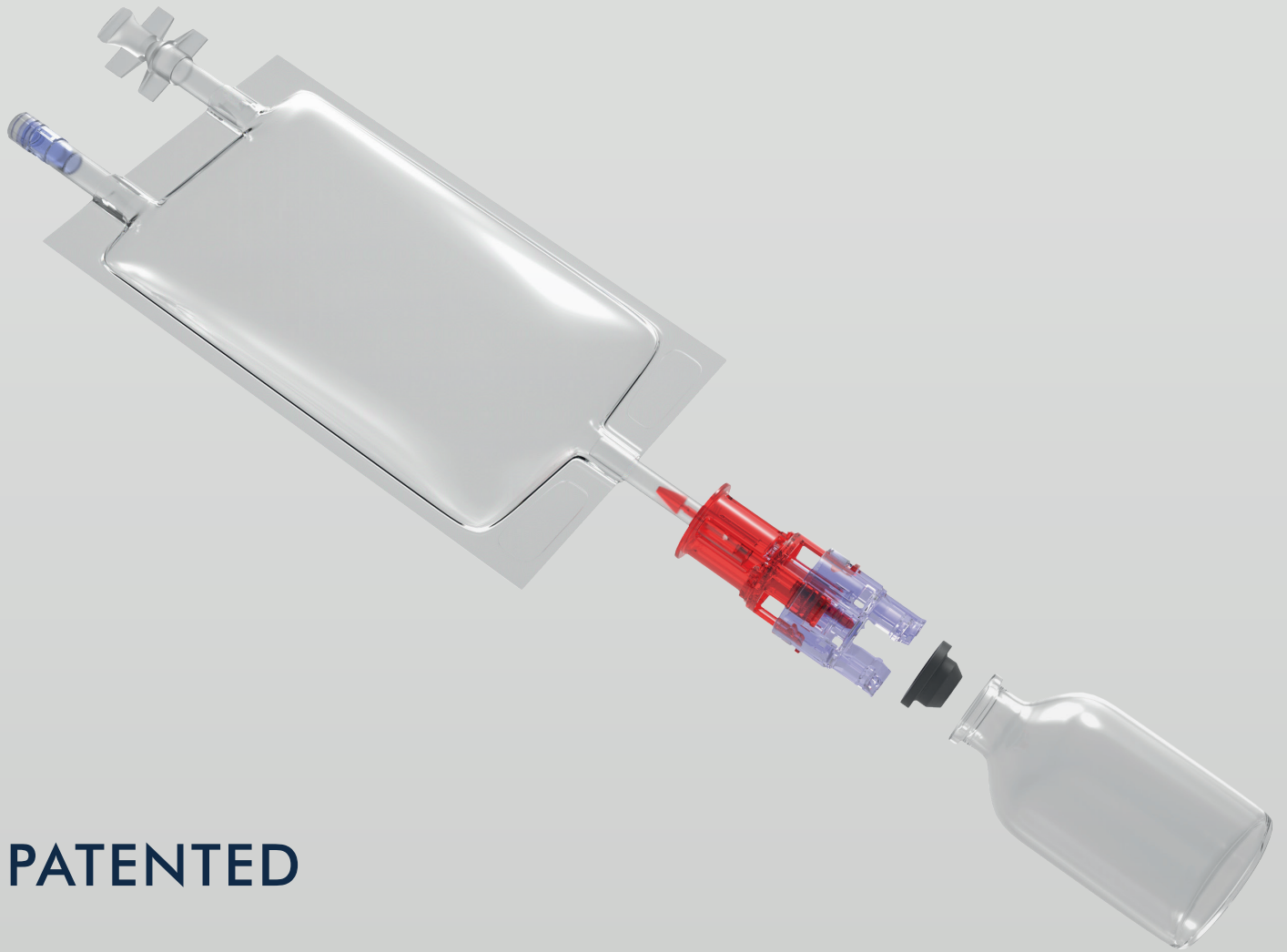




SIV[®] CSTD

Sterile connection in closed system



PATENTED



“Sterile Injection Vial” CSTD

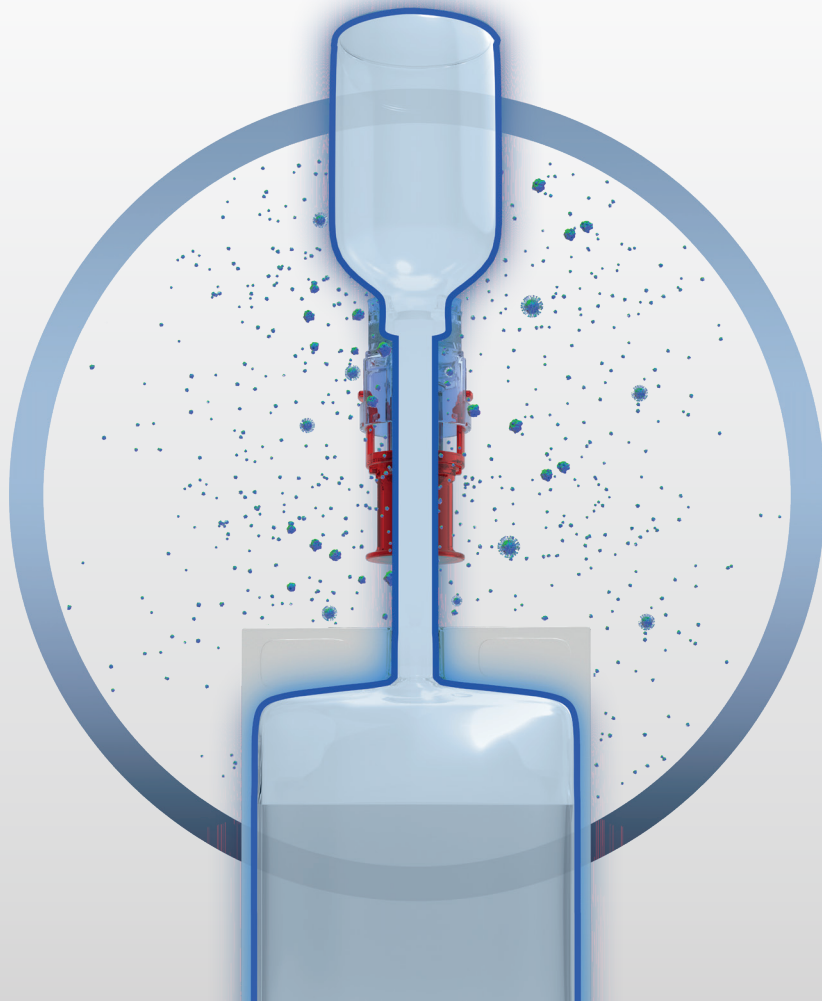
Closed System Transfer Device, that allows a sterile connection between the administration bag and the vial.

The preparation of cytotoxic drugs requires a delicate and complex multi-step procedure, to be performed with extreme care. In a typical reconstitution process, the drug contained in the vial is solubilized and transferred into the bag for administration to the patient, with the use of a syringe with a needle. At each step, the contact surfaces must be disinfected to avoid microbial contamination of the drug. These operations require the utmost caution, in order to not compromise sterility and avoid damage to the health of the operator and patient. The procedure is performed by healthcare personnel in a controlled environment in compliance with the strictest hygiene and safety standards such as, for example, under a laminar flow hood in the pharmacy departments of hospital facilities.

SIV® CSTD is a patented closed transfer device that allows the sterile connection between the vial containing a drug to be reconstituted and a bag with solvent.

The SIV® CSTD System consists of a connector and a dedicated vial stopper, suitable for all standard sized drug vials. No modification is required in the capping system of the pharmaceutical manufacturing process.

In compliance with NIOSH recommendations SIV® CSTD allows operators to perform a sterile operation in an uncontrolled environment, thanks to the patented connection between the stopper and the connector. This feature speeds up and simplifies the logistics of healthcare facilities, guaranteeing the safety of operators and patients.



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- USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings
- ISO 80369-7 “Small-bore connectors for liquids and gases in healthcare applications / Part 7: connectors for intravascular or hypodermic applications” and “Part 20: Common test methods”

THE ADVANTAGES OF SIV® CSTD

Sterile connection. With SIV® CSTD the drug vial connects to the bag in sterile conditions with a simple handling, even in a NON-controlled environment, such as, for example, the hospital ward. The patented SIV® system prevents any microbial contamination, without the need for manual sanitization with disinfectant, required with common CSTDs on the market.

Easy to use. SIV® CSTD simplifies the reconstitution procedure: the entire operation can be performed directly in the administration bag, in a single step and with a single device, minimizing the risks and the possibilities of error.

Reconstitution without needles. SIV® CSTD is designed in accordance with international needle-free policies: this eliminates the risk of accidental needle sticks, which could cause serious damage to the operators' health, especially in the presence of cytotoxic and dangerous drugs.

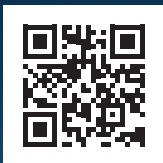
Vial stopper in innovative material. The stopper of SIV® CSTD system is produced in an innovative material and with a patented geometry that allows the connector to connect the vial stably and hermetically without the risk of detachment of particles from the cap.

Safety of the closed circuit. During the reconstitution operations there is an important risk of leakage of dangerous drugs in the form of drops, particles or aerosol into the surrounding environment. This involves a serious danger to the health of healthcare professionals who perform the drug reconstitution. Thanks to its validated closed system, SIV® CSTD prevents the risk of drug leakage avoiding external contamination.

All in one & ready to use. The combination of the dedicated bag and SIV® CSTD allows to prepare, reconstitute and administer the drug to the patient, with a single ready-to-use device. The system simplifies and speeds up the operations performed by healthcare personnel.

Home therapy. The safety and ease of use of SIV® CSTD make it suitable for the preparation and administration of drugs at home.

Logistics and sustainability. The possibility of performing all the reconstitution and administration operations using a single device, without additional consumables (syringes, gauze, disinfectant, and more), speeds up and simplifies the logistics and warehouse management of healthcare facilities, reducing consumables and waste, and therefore the environmental impact.



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