InsuJet™

Inject Needle-Free

Post Market Surveillance (PMS) summary

InsuJet™ market history

Previous versions of the InsuJet™ have been test marketed in various countries in Europe and Asia. Post Market Surveillance data was gathered to evaluate the suitability of the design. This limited soft market launch allowed for critical end user feedback.

These surveys were done in countries where the devices were initially introduced; the Netherlands and the United Kingdom.

This document summarizes the data obtained from cross-sectional surveys, which provided critical real market input and the feedback was instrumental to focus on key improvement that were introduced in the latest version: the InsuJet™ V5.

The new InsuJet™ V5 is marketed since 2021, so limited Post Market data is available for this device. Instead, usability test data will be provided that validates the latest design. The usability test results are presented in the Usability Summary.

The new InsuJet™ V5 injector

InsuJet™ user survey feedback and key findings

InsuJet™ has and continues to run a multi-year survey study for InsuJet™ end-users. The surveys confirm the suitability of the InsuJet™ and its labeling information for its target groups. Around a 100 end-users participated in 4 cross-sectional surveys, conducted globally with the majority coming from The Netherlands and The United Kingdom.

Besides survey data, this document will summarize the data obtained through complaint handling.

Key findings are separated into categories below:
(i) End-users demographics,
(ii) Types of insulin commonly used by the InsuJet™ test groups,
(iii) The ease of use of the InsuJet™ Injector and consumables,
(iv) Interesting study findings, and
(v) Overall usability and preference

(i) End-user demographics

The survey study's initial results show that the end-users predominantly are 40 to 70 years old and 62% male. The vast majority (83%) had type-2 diabetes, where they contracted diabetes later in life.

End-users age:

15-80

The InsuJet™ is also approved for pediatric use, however, in historical end-user surveys, no children younger than 15 years old participated. To close this gap, in 2022 a Post Market Clinical Follow up study is started, specifically into this target group, as the InsuJet™ is used in different markets for pediatrics. Results are pending, but will be added to this document by late 2022.

At 91%, the most significant driver to look for an alternative for their insulin treatments is a fear of needles[1].

91%

Solution for fear of needles

44% of the end-users are patients actively looking and informing their medical professionals for an alternative to needle insulin therapy[2]. 80% of the participants must administer insulin multiple times a day[3].

(ii) Types of insulin commonly used by the InsuJet™ end-users

Many types of insulins are used in combination with the InsuJet™, include rapid acting, regular insulins and long-acting insulins. It was noticeable that the type of insulin most commonly used was the long-acting insulin, at 42%[4].

42%

Use long-acting insulin

Many patients administer a mixture of rapid/short-acting and long-acting insulin.

(iii) The ease of use of the InsuJet™ Injector and consumables

Overall, over 81%[5] of participants find the InsuJet™ Injector and consumables simple to use from the first time.

81%

No problems using InsuJet™

Suitability for lay users

Although the survey shows that participants would like to have a introduction/training from a medical professional, most participants did not have any introduction, but were able to use the device without problems with the instructions for use provided.

The end-users stated that the InsuJet™ Injector manual as very clear, with over 75% immediately understanding what to do[6].

When using the system and drawing the insulin from various cartridges or vials, the clear display for the number of insulin units you draw feels more controlled and is seen as very easy by the majority of the end-users.

Ease of use of consumables

The consumables are divided into the InsuJet™ Nozzle and the InsuJet™ Adaptors. The InsuJet™ Nozzle is seen to be very easy to use and reuse. Where 88% of the end-users found it convenient to, and sanitary to change the InsuJet™ Nozzle every 1 to 2 weeks after use[7]. Changing of consumables including installing adaptor for each new cartridge or vial of insulin is seen as easy by over 79%[8].

(iv) Interesting findings regarding the InsuJet™

One of the benefits of the InsuJet™ reported in clinical investigations is faster insulin absorption and onset of insulin action. In the survey, 70% of the users reported that they noticed faster insulin absorption[9].

70%

Noticed faster absorption

One of the findings in the survey is that 40%[10] reported using less insulin with the InsuJet™ compared to their previous insulin administration system.

40%

Reported using less insulin

Although currently not supported by data from clinical investigations, this could potentially be an important benefit of the InsuJet™. However, clinical investigations performed did not study the long term benefits using InsuJet™, but this finding could be an important target for long term Post Market Clinical Follow up.

(v) Overall usability and preference

96% of the respondents found the InsuJet™ pleasant, user friendly or mostly and efficient method[11], and over 78% would recommend the InsuJet™ systems to others[12].

78%

Would recommend InsuJet™

Several suggestions were provided on how to further improve the device, summarized in the chapter "InsuJet PMS follow-up"

InsuJet™ PMS follow-up

The data obtained from the surveys applies to previous models of the InsuJet™, which have been marketed in the past. Feedback about improvement areas of the device provided [13] invaluable input to design & development to improve device performance, functionality and usability. Several items of improvements were identified:

1) Reducing the occurrence of wet injections
2) Reducing the winding torque required to charge the injector
3) Improving the visibility of the dose indication
4) Improving the user interface of the injector
5) Reducing the weight of the Injector

The follow up on each of these items is further explained in the Usability Summary document.

The results of future PMS studies performed for the InsuJet™ V5 will be added to this document.

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References:
(1) Post Market Surveillance Appendix 1 - Question-05
(2) Post Market Surveillance Appendix 1 - Question-08
(3) Post Market Surveillance Appendix 2 - Question-18
(4) Post Market Surveillance Appendix 2 - Question-17
(5) Post Market Surveillance Appendix 1 - Question-11
(6) Post Market Surveillance Appendix 1 - Question-10
(7) Post Market Surveillance Appendix 3 - Question-29
(8) Post Market Surveillance Appendix 3 - Question-33
(9) Post Market Surveillance Appendix 4 - Question-47
(10) Post Market Surveillance Appendix 4 - Question-46
(11) Post Market Surveillance Appendix 4 - Question-45
(12) Post Market Surveillance Appendix 5 - Question-49
(13) Post Market Surveillance Appendix 5 - Question-50

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