Delivering a True ‘Platform’ Autoinjector – Customisable vs Configurable vs Adaptive

A Case Study focused on a device without customised components whilst achieving a wide performance capability

Introduction

On the design journey to creating a new autoinjector OwenMumford Ltd made assessments of what a true platform device should offer and evaluated solutions presented as sub-categories of device.

A definition of a platform autoinjector: A needle insertion system designed to work with a variety of syringe types (1 and 2.25ml), associated removable needle shields, varying fill volumes within the primary container and a range of drug viscosities. The platform should offer a minimal number of change parts to accommodate the offered primary packaging and drug.

A choice

The sub categories defined and evaluated:

Customisable: custom parts installed in device to accommodate starting position of the stopper.

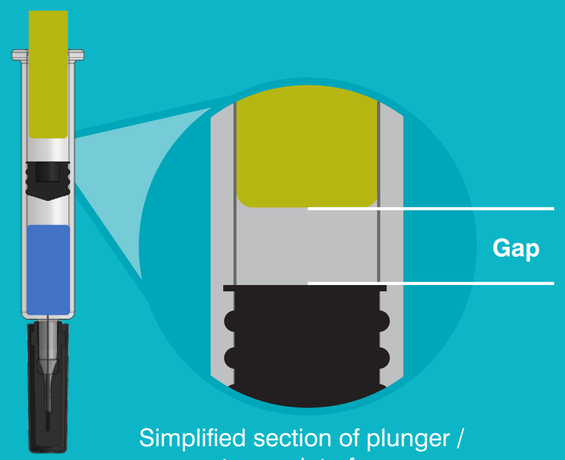
Configurable: pre developed parts selected to set the device to a predefined plunger position and envelope of operation.

Adaptive: device auto configures during assembly process setting the plunger relative to the stopper and has minimal change components to offer the full performance envelope.

Mind the gap

Due to specification of syringe, allowance for tolerancing of parts in device and variation of the stopper height a gap between the stopper and plunger should be implemented.

The greater the gap the greater the speed of impact on the syringe. With high powered springs this impact risks damage to the syringe. How big a gap is too big? Industry-wide experience led to a target of limiting impact speeds to 10m/s.

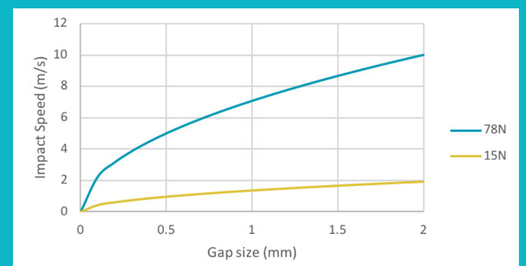


Simplified section of plunger / stopper interface

Handling the Impact speed

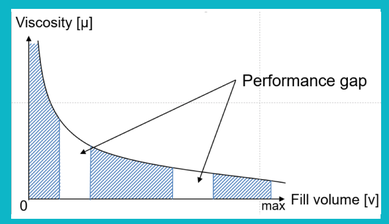
Both customisable and configurable devices can attempt to minimise the gap. As delivery spring forces increase to handle high viscosity drugs the gap must be reduced to avoid excessive impact speeds. In the customisable device this would likely lead to more custom parts.

What is the implication of custom parts?
To our customers this requires greater initial investment in the creation of tooling to produce unique components.
Greater planning required to manage inventory to ensure unique component stock levels match forecasted demand.
Greater levels of documentation and design verification to meet regulatory requirements.

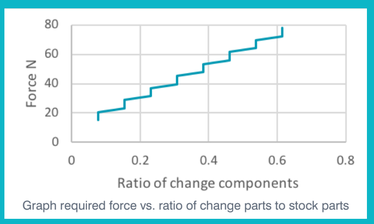


Graph of speed of impact vs. gap size two spring forces shown 78 and 15N (force at the moment of release)

As forces increase to deliver higher volume and/or increasing viscosity, setting positions within the configurable device get closer together. The increase of positions is in conflict with the required material performance to handle increased forces experienced in the device. This leads to greater number of change parts of the configurable device (increasing ratio of change components to platform components)



Filling the performance gaps with additional components



Graph required force vs. ratio of change parts to stock parts

The solution: Adaptive

Allowing the design of the non change parts within the device to create the gap that limits the impact speed to less than the target of 10m/s. By using the non- change components to adapt the device only the plunger, delivery spring and syringe adapter (1 or 2.25ml) change between devices.

The result: A true platform device with no customer specific components with a wide performance envelope.

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Parenteral Drug Association (PDA) Universe of Prefilled Syringes and Injection Devices conference, Oct. 2020

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