

Portal Instruments

DARE TO BE DIFFERENT: INNOVATION VERSUS THE STATUS QUO

In this article, Barb Taylor, Senior Director of Marketing, Portal Instruments, discusses the need to differentiate drug products in an ever more competitive market by providing a delivery device that fits comfortably into a patient's everyday lifestyle, and how Portal Instruments' Prime needle-free injector does exactly that.

If you ask a physician how they decide what medication to prescribe, the first answer is almost always:

- Efficacy and safety – will this drug work for my patient and help their symptoms?

The second is:

- Insurance – is it covered and what are the costs? Can the patient afford this drug?

And lastly, physicians consider a widely overlooked dimension:

- Ease of use – how does this treatment fit into the patient's day-to-day life? For injected products, can a patient administer a self-injection, or would they be better at an infusion centre? Do they

have support at home to help them remember to take their medication and to manage any anxiety they may feel? Conversely, are there kids or pets at home? Would that make self-injecting at home more stressful and less desirable than other means?

“With the emergence of biosimilars and increasing competition, there is a threat that safety and efficacy alone may not meaningfully differentiate products.”

1937 – “Penetration of Tissue by Fuel Oil Under High Pressure from Diesel Engine” C.E. Rees

1947 – First clinical evaluation of “Hypospray” device

1954-1997 – Widespread use of jet injection
Polio, cholera, small-pox

1997 – US Military sees Hepatitis B outbreak from shared jet injector

2013 – Single-use flu vaccine approved for 0.5 mL injections



“Hypospray,” TIME Magazine, 29 Aug, 1960



“Peace Gun” Smithsonian Institute



Ms Barbara Taylor
Senior Director of Marketing
T: +1 617 500 4348
E: barb.taylor@portalinstruments.com

Portal Instruments, Inc
190 5th Street
Cambridge
MA 02141
United States

www.portalinstruments.com

Figure 1: A brief history of needle-free devices.

With the emergence of biosimilars and increasing competition, there is a threat that safety and efficacy alone may not meaningfully differentiate products. Access and payer strategies are certainly important, but that is a difficult area by which to differentiate oneself. What may make the difference with physicians and patients in such a competitive space is the drug delivery device. Drug delivery that fits into a patient's day-to-day life, with minimal pain, disruption and hassle is an important consideration for doctors as they choose what to prescribe. Needle-free drug delivery can solve that lifestyle challenge and presents a significant improvement in the way that injectables are delivered.

The concept of a "needle-free" device has been around for decades (Figure 1). First assessed in the 1930s and made popular via Star Trek's "Hypospray", the broader use of needle-free injectors did not occur until the 1980s. These legacy needle-free delivery systems were powered by mechanical or gas-based means with limited pressure controls and poor regulation of injection depth and volume, which resulted in low-volume, painful and loud injections.¹ As such, needle-free drug delivery was not widely adopted.

PORTAL PRIME DEVICE – NEXT GENERATION NEEDLE-FREE

Portal Instruments is reinventing needle-free drug delivery (Figure 2). Portal Instruments' Prime device administers the drug through a computer-controlled, highly-pressurised jet stream. The narrow jet pierces through the epidermis and delivers the drug into the subcutaneous space (Figure 3). One of the advantages of Portal's needle-free device over

Computer Controlled: The closed-loop control system allows for the device to adjust the speed of the jet in order to deliver drugs with different properties to the correct tissue depth.

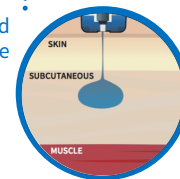
Digitally Connected: Adherence data is seamlessly collected.

Cartridge: Single-use cartridge can be disposed with general waste.



Jet Stream: Through a computer-controlled jet stream, Prime quietly administers the drug subcutaneously.

- **Volume:** Up to 1.2 mL
- **Speed:** <0.5 seconds
- **Viscosity:** 60 cP+



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Figure 2: Next generation needle-free drug delivery.

needles is the jet-stream's 200 µm diameter, whereas commonly used needles have a diameter of 400 µm (27 gauge), as shown in Figure 4. The drug is delivered from a one-time use, sterile ready-to-fill (RTF) cartridge that is provided to the fill/finish manufacturer in a standard 16 x 10 nest and tub. The design of the cartridge and nest and tub format enables seamless, easy product filling.

"The Prime device has been successfully tested with a wide array of drugs, from small molecules to peptides and mAbs over 60 cP."

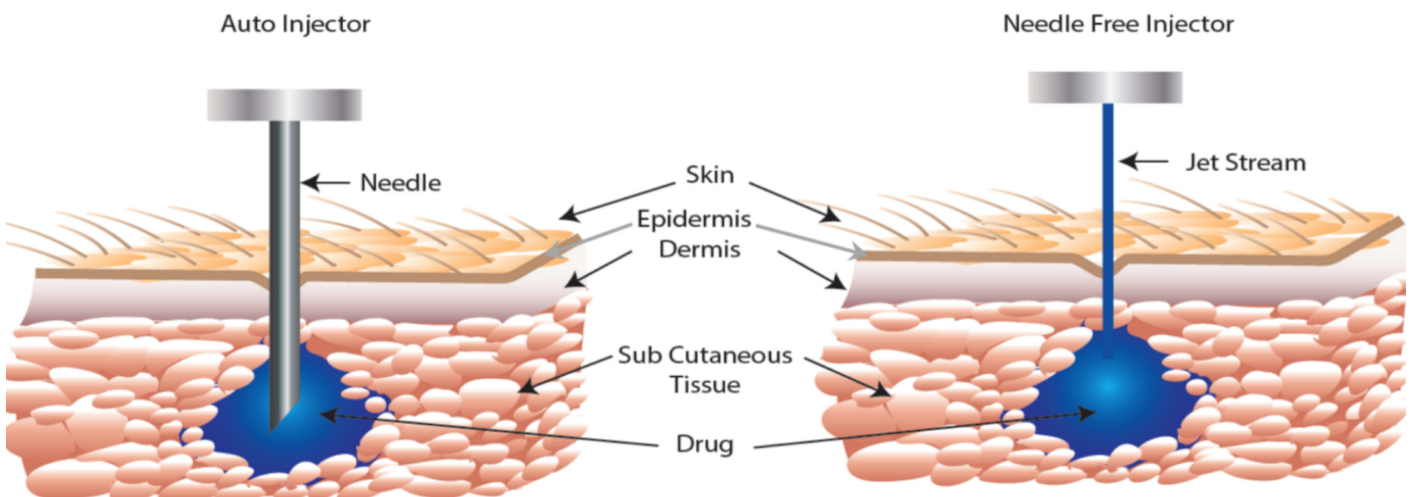


Figure 3: A high pressure, narrow jet pierces through the epidermis, delivering drug into the subcutaneous space.

27 Gauge

400 µm diameter needle



31 Gauge

260 µm diameter needle



PORTAL

200 µm diameter liquid drug jet



Figure 4: Diameter comparison of Portal's Prime device versus needle & syringe.

“With data and analysis, teams will be able to identify challenges related to adherence, predict trends in patient populations, and use that data to create a better patient experience.”

In Prime's closed-loop system, the computer-controlled motor and internal feedback control system work together to sense the pressure and adjust the velocity of the jet-stream accordingly. The device also provides feedback to the patient to lead them through the injection process, and to confirm that the injection has been completed.

The Prime device has been successfully tested with a wide array of drugs, from

small molecules to peptides and mAbs over 60 cP. Regardless of the viscosity, the subcutaneous injection is able to be administered in less than 0.5 seconds.

CONNECTIVITY & ANALYSIS TO DRIVE OUTCOMES

As with many modern advanced drug delivery technologies, the Prime needle-free device logs all injections and can be automatically connected to a secure cloud server, presenting patients with the ability to track their injections without having to input their data manually. Portal's vision is for this data to provide real-time adherence insights which can ultimately be used by healthcare teams, and others, to drive better outcomes. For example:

- Pharmaceutical partners can analyse aggregated and anonymised data to enhance pharmaceutical lifecycle management and use the quantitative

insights to launch specific, targeted campaigns that drive population penetration and adherence programmes.

- Patient service providers can quickly identify “late doses” before they become “missed doses” and be proactive in reaching out to patients who may need support.
- Patients may choose to share this data with their physicians in order to have a more well-rounded picture of the progression of their disease. This insight may create more efficient physician visits and more tailored treatment plans.
- Payers could use this adherence data to inform value-based contracts that are dependent on adherence.

With data and analysis, teams will be able to identify challenges related to adherence, predict trends in patient populations, and use that data to create a better patient experience. It may also lead to trends that were previously undetected becoming noticeable.

DARE TO BE DIFFERENT

It is not uncommon for companies to tout innovation as a core pillar. There are several areas in which companies can innovate beyond the science of drugs to strengthen their positions as leaders. Drug delivery is an obvious choice for innovation as it can involve cutting-edge technology, lead to patient and physician preference, and set oneself apart by being radically different from a field of autoinjectors or prefilled syringes that are all fairly similar. Nevertheless, choosing to go with a new delivery solution may feel unfathomably risky versus staying with the tried-and-true needle and syringe.

Fortunately, Portal instruments has identified and systematically de-risked the major concerns while developing its needle-free injector:

- Over 16 mAbs have been successfully tested for structural and functional integrity



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- Animal models have been built to analyse the fluid path and disbursement
- Pain and preference studies have been conducted in Institutional Review Board (IRB) approved human clinical trials
- Numerous human factors studies have been conducted.

For companies that would like to test a particular asset with the Portal needle-free device, there is a straightforward evaluation process. The main question that pharmaceutical firms should be asking themselves is – what if my competitors go needle-free? Is there more risk in the status quo or being on the forefront of innovation?

ABOUT THE COMPANY

Portal Instruments is a clinical-stage connected drug delivery firm, commercialising a next generation, needle-free drug delivery platform to transform the treatment experience for patients suffering from chronic diseases such as ulcerative colitis, multiple sclerosis, rheumatoid arthritis and psoriasis. Portal is looking to develop strong partnerships with pharmaceutical firms seeking to gain an edge by offering their therapeutics fully integrated with a digital, patient-centric delivery system.

REFERENCES

1. Ravi AD et al, "Needle Free Injection Technology: A complete insight". *Int J Pharm Investig*, 2015, Vol 5(4), pp 192–199.

ABOUT THE AUTHOR

Barbara Taylor is the Senior Director of Marketing at Portal Instruments. With over 20 years' experience in health tech strategy and marketing, she brings to Portal expertise in healthcare software development, new product introduction, lifecycle and service strategy and business model innovation. Prior to Portal Instruments, Ms Taylor was at a number of large and small firms including Philips Healthcare and Mercer Management Consulting. Ms Taylor holds an MBA from the Kellogg Graduate School in Evanston, IL, US, and a BS in biology from the University of Michigan in Ann Arbor, MI, US.



2019 EDITORIAL CALENDAR

Publication Month	Issue Topic	Materials Deadline
Jan 2019	Ophthalmic Drug Delivery	PASSED
Feb 2019	Prefilled Syringes & Injection Devices	Jan 3rd 2019
Mar 2019	Skin Drug Delivery: Dermal, Transdermal & Microneedles	Feb 7th 2019
Apr 2019	Pulmonary & Nasal Delivery	Mar 7th 2019
May 2019	Injectable Drug Delivery	Apr 4th 2019
Jun 2019	Connecting Drug Delivery	May 2nd 2019
Jul 2019	Novel Oral Delivery Systems	Jun 6th 2019
Aug 2019	Industrialising Drug Delivery Systems	Jul 4th 2019
Sep 2019	Wearable Injectors	Aug 1st 2019
Oct 2019	Prefilled Syringes & Injection Devices	Sep 5th 2019
Nov 2019	Pulmonary & Nasal Drug Delivery	Oct 3rd 2019
Dec 2019	Connecting Drug Delivery	Nov 7th 2019

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Needle Free Injections



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helping patients take control of their chronic disease*



Portal Instruments Inc. • 617.500.4348 • www.portalinstruments.com • info@portalinstruments.com

*Kojic, N., Goyal, P., Lou, C.H. et al. *AAPS PharmSciTech* (2017) 18: 2965. <https://doi.org/10.1208/s12249-017-0779-0>

** The Portal device can deliver 1ml of drug in 1/3 of a second per Portal internal studies