

Tkmd[®]

INSTRUCTIONS FOR USE

Product Name

Bifurcated Needle

Intended Use

The Bifurcated needle is intended for scratching the skin, to deliver vaccines by the skin prick method or the scarification method. The device is reusable after cleaning and sterilisation.

Intended User

Only used by professional medical staff.

Product Models, Components and Materials

Model	Components
BFN001	Bifurcated needle
	Needle tip Protector
BFN002	Needle handle
	Protective Cap

Cautions

1. Disposed of in accordance with the requirements of the medical institution;
2. Do not use it if the package is opened or damaged;
3. This device is not made with plasticizer bis (2-ethylhexyl) phthalate (DEHP).
4. The product is not made with natural rubber latex;
5. The product valid for 10 years, do not use after expiration.
6. The product is NON-STERILE, sterilization is required before use. The sterilization process is completed by the medical institution used, and the sterilization process should be validated.

Cleaning and sterilization

1. Pre-Cleaning

- 1.1 Remove all packaging materials prior to cleaning and sterilization.
- 1.2 Immerse device in prepared RO water. Soak for 5 minutes.
- 1.3 After soaking, use suitable soft bristle brushes to thoroughly clean the device for 1 minute. Thoroughly clean rough surfaces and features where soil may accumulate or be shielded from the cleaning process.
- 1.4 Rinse in running RO water for 1 minute.

2. Ultrasonic Cleaning

- 2.1 Prepare enzymatic detergent (e.g., Enzol[®]) in a container used in the field of medical devices that will be placed inside of an ultrasonic bath large enough to allow complete immersion of the device.
- 2.2 Fully immerse the device in the prepared detergent. Activate ultrasonic bath and soak device for 10 minutes.
- 2.3 Following the soak time, while the device is still immersed, use a soft-bristled brush to thoroughly clean all areas of the device for 1 minute. Thoroughly clean all holes, lumens, threads, knurls, grooves, and other hard to clean areas.
- 2.4 Remove the device from the ultrasonic tank.
- 2.5 Thoroughly rinse device under Critical water (RO or Distilled water) for 1 minute. Thoroughly clean all holes, lumens, threads, knurls, grooves, and other hard to clean areas.
- 2.6 Dry devices using a clean, soft non-linting cloth.
- 2.7. Visually inspect the device after cleaning. If visible soil is still observed, repeat the Pre-Cleaning and Ultrasonic Cleaning instructions.

3. Moist Heat Sterilization

Moist heat sterilization according to ISO 17665, if the lower row sterilizer is used, generally 121 °C, not less than 15 minutes; if the pulse vacuum sterilizer, sterilization temperature 134 °C, not less than 3 minutes.

4. Number of reuses

The number of reuses was set as 2 times. Disposal of the Bifurcated Needle should be done in the proper manner of medical waste or in accordance with applicable national and local laws and regulations.

Warning

1. Do not use if the package is opened or damaged, or foreign matter is found;
2. It should be used by special trained person, and the skin should not be sterilized.

Usage

1. Open the individual package and take out the bifurcated needle;
2. Remove the protective cap from the needle tip;
3. Approximately 0.0025 mL of vaccine adheres by capillary action between the lines of the bifurcated needle when it is dipped into the vaccine;
4. The needle is positioned vertically to the skin surface, usually the lateral surface of the upper arm, with the heel of the hand resting on the arm. Three (for primary vaccination) or 15 (for rev7accination) rapid strokes are made sufficiently forcefully so that a trace of blood appears at the vaccination site within 20 to 30 seconds.

Expiration Date

The product is valid for 10 years.

Storage and transportation conditions

Product should be kept in a condition that relative humidity is less than 80%, it also should be free from corrosive gas, cool, dry with good ventilation and clean. Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation.

Explanation of Symbol

	Consult instructions for use
	Manufacturer
	Authorized representative in the European Community
	Caution
	Do not use if package is damaged
	Batch code
	Date of manufacture
	Use-by date
	"Medical device" Marking
	CE Marking
	Keep away from sunlight
	Keep dry
	Catalogue number

Production Date: see on the packaging.

Anhui Tiangkang Medical Technology Co., Ltd.
Add.: No. 288 Weiyi Road Economic Development Zone
Tianchang City 239300 Anhui China

Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

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Intended User

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Product Models, Components and Materials

Model	Components
BFNS001	Needle handle
	Bifurcated needle
	Protective Cap
	Safety sheath

Cautions

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Warning

1. Do not use if the package is opened or damaged, or foreign matter is found;
2. It should be used by special trained person, and the skin should not be sterilized.

Usage

1. Open the individual package and take out the bifurcated needle;
2. Move the safety sheath away from the needle;
3. Remove the protective cap from the needle tip;
4. Approximately 0.0025 mL of vaccine adheres by capillarity action between the tines of the bifurcated needle when it is dipped into the vaccine;
5. The needle is positioned vertically to the skin surface, usually the lateral surface of the upper arm, with the heel of the hand resting on the arm. Three (for primary vaccination) or 15 (for revvaccination) rapid strokes are made sufficiently forcefully so that a trace of blood appears at the vaccination site within 20 to 30 seconds.
6. Activate sheath. Position the sheath approximately 45 degrees to flat surface, press down with a motion or push the sheath until a distinct audible click is heard and visually confirm that the needle is fully engaged under the lock.

Expiration Date

The product is valid for 5 years.

Storage and transportation conditions

Product should be kept in a condition that relative humidity is less than 80%, it also should be free from corrosive gas, cool, dry with good ventilation and clean. Products shall be protected from heavy pressure, direct sunlight and rain and snow during transportation.

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