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DropSafe Safety Pen Needle Helps to Prevent Accidental Needlesticks After Injections: Results of a Simulated Clinical Study

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Summary

Most needlestick injuries (NSIs) result from unsafe needle devices. DropSafe safety pen needle (SPN) was designed to help prevent such injuries before, during and after use through a built-in sharps injury prevention feature (SIPF).

Methods

A two-phase study was undertaken. For the pilot study, five non-healthcare users (NHCUs) performed evaluations. For the validation study, 30 evaluators comprising 10 healthcare professionals (HCPs) and 20 NHCUs performed evaluations. The aim of the study was to validate the performance of the SIPF of the SPN and to collect feedback from the evaluators on several aspects of the safety device. Participants performed simulated injections into an orange.

Results

The results show that no device failures were observed, and all manipulations were performed without a needlestick or without contact with the needle after injection. The safety feature of the SPN was activated successfully. It was shown that: the label on the seal was legible; the SPNs were easy to attach to the pen injector; injections were easy to perform; it was clear when safety feature was activated; removing the SPN from the injection pen was easy; and the written instructions were easy to understand.

Conclusion

The performance of the safety feature of SPN was successfully evaluated in terms of the prevention of NSIs. User feedback demonstrate that the device's ease of use, handling and instructions for use ensure safety and effectiveness of the SPN when used as intended.

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Abstract

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Methods: A two-phase study was undertaken. For the pilot study, five non-healthcare users (NHCUs) performed evaluations. For the validation study, 30 evaluators comprising 10 healthcare professionals (HCPs) and 20 NHCUs performed evaluations. The aim of the study was to validate the performance of the SIPF of the SPN and to collect feedback from the evaluators on several aspects of the safety device. Participants performed simulated injections into an orange.

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Conclusion: The performance of the safety feature of SPN was successfully evaluated in terms of the prevention of NSIs. User feedback demonstrate that the device's ease of use, handling and instructions for use ensure safety and effectiveness of the SPN when used as intended.

Keywords

Accidental blood exposure, needle stick injury, pen needle, safety pen needle, sharps injury prevention, bloodborne pathogen

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Introduction

Accidental blood exposure (ABE) is defined as an accident associated with exposure to blood, bloody fluids or other fluids. Most ABEs are caused through contaminated needlesticks, sharps or splashes and expose healthcare professionals (HCPs) and non-healthcare users (NHCUs) to the risk of serious infections including the human immunodeficiency virus (HIV) and hepatitis B (HBV) or C (HCV) (Jahic et al., 2018; Motaarefi et al., 2016). The World Health Organization (WHO) reported that there were 3 million exposures among HCPs in 2002 to bloodborne pathogens due to needlestick injuries (NSIs) (WHO, 2002). It is

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estimated that around 400,000 (Tuma and Sepkowitz, 2006) to 800,000 (Gabriel, 2009) sharps injuries occur annually among hospital-based HCPs in the United States. In Europe, approximately 1 million NSIs occur each year (Eucomed, 2004).

One of the most effective risk-control measures to prevent healthcare workers' exposure to injuries and infectious agents is using safe devices (Adams et al., 2012). Over 80% of NSIs can be prevented with the use of sharps with engineered sharps injury protections system (Elder and Paterson, 2006). These devices have built-in safety features that reduce the risk of injury and can include needle sliding shields, needle protective covering and retractable needle systems. They can be classified as either 'passive', when they require no further action to make them safe, or 'active', when they require additional action to make them safe (Ford and Phillips, 2011). These devices allow needle-safe intravenous (IV) insertion and delivery, blood collection and intramuscular, intra-dermal and subcutaneous injections (Harb et al., 2015).

The United States was among the first countries in the world to introduce legislation that required healthcare employers to use safety-engineered sharps in preference to traditional sharps (U.S. Department of Labor, 2001). In Europe, the Council Directive 2010/32/EU introduced similar specific regulations (Council of the European Union, 2010). Several other countries also have enacted legislation regarding NSIs and safety-engineered devices including Canada, UK, Brazil and Taiwan (Cooke and Stephens, 2017). In response to this, to meet rising global demand, medical device manufacturers increased the availability of alternatives to traditional sharp medical devices in many countries, particularly those with well-developed healthcare systems. In the United States, the Food and Drug Administration (FDA) developed guidance to assist industry in clearing medical devices that incorporate a SIPF for marketing (U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health, 2005). The manufacturer is expected to demonstrate the performance of the SIPF through the use of appropriate simulated or clinical use study.

Pen needles are essential for drug injections using pen injectors (also called pen injector devices or injection pens). The use of pen injectors with needles sometimes causes accidental puncture (Pellissier et al., 2006). Published data report that insulin injection pen-related injury is the most common injury, accounting for 26% of all sharp injuries (Zhao et al., 2019). The introduction of SPN, with an incorporated SIPF, is an advantage over the traditional pen needles reducing the risk of injury and the spread of infectious diseases (Bossi et al., 2016; Floch, 2014; Veronesi et al., 2015). The DropSafe SPN was designed for use with pen injectors and has an automatic needle lockout after use as well as the ability to visually confirm the fluid flow through the needle and that the needle is in the lockout position and a protective sliding shield.

The aim of the present study was to validate the performance of the SIPF of the SPN in the simulated clinical use and evaluate the user's satisfaction with regards to the handling characteristics of the product.

Material and methods

Evaluators

All evaluators were selected in accordance with the inclusion/exclusion criteria set in the study protocol. An evaluator was eligible for the study if she/he met the following inclusion criteria: be aged $\geqslant$ 18 years; be able to understand and provide signed consent for the study; be willing to comply with the study protocol, including being willing to answer questions and complete questionnaires; have no concerns about the ability to perform the simulated injections; and have no financial interest in the sponsor (HTL-Strefa S.A.) or the medical research organisation (MRO) (NAMSA). An individual was not eligible for the study if, in the opinion of the sponsor or MRO, including the observer/monitor, the potential evaluator was not a good candidate for the study, including for reasons such as mental health.

Environmental conditions

The study environment met the requirements of the simulated clinical use testing including that the study space was private (quiet with no other activity), clean, comfortable (temperature, humidity), well-lit and had adequate equipment (a large table with chairs for the evaluator and the observer).

Study design

This simulated clinical use study design, sample size and statistical methods were planned in accordance with the Guidance for Industry and FDA Staff on Medical Devices with Sharps Injury Prevention Features (U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health, 2005).

A two-phase study was undertaken including the pilot and validation phases. The primary objective of the pilot phase was to identify device failures and to evaluate the instructions for use (IFU) for clarity and utility. The primary objective for the validation study was to estimate the failure rate of the device. For this study, failure was defined as NSI or contact with the needle after injection or non-complete activation of the safety feature reported by the evaluators for each device. Success was defined as complete manipulation performed by the evaluator without NSI or without contact with the needle after injection and complete activation of the safety feature following injection. Moreover, specific secondary objectives were also included

Table 1. Number of DropSafe SPNs used per evaluator.

Study phase	Evaluators		Total
	HCPs	NHCUs	
Phase I pilot	N/A	5 NHCUs, 50 DropSafe SPNs (10 per NHCU evaluator)	5 evaluators 50 tests
Phase II validation	10 HCPs, 180 DropSafe SPNs (18 per HCP evaluator)	20 NHCUs, 360 DropSafe SPNs (18 per NHCU evaluator)	30 evaluators 540 tests

HCP, healthcare professional; NHCU, non-healthcare user.

for this study: (1) to evaluate the ease of use; (2) the ability to follow the IFU; (3) the ease of understanding the IFU; and (4) to detect any problems associated with the device.

The present study was approved by the New England Independent Review Board (NEIRB) and all participants provided informed consent. Evaluators were paid US$50 at the conclusion of the study for their participation. Safety assessments included monitoring and recording of adverse events.

Evaluation sessions

Evaluation sessions for this simulated use study were conducted by the specialised, independent, contracted MRO and monitor, NAMSA (Minneapolis, MN, USA). The SPNs are intended for over-the-counter (OTC) use; thus the majority of evaluators were NHCUs to verify that the device can be used safely and effectively by individuals who do not receive professional training before using the device. For the pilot study, five NHCUs evaluated 10 SPNs each (a total of 50 SPNs). For the validation study, the group of 30 evaluators comprised 10 HCPs and 20 NHCUs who tested 18 SPNs each (a total of 540 SPNs) (Table 1).

The observer of the evaluation session explained to the evaluators what was expected from them per the study protocol and provided the test devices (SPN and pen injector) with instructions. In addition, a demonstration of the pen injector (without a pen needle) was given to the evaluators. No additional training on how to use the SPN was provided.

The evaluators performed a series of simulated injections into an orange (Guerlain et al., 2010). The use of fruit as a model mimicked a subcutaneous (SC) route of administration. For each device, the evaluators were to administer the injection with the SPN and pen injector with a sterile, water-filled cartridge, strictly following the IFU. The used device was then discarded by the evaluator in a sharps container. To mimic real clinical conditions of device use, the HCPs wore gloves whereas NHCUs performed the injections without gloves. For each manipulation, the evaluator was to inform the observer of any injury at the onset of that injury and was to inform the observer of any non-activation of the safety feature. In addition, the observer watched for any injury and checked for any non-activation of the safety feature for each manipulation. Evaluator comments and specific observations, such as the evaluator referring back to the instructions or asking questions, were documented by the observer. Following completion of all the simulated injections, the evaluators were asked to complete the evaluation questionnaire, using a 5-point Likert scale, in which 1 = strongly disagree and 5 = strongly agree. The evaluation sessions took approximately 1 h per participant.

Study device

DropSafe SPNs (HTL-Strefa S.A., Poland) are sterile, single-use safety needles intended for use with pen injectors for the injection of drugs. A SPN consists of a hollow needle that is embedded in a plastic hub and attached to injection pens. The viewing window enables the user to check if the needle is visible (Figure 1). The device is designed to minimise the risk from accidental needle sticks with a used needle by application of the SIPF. After use, the needle is locked out, preventing reuse (passive mechanism). The shield also serves to hide the needle before and after injection. The red safety lock indicator informs the user that the safety lock has been activated (Figure 2).

During the simulated use study, the SPN was tested with the AutoPen® pen injector (Owen-Mumford, UK). This pen injector requires priming, a step not required by all pen injector manufacturers, particularly ones who manufacture drugs other than insulin. There were no significant differences in physical design among pen injectors that would be expected to affect the ease of attaching or removing the needle, as all pen injectors comply with the same standard for needle-to-hub fitting. Using this pen injector allowed evaluation of the full set of SPN IFU. The evaluators were instructed on the pen injector IFU and by verbal instructions on how to prime the pen injector before being given the SPN IFU to follow.

Statistical analysis

The number of evaluators was selected to align with the FDA's guidance, which indicates minimising bias by selecting a sufficient number of evaluators, and to avoid evaluator fatigue and, thus, the risk of a NSI.

Figure 1. Components of the DropSafe safety pen needle.

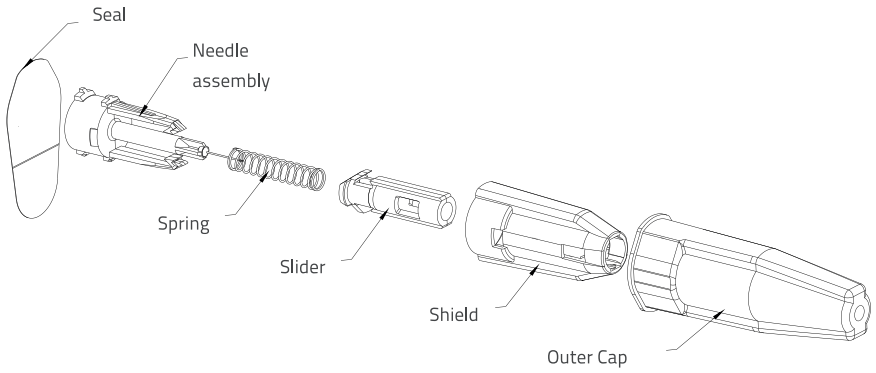

Figure 2. Safety lock indicator of the DropSafe safety pen needle.

For the pilot study, a sample size of 50 devices was considered large enough to gather a sufficient amount of information to identify any deficiencies in the SPN and in the IFU. To demonstrate that the true failure rate of the SPN safety feature is $< 1\%$ per FDA guidance (acceptance criteria), the number of devices, rather than the number of participants, was used to determine sample size. For the validation study, a sample size of 540 devices was estimated in order to gather data on a sufficient amount of SPN simulated uses to maximise the likelihood of estimating the true failure rate while also minimising burden to the study participants. The failure rate of the safety feature for the SPN was estimated using the proportion of devices that fail out of the total tested. A 95% confidence interval was constructed about this estimate using the Clopper–Pearson (or exact binomial) method (Clopper and Pearson, 1934). The confidence interval was one-sided, including only an upper bound to serve as the worst-case approximation for the 'true' failure rate of the SPN. The secondary endpoints were evaluated and are presented with summary statistics. Data from the evaluator questionnaires were analysed using a frequency distribution. Data were prepared and analysed using SAS statistical software (version 9.3, SAS Institute, Cary, NC, USA).

Results

The characteristics of the evaluators in the study are presented in Table 2. A total of five evaluators participated in the pilot phase. All were women with a mean age of 57.4 years, right-handed, 60% graduated from college and 80% had never used pen needles. A total of 30 evaluators participating in the validation phase were divided into two groups: HCPs (10 evaluators) and NHCUs (20 evaluators). Overall, 57% of the evaluators were women, 17% were left-handed and 77% graduated from college. The mean age of the evaluators was 46.5 years.

Among HCPs, 80% of the evaluators were women, 30% were left-handed, 60% graduated from college, 80% were nurses and 60% used pen needles regularly or very regularly. The mean age of HCP evaluators was 50.8 years.

Among NHCUs, 45% were women, 10% were left-handed, 85% graduated from college and 85% had never used pen needles. The mean age of NHCUs was 42.1 years.

In the pilot study, there were zero failures and 50 successful uses in the 50 SPNs tested. The information gathered during the pilot study was used to improve the design of the validation phase of the study. At least one evaluator asked what the 'safety feature' is, despite the fact that information was provided in the device section of the consent form, including the device diagram. In phase II, the device information, including the device diagram and individual device components in the consent form, was reviewed in great detail to ensure a thorough understanding of the safety feature. It was also noted that evaluators did not understand what gauge is. After this, the gauge value/meaning was presented more clearly. Based on the observations and comments from the evaluators during the pilot study, changes to the IFU were made to improve legibility and utility.

Table 2. Characteristics of evaluators.

Phase I pilot		
Group	NHCUs (n = 5)	
Age (years)	57.4 ± 13.5	
Gender		
Male	0 (0)	
Female	5 (100)	
Dominant hand		
Right	5 (100)	
Left	0 (0)	
Highest education level completed		
High school	2 (40.0)	
College	3 (60.0)	
Experience with pen needles		
Never used	4 (80.0)	
Have not used within 12 months	1 (20.0)	
Phase II validation		
Group	HCPs (n = 10)	NHCUs (n = 20)
Age (years)	50.8 ± 13.3	42.1 ± 11.8
Gender		
Male	2 (20.0)	11 (55.0)
Female	8 (80.0)	9 (45.0)
Dominant hand		
Right	7 (70.0)	18 (90.0)
Left	3 (30.0)	2 (10.0)
Highest education level completed		
Trade school	4 (40.0)	0 (0.0)
College	6 (60.0)	17 (85.0)
High school	0 (0.0)	2 (10.0)
Graduate school	0 (0.0)	1 (5.0)
Experience with pen needles		
Never used	0 (0.0)	17 (85.0)
Have not used within 12 months	2 (20.0)	3 (15.0)
Used sometimes	2 (20.0)	0 (0.0)
Used regularly	3 (30.0)	0 (0.0)
Used very regularly	3 (30.0)	0 (0.0)
Profession		
LPN	3 (30.0)	N/A
RN	5 (50.0)	N/A
EMT	1 (10.0)	N/A
Medical assistant	1 (10.0)	N/A

Values are given as n (%) or mean ± standard deviation.
EMT, emergency medical technician; HCP, healthcare professional; LPN, licensed practical nurse; N/A, not applicable; NHCU, non-healthcare user; RN, registered nurse.

A summary of changes to the IFU after the pilot phase are presented in the Supplemental material. The revised IFU was approved by the IRB and then was used in the validation study.

Of the 540 simulated injections performed with SPNs in the validation phase, there were no device failures. All observations met the criteria for success. In all observations there was complete manipulation performed by the evaluators without a NSI or without contact with the needle after injection and with complete activation of the safety feature after the injection. The failure rate upper one-sided 95% exact confidence bound in the validation phase was 0.6%. Therefore, the study met the primary objective of a failure rate $< 1\%$.

Pen needles were well appreciated by both groups of evaluators: the highest two scores were given by 92% of HCPs and 94% of NHCUs on the different aspects of the device. Figure 3a presents detailed self-reported data per user group on convenience using the device; the combined results per user group are shown in Figure 3b. About 53% of evaluators reported that they would 'strongly agree' with the statement that the label on the seal was legible and identified the length of the needle, whereas 40% reported that they would 'agree' with this statement. The combined rating for the two categories (the highest two scores on the scale) was 93% of all evaluators. Only 10% of the non-healthcare evaluators rated the seal of pen needle as illegible.

The ease of attachment of the SPN to the pen was reported by 87% of evaluators (70% of HCPs and 95% of NHCUs). The negative comments about this device feature were given by 20% of HCPs, whereas the remaining 10% rated the degree of ease of use as neutral.

Looking at the rating per evaluator group, it appears that 100% of participants in both groups would either agree or strongly agree that: removing the outer cap, injection and needle disposal were easy; and that the needle was visible through the viewing window.

Almost all the evaluators (97%) considered that the priming test could be assessed through the viewing window of SPN, removing the needle from the pen was easy and the written instructions were easy to understand.

The perceived feedback on the safety feature of the pen needle revealed that for 100% of HCPs and 90% of NHCUs it was clear when the safety feature was activated. A desirable characteristic of SPN, which is engagement of the safety feature with a single-handed technique, was positively scored by 63% of participants. The rates for each group vary slightly, with 20% of HCPs and 30% of NHCUs who answered 'neither agree nor disagree' to the provided statement, and 20% of HCPs and 5% of NHCUs who would 'disagree' and 'strongly disagree', respectively.

Discussion

NSI is one of the most common health hazards in the healthcare setting (Costigliola et al., 2012). Pen needles are often implicated in the risk of sharps injury, as they are used

Figure 3. (a) Evaluator feedback scores on usability statements (from S1 to S11) after completion of all the simulated injections. Evaluators reported their agreement/disagreement using a 5-point Likert scale, in which 1 = strongly disagree and 5 = strongly agree. Each bar presents a breakdown of the percentage of evaluators assigning their attitude to presented statements, with the absolute number of users per rating given as a numeral. (b) Global evaluator data (HCUs and NHCUs) on usability statements (from S1 to S11) after completion of all the simulated injections. Each bar presents a breakdown of the percentage of evaluators who 'strongly agreed' or 'agreed' with presented statements, with the percentage of evaluators per rating given as a numeral. The 'strongly agree' and 'agree' ratings are two highest ratings on the 5-point Likert scale. HCP, healthcare professional; NHCU, non-healthcare user.

widely by patients self-administering injections for medical treatments, as well as by healthcare workers giving subcutaneous injections to patients (Lee et al., 2005; Smallwood, 2017). Pen needles with automatic protective safety features allow patients who are temporarily incompetent to continue self-administering drugs with assistance but without compromising HCP safety (Markkanen et al., 2015). Moreover, SPNs have been found to minimise the risk of exposure to bloodborne infections, associated with NSIs, without any related adverse events (Gillespie and Canning, 2014; Yakushiji et al., 2012). It was shown that HCPs usually stick themselves in conjunction with insulin injections, which are mainly given in nursing homes, old age homes and in home care, suggesting that the devices

used for that purpose should be improved (Vos et al., 2006). In the case of needled safety devices, lack of activation of safety feature, only partial activation and inability to tell whether safety feature malfunctioned were reported (Lee et al., 2005).

For this study, 30 evaluators (10 HCPs and 20 NHCUs) confirmed the design performance of the SPN safety feature in preventing NSIs during in a simulated clinical use. The study reported zero failures of the SIPF. The success rate in performing injections was 100%. This study not only confirmed the performance of the device safety feature but also gave the opportunity to capture feedback from the evaluators on several aspects of the safety device.

Virtually all evaluators reported high rates of satisfaction and handling comfort in using the device. The same holds for the rating of understanding the IFU as a result of changes implemented after pilot phase. It is worth noting that lower rates of step involving attachment of the needle were seen with the professional evaluators. In contrast, the NHCUs gave higher rates. This is in line with previous studies finding needle handling to be the main source of use error (Lange et al., 2014, 2018). It is not known why the observed rate in the present study was lower in the HCP group. It is believed to be because they were seen to spend less time studying the IFU (or less carefully) before the injections compared to the naïve evaluator group. Furthermore, as the interface between the pen needle and the pen injector is standardised, this step is independent of the design of the particular device and thus by definition the same for all pen needles.

The present study, in which the majority of evaluators were NHCUs who did not receive professional training, shows that no extensive training is needed to use the safety device effectively. Similarly, it has been shown that no additional education is required for patients who self-administer their insulin when a SPN was used compared with a non-safety pen needle (Gillespie and Canning, 2014). In contrast, a random survey of 80 outpatients self-injecting insulin at home revealed that 70% self-reported suffering needlestick incidents and found the principal causes of these incidents were, among others, the absence of educational training and the shortage of educational instruction sheets for patients (Chang et al., 2014). Following implementation of the abovementioned measures, the rate of needlestick incidents decreased to 2.6%.

With regard to the degree of ease of injection and safety feature activation using a one-handed technique, it is also not known why both groups of evaluators reported lower values. One possible explanation could be that a one-hand injection might be different in simulated conditions, for example on a flat surface. One instance where the needle slipped off the orange before the injection was also observed. The other explanation could be that the length of the pen needle equipped with an automatic recapping ability and pen injector was too long compared with a conventional pen needle (Yakushiji et al., 2012).

In addition, it is reasonable to assume that these unfavourable ratings were more likely due to the AutoPen® pen injector used in the simulated clinical study rather than from the SPN itself. The selected pen constitutes a 'worst-case' pen injector model because it has a slider-type release button on the side of the pen injector rather than a push-button on top of the pen injector (Owen Mumford). Push-button operation can be done more easily than slider-type release button operation because the former allows wrapping of the fingers around the entire body of the pen injector without any need to avoid touching the release mechanism. This makes the push-button models easier to use, whether operated with one hand (e.g. gripping the pen injector with the fingers and activating the push-button with the thumb) or with two hands. Overall, this could make it more difficult to operate the AutoPen® pen injector/SPN needle system.

Moreover, it can only be speculated why the acceptability of this attribute of safe needle handling was given somewhat lower ratings among HCPs. It can most likely be attributed to the fact that HCPs can be more critical than other evaluators or that the simulated injections were perceived to be less comfortable when injecting others as opposed to when self-injecting. It was also noted that some HCPs felt odd during injections because the needle had to go through the shield before reaching the skin while most needles go into the skin directly.

Furthermore, in both evaluator groups, satisfaction with the use of the SPN and a sense of security during use was high, for all steps necessary for proper device handling, both before and after the injection. Such a sense of security that users consider important during the daily use of the SPN has also been assessed in another study (Floch et al., 2014). Regarding the safety of use, the superiority of the safety needle over the conventional pen needle appeared mainly during the phases after the injection, such as withdrawal, unscrewing and disposal of the needle, whereas the results concerning the sense of security were uncertain during the initial steps of the injection.

Conclusion

These results indicate that the design objective of this simulated clinical use study was achieved for the safety feature of the SPN. The SPN was well appreciated by all evaluators, with very high feedback scores on most of the questions asked regarding the device. It was demonstrated that no extensive training was needed to use the SPN effectively, injection and activation of the needle safety feature was easy, use of the safety feature was obvious, it was clear when the safety feature was activated, and that the safety feature activated only when the injection was complete.

The observations coming from the user feedback on the device's safety feature, ease of use, handling and IFU ensure safety and effectiveness of the SPN when used as intended.

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Supplemental material

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