

DBA Design Effectiveness Awards 2009

SoloSTAR®

A disposable pen injector for insulin



Category:	Product
Sub category:	Consumer
Client company:	Sanofi Aventis GmbH
Design consultancy:	DCA Design International Ltd
Current date:	2nd June 2009

Sanofi Exhibit 2121.001

Executive summary

Pen injectors were introduced over 20 years ago to deliver liquid medication. They allow users to select a dose of medication and inject this via a needle connected to a small reservoir within the pen.

In Europe, Japan and the US, pen injectors are commonly used to deliver insulin for the treatment of diabetes mellitus. In many countries they have largely replaced the traditional vial and syringe because they benefit patients by allowing accurate and easy dosage, whilst being convenient and discrete.

Lantus[®], a new once a day basal insulin, was originally offered in a licensed injector device but in order to sustain the development of the new insulin, Sanofi Aventis decided to begin developing its own pen in 2003. The new device could not be a 'me too' product; it had to offer significant improvements over all other disposable insulin devices on the market.

The design brief was suitably ambitious. In order to satisfy the needs of patients requiring high dose volumes of insulin, the new pen injector had to be capable of delivering a single dose of 80 insulin units (over 30% larger than all comparable devices on the market) with no penalty for comfort and convenience. In addition to being extremely robust, the device also had to satisfy the very high accuracy standards outlined in ISO-11608.

The solution is SoloSTAR[®]. SoloSTAR[®] meets all of these requirements and exhibits significant advantages over previous devices in terms of comfort, safety and ease of use¹. Since its launch in 2007, SoloSTAR[®] has rapidly established itself as a leading disposable pen injector for insulin, accounting for 41% of all growth in the global injectable insulin market in 2008².

(277 words)



Project overview

Outline of project brief

To develop a 'best-in-class' disposable pen injector with the following key features:

- Maximum selectable dose up to 80 units in 1 unit increments.
- Dose correction without penalty, i.e. the possibility to dial back without expelling liquid.
- The lowest injection force in its class.
- User interface design based on good ergonomic principles.
- Simple, obvious operation with no additional steps beyond selecting and dispensing a dose.
- Suitable for extremely high volume manufacture at low cost.
- Safe, robust and reliable.
- Maximum differentiation for devices containing different insulins.

Description

SoloSTAR[®] contains 3ml of insulin, dispensable in single unit increments (0.01ml). The user selects a dose by rotating a dial and injects this volume by simply depressing the dose button.

Improvements over predecessor devices have been achieved in all key areas (from initial learning through to daily usage) and together they provide genuinely important advantages for users. SoloSTAR[®] is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum dose capability, an important breakthrough.

Overview of market

Measured by the number of insulin units (IU) prescribed worldwide, the total market for injectable insulin grew from 217 Billion IU in 2003 to 302 Billion in 2008.

Of the different methods of injecting insulin available, disposable pen injectors form the fastest growing sector, up from approximately 20% of the market in 2003 to 31% in 2008³.

In 2003, Sanofi Aventis held just 6.1% of the total disposable insulin pen market, well behind its two main rivals Novo Nordisk (60.2%) and Eli Lilly (29.2%)⁴.

Project launch date

April 2007 in Germany.

Size of design budget

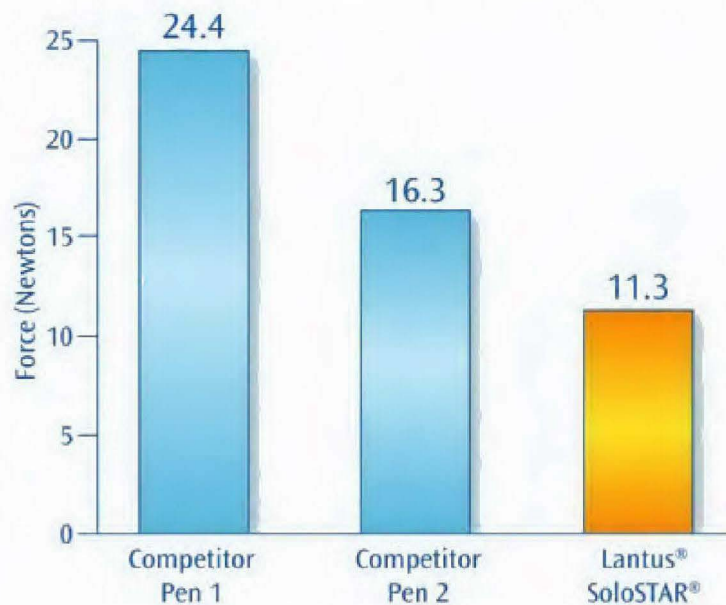
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Outline of design solution

The key technical challenges faced in developing SoloSTAR[®] resulted from worldwide research, which indicated that users strongly desire low injection force together with a large selectable dose range.

A fundamentally new operating mechanism was needed to resolve this problem. The highly efficient mechanism at the heart of SoloSTAR[®] is the product of a rigorous, evidence-based engineering design process. This innovative mechanism gives SoloSTAR[®] the lowest injection force in its class (over 30% less than key competitor devices)⁵.

Average force to deliver a 40 unit dose in 4 seconds



During the development of SoloSTAR[®], the design team held the needs of users in primary focus and careful consideration was given to visual design. SoloSTAR[®] has a discretely appealing form that helps to neutralise any stigma that may be attached to its use in public.

Colour is used to enhance safety by minimising the risk of a misidentification. In fact SoloSTAR[®] Lantus and Apidra have a total of five differentiation features for improved safety: body colour, dial colour, button colour, label design and a tactile feature on the injection button of the Apidra pen.

As many diabetic sufferers experience vision deficiencies, a very clear, high-contrast dial number display with magnification was also developed.

(480 words)



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