



A New Force in Drug Delivery Devices

Supporting High Viscosity and High Volume Needs Through Partnership

Steven Kaufman, Global Business Development Lead

Bespak Europe Ltd.

Evolution of Bespak over 58 Years

Who We Are

- Design, develop, & manufacture drug delivery devices, specifically auto injectors
- Broad range of moulding, tooling & assembly capabilities
- Parent Company Consort Medical CSRT:LSE
- ISO 13485 / FDA Audited
- Six Sigma quality levels
- Strong regulatory/post-market surveillance expertise
- Scalable production to 100s of millions of units per annum



Evolution of Bespak over 58 Years

Who We Are

- Commercial drug handling license
- Final Assembly of auto injectors with sister company Aesica, cold chain management with capacity to handle millions of auto injectors annually
- Expanded production with manufacturing sites in King's Lynn & now setting up Milton Keynes, UK facilities
- Expanded our design/development teams Innovation Centre, Cambridge, UK



Evolution of Bepak over 58 Years

Launched Bepak Technology

- Generic injectable, aqueous
- A 3-step, button activated auto injector with automatic needle retraction
- Device based on the Bepak ASI spring-based power pack
- FDA approved, launched in Q1 2014
- Millions of devices already on the market
- Positive patient uptake
- FTO & diverse IP / Patent portfolio in the area of injection devices such as auto injectors



Evolution of Bespak over 58 Years

Launched Bespak Technology

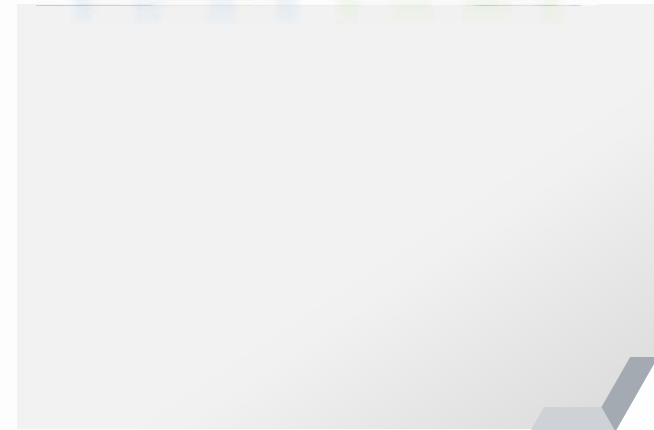
- EMA approved 'AutoClicks' device Sept 2016
- Launched soon afterwards in a number of countries
- Design & development involved a broad range of expert partners & consultants
- Simple 2 step operation
- Unique 'good grip' feature for RA patients
- Large transparent cap that's easy to remove
- Customized packaging for RA patients
- Intuitive design
- Utilizing Bespak ASI spring-based technology that can deliver high viscous injectables



Trends & Challenges in the Device Market

What is Everyone Talking About?

- High Viscosity & Higher Volume
- Wearables
- Regulatory
- Human Factors
- Electromechanical devices
- Connectivity
- IP, FTO & Know-how
- Platform auto injectors
- Risk mitigation
- New technologies



Trends & Challenges in the Device Market

What is everyone talking about?

- New patient groups require customized self-injection devices
- Increased demand for a broader range of devices
- Biopharma companies seek to differentiate / compete
- Limited number of suppliers



Trends & Challenges in the Device Market

Patient Adherence

- Remains an issue that we need to overcome
- More than 15% of prescriptions are never filled
- Up to 40% of patients go off their treatment in the 1st 90 days
- One study¹ of an emergency use IM auto injector found that only 44% used proper auto injector techniques to administer medication

Source¹: Goldberg A, Confino-Cohen R.
Insect sting-inflicted systemic reactions: attitudes of patients with insect venom allergy regarding after-sting behavior and proper administration of epinephrine.
J Allergy Clin Immunol 2000;**106**:1184–1189.



Trends & Challenges in the Device Market

Selecting Consultants

Consultants can make a real difference in the device programs of biopharma:

- Device Landscaping
- Human Factors Study
- Program Management
- Regulatory Support
- Post Market Surveillance



Trends & Challenges in the Device Market

Viscosity, Volume & Time

- Increasing volumes beyond 1.2 – 10ml
- 2.25ml auto injectors are now here at 2ml
- Viscosity can cause serious issues with completeness of injections
- Target injection times of ≤ 10 seconds
- Breakage, siliconisation, flange and RNS remain concerns for PFS



What is Vapoursoft?

A New Force in Drug Delivery

- Novel container of liquefied gas provides sufficient energy as pressurised vapour to power delivery
- HFA propellant refers to hydrofluoroalkanes commonly used in industry for many years, most well known in the medical field for its use as a propellant in asthma inhalers/puffers
- Based on proven valve technology with over 2 billion produced to date



What is Vapoursoft?

A New Force in Drug Delivery

- Compact, flexible energy source to power drug delivery, ideal for highly viscous drugs
- Range of liquefied gases available providing the complete spectrum of delivery performance within the single novel container format
- Dampened nature of delivery avoids impacts, ideal for glass primary containers, minimize breakage
- Enables 2 product lines:

Syrina

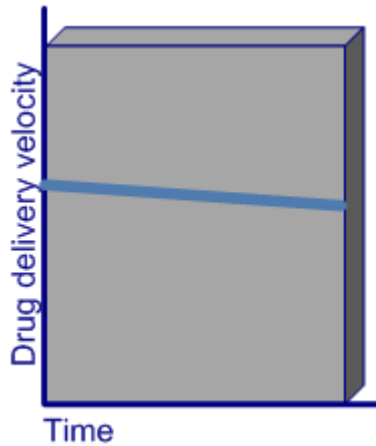
 *Lapas*

HFA Type	Pressure
	Barg
227	2.9
423A	4.0
134a	4.7
437a	5.4
417a	6.8
407C	7.6
422d	8.0
422a	9.7
507	10.0
410	13.0

What is Syrina?

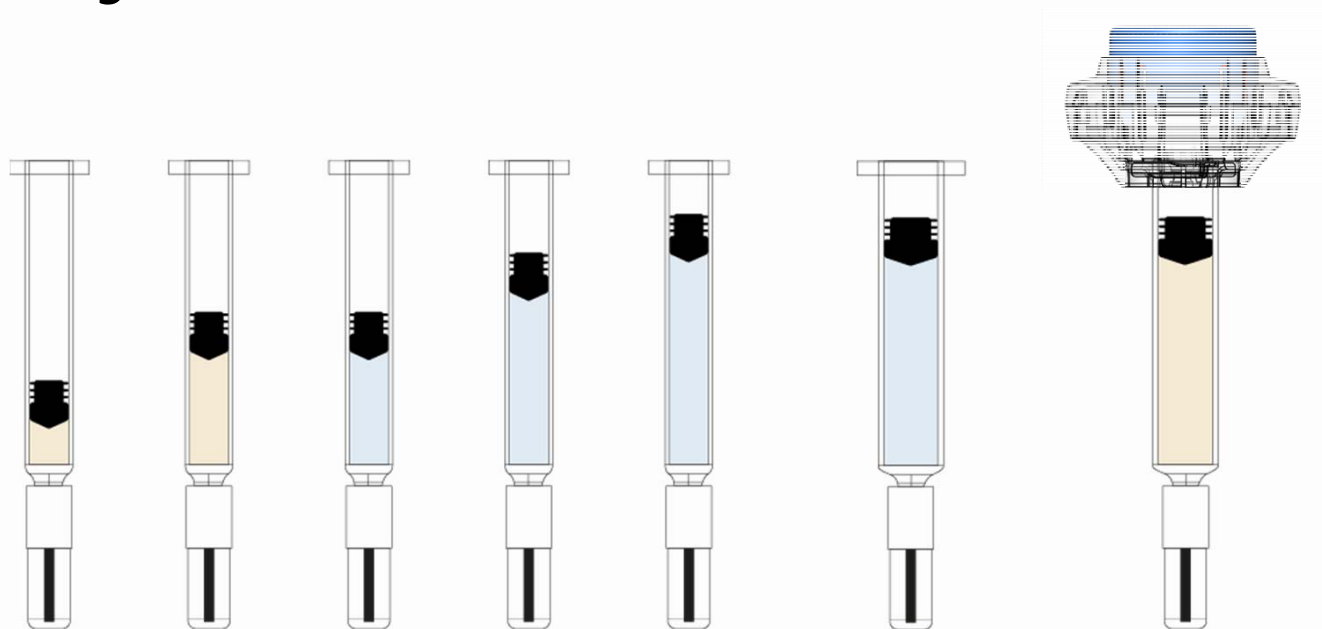
Full Range of Drug Delivery Devices

- Five devices with one identical delivery profile



Compatibility

A True Platform



Pre-filled Syringe	1mL					2.25mL	
Viscosity	high	high	low	low	low	low	high
Delivery Volume	Low - Average					High	

Syrina S Platform

Features

- Compact design allows for unique, non-linear form factors
- Suitable for all standard PFS
- 1ml or 2.25ml with one minor component change
- Suitable for aqueous solutions & viscous drugs up to 300cP & higher
- Simple two-step injection
- Tactile, audible and visual indication
- Soft start to injection eliminating syringe breakage



Syrina | S
2.25

Syrina AR

Features

- Incorporates standard 2.25ml PFS
- Suitable for aqueous or viscous drug
- Simple two-step injection
- Tactile, audible and visual indication
- Automatic needle insertion
- Soft start to injection eliminating syringe breakage
- Dwell at end of injection prior to needle removal
- Active needle safety system automatically retracts needle

Performance with 27G ½" TW Needle

- 2ml 20cP silicone oil <10 seconds
- 2ml 50cP silicone oil in 15 seconds



Syrina | AR

Final Assembly

Experienced Handling Auto Injectors

- Both Bespak & Aesica have the are licencing to handle drug product
- Aesica has had more than 10 years experience in the assembly of millions of auto injectors
- Range of secondary packaging options such as blister packs, trays and cartons
- Large 250 pallet cold store (2-8°C) & cold chain management
- Flexible serialisation cell in place to meet EU & known RoW requirements for serialisation



Partnership

Experience

- Proven design, development capabilities & manufacturing quality
- Millions of Auto injectors using Bespak technology currently on the market
- Expertise in high volume production & scale up from lower volumes
- Experience in the final assembly of high & low volume quantities of auto injector, including labelling, packaging & serialization

Innovation

- We are a technology innovator, expanding our market presence in the injectable device field with both spring-based & VapourSoft-based devices
- Specializing in viscous delivery & platform development of injection devices
- Experienced innovation team



Visit Us At Stand X80

- Ask for Private Meetings
- Ask for Demonstrations of our Next Generation Technology
- Ask questions after the conference: enquires@bepak.com

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