

## BD MEDICAL – PHARMACEUTICAL SYSTEMS

### Products

[Prefillable Syringe Systems](#)

[Self-Injection Systems](#)

[Safety & Shielding Systems](#)

[Needle Technologies](#)

### Services

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## BD Biotech Plunger Stoppers

BD offers selection and integration services. These solutions were selected by BD to:

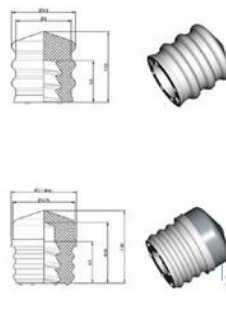


- Optimize performance in BD Hypak™ for Biotech and BD Neopak™ Glass Prefillable Syringes
- Meet the requirements of sensitive drugs
- Minimize the potential for organic and inorganic extractables

### Supply Made Simple

BD can simplify supply chain management by offering a syringe system where everything from syringe components to technical and regulatory support is offered by a single organization. BD's evaluation of elastomer offerings helps ensure that the most compatible plunger stopper for customer drug/device combination is selected.

#### 1 mL Long Biotech Stopper Offerings Include\*



#### 6901

Considered to be an ultracure formulation; therefore, extractables are minimized through superior rubber formulation science.

#### Fluotec®

A 4023 rubber formulation that is film coated only on the drug surface contact area (bladed area). The Fluotec film is intended to reduce the level of extractables into the drug.

Stoppers are molded by the world's leading rubber stopper suppliers: Dushylo, Stabini and West Pharmaceutical Services, Inc.

\* Several other 1 mL long non-Biotech stopper formulations are also available through BD. Fluotec is a trademark of West Pharmaceutical Services, Inc.

## The BD Experience

Customize container selection by using BD's stopper compatibility expertise and system integration capability.

### BD Stopper Selection and Syringe System Validation

The plunger stopper interaction with all BD syringe components has been carefully studied by BD in order to deliver consistently reliable syringe systems. System validation includes:

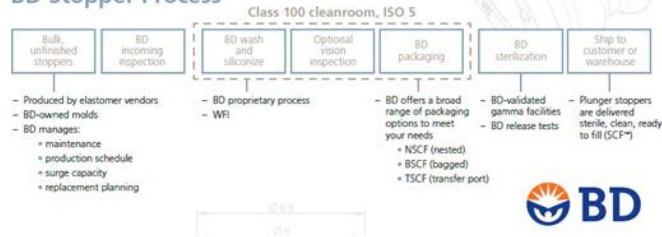
- Biocompatibility, Toxicology, Extractable, Leachable, and Pharmacopeia compliance
- ISO dye immersion and stopper leak under pressure for container closure integrity
- Break-out and sustaining force verification
- Performance verification through stacked stopper and syringe dimensional-tolerance analysis
- Plunger rod and plunger separation force testing
- Manual and automated visual inspection for dimensional conformance, foreign matter and particulates
- Shipping verification tests
- Shelf life and real-time aging in BD Glass Prefillable Syringes

### Risk Mitigation

BD can help minimize supply interruptions because of robust supply planning capabilities. BD offers:

- Several rubber formulation options from various vendors validated with a wide range of prefillable syringe systems
- At least two elastomer molding locations
- Two validated BD processing sites
- Same specifications for all plunger stoppers regardless of molder
- Same washing and packaging process regardless of formulation
- Customized risk-mitigation strategies

### BD Stopper Process



To request a brochure on BD Biotech Plunger Stoppers or for additional information, [click here](#)



### RELATED PRODUCTS



BD Hypak™ for Biotech

BD Neopak™

BD Neopak™ XSi™

BD Sterifill™ for Biotech