



CREDENCE MEDSYSTEMS & THE CREDENCE COMPANION SAFETY SYRINGE SYSTEM

In this article, John A Merhige, Chief Commercial Officer, Credence MedSystems, Inc, summarises the Credence Companion Safety Syringe System, and how it fits with the company's core philosophy of Innovation Without Change for the benefit of biopharmaceutical partners.

INNOVATION WITHOUT CHANGE

The Credence Companion Safety Syringe System was born from Credence's core philosophy of *Innovation Without Change*. Traditionally, pharmaceutical companies have been forced to make an undesirable compromise between delivery system innovations and the time, cost and risk associated with implementing those innovations. The choices have been either to do nothing, to persevere along the long development path traditionally required with implementing innovations, or to seek a middle ground that checks the "needlestick safety" box but misses the opportunity to differentiate.

"Drug companies no longer have to ask, 'What trade-offs must we make?'"

Innovation Without Change is a product design and business partnering philosophy that reframes the question. Drug companies no longer have to ask, "What trade-offs must we make?" *Innovation Without Change* enables them to ask, "How can we help the end user performing the injection and satisfy our own needs for a streamlined development path and trusted supply chain?"

INNOVATION – A BEST-IN-CLASS DRUG DELIVERY DEVICE

Safety and Compliance

The Companion Syringe is a best-in-class safety device with integrated, passive needlestick prevention features. The needle

retracts automatically into the barrel of the syringe after the injection. The user is provided audible, tactile and visual cues of the safety engagement and the syringe is then automatically disabled, thereby preventing reuse. This passive safety is applicable even to deep intramuscular applications where long needles are used.

Differentiation that Goes Beyond Needlestick Prevention

The Companion allows the user to perform routine syringe procedures such as standard air bubble removal and aspiration techniques without concern for the premature activation of the safety mechanism that plagues other safety products. The Companion can even be utilised for reconstitution applications. The diluent can be injected into the vial and then the solution drawn up into the syringe without concern for premature safety engagement, all while maintaining the passive safety intact for the subsequent injection into the patient (see Figure 1, left section).

Luer or Staked: Which is best for the application?

Certain applications require a luer connection needle. For example, drugs requiring reconstitution mandate that a needle be attached after reconstitution but before patient injection to ensure a sharp needle. Intramuscular applications require needle choice flexibility at the point of injection to ensure the needle can reach the intramuscular space. However, luer needles come with a risk of a poor connection between



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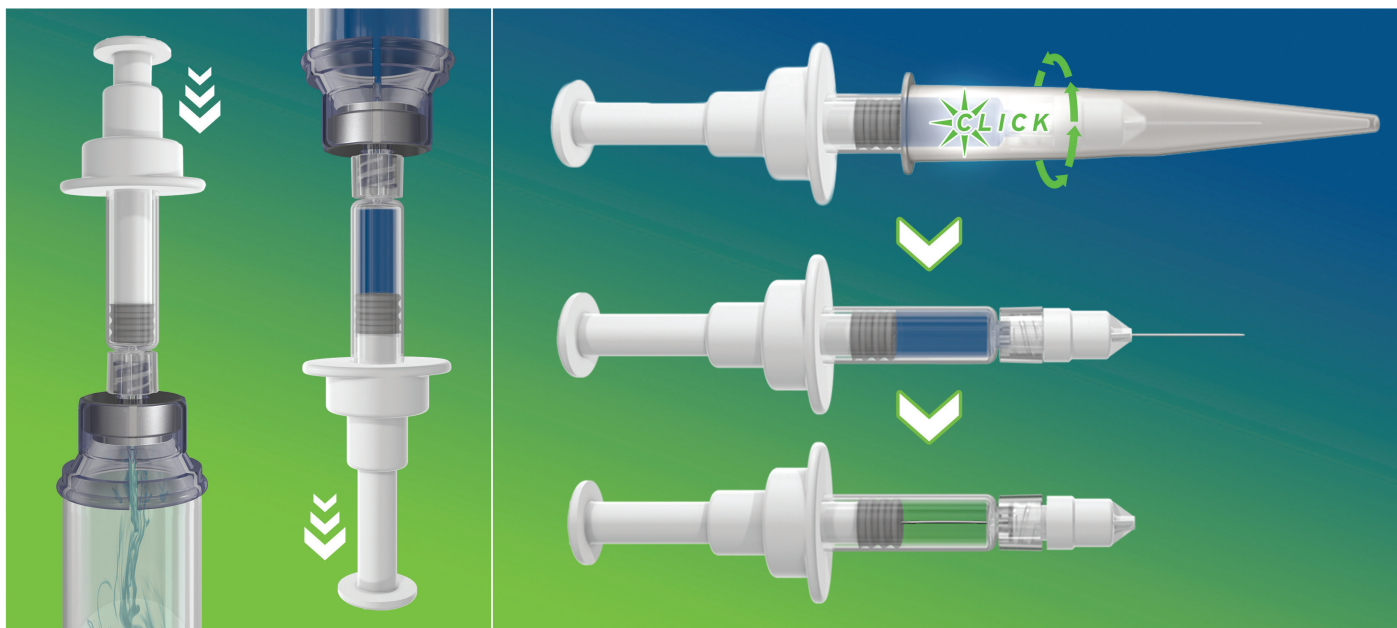


Figure 1: Best-in-Class Drug Delivery: The freedom to perform standard syringe procedures, Click Confirmation of a proper needle attachment, and passive needle-retraction safety.

the needle and the syringe. The Credence Guide-On Needle Cover addresses this risk by providing the user audible, tactile and visual feedback that the needle connection is secure. It does not expose the needle until the needle has been attached properly (see Figure 1, right section). If on the other hand a staked-in needle is preferred, the *Innovation Without Change* design philosophy has yielded a staked needle version of the Companion. The user still experiences the passive needle safety and human factors benefits seen in the luer solution, but does not have to attach a needle. Further, there are no adhesives used in the manufacture of the Companion system, removing the risk of drug substance/adhesive interaction.

WITHOUT CHANGE – A SIMPLIFIED COMMERCIALISATION PATH

The Companion staked and luer syringes are built around the foundation of any existing prefilled syringe, plunger / stopper, and tip-cap / needle-shield primary package components. The filling process is unchanged. The Companion plunger rod and Flex Finger Flange are added to the already-filled syringe in a secondary assembly process. The Guide-On Needle is either included in the kit in the luer presentation or already affixed to the syringe in the staked presentation. Because the pharmaceutical manufacturer can choose any existing prefilled syringe from any vendor and can keep their syringe filling process unchanged, much of the development and regulatory

work as well as the sourcing risk traditionally associated with delivery system advances can be avoided. This reduces the cost, time and complexity of launching drugs in a differentiated device.

INNOVATION WITHOUT CHANGE – IN THE PARTNERING MODEL

This passion for offering our partners Innovation Without Change extends to our business model and the supply chain flexibility it provides. Just as our biopharm partners have the freedom and flexibility to choose and source the critical primary package components of the syringe, they *also* have complete freedom to choose their preferred molding and assembly partners. Credence provides its expertise in technology transfer and automation to deliver a seamless integration into the assembly process.

Credence approaches every challenge

ABOUT CREDENCE MEDSYSTEMS

Credence MedSystems is focused on delivering medications safely for the benefit of our patients, caregivers and pharmaceutical partners. The Credence team brings curiosity, a fresh perspective and an intense desire to understand the needs of both the end-user and pharmaceutical manufacturer to the overriding goal of improving patient care.

HOW TO CONTACT CREDENCE

Come see the Companion Safety Syringe System at **Pharmapack Europe, Stand #728**.

For more information, please visit www.CredenceMed.com or reach out to John Merhige.

Note: This product has not been evaluated by US FDA.

“There are no adhesives used in the manufacture of the Companion system, removing the risk of drug substance/adhesive interaction”

with the philosophy of offering Innovation Without Change in order to improve patient care by addressing the needs of both the end-user and our pharmaceutical manufacturer partners.

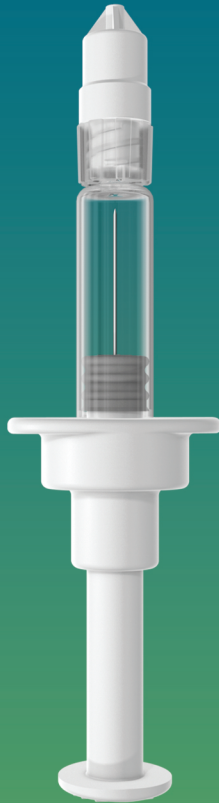
THE CREDENCE
COMPANION
SAFETY SYRINGE SYSTEM

THE CREDENCE COMPANION

SAFETY SYRINGE SYSTEM

SEE THE COMPANION SYRINGE
(AND IT'S STAKED FRIEND):
PHARMAPACK EUROPE
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STAND #728



INNOVATION WITHOUT CHANGE



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This product has not been evaluated by FDA.

