Drug delivery

solutions you can trust

Proven experience developing innovative solutions, extending from platform products to bespoke services for drug delivery.

Owen Mumford
Pharmaceutical Services

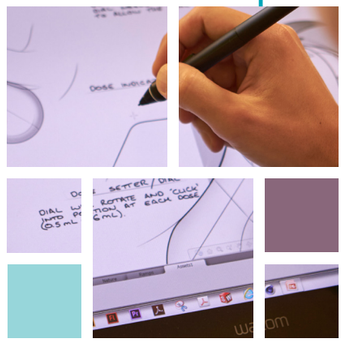
With more than 65 years' experience, your device is in trusted hands with Owen Mumford Pharmaceutical Services

From day one, we will guide you throughout the development process; at every step, you will benefit from professional and supportive project management, processes, industrialisation and production for a smooth development and launch.

Consultation

We listen to your needs to determine the best solution, drawing on our experience of multiple primary containers, formulations and therapies.

From simple rebrands of an existing technology to wholly bespoke designs – **we can help you achieve your goals**.



Design

A multi-disciplinary team of professionally qualified experts ensures that design concepts **meet your exact requirements.** Their thorough understanding of your end-users' needs includes the incorporation of human factors and ergonomics studies.

Develop

A close collaboration between design, production and your own team will ensure your device is designed for manufacture while still **keeping patient satisfaction in mind.**

Deliver

The production of your device is **tailored to your needs** - from low-volume hand assembly to high-volume automation. We are also licensed for the final assembly of combination products.

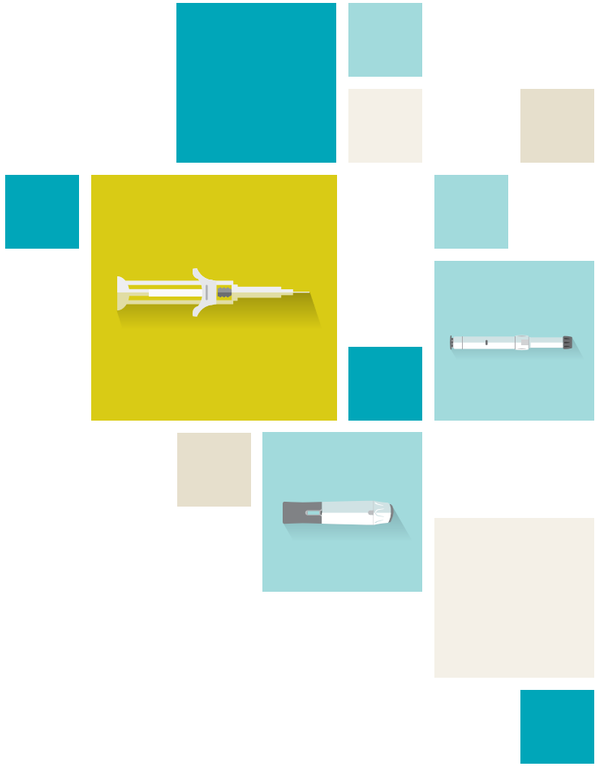
Continuous improvement

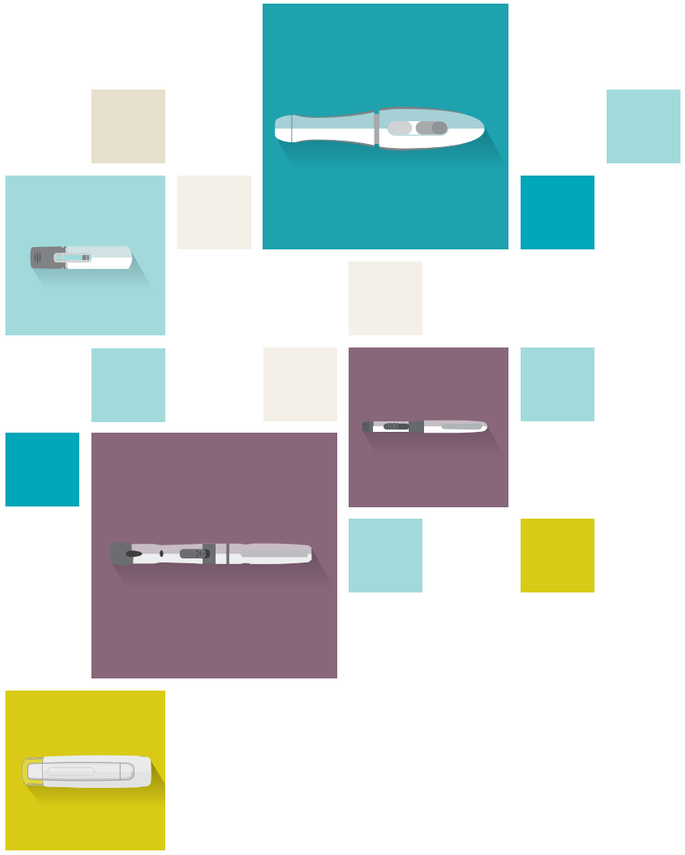
As markets, regulations and formulations change, your device requirements can evolve. **Through continuous improvement, we can help ensure these needs are met.**

Self-Injection Devices

Ensuring that patients are willing and able to inject their medication is key to their well-being.

As pioneers in self-injection technologies, our experience enables us to effectively work with you to find the right drug delivery solution.





UniSafe®

A springless, passive safety device for 1mL pre-filled syringes, designed for simple assembly and use.

TALK TO US ABOUT NEW SOLUTIONS IN OUR UNISAFE® FAMILY

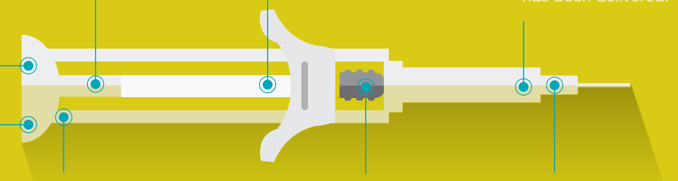
COMFORT
Large, ergonomic plunger head and a smooth, integrated finger flange, resulting in an integrated look and feel.

RELIABILITY
Prevention of accidental activation e.g. in transit.

SECURE PLUNGER
Plunger cannot detach when removing the RNS.

SIMPLE 2-STEP ASSEMBLY
Final assembly process is simple and can be outside of the sterile filling area.

USER CONFIDENCE
Syringe barrel is unobscured, allowing the user to check the contents of the syringe, and to confirm the full dose has been delivered.



COST EFFECTIVE
Designed to work with standard, pre-filled syringes which means no change to existing primary container and minimises training costs.

REDUCED RISK
No compromise to sterility in assembly - plunger does not touch the stopper.

PASSIVE SAFETY
Passive needle retraction means that the needle is shielded as soon as the plunger is fully depressed.

As easy as...

1. Remove the needle shield and insert needle into the skin at the injection site
2. Fully depress the plunger to evacuate the drug in the same way as a normal pre-filled syringe. Remove the device from the injection site and dispose in a sharps container.

Specification

Disposable	✓
Passive needle safety	✓
Standard glass syringe	✓
Syringe type	Glass pre-filled syringe
Reusable Auto-injector solution	✓
Fixed dose	✓
Subcutaneous	✓
Manual activation	✓
Needle hidden after injection	✓
Visual and tactile end of dose indication	✓
High volume manufacture and assembly	✓

Case study

Designed to enhance confidence when injecting.

UniSafe® has no spring which means:

- User confidence as the syringe barrel is unobscured
- Safer in transit
- Cost effective
- Simple final assembly

The Challenge
The task here was to develop a passive safety device which can overcome challenges associated with springs in safety syringes. Typically, there are common approaches to developing a safety syringe. The first option is to start with an existing proven pre-filled syringe and build a spring driven safety mechanism around it; but this can introduce other compromises to device performance. A second is to design a completely new safety syringe to make a brand new solution, however this would necessitate the use of an unproven primary container and can therefore be considered unattractive.

It's predicted that the **demand for safety syringes** will **increase** at **9.7%** Compound Annual Growth Rate (CAGR)[1]

The Solution
Owen Mumford has developed UniSafe®, a springless, passive safety device designed to work with standard, pre-fillable syringes. This means nothing that touches the drug needs to change.

UniSafe® is designed to increase patient confidence when injecting, eliminating the possible risks and challenges of sprung syringes.

Engineering Design
Early formative studies gave Owen Mumford further confidence in the UniSafe® concept as well as helping further enhance usability. The finger flanges have been made smoother, creating a more integrated look and feel, and the plunger head has been made larger for easier handling. It is vital to encourage adherence and help patients effectively self-manage their condition by providing devices that are intuitive and easy to use, for both patients and healthcare providers. UniSafe®

References
1. Industry Today (September 16, 2015). Safety Market ReportL A new market report published by Transparency Market Research.

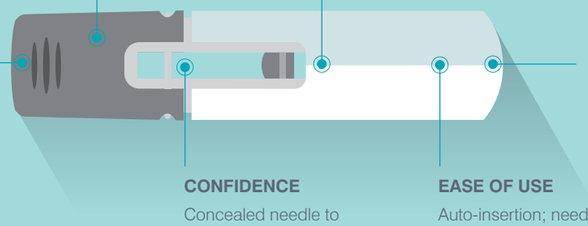
Autoject® Micro

Single-use auto-injector with automatic needle insertion in a compact body

COMFORT
Ergonomic oval design, with large grip detail on the cap.

PRACTICAL
Convenient size for storage and portability.

SAFETY
Protective cap and locking mechanism prevent accidental activation. Needle is hidden before and after use with Sharps Injury Prevention.



INTUITIVE
Use as a press-button or pressure-activated device. The activation button appears when device is unlocked and ready to use.

CONFIDENCE
Concealed needle to reduce injection anxiety plus large viewing window for easy viewing of syringe.

EASE OF USE
Auto-insertion; needle is inserted and dose delivered at the touch of a button, with audible and visual feedback at the start and end of dose.

As easy as...

1. Remove the needle shield and insert needle into the skin at the injection site
2. Fully depress the plunger to evacuate the drug in the same way as a normal pre-filled syringe
3. The needle then retracts and is locked into the device

Specification

Disposable	✓
True auto-insertion	✓
Needle hidden before injection	✓
Safety lock to prevent accidental activation	✓
End-of-dose indication	✓
Needle shield removal feature	✓
Fixed dose	✓
Syringe type	Glass pre-filled syringe
Subcutaneous	✓
Intramuscular	✓

Case study

A true auto-injector with automatic needle insertion in a compact body

Autoject® Micro is the next generation disposable auto-injector. Its compact design is the result of patented drive mechanism technology and an aim to improve adherence – and, ultimately, minimise your cold store and logistic costs.

The Challenge

For many patients, being prescribed an injectable medication means their condition is serious. Anxiety about self-injecting is one of several factors which can negatively impact adherence. Providing patients with a device suited to them may help break down barriers to self-injection.

84%
of patients **prefer a pre-filled device** over a reusable device or vial and syringe [4]

The Analysis

One of the most significant challenges is ease of use – particularly where dexterity can be an issue, for example RA and MS.

Another concern with self-injection is the physical and psychological pain associated with administration. Whilst drug formulation is a major factor of administration pain, a device that helps reduce or alleviate injection pain is a significant unmet need in many conditions. Ease of penetrating the skin is a factor which may help reduce perceived injection pain.[1]

Engineering Design

Autoject® Micro is an example of a new technology developed from a demand for compact, discreet self-injection options. This compact design, which is the result of a patented drive mechanism, offers patients a convenience with storage, as well as portability. The smaller package also has the potential to lower cold store and logistics costs.

It is also capable of supporting two methods of activation. These features can provide patients with a greater sense of control over their treatment – giving them confidence to take it as prescribed.[3]

Our Insight

Owen Mumford understands how the right device and routine can positively influence adherence rates and help make treatments manageable and effective for patients. Hence, Autoject® Micro has been designed to improve adherence by overcoming barriers to self-injection, providing a versatile platform that can be adapted for a range of conditions.

50%
of patients with **chronic conditions** are **not taking medicines as prescribed** [2]

References

1. Data on file
2. World Health Organisation. Adherence to long term therapies. 2003
3. Owen Mumford. Auto-inectors. Autoject Micro.
4. Beer K., Müller M., Hew-Winzeler A.M. 'The prevalence of injection-site reactions with disease-modifying therapies and their effect on adherence in patients with multiple sclerosis: an observational study' BMC Neurology 2011; Nov 10 11:144

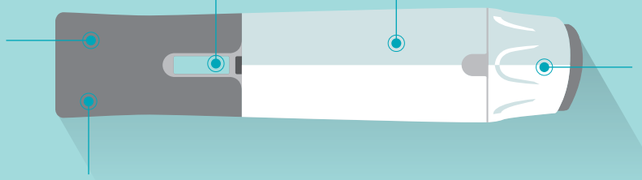
Autoject® Visco

A disposable auto-injector developed for high viscosity formulations

SAFETY
Protective cap and locking mechanism prevent accidental activation. Needle is hidden before and after use with Sharps Injury Prevention.

CLEAR VISIBILITY
Large drug viewing window.

LARGE AREA FOR BRANDING



TECHNOLOGY
Quiet on activation with minimal vibration using a velocity regulator mechanism.

DOSE ACCURACY
Self-priming – prepares the device for precise dose accuracy and reduces user steps.

As easy as...

1. Remove cap which removes the needle shield and primes device
2. Place device on injection site, press button to inject
3. Audible and visual indication signifies end-of-dose; needle shroud prevents injury

Specification

Disposable	✓
True auto-insertion	✓
Needle hidden before injection	✓
Safety lock to prevent accidental activation	✓
Visual end-of-dose indication	✓
Needle shield removal feature	✓
Fixed dose	✓
Syringe type	Glass pre-filled syringe
Fixed/removable needle options	✓
Subcutaneous	✓
Intramuscular	Optional
Variable dose	✓

Case study

Autoject® Visco
A disposable auto-injector
developed for high viscosity formulations

The Challenge
The objective for Owen Mumford was to develop a high viscosity disposable auto-injector - which also featured variable dosing and high levels of dose accuracy using a standard pre-filled syringe.

Engineering Design
One of the challenges of working with high viscosity formulations is around the use of a larger spring and the higher noise level when the device is activated. In order to address this, we developed a velocity regulator, which works by progressing the syringe forward in a more controlled manner and minimising noise levels during activation, as well as helping to maintain syringe integrity.

The Analysis
The Autoject® Visco is developed for high viscosity drug formulations which include a high force spring so that the drug will be delivered within the desired delivery time. Our customer had several unique requirements, including a variable dose as weight based dosing was required for the drug, and precise dose accuracy requirements due to drug action, meaning that priming was required to ensure a consistent stopper location of the pre-filled syringe.

The Solution
When a customer approached us with their requirements of a variable dose device with dose accuracy, Autoject® Visco could meet their needs with the following features:

- Self-priming - prepares the device for precise dose accuracy
- Quiet on activation with minimal vibration, despite an energy spring
- Audible and visual end-of-dose indication
- Automatic needle insertion and drug delivery – for true auto-injection
- Lockout shroud function to prevent needle stick injury
- Large drug window for easy viewing
- Multiple colour variants for easy dose recognition

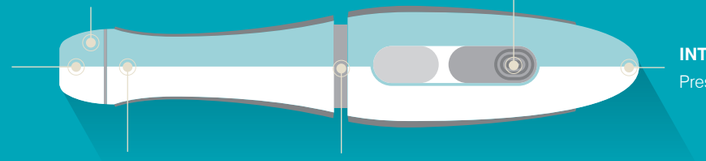
Autoject® 2

The versatile auto-injector proven across multiple therapy areas

EASE OF USE
True auto-injection; needle is inserted and dose delivered at the touch of a button, with visual feedback at the start and end of dose.

ADJUSTABLE NEEDLE DEPTH

PRACTICAL
Safe and easy needle shield removal for both rigid and soft needle shields.



INTUITIVE
Press-button activation.

CONFIDENCE
Concealed needle to reduce injection anxiety.

SAFETY
Interlock mechanism prevents accidental activation until device is pressed against skin.

As easy as...

1. Prime device and load syringe
2. Place against skin and press button
3. Marker indicates when the dose is delivered

Specification

Refillable	✓
Button activation	✓
True auto-injector	✓
Needle hidden before injection	✓
Safety lock to prevent accidental activation	✓
Visual end-of-dose indication	✓
Needle shield removal feature	✓
Fixed dose	✓
Syringe type	Glass pre-filled or plastic Syringe
Fixed/removable needle options	✓
Subcutaneous	✓
Intramuscular	✓

Case study

The versatile **auto-injector proven across multiple therapy areas**

The Challenge

Multiple Sclerosis (MS) is a chronic and debilitating inflammatory disease of the central nervous system and currently affects 2.5 million people worldwide.[1] One particular treatment (interferon beta-1b) has shown some impressive results by reducing all-cause mortality by 47% at 21 years.[2] Poor patient adherence to interferon beta-1b is often the result of adverse events relating to injectable therapies, like anxiety of injecting,injection site pain (ISP) and injection site reactions (ISRs).[1]

The Analysis

We created an original injection device for Extavia®, an interferon beta-1b, based on our clinically robust and successful auto-injector platform: the Autoject®2. This platform not only helps minimise ISP and ISRs, but also makes injecting easier and reduces patient anxiety.

86%
of patients preferred **ExtaviPro® 30G** over a competitor device

Engineering Design

The new device, called ExtaviPro® 30G, is more ergonomically designed; assisting one-handed use and enhancing patient confidence when injecting.[3] Constant force spring technology is also incorporated to enhance ease of use.

Patient Responses

The most common reasons for this preference were the ergonomic shape of the device, easy operation, reach and being able to inject one-handed. All these attributes are associated with convenience, which is an important factor that increases adherence and can shift patient preference from one auto-injector to another.[3]

Our Insight

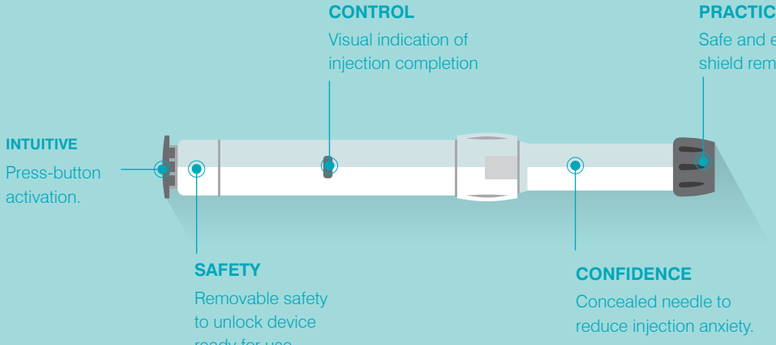
The ExtaviPro® 30G has been shown to solve some aspects of low adherence – and, as a result, increases drug administration. With greater adherence, there are not only better health outcomes for patients, but also better commercial outcomes for pharmaceutical companies.

References

1. Menzin J et al. Narrative R3view of the Literature on Adherence to Disease-Modifying Therapies among Patients with Multiple Sclerosis. Supplement to JMCP 2013; 19(1-a):S24-33
2. Boeru G et al. ExtaciJect®30G device for subcutaneous self-injection of interferon beta 1-b for multiple sclerosis: a prospective European study. Medical Devices: Evidence Research. 2013; 6:175–184
3. Thakur K et al. Autoinjectors for administration of interferon beta-1b in multiple sclerosis: patient preferences and the ExtaviPro™ 30G and Betacomfort® devices. Pragmatic and Observational Research. 2013; 4:19-26

Autoject® Mini

The simple auto-injector platform trusted for use with blockbusters and emerging brands alike



As easy as...

1. Remove needle shield first, then unlock activation button
2. Place on injection site and press button
3. Indicator shows when dose is complete

Specification

Refillable	✓
Disposable	✓
True auto-injector	✓
Needle hidden before injection	✓
Safety lock to prevent accidental activation	✓
Visual end-of-dose indication	✓
Needle shield removal feature	✓
Fixed dose	✓
Syringe type	Glass pre-filled syringe
Subcutaneous	✓
Intramuscular	✓

Case study

The simple auto-injector platform **trusted** for use with **blockbusters** and emerging brands **alike**

The Challenge

Anaphylaxis is a serious and severe allergic reaction that affects the whole body; it is often life threatening, and in severe cases, the cardiovascular system can completely collapse. Although anaphylaxis is treated with an intramuscular injection of adrenaline into the thigh, it still kills 0.65%-2.0% of patients who experience and episode.[1] The main cause of anaphylactic fatalities is the late injection of adrenaline, which leaves symptoms to worsen resulting in death.[2]

The Analysis

Common mistakes patients make when injecting include: not removing the safety cap, operating the device upside down, injecting into the arm, and not pressing the device hard enough to deploy the needle and adrenaline.[3]

Engineering Design

The new Anapen® 2 was designed to solve the problems training alone could not. The Autoject® Mini has an established and trusted profile amongst clinicians and patients, and proved an ideal platform for the development project.

If patients use a device that **consistently performs,** this not only **reduces wastage of medicine,** but **increases patient confidence**

Our Insight

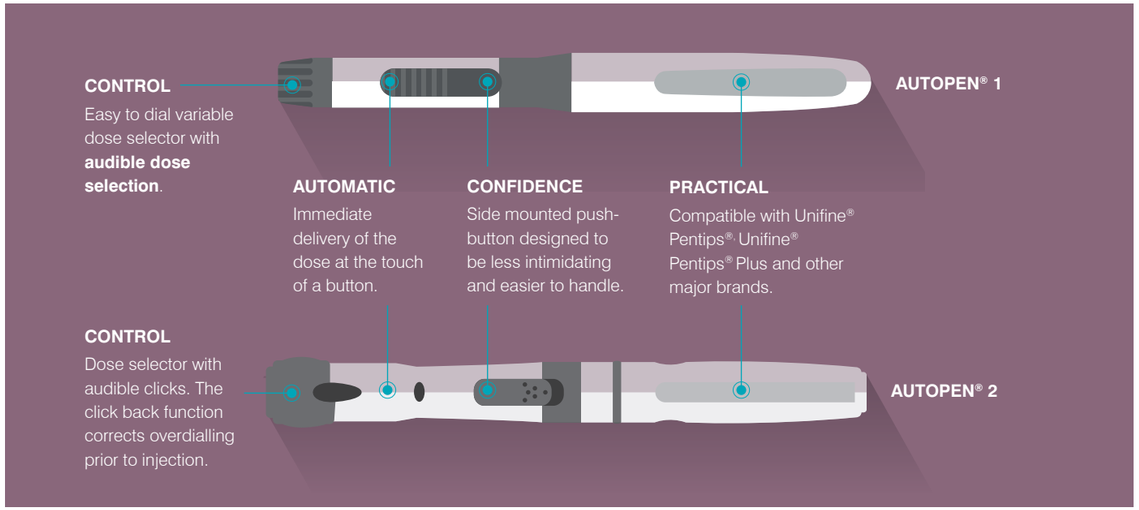
If patients use a device that consistently performs, this not only reduces wastage of medicine but increases patient confidence. This allows the patient to manage their anaphylaxis more pro-actively by using their device and injecting as appropriate, rather than waiting for symptoms to worsen.

References

1. Frew AJ. What are the ideal features of an adrenaline (epinephrine) auto-injector in the treatment of anaphylaxis? Allergy 2011; 66:15–24
2. Schwirtz A, Seegar H. Comparison of the robustness and functionality of three adrenaline auto-injectors. Journal of Asthma and Allergy 2012; 5:39–49
3. Lombardelli S. (2010, June) Adrenaline auto-injectors: how effective are written patient instructions when used alone in a simulated self-administrration test? Presented at Exhibition Hall, Hungerford UK

Autopen® 1/Autopen® 2

The first injection pen with side-button automatic delivery



As easy as...

1. Load cartridge and attach pen needle
2. Adjust dosage with the dose selector
3. Push the side-mounted button to automatically deliver dose

Specification

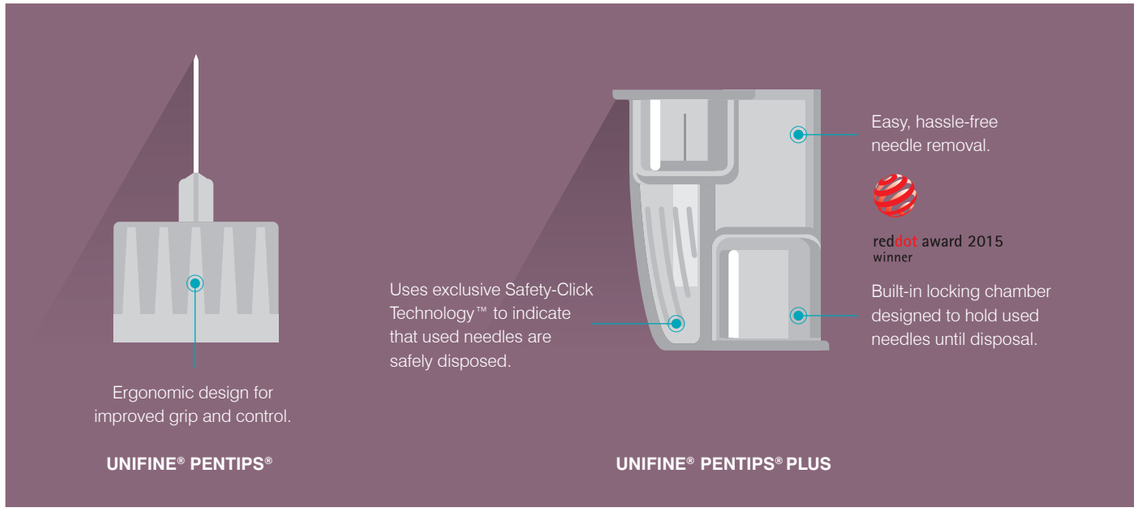
Refillable	✓
Disposable	✓
Needle hidden after injection (when used with safety needle)	✓
Visual end-of-dose indication	✓
Multi-dose	✓
Variable dose	✓
Cartridge size	1.5 mL, 2.0 mL and 3.0 mL
Adjustable needle depth	4, 5, 6, 8 and 12 mm

Designed to be less intimidating than a plunger and easier to handle.

Autopen platforms have been trusted by **2/3** of the largest insulin suppliers.

Unifine® Pentips®/Pentips® Plus

Pen needles with advanced proprietary siliconisation for smoother injections



Specification — Unifine® Pentips®

	12mm	8mm	6mm	5mm	4mm
Proprietry siliconisation process for comfort	Yes	Yes	Yes	Yes	Yes
Needle gauge	0.25mm (31G)	0.25mm (31G)	0.25mm (31G)	0.25mm (31G)	0.23mm (32G)
Compatible with all major diabetes medication pens	Yes	Yes	Yes	Yes	Yes

Specification — Unifine® Pentips® Plus

	12mm	8mm	6mm	5mm	4mm
Proprietry siliconisation process for comfort	Yes	Yes	Yes	Yes	Yes
Needle gauge	29G	31G	31G	31G	32G
Compatible with all major diabetes medication pens	Yes	Yes	Yes	Yes	Yes

Self-injection device overview

Platform	UniSafe®	Autoject® Platforms				Autopen® Platforms	
		 Autoject® Micro*	 Autoject® Visco*	 Autoject® Mini	 Autoject® 2	 Autopen® 1	 Autopen® 2
Features							
Refillable				■	■	■	■
Disposable	■	■	■	■		■	■
Subcutaneous	■	■	■	■	■	■	■
Intramuscular		■	■	■			
User-adjustable needle depth					■	■	■
Auto-insertion of needle		■	■	■	■		
Pre-filled Syringe							
1.0 mL	■	■	■	■	■		
2.25 mL	■	■			■		
Cartridge							
1.5 mL						■	■
3.0 mL						■	■
Viscosity							
1-2 cP	■	■	■	■	■	■	■
High viscosity		■	■		■		
Dosing							
Multi-dose						■	■
Fixed dose	■	■	■	■	■		
Variable dose			■			■	■
Activation							

Platform	UniSafe®	Autoject® Platforms				Autopen® Platforms	
		 Autoject® Micro*	 Autoject® Visco*	 Autoject® Mini	 Autoject® 2	 Autopen® 1	 Autopen® 2
Pressure		■					
Button		■	■	■	■	■	■
Manual	■						
Safety							
Needle hidden before injection		■	■	■	■		
Needle hidden after injection	■	■	■			■	■
Safety lock to prevent accidental activation		■	■	■	■		
Visual end of dose indication	■	■	■		■	■	■
Audible end of dose indication		■	■				
Needle shield removal feature		■	■	■	■		

■ Standard ■ Optional

* Device in development

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