

# Blunt Fill Needle and Blunt Fill Needle w/5 Micron Filter

## Technical Summary Sheet

### CE MARK

BSI CE 0086

### MANUFACTURER

Sol-Millennium Medical, Inc.  
5415 Sugarloaf Parkway  
Suite 2203  
Lawrenceville, GA 30043

### COUNTRY OF ORIGIN

Poland

### DEVICE DESCRIPTION

The Blunt Fill Needle & Blunt Fill Needle w/5 Micron Filter are sterile, non-pyrogenic, single use hollow, bore blunt needles used for draw up of medication. The product does not contain latex and is not manufactured using DEHP.

### INDICATIONS\*

The Blunt Fill Needle & Blunt Fill Needle w/5 Micron Filter are intended to be used in a variety of medical, pharmaceutical and laboratory procedures to extract fluid or medication from vials or ampules for transfer or irrigation.

### PRECAUTIONS\*

1. Do not use the device after the expiration date.
2. The Blunt Fill Needle is designed for penetration into vials and accessing IV bags, not for patient injection.
3. The Blunt Fill Needle w/5 Micron Filter is to be used to draw up medication from an ampule only, not for patient injection.

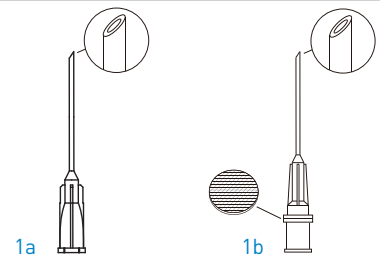
Follow standard infection control precautions as specified by the Centers for Disease Control and Prevention (USA) or local equivalent.

\*Note: Please refer to the Instructions For Use provided with the device for a full listing of the Indications and Precautions.

### INSTRUCTIONS FOR USE

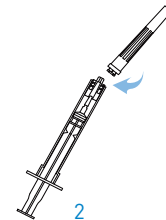
#### 1 REMOVE FROM PACKAGING

- Remove the Blunt Fill Needle (Figure 1a) or Blunt Fill Needle w/5 Micron Filter (Figure 1b) from its package.



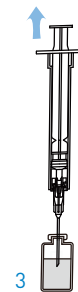
#### 2 CONNECT TO THE SYRINGE

- Connect the Blunt Fill Needle (Figure 1a) or Blunt Fill Needle w/5 Micron Filter (Figure 1b) to the syringe (Figure 2).



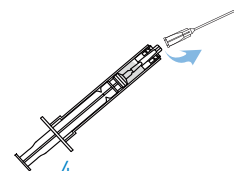
#### 3 MEDICATION PREPARATION

- Blunt Fill Needle:** Insert the needle into the corner of the vial stopper at a 90° angle. This will help reduce the risk of rubber fragments from the side of the vial stopper contaminating the medication. (Figure 3)
- Blunt Fill Needle w/5 Micron Filter:** Draw up the medication from the glass ampule. (Figure 3)

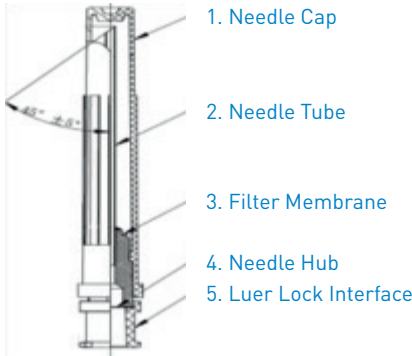
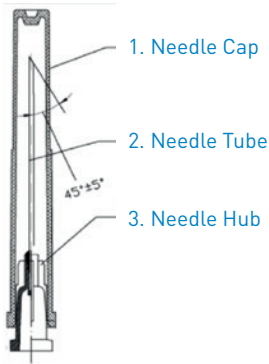


#### 4 ONCE PREPARED

- Once medication has been prepared and is in the syringe ready for administration, remove the Blunt Needle with Filter and dispose of in a sharps container. (Figure 4)



## DEVICE SPECIFICATIONS



## COMPONENTS OF HYPODERMIC NEEDLE TUBE

**Tube:** 316 stainless steel

**Plastic Outer Hub:**  
Medical grade polypropylene

**Plastic Sheath:**  
Medical grade polypropylene

**Silicone Oil(s) / Solvents:**  
Conforms to ISO 19993 requirements

**Filter Membrane (BN1815F0 Only):**  
Versaspor

## PHYSICAL CHARACTERISTICS

**Cannula Removal Force:**  
Luer conical fitting under 4.49 kg shall remain fixed

**Puncture Force:** ≤ 0.95 kg

**Deflection:** >0.5mm (+/- 5°)

**Penetration Force:** .065 kg-0.65 kg

**Sterilization:** Ethylene Oxide

**Temperature Range:** -17°F-+65°C

**Glue for Bonded Needle:**  
Conforms to ISO 10993 requirements

## DIMENSIONS

O.D	Tube Length	ID	Bevel Angle	Overall Length	Length with Cap	Code
1.27mm (+/-0.02)	38mm (+1.-2)	87mm (+0.02)	45° (+/-5°)	55.5mm (+/-5mm)	59.55 (+/-5mm)	BN1815
1.27mm (+/-0.02)	38mm (+1.-2)	87mm (+0.02)	45° (+/-5°)	55.5mm (+/-5mm)	59.55 (+/-5mm)	BN1815F

## LABELING AND PACKAGING

One (1) Blunt Fill Needle unit is packaged per each flexible, peel-open blister. The blister lid is printed with product specific information. Product is sterile, non-toxic and non-pyrogenic unless the package is open, wet, or damaged. Discard if open, wet, or damaged. One Hundred (100) units are packed per shelf pack and ten (10)

shelf packs are packed per shipper. The lot number and expiration date are located on the right side of the blister, shelf and case pack labels. The manufacturing date is included on the shelf pack and shipper label.

## SHELF LIFE

### Sterile Devices

A 5-year expiration date is assigned to the products as long as the packaging is undamaged and unopened, based on accelerated aging stability shelf-life testing and real-time aging.

Product Code	Description	Blister (mm)	Blister NW/GW	Box (100 Units) LxWxH (mm)	Box NW/GW	Case (1000 Units) LxWxH (mm)	Case NW/GW
BN4815	Blunt Fill Needle 18Gx1 1/2	85x19.2	1/1.4	105x84x86	140/160	545x188x116	1.6/2.4
BN1815F	Blunt Fill Needle w/Filter 18Gx1 1/2	92x19.2	1/1.5	105x84x93	150/170	545x188x125	1.7/2.5

## Packaging Materials

Box	Case	IFU
350g White board paper	AB corrugated paperboard	70g writing paper

For more information visit our website at [www.smiths-medical.com](http://www.smiths-medical.com)

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

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