

PRODUCT SHOWCASE: SCHOTT's syriQ® and TopPac® Rigid Caps

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SCHOTT'S RIGID CAPS ADD NEW TWIST TO PREFILLED SYRINGES

Schott has added new closure systems to its already extensive portfolio of prefilled syringes (PFS), offering more flexibility for pharma companies while keeping patients safe. syriQ® Rigid Cap (SRC), shown in Figure 1, and Schott TopPac® Rigid Cap (TRC), shown in Figure 2, feature an intuitive twist-off mechanism. The caps ensure the integrity of the container, yet can easily be opened by healthcare professionals or patients.

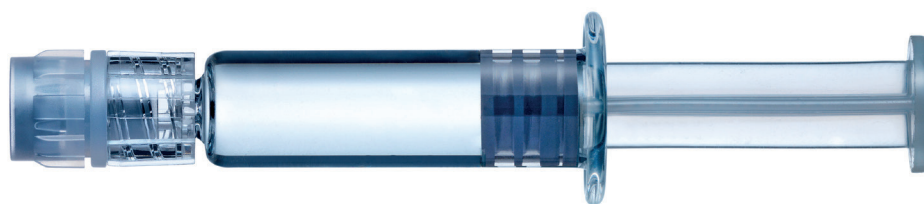


Figure 1: The syriQ® Rigid Cap (SRC) for glass prefilled syringes.



Figure 2: The TopPac® Rigid Cap (TRC) for polymer prefilled syringes.

“Container closure integrity (CCI) is one major concern in the pharma industry. Another one is usability. Our new closure systems deliver in both areas.”

These advanced closure systems for glass and polymer syringes improve patient safety while securing packaging supply chain. They offer a seamless fit for Schott's prefilled glass syringes known under the brand name syriQ®, and Schott TopPac®, its polymer equivalent. SRC is already commercially available, with TRC to follow later this year.

“Container closure integrity (CCI) is one major concern in the pharma industry. Another one is usability. Our new closure systems deliver in both areas,” said Anil Busimi, Global Product Manager at Schott Pharmaceutical Systems. “The design of SRC, our solution for syriQ® glass PFS, matches a closure system the industry is already familiar with. This adds a great deal

of flexibility to our customer's supply chain, and it speeds up time to market for new or already existing drug products.”

SRC combines a rubber tip-cap with a rigid cap screwed in a Luer lock adapter. The closure system comes pre-assembled with Schott's high-quality syriQ® glass syringe barrels, all pre-sterilised and in a standard nest-and-tub configuration. Thanks to standardisation and since the materials are similar to Schott's existing product line, drug manufacturers can quickly integrate SRC into existing production set-ups.

Schott is also ready to support drug developers in product documentation and the regulatory approvals process. This will help drug manufacturers get their product to market faster.

Schott developed TRC, the rigid cap for the Schott TopPac® polymer PFS portfolio, simultaneously with SRC. The rigid cap, fitted with a rubber tip-cap and twist-off mechanism, offers superior CCI during filling, processing, transportation, and shelf life. TRC, like SRC, is easy to open and easy to connect with hypodermic needles, IV connectors, or vial adapters, and reduces the risk of contamination while opening the closure system.

COMPLETE SYRINGE PORTFOLIO

New solutions like SRC and TRC derive from Schott's broad experience in syringe manufacturing. The company has been producing syringes in Europe since 1996. Today, the production is concentrated in Switzerland and is supported by an R&D team based at the site. From here Schott has developed a complete portfolio of both glass and polymer syringes, which is now even further expanded by the rigid closure systems. This offers pharma companies a broad range of solutions, suitable for a variety of applications like heparin, vaccines, biotech, and special applications such as intensive care.

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PRODUCT SHOWCASE: perfeXion™

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perfeXion™ is a new quality approach from Schott, which controls every inch of pharma glass tubing and with its launch the company pushes towards a zero-defect philosophy in pharmaceutical glass tubing production.

“We are taking a major step towards a holistic view of quality in pharma glass production.”

In quality control, details matter. When it comes to pharmaceutical primary packaging such as vials, cartridges or syringes (Figure 1), fluctuations in tubing dimensions such as the inner diameter or wall thickness can have a significant impact on the container performance – for instance, the filling or dosing accuracy for high potential drugs. Up until now, manufacturers of glass tubing have usually been monitoring quality parameters on a random sample base. However, Schott has

Figure 1:
Fluctuations in tubing dimensions significantly impacts performance of syringes and other primary drug containers.

developed a new production quality process. perfeXion™ controls and monitors every inch of the glass tubing that is later converted into a primary packaging container used by pharma companies to store and administer perhaps lifesaving drugs. With this, Schott aims to contribute to patients' safety from the very beginning of the value chain.

Schott officially introduced the perfeXion™ process to the industry with a presentation from Folker Steden, PhD, at CPhI Worldwide in Barcelona, Spain, on 4th October, 2016.

FROM BELIEVING TO KNOWING

“We are taking a major step towards a holistic view of quality in pharma glass production,” says Patrick Markschräger, Executive Vice-President at Schott Tubing. “We could see from our existing control mechanisms, which were already extremely tight, that the quality of our glass tubes meets the highest requirements. Now with perfeXion™, we can verify that every inch of the glass tube is accurate.”

This is a significant achievement, as Markschräger explains: “Pharma glass is mostly drawn in tubes when it comes from the melt. Schott as well as other quality-oriented converters use these tubes later on to produce vials, syringes, ampoules and cartridges. The challenge lies in monitoring and measuring the curved tubing surface with 100% accuracy, in a high-speed production process.” This is achieved by using a combination of line scan and area cameras, laser and IR inspection systems that literally investigate the entire glass tube on-line. The measurement data is then collected and evaluated by a holistic inter-connected IT solution.

“This system recognises even the smallest defective spots in the “endless” glass tube that comes from the melt. It is then able to

attribute these spots to a certain position at a single tube once the cooled down glass string is being cut,” Markschräger continued. “This sophisticated system enables us to customise the quality level to the specific needs of the industry.”

By storing the collected quality information in a database, measurements can be traced back even years later if needed.

Markschräger confirms that Schott has already started implementing perfeXion™ at its main site in Mitterteich, Germany. A company-wide roll-out at its other facilities in Europe, Asia and South America is underway.

With this development, Schott is not only passing another milestone of its future oriented quality roadmap. More importantly, the company's pharma glass known under the brand name SCHOTT FIOLAX® will enable even more sophisticated primary packaging solutions for advanced medical treatment than it already does today.

Each year, the international Schott Group manufactures around 140,000 tons of glass tubing and more than 10 billion pharmaceutical containers such as vials, syringes, ampoules and cartridges.

FIOLAX® and perfeXion™ are registered trademarks of SCHOTT AG.

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SCHOTT Rigid Caps

IT'S YOUR TURN!

By offering our prefillable syringes portfolio for syriQ® and SCHOTT TopPac® with an intuitive screw-off closure system, we enable pharmaceutical companies to ensure improved stability and more ease of use.

What's your next milestone?



IMPROVED
STABILITY



IMPROVED
EASE OF USE



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