apiject™

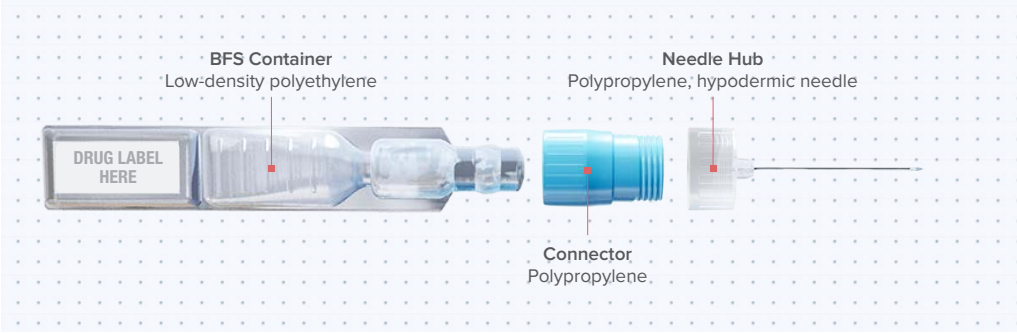
ApiJect's Procurement & Supply Chain

HIGHLIGHTS

- **Two Primary Materials**
  The ApiJect Prefilled Injector* is made from only two widely available materials: hypodermic needles and pharmaceutical-grade resin
- **Compact Supply Chain**
  Making Prefilled Injectors and fill-finishing them only requires two facilities
- **Expanding Manufacturing Locations**
  Projected to start manufacturing in late 2022, the new ApiJect 1.2 million sq. ft. Campus in North Carolina will manufacture all Prefilled Injector* components
- **Robust and Reliable Service**
  The reliability of Blow-Fill-Seal and the availability of its materials in major markets gives ApiJect a reliable supply chain, even in a very challenging global environment

A RELIABLE ALTERNATIVE SUPPLY CHAIN

One of the major points of differentiation between ApiJect's Prefilled Injector* and more traditional fill-finish formats is the simplicity and reliability of its material procurement and production supply chain. The Prefilled Injector* is composed of two well-known materials that can be domestically sourced in most major markets. Its components can be reliably mass-produced using the Blow-Fill-Seal (BFS) filling process and plastic injection molding. Even after secondary packaging, this process only requires two facilities to go from sourced materials to final product. Altogether, this compact, alternative supply chain is safe and reliable – enabling ApiJect to operate even when a pandemic causes the global supply markets to become overburdened from previous commitments, interrupted by fragile glass or rubber shipments, or into markets where sterile manufacturing is not established.



TWO PRIMARY MANUFACTURING MATERIALS

The ApiJect Prefilled Injector* is made from two materials:

1. **Pharmaceutical-Grade Resin:** Most of the Prefilled Injector is made of plastic resin. The BFS Container holding the drug is made entirely of low-density polyethylene (LDPE), while the

(continued)

*The ApiJect Prefilled Injector has not been approved by the FDA or other regulatory authorities for distribution.

Connector and most of the Needle Hub are made of Polypropylene (PP). Pharmaceutical-grade resin is widely procurable in most major pharmaceutical markets.

2. Hypodermic Needle: ApiJect's Prefilled Injector* uses a double-ended hypodermic needle to both pierce the BFS container upon activation and pierce the patient's skin for injection. ApiJect's relationship with Tae-Chang Industrial of South Korea – the world's second-largest needle manufacturer by volume – ensures a reliable supply of high-quality hypodermic needles in a range of gauges and lengths.

Both needles and resin can be stockpiled in large quantities for years at ApiJect's and partner company facilities, ensuring localized supply in the event of a global emergency. There are additional secondary materials involved in the fill-finish process (but not in the creation of the Prefilled Injector) such as a drug label, foil pouch and boxing for secondary packaging of the drug product.

RELIABILITY OF BLOW-FILL-SEAL (BFS)

ApiJect's supply chain leverages the scalability and reliability of the BFS process. Recognized by the FDA as an advanced aseptic filling process, BFS production lines require minimal human intervention. In addition, a BFS machine has a very quick turnaround time; with the right molds installed, a BFS machine could begin production on a drug product in a day. The positive control exerted on the extruded plastic through the BFS machine cycle automatically produces a consistent and reliable container, with higher-end BFS machine models being able to aseptically fill upwards of 15 million units a month.

COMPACT SUPPLY CHAIN

As opposed to traditional fill-finish formats, ApiJect Prefilled Injectors* only require two facilities: one to make the Needle Hubs and Connectors using plastic-injection molding, and another for the BFS fill-finish (and any pre-delivery assembly, if required by the pharmaceutical company). ApiJect is building a 1.2 million sq. ft. manufacturing campus in North Carolina that will contain more than a dozen BFS lines as well as a Needle Hub manufacturing facility. This streamlined and co-located North American site provides a more resilient supply chain in the event of international disruptions or emergencies.

ApiJect Systems, Corp., 2 High Ridge Park, Stamford, CT 06905 | Phone: (203) 998-6176
Email: solutions@apiject.com.

MEET OUR EXPERTS

To learn more about how ApiJect uses Blow-Fill-Seal to package sterile pharmaceuticals and other liquids, contact one of our experts at solutions@apiject.com.

Cindy Benedict
Executive Director

Philip Leslie
Head of Manufacturing

Dave Boerschel
Commercial Project Manager

FOR MORE INFORMATION:

Blow-Fill-Seal:
visit apiject.com/publications/BFS

Manufacturing:
visit apiject.com/publications/manufacturing

Company:
visit www.apiject.com

* The ApiJect Prefilled Injector has not been approved by the FDA or other regulatory authorities for distribution.