INJAY: SIMPLE BY CHOICE, ADAPTABLE BY DESIGN

In this article, Arnaud Guillet, Vice-President Business Development at Biocorp, discusses Biocorp's Injay solution for adding connectivity to a wide variety of PFS devices, focusing on how Injay's designed-in simplicity and flexibility makes it easily applicable across the spectrum of PFS platforms on the market today.

INTRODUCTION

Traditionally used primarily for vaccines and anticoagulants, prefilled syringes (PFS) have now gained broad acceptance as delivery systems – especially for the delivery of biologics for the treatment of chronic conditions such as rheumatoid arthritis, multiple sclerosis and Crohn's disease – that require the repeated administration of medication. As a result, there has been a boom in the PFS market in the past few years. The global PFS market is expected to reach US$10.57 billion (£7.7 billion) by 2027. At the same time, the need for connected solutions in the drug delivery space is growing, especially because of the impact of the covid-19 pandemic and the increasing dependence on, and acceptance of, telemedicine.

But the application of digital connectivity to drug delivery devices isn't easy, specifically for PFSs, where costs and usability challenges are fierce. Besides, PFSs are available in various formats, sizes and materials, and they can be used in conjunction with different tools, such as finger flanges or safety systems, with strong consequences on their overall form factor and usability performance. In that context, simplicity, flexibility and adaptability are paramount to bring a successful connected solution for PFSs to market.

Injay has been designed with these challenges in mind. The technological proposal is extremely simple, based on the combination of two components that can be implemented in many different ways, while providing the same reliability and delivering the same benefits to end users (Figure 1).

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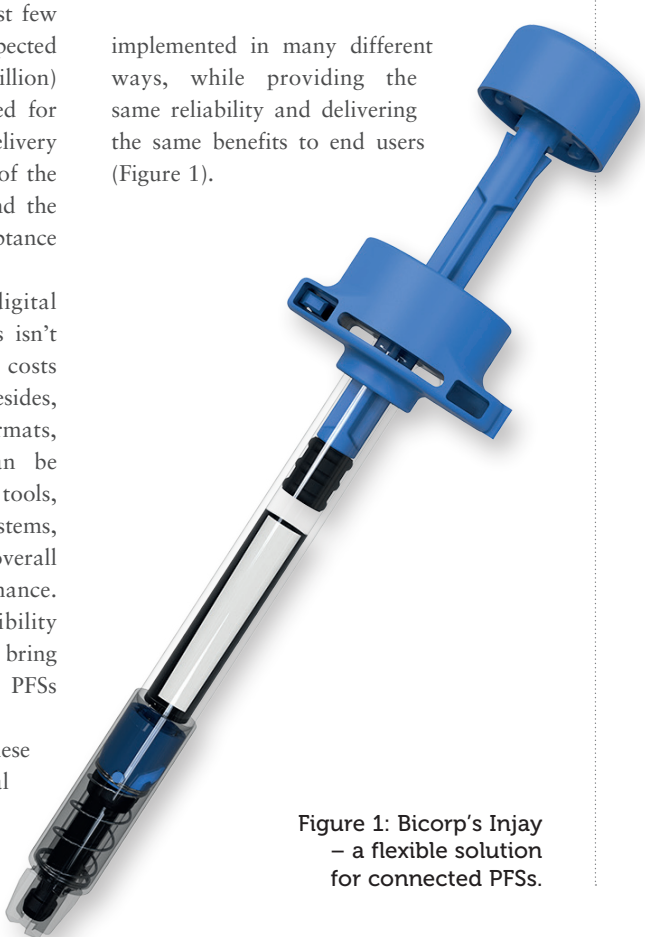

Figure 1: Bicorp's Injay – a flexible solution for connected PFSs.

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SIMPLE BY CHOICE

The value proposal of Injay for patients and healthcare providers (HCPs) using PFSs is extremely simple, deliver the right product, the right way, at the right time:

- The Right Product: Critical product information (product reference, concentration, batch number, expiry date, syringe unique ID) are stored on an NFC tag located on the syringe piston rod. This information can be read before injection using a standard reader or a smartphone equipped with NFC-reading capabilities to check the characteristics of the product.
- The Right Way: Injay detects a complete injection when the piston rod is pushed down to the stopping point, thanks to an activator located in the syringe finger flange.
- The Right Time: After injection, users scan the data with the NFC reader to register the complete injection with a specific time stamp and link the information with the treatment plan.

Injay follows basic requirements to make it easily implementable:

- Injay must not require any modification of the syringe barrel or any other critical components of the syringe (RNS, stopper, needle, etc.).
- Injay must not affect drug filling.
- Injay must not modify regular user experience and impact injection process.

The technological proposal is even simpler, based on two components: an NFC tag and an activator. In the standard Injay configuration, the NFC tag is located on the syringe piston rod and the activator on the finger flange, which makes it by design compatible with all standard PFSs, regardless of their materials (plastic, glass), needle formats (staked needles, luer lock, luer cone) or size (0.5 mL, 1 mL long and short, 2.25 mL or other specific sizes). But other configurations can be explored to meet specific requirements, such as compatibility with certain safety systems.

ADAPTABLE BY DESIGN

Safety systems have slowly become a must. From the regulatory standpoint, both EU and US authorities have implemented specific requirements around needlestick protection, EU Directive 2010/32/EU – "Prevention from Sharp Injuries in the Hospital and Healthcare Sector" and the US Needlestick Safety and Prevention Act (2000). From a user standpoint, this issue has become critical, not only in hospital settings, where the frequency and repetition of injections performed by doctors and nurses increase the risks of needlestick injuries, but also for patients delivering their treatment at home, for whom safety has become a primary concern. As a result, the syringe safety-systems market is booming and market penetration of these devices is rapidly growing. Delivering a connected solution compatible with those systems has therefore become a must.

Compatibility of Injay with integrated passive safety systems, such as Biocorp's Newguard, Stevanato Group's EZ-fill® (Padua, Italy) or Gerresheimer's Gx InnoSafe® (Düsseldorf, Germany), is obvious and the standard format can perfectly apply in this configuration. Compatibility with add-on options, such as BD Medical – Pharmaceutical Systems' UltraSafe Plus™ (Le Pont-de-Claix, France) or Nemera's Safe'n'Sound® (La Verpillière, France) is significantly more challenging, specifically when such systems feature their own specific piston rod, which is entirely part of their technical dossier. In that configuration, the standard format of Injay cannot apply as any modification on the piston rod will impact the safety-system regulatory dossier and the ability to implement an activator in the finger flange component is highly dependent on the add-on form factor.

> "Injay is designed around an NFC tag for product ID and an activator to detect a complete injection. The location, position and interactions of these components is not carved in stone, and could be designed in many different ways."

This is where the simplicity and adaptability of Injay comes into play. Injay is designed around an NFC tag for product ID and an activator to detect a complete injection. The location, position and interactions of these components is not carved in stone, and could be designed in many different ways. The intellectual property (IP) filed on this technology actually allows this flexibility and protects different configurations. Thanks to the inherent flexibility of the technology, the scope of IP protection and Biocorp's strong delivery device engineering capacities, Injay's design can be adapted to a variety of safety devices, while guaranteeing the same value proposal for end users and complying with the same industrial constraints.

CONCLUSION

When it comes to connected options for drug delivery devices, Biocorp wants to keep ease of implementation as one of its primary requirements. Injay is very much in line with this principle, thanks to its design simplicity. Injay is an effective, economically viable solution applicable for any PFS, whatever the use case.

ABOUT THE COMPANY

Recognised for its expertise in the development and manufacture of medical devices and delivery systems, Biocorp has acquired a leading position in the connected medical device market, thanks to Mallya. This intelligent sensor for insulin injection pens allows reliable monitoring of injected doses and thus offers better compliance in the treatment of diabetics.

ABOUT THE AUTHOR

Arnaud Guillet is Vice-President Business Development at Biocorp, in charge of finding partnerships and licence opportunities for Biocorp's range of connected devices. Previously, Mr Guillet worked for a healthcare consulting firm with a strong focus on connected health strategies for pharma and insurance companies and has additional past experience in the pharmaceutical industry with Sanofi and the insurance industry with AXA (Paris, France). He graduated from HEC Paris (France), a major European business school.

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