



CASE STUDY

MOLLY®

**WINNER OF
GOOD DESIGN
AWARD 2011**

2-STEP ULTRA-COMPACT AUTO INJECTOR DESIGNED FOR EASE-OF-USE AND MAXIMIZED SPEED TO MARKET

The Molly® Auto Injector is a revolutionary, ultra-compact device designed for convenience and portability. With the handling process reduced to only 2 simple steps-uncap and inject, Molly® is incredibly intuitive to use and quickly became a new benchmark for the auto injector industry. In addition to the many enhanced features that benefit patients, Molly® was also uniquely designed to offer an alternative business model for customers, one that allowed them to minimize initial investments while maximizing speed-to-market.

Introduced in late 2010 as SHL's first pre-configured auto injector, Molly®'s business model meant that the customer only needed to make minor investments, thus removing the need for individual investments in tooling, assembly and/or test equipment. On top of this more economical business model, Molly® offered some key design advantages and quickly became a highly popular product with customers - and is the base for several current projects. Within one year of its launch, Molly® was awarded as the winner of the 2011 Good Design Award.



DEVICE SPECIFICATIONS

Device Type
Auto Injector

Usage
2-Step Operation
Fixed Dose | Disposable

Primary Container
1mL long syringe with
staked on needle

Activation
Shield Activated

Versions
FNS and RNS

“ The Molly®
Auto Injector
created a new
paradigm in the
market place.
Projects could
start faster and
products could
go into clinical
trials earlier.

- Frederik Stromvall
Project Leader,
SHL Group

THE CONCEPT

For years, SHL had been designing, developing and manufacturing various auto injectors for big pharmas around the world. Each of these projects can often take more than 5 years to complete including clinical trials and scale up and usually results in a highly customized device intended only for its original therapeutic drug.

While SHL recognized the need for customization for some projects, the SHL R&D and business teams also saw the need for a device that offered a faster development time without sacrificing any key design features. Consequently, an internal program was put in place with the goal of innovating a device with technical features that not only surpassed its predecessors, but could be developed rapidly. This project would also need to have a business model in place that allowed tools to be made quickly and significantly reduce the project development time required.

THE CHALLENGE

The auto injector market has been evolving rapidly in recent years and already offered a large range of products with integrated safety features and enhanced usability. To support the need of our customers, the Molly® Auto Injector had to encompass all these key fundamental design features while introducing new improvements such as an ultra-compact size and a simplified 2-step operation. In addition, with the development cost of an auto injector also dependent on the number of components, minimizing Molly®'s component count was important as well.

However, with the number of device components directly affecting functionality, SHL engineers had to design the device with an optimal balance between the two. The device's inner mechanism had to be robust enough to guarantee injection requirements could be met while compact enough to reduce the overall size.

THE SOLUTION

After proposing and testing various creative ideas for a mechanical design that could meet this project's specifications, SHL engineers were able to design a unique power pack that offered the same injection capabilities but with reduced components. At approximately 5cm, this compact mechanism could deliver the desired injection speed and force for a 1mL pre-filled syringe while still offering key design features such as a 2-click audible feedback to indicate the beginning and end of the injection.

Owing to this compact power pack, Molly® measured only 13cm, consisting of minimal components and required just 2 simple steps – uncap & inject. With no activation button, the Molly® is activated by pressing down on the needle cover. To enhance safety, the ideal threshold value was calculated and tested for the shield activation so that the user would have to overcome a small resistance before triggering the injection. At the end of the injection, the needle cover will passively lock to permanently hide the needle for safety.

Taking into consideration potential glass breakage issues with the primary container, Molly® was designed to hold the PFS firmly in place by the neck instead of at the flange, improving force absorption while parts of the rear and body shell provided enough support to keep it in the correct axial position before, during and after injection.

Addressing the economic aspect of Molly®'s business model, the device was made available to customers as a pre-configured device with the spring and color available for adjustments. This model allowed for significant savings as individual investments in additional tooling, assembly and testing equipment can be minimized. In addition, Molly®'s individual components were optimized for manufacturability.

A PRE-CONFIGURED 2-STEP AUTO INJECTOR WITH MINIMAL COMPONENTS AND MAXIMIZED SPEED TO MARKET OPTIONS



“ Developing an auto injector this compact that could still offer robust features was both a true challenge and accomplishment for us.

- Mattias Daniel
Design Engineer,
SHL Group

THE RESULTS

Molly®, SHL's first pre-configured auto injector, introduced an alternative business model for biopharmaceutical companies that desired to start a project with less upfront investment and shortened timeline from clinical trials to being ready-for-submission.

With a simple 2-step operation and an unprecedented compact size, Molly®'s ease-of-use received great feedback from preference studies as well as customers. Not only is Molly® a technology based platform, it has also evolved into a branded platform with its own family of products including variations like the Molly® RNS auto injector.

Finally, SHL offers robust final assembly expertise and equipment in-house for Molly® that enable biopharmaceutical partners to further enhance speed to market and reduce the number of parties involved.

KEY PRODUCT FEATURES:

- › Ultra-Compact Design
- › Simple 2-step Operation
- › Integrated Safety Features
- › Audible, visual and tactile feedback
- › One-Handed Operation
- › Versions for both FNS and RNS

BUSINESS MODEL:

- › Minimized Investment Upfront
- › Maximized Speed to Market

