91.124.238.3566
fax: 91.124.238.3224

Visit us at: www.bd.com/immunization/biodefense

*Please consult your local sales representative for product availability.

BD, BD Logo and BD Eclipse are trademarks of Becton, Dickinson and Company. ©2003 BD
Printed in USA BD 9/03 BDI7075 Eclipse Bifurcated Intl.