



SCHOTT
glass made of ideas

SCHOTT TopPac® SD

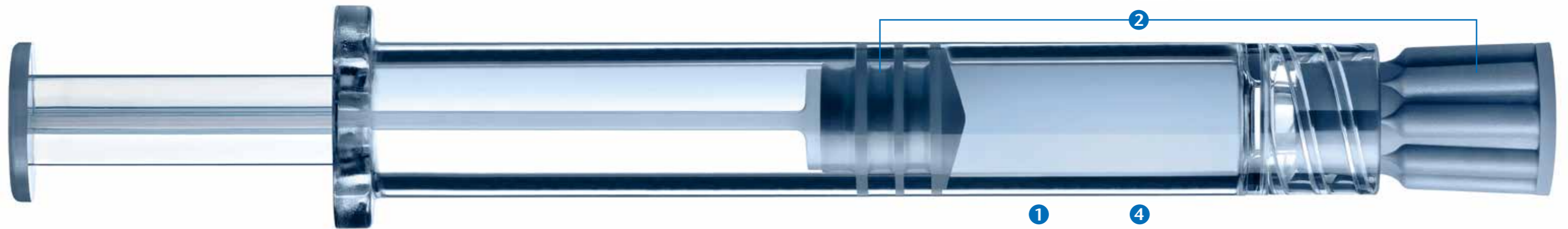
Polymer Prefillable Syringes
for Sensitive Drugs

SCHOTT TopPac® SD – Sensitive Drugs

The SCHOTT TopPac® SD is a new COC polymer prefillable syringe system (PFS) specially developed to ensure drug stability of highly sensitive drugs.

Case Study: Sensitive drugs

Sensitive parenteral medications often have a tendency to interact with the container system. Leachables or impurities from the components, subvisible particles from silicone oil or the pH level of the drug could lead to drug container interactions, which in turn could impact drug stability. Not only the choice of the different container components, but also processing and the sterilization of the syringe system, have an impact on the extractables and leachables (E&L) profile. With this in mind, the pharmaceutical industry is looking for innovative PFS solutions to protect and safely deliver sensitive drugs.



Container requirements

To design a PFS system that minimizes the risk of drug container interaction without compromising its functional characteristics is a major challenge for pharma companies. In addition to all functional benefits inherent to the SCHOTT TopPac® PFS system, an optimized container system for sensitive drugs should offer:

- Pure components with lowest levels of E&L
- Inert barrel material with no ion or heavy metal release
- Sterilization methods which enable low E&L profile
- Lowest level of contaminations or subvisible particles
- Easy integration into existing filling lines

Our Solution: SCHOTT TopPac® SD polymer syringes

SCHOTT TopPac® SD reduces the risk of drug container interaction through a considered selection of components, the lowest levels of impurities and an optimized processing:

Benefits of SCHOTT TopPac® SD

- 1 Inert COC barrel**
Due to the inert COC material used for the barrel, no ion or heavy metal is released and the chemical interaction with sensitive drugs is reduced.
- 2 Pure elastomer components**
The use of pure elastomer components combined with steam sterilization of plungers results in a reduced E&L profile.
- 3 ETO sterilization**
Using ETO sterilization instead of ionizing radiation for barrel and tip cap can significantly reduce potential E&L.

- 4 Cross-linked silicone**
Compared to conventional silicone coating, cross-linked silicone significantly reduces subvisible particles while retaining lubrication performance.

Clean with low particle level
Fully integrated clean room production results in syringes with low particles and low contamination.

General SCHOTT TopPac® advantages:

- Glass-like transparency
- Standard tub and nest offering
- Integrated Luer Lock
- Compatible with needle-less IV connectors

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