

ADVANCEMENTS IN SAFETY PEN NEEDLES

A review of new-generation solutions
that impact quality and safety.

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A new generation of safety pen needle promises to enhance protection for caregivers and patients, while reducing concerns regarding premature activation and injection delivery.

Abstract

First generation safety pen needles have played a significant role in the protection of health workers by reducing the risk of needlestick injuries (NSIs). The occurrence of fewer needlesticks each year has resulted in reduced exposure among health workers and patients to disease from contaminated sharps, including HIV and hepatitis B and C. In addition, the use of safety pen needles helped improve compliance among diabetes patients who self-administer. Multiple studies have shown a rising preference among both healthcare professionals and patients for safety pen needles over other delivery systems.

However, problems still exist.

NSIs still occur at unacceptably high rates because most conventional safety pen needles only protect the patient-side of the needle, leaving the healthcare professional-side of the needle exposed.

Another major concern among healthcare professionals is that traditional safety pen needles make it virtually impossible to verify that the medication has been delivered during injection. This is for two reasons: 1) The needle itself is hidden from view, leaving the health worker no clear way to determine penetration. 2) Traditional safety pen needles are designed to retract the needle automatically by sensing the release of pressure. This automatic trigger is too often a “hair trigger” that can activate prematurely, preventing a proper injection or full medication delivery.

In response, Owen Mumford has developed a next-generation safety pen needle that protects both patient and healthcare professional. This pen needle, called Unifine® SafeControl®, provides the healthcare professional with the perfect balance of safety and control, thus ensuring injections are properly administered.

The trend toward injection pen use and continuity of care

Since their introduction in the 1980s, injection pens have been used in a wide range of therapy areas such as infertility conditions, osteoporosis, growth hormone deficiency, and mostly type 1 and type 2 diabetes.

To manage their diseases at home, patients have adopted injection pens for delivering medication. However, despite injection pens being increasingly favored by both patients and healthcare professionals,¹ hospitals predominantly use syringes and vials.¹ This disparity in injection method can confuse patients when faced with having their treatment administered during hospital visits.¹

In hospitals that have adopted injection pens, the trend toward using these devices aligns with healthcare professional preference. Compared with syringes and vials, healthcare professionals experience greater satisfaction with injection pens for several reasons:

- Healthcare professionals believe it takes less time to teach patients how to self-inject and feel more confident that patients deliver the required dose²
- Injection pens add value to the continuity of care because patients can replicate the hospital experience and self-inject with greater confidence and treatment adherence¹
- People with diabetes who use injection pens suffer fewer hypo- and hyperglycaemic events, which, in the hospital setting, is a challenge for clinicians and correlates with poor patient outcomes¹
- Nurses in the USA spend less time preparing and administering a dose with injection pens, improving their workload²

However, a study in France also identified that injection pen use correlates with a higher rate of NSIs among healthcare professionals who give injections.³

In response, manufacturers have developed safety pen needles, which, when used with injection pens, help protect healthcare professionals against NSIs.

While supporting the implementation of sharps regulations, safety pen needles come with challenges of their own.

Injection pen users: Concerns about dose accuracy and research insights on challenges

Managing dose delivery with safety pen needles

Until recently, passive safety pen needles have been the only safety-engineered alternative to conventional pen needles, ensuring that the needle is covered before and after injection. Due to the design of passive safety mechanisms, some users find it hard to see the needle and also need to adopt a different injection technique to conventional pen needles.

Moreover, the passive safety mechanism can activate before the full medication dose is delivered, and without the healthcare professional's knowledge. This can happen before or during injection if the safety pen needle is lifted off the skin by accident.

For example:

- When the injection site and angle are difficult to see because of how the skin folds
- When the patient withdraws or pulls away from the needle
- When the healthcare professional lets go of the pinched skin prematurely

Events like these may affect the delivery of the full drug dose and, if unnoticed, may also interfere with the standard of patient care; both cause concern for healthcare professionals. A thorough understanding of potential challenges is, therefore, relevant for enabling good injection practice and confidence in medication delivery.

To gain a comprehensive understanding of the challenges for healthcare professionals using passive safety pen needles,

detailed insight was gathered by an independent research company specialized in medical devices.

A closer look at passive safety pen needle use⁴

Initially, the majority of healthcare professionals were satisfied with their current safety pen needle. However, a closer look at their responses revealed issues with needle visibility, control over the injection process, and standard of patient care.

When asking healthcare professionals about passive safety pen needles:

- **39.7%** agreed that they can't see the needle as well as they would like
- **40.7%** agreed that they did not feel as much in control of the injection process as they had with the conventional pen needle

71% agreed that the safety pen needle activates before they have finished administering the injection

69% agreed that premature activation of the safety pen needle makes them unsure that the full medication dose has been delivered to their patient (of the 71.0%)

Also, **48.0%** agreed that premature activation of the safety pen needle makes delivering a consistent standard of care to their patients difficult (of the 71.0%).

86.2% agreed that it is equally important for their pen needle to provide them with a combination of safety and control of the drug delivery during the injection process

Currently, all safety pen needles on the market rely on passive activation of the safety mechanism—except for one.

Both safety and control are key elements of clinical best practice, yet healthcare professionals could only choose between compromising safety for control (with conventional pen needles) or control for safety (with passive safety mechanisms).

The next generation of safety pen needles: Putting more control back in the hands of healthcare professionals

As a solution that combines safety and control, R&D engineers at Owen Mumford designed a pen needle with a safety mechanism that is manually activated after the injection process, using just one hand. This safety mechanism helps prevent NSIs by covering both ends of the needle, while enabling the healthcare professional to use the same injection technique as a standard pen needle (see image below). Fittingly, this safety pen needle was named Unifine® SafeControl®.

To assess whether these safety pen needles overcome challenges for users, face-to-face interviews were held with 106 healthcare professionals (who had not participated in the online survey and were using either passive safety pen needles or conventional pen needles) before and after they tested this



After healthcare professionals had tested Unifine® SafeControl®:⁵

Safety

66.7%

agreed that they were confident that the device protected them against the possibility of NSIs

Confidence

86.7%

agreed that they felt confident injecting with the device

Usability

84.8%

agreed that they felt that the device was intuitive to use

Convenience

81.0%

agreed that they could use the same technique as when they were using a conventional pen needle

Unifine® SafeControl®—a new approach for challenges with conventional safety pen needles:

75.2% A balance of safety and control

agreed that the device gives them the right combination of safety and control of the drug delivery during the injection process

92.4% Dose delivery

agreed that they were 100% sure that the medication dose was fully delivered

70.5% Preference

agreed that they would prefer to use Unifine® SafeControl® if given the choice

Conclusion: A balance of safety and control for healthcare professionals

Safety pen needles help protect against NSIs, but until recently, all models were based on passive activation of the safety mechanism. These safety mechanisms can activate prematurely (before or during injection, and without the healthcare professional's knowledge), making healthcare professionals uncertain if they have delivered the full medication dose to their patient.

Unifine® SafeControl® is a next-generation safety pen needle that is designed to provide a balance of safety and certainty that the full medication dose is delivered. The manually activated safety mechanism covers both ends of the needle to help prevent NSIs, while enabling the healthcare professional to use the same injection technique as a conventional pen needle.

After testing Unifine® SafeControl®, the majority of healthcare professionals were certain that the full medication dose was delivered and that the safety mechanism protected them against the possibility of NSIs. They also found the device intuitive to use and that they could apply the same injection technique as used for conventional pen needles.

Overall, healthcare professionals agreed that Unifine® SafeControl® provided the right combination of safety and control of the drug delivery during the injection process.

If given the choice, the majority of healthcare professionals agreed that they would prefer to use Unifine® SafeControl®.

Research notes

All research was performed by an independent research company specialized in medical devices. For statistical analysis, a z test was used. For all relative figures on statements quoted here, p < 0.05 was applied.

References

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About Owen Mumford

Owen Mumford is an international family company and global leader in designing and manufacturing pen needles. With over 60 years of experience in medical devices, Owen Mumford understands the importance of listening to the needs of both users and decision-makers.

This understanding of key needs translates directly into innovative device solutions that support self-management plans, hospitals, doctors' surgeries, pharmacies, care homes, and clinics around the world.

Owen Mumford is committed to constantly developing life-saving and life-changing devices.

