Cyto-Set®

Safe preparation and application of hazardous drugs

NEW

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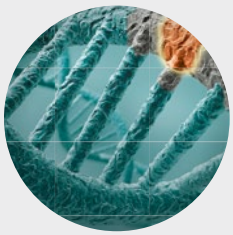
SHARING EXPERTISE

Challenges in chemotherapy

The treatment of chemotherapy is one of the most challenging processes within the infusion therapy. Starting with the preparation of the drug by way of transportation, administration to the patient and disposal after the treatment, healthcare workers, physicians, pharmacists and also the patients are permanently at the risk of endanger their health. International guidelines dictates the special handling of cytostatic drugs to reduce risks during the process. In line with the regulatory requirements Cyto-Set® is supporting the user to prevent the following risks:

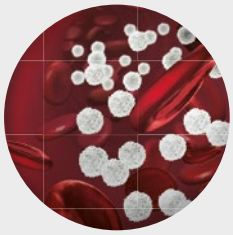


Chemical Contamination

- Unintended exposure of a healthcare professional to hazardous drugs.

Consequences[1]

- Toxic contamination can lead both to acute symptoms (nausea, diarrhea, throat irritation, skin rashes, hair loss, even mutagenicity) or chronic symptoms (carcinogenicity, secondary malignant neoplasia due to the exposure to high doses of cytotoxic medication, reproductive effects).[2, 3]



Drug Incompatibility

- Undesirable reaction that occurs between the drug and a) the IV solution b) the container or c) another drug.

Consequences[4]

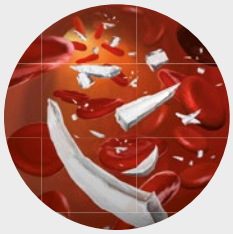
- damage from toxic products
- particulate emboli from crystallization and separation
- tissue irritation due to major pH changes
- therapeutic failure

Microbiological Contamination

- Infection which a patient incurs in a healthcare facility and which was not present at the time of admission. (incl. infections acquired in the hospital but appearing after discharge, and also occupational infections among the staff of the facility.)
- Infections are caused by microbiological pathogens like bacteria, viruses, prions or fungi, as well as by toxins and by-products that these pathogens release.

Consequences[5]

- Local infection consequences: surgical wound infections, skin irritations and catheter entry site infections
- Systemical inflammation consequences (pathogens reaching the systemic circulation): septicemia, sepsis and septic shock[6, 7]

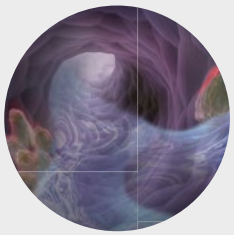


Particulate Contamination

- Unintended presence of extraneous, mobile and undissolved particles in a parenteral solution.

Consequences[8]

- Unfavorable effects (phlebitis, damage lungs[9], kidneys, nodular fibrosis of the liver and spleen, granulomatous lung disease, myocarditis, occult pulmonary granulomas to local tissue infarction and pulmonary infarction)[10]

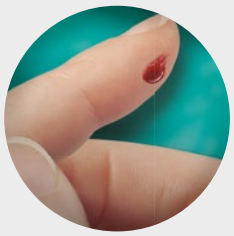


Medication Error

- An error in prescribing, dispensing or administering of a drug, irrespective of whether such errors lead to adverse consequences or not.

Consequences [11]

- Errors in IV drug preparation can have a broad range of consequences ranging from harmless to serious to fatal.

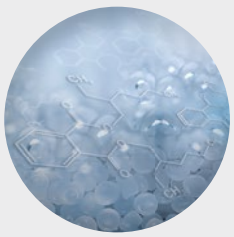


Sharp Injuries

- Skin penetrating stab wounds caused by sharp instruments and accidents in a medical setting. These instruments include needles, lancets, scalpels and broken glass.

Consequences [12]

- The main concern regarding a needle stick injury (NSI) is not characterized by the trauma itself, but by the percutaneous exposure to a patient´s blood and body fluids (BBF) which may carry infectious diseases. [13] The likelihood of developing a disease after a NSI depends on various independent factors: pathogen concentration in the blood and body fluids, depth of the wound, blood volume, amount of pathogens transmitted and the infection phase of the pathogen carrier.



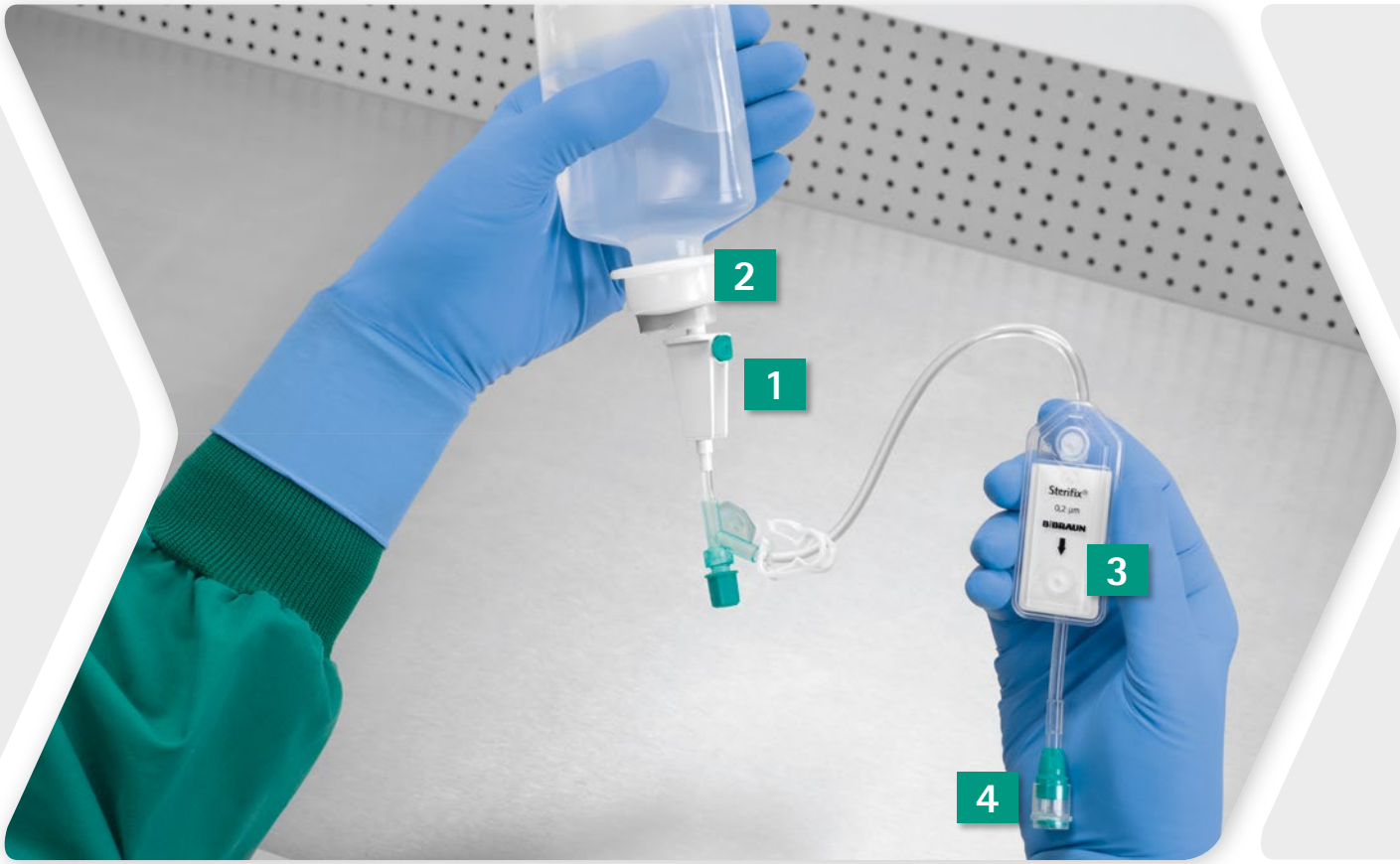
DEHP-Exposure [14]

- Polyvinyl chloride (PVC) plastic is used to manufacture a huge number of articles for daily life, e. g. toys, building material such as flooring, cables, as well as medical products. Unplasticized PVC is hard and brittle at room temperature. As a result, plasticizers are necessary to impart flexibility to the polymer.

Consequences

- Health concerns about phthalate plasticizers are currently the subject of considerable media, legislative and scientific debate. The exposure of human beings and especially developing children to DEHP can have significant health consequences.

Safe drug preparation in the pharmacy



Priming of Cyto-Set® Mix in the pharmacy

Protect yourself and your enviroment during the preparation of cytostatic drugs in the pharmacy by priming Cyto-Set® Mix first. As it is a matter of common knowledge cytostatic drugs can pose serious health harzards, Cyto-Set® Mix is supporting the pharmacists reducing the risk of contamination and increases the process efficiency of admixing drugs.

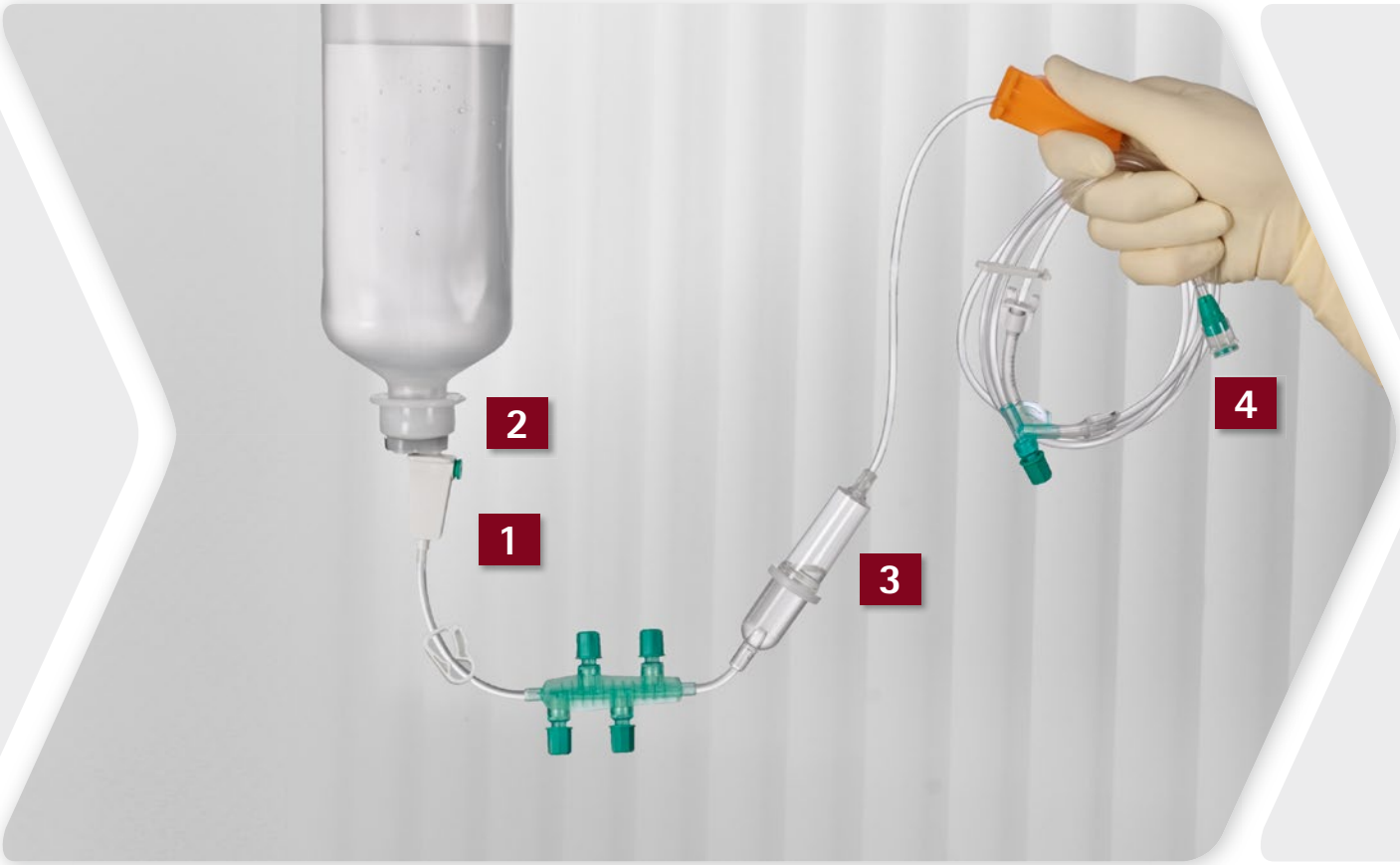
Process steps	Safety-Benefits
1 Close venting cap.	Air vent filter in spike with integrated B.C.V to avoid contamination during venting.
2 Spike the container.	Container stability of Ecoflac® plus allows easy and safe spiking to avoid sharps injuries.
3 Prime the filter.	0.2 µm Sterifix® filters every particals larger than 0.2 µm to avoid particular contamination.
4 Prime the line completely.	Hydrophobic, bacteria retentive cap maintaining a closed system until connection to the main line without spillages of fluid – the connector remains dry.

Safe drug preparation in the pharmacy with Cyto-Set® Mix

During the admixture process not only Cyto-Set® Mix but also alot of supporting products of the widespread B. Braun portfolio is used. Besides proctective equipment (e.g. gloves) and disinfectiants, the closed male connector PureSite, the semi-rigid container Ecoflac® plus and the luerr-lock syringe Omnixfix® is used during the preparation process.

Process steps	Safety-Benefits
1 Close white clamp near the needle-free valve.	No chemical contamination as only salin will remain at the connection site.
2 Connect prepared syringe with diluted drug to the needle-free valve by using the finger plate.	Reduced risk of microbiological contamination since no direct contact to the needle-free valve.No risk of needle-stick injuries.
3 Inject drug into container and mix the high concentrated drug well by aspirating once or twice.	Drug is administered in accordance with the prescripted concentration.

Application on the ward



Priming of Cyto-Set® main line on the ward

Cyto-Set® main line ensures a safe drug application on the ward while supporting the idea of a safe procedure of handling before, during and after the treatment. Cyto-Set® is supporting the process with features dedicated to the enviroment of an oncology ward.

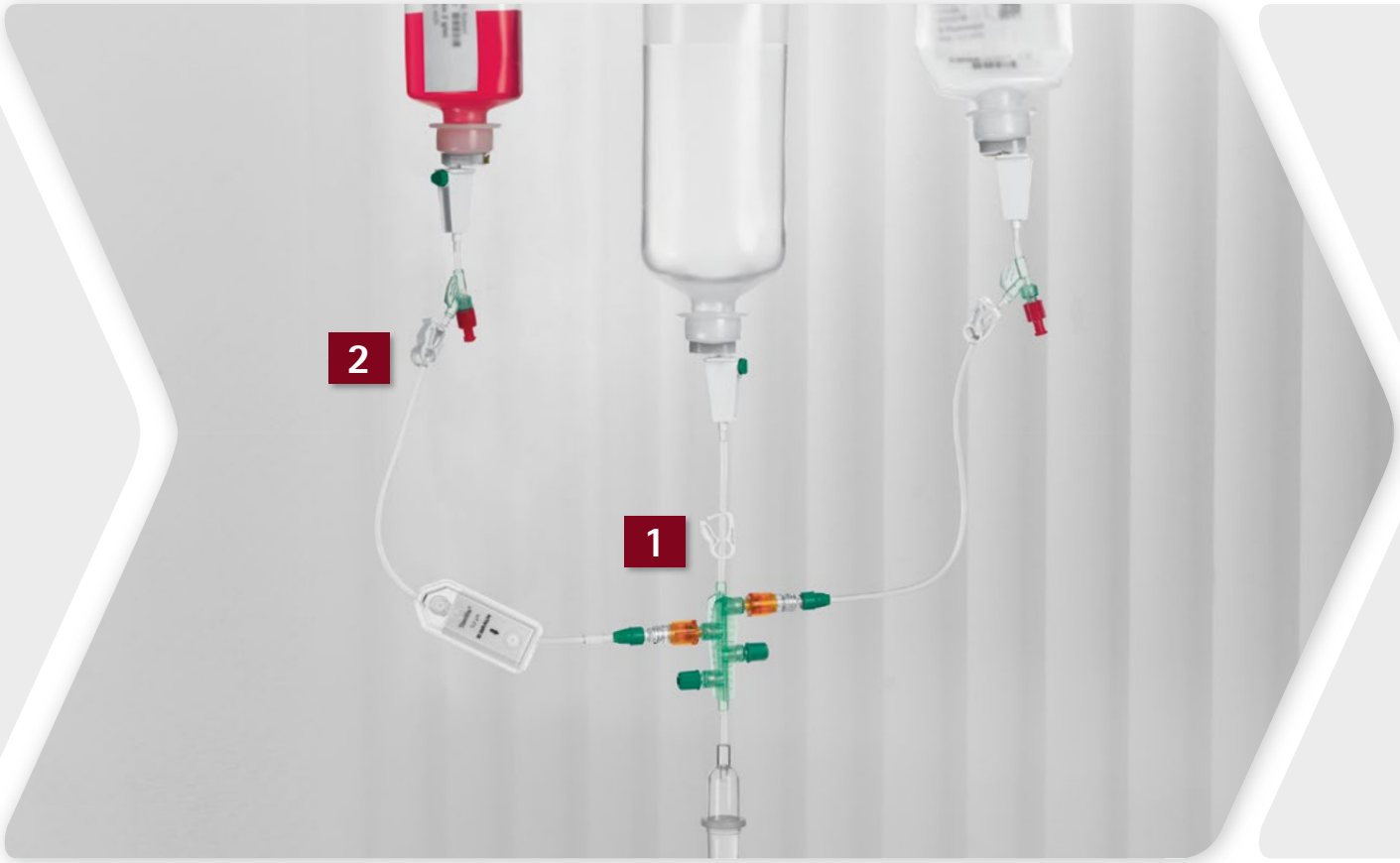
Process steps	Safety-Benefits
1 Close venting cap.	Air vent filter in spike with integrated B.C.V to avoid contamination during venting.
2 Spike the container.	Tight connection. Once inserted the spike stays firmly connected to avoid any risks of accidental disconnection.
3 While allowing system to fill, hold the drip chamber upside down.	Fluid filter in the drip chamber with pore size of 15 µm to avoid particular contamination.
4 Prime the line completely.	Hydrophobic, bacteria retentive cap maintaining a closed system until connecti-on to the main line without spillages of fluid – the connector remains dry.

Safe drug application on the ward with Cyto-Set® & Cyto-Set® Mix

The fact that the numbers of cytostatic drugs available on the market increase and the prices for most of the drugs are stable on a high level any residual volume in the IV-Set as well as drug incompatibilities increases the risk of an uneffective treatment or of an unefficient process. The concept of Cyto-Set® is supporting the process by increasing: efficiency, effectiveness and safety!

Process steps	Safety-Benefits
1 Close white clamp of main line.	Closed clamp prevents a contamination of flushing solution to reduce the risk of drug incompatibilites.
2 Connect Cyto-Set® Mix to main line, open white clamp and start treatment.	A tactile "click" will let the user know that the sets are connected securely.

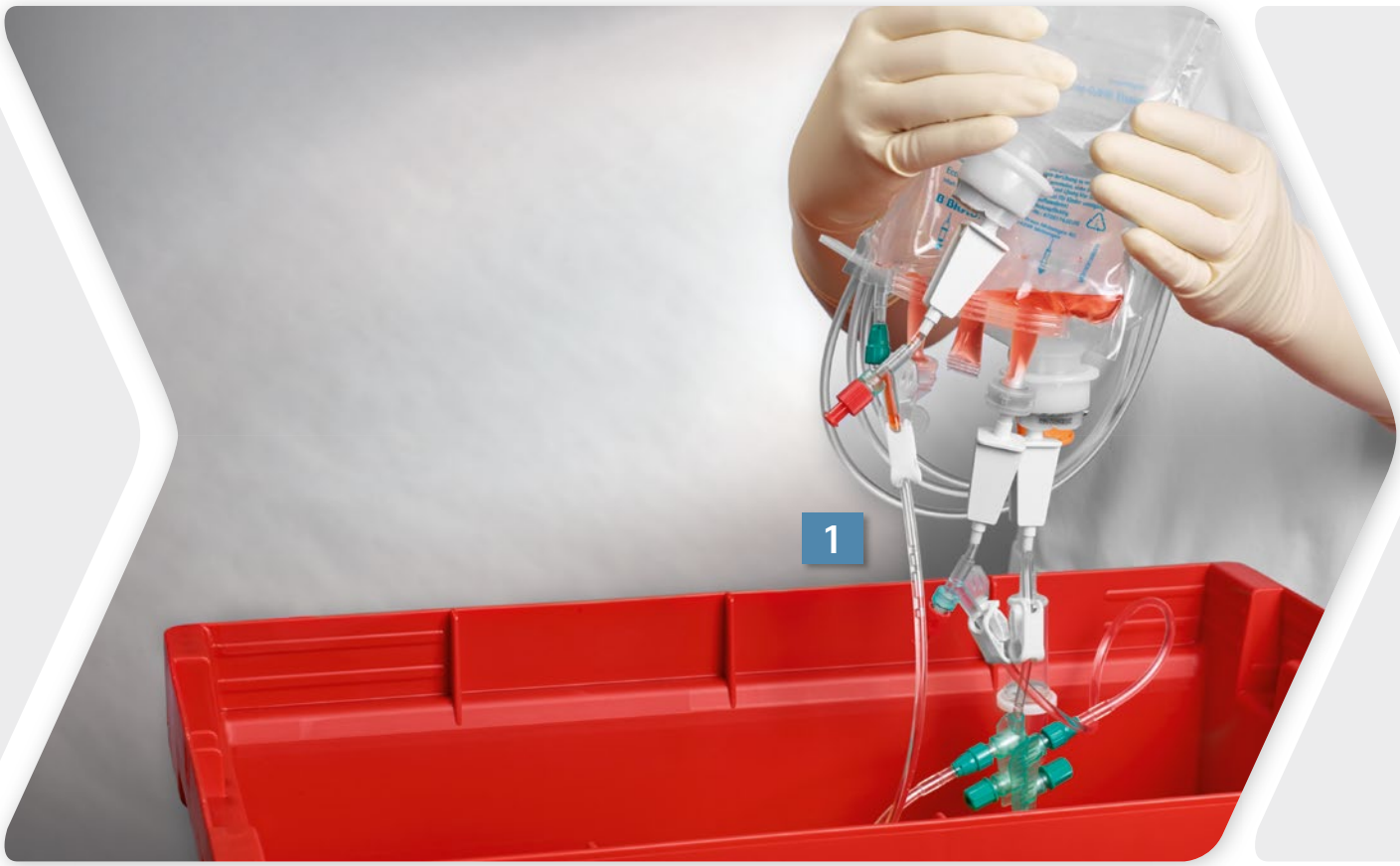
Application on the ward and disposal



Safe drug application on the ward with Cyto-Set® & Cyto-Set® Mix

In order to increase the effectivness of cancer treatment Cyto-Set® is enabling the user to flush the IV-Set after the treatment completely to ensure the whole medication is given to the patient in accordance with the prescription.

Process steps	Safety-Benefits
1 After each drug flush the line completely with flushing solution.	The full amount of drug is given to the patient to avoid medication errors.
2 Open clamp of next Cyto-Set® Mix to start the next treatment.	Flushing plus integrated back check valves for less risk of drug incompatibilities.



Safe disposal as a complete system

Even after the treatment the IV-Set and the contaminated containers need the undivided attention to protect the user and the enviroment. The whole Cyto-Set® portoflio is also supporting the healthcare worker afterwards to dispose of the system in a safe and convenient way.

Process steps	Safety-Benefits
1 Dispose of as a closed system.	No risk of chemical contamination because no disconnection is necessary.

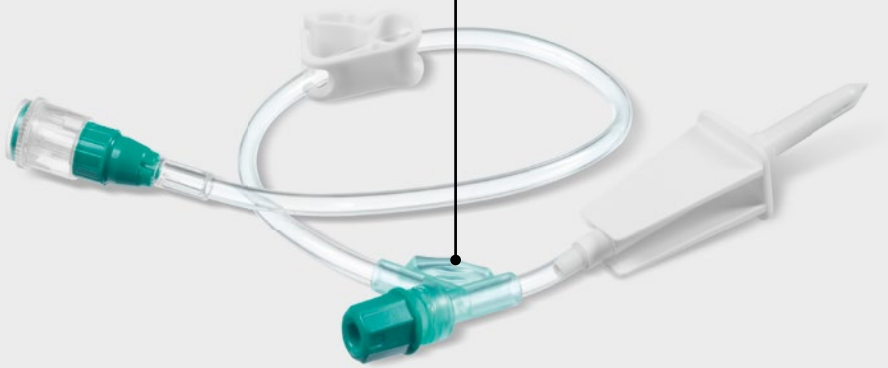
Always a closed system

Optimized design of Cyto-Set® offers a higher level of patient and user safety due to it's new features. In addition to this, the features increase the usability of the new portfolio because of the intuitive handling of the IV-Set.

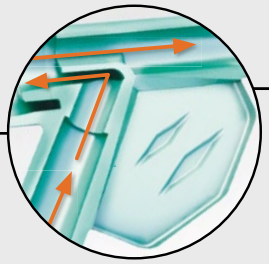
As the precursor the new Cyto-Set® is a closed system, and the new portfolio has been tested according to NIOSH guidelines.* No disconnection during the treatment or afterwards are necessary to dispose of the system.

CLOSED SYSTEM*

Needle-free valve with finger stopper and finger grip to reduce the risk of microbial contamination.



Optimized fluid flow for reduced dead space volume.



PrimeStop cap
Bacteria tightness without any limitation!

Vented spike
High filter performance! The bacterial and viral filter efficiency is higher than 99.99%!

* Cyto-Set® is tested according to NIOSH guidelines as a closed system. Confirmation available.

Innovation in design and technology

User benefits

- Cytostatic resistant material "Tritan™" is used for the needle-free valve to reduce the risk of chemical contamination.
- Systematic arrangement of the needle-free valves to avoid medication error.
- Integrated back check valves to avoid drug incompatibilities and medication errors.
- Ergonmic design of grip plate and Y-site needle-free valve supports safe handling and prevents microbial contamination.
- Optimized fluid flow leads to a minimized dead space volume of Y-site needle-free valve which is decreasing the risk of drug incompatibilities and air embolism.

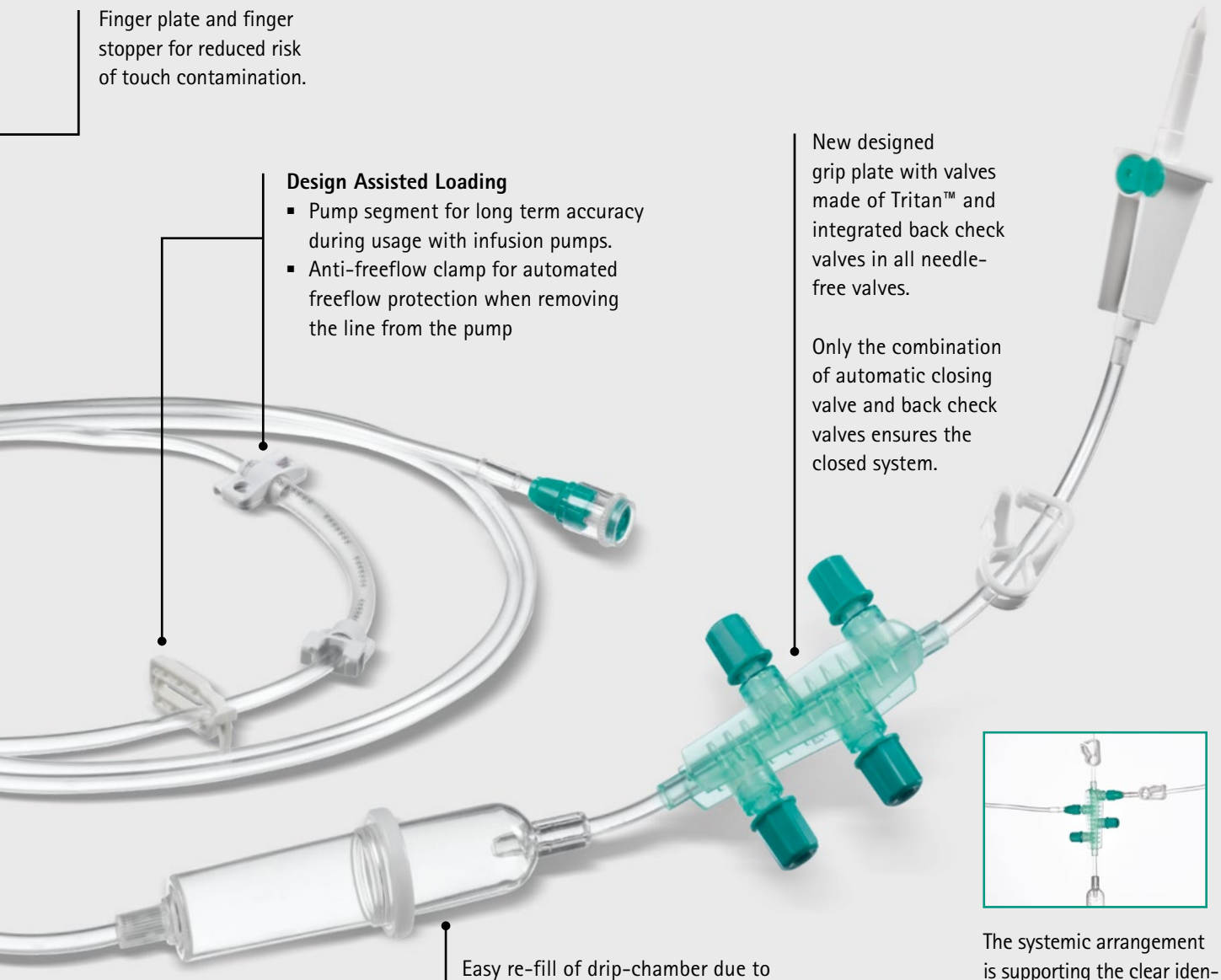
Finger plate and finger stopper for reduced risk of touch contamination.

Design Assisted Loading

- Pump segment for long term accuracy during usage with infusion pumps.
- Anti-freeflow clamp for automated freeflow protection when removing the line from the pump

New designed grip plate with valves made of Tritan™ and integrated back check valves in all needle-free valves.

Only the combination of automatic closing valve and back check valves ensures the closed system.



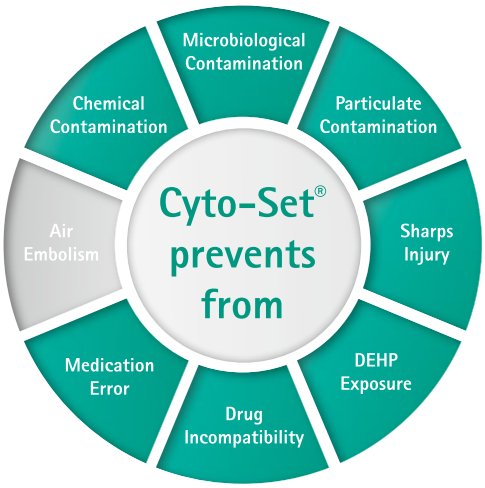
The systemic arrangement is supporting the clear identification of which line is connected to which drug.

Easy re-fill of drip-chamber due to short tubing above and low priming volume of grip-plate.

Risk prevention

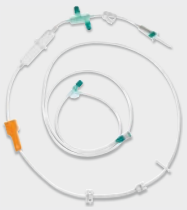
The new and optimized Cyto-Set® design is in line with our Safe Infusion Therapy concept to protect users and patients. The high safety standard of the features and the wide spread portfolio of Cyto-Set® is unique and exceptional in the field of drug preparation. During the application on the ward the new Cyto-Set® portfolio not only improves handling but also increases the safety standard.

The variety of Cyto-Set® products is widespread and offers a convenient and safe solution for the application of cytostatic drugs in ervery situation. When used together Cyto-Set® Mix and Cyto-Set® provide a closed system from preparation in the pharmacy to the application on the ward, all the way to the disposal after the treatment.



Risk	Safety feature	Safety-Benefits
Chemical Contamination	▪ Needle-free valve	▪ Reduces the risk of chemical contamination as the valve prevents spillage / drug exposure.
Microbiological Contamination	▪ Finger stopper and finger grip	▪ Effective reduction of microbial contamination due to the finger stopper and finger grip.
	▪ PrimeStop	▪ Higher safety against microbial contamination due to the hydrophobic, bacteria retentive PrimeStop cap on the patient connector which provides a closed system until connection to the patient.
	▪ Needle-free valve	▪ Provides easy access, while reducing the chance of accidental touch contamination.
	▪ Air vent filter in the spike	▪ The bacteria tight air vent filter in the spike ensures the venting of the infusion solution container without contamination risk.
Drug Incompatibility	▪ Grip plate with integrated back check valves	▪ Integrated back check valves ensure high safety and less risk of unmeant mixture of drugs.
Particulate Contamination	▪ 15 µm filter in the drip chamber	▪ A particle filter in the drip chamber with pore size of 15 µm prevents effectively the infusion of particles from the infusion container.
	▪ 0.2 µm Sterifix® filter	▪ The 0.2 µm Sterifix® filter retains bacteria, fungi and particles.
Sharps Injury	▪ Needle-free valve	▪ Provides needle-free access, while eliminating the risk of needlestick injuries.
Medication Error	▪ Structure of the regime	▪ Due to the 90° angle of the valves in the grip plate, the whole Cyto-Set® regime is structured well, which reduces the risk of mistaking the drugs within the therapy.
DEHP Exposure	▪ PVC / DEHP free tubing	▪ All lines are PVC-free, there is no risk of DEHP exposure.

Product portfolio

Cyto-Set®	Preparation	Type	Light protection	Units per box	Code No. (REF)
	Cyto-Set® Mix	with 1 needle-free valve		20	A2900N
	Cyto-Set® Mix	with 1 needle-free valve, with 0.2 µm filter			A2903N
	Cyto-Set® Mix	with 1 needle-free valve	■		A2906N
	Cyto-Set® Line	without needle-free valve			A2581NF
	Cyto-Set® Line	without needle-free valve, with 0.2 µm filter			A2582NF
	Application (Gravity)	**Type**		**Units per box**	**Code No. (REF)**
	Cyto-Set® Infusion	with 3 needle-free valve		20	A1687
	Cyto-Set® Infusion	with 5 needle-free valve			A1686SNF
	Application (Pump) Infusomat® Space	**Type**	**Light protection**	**Units per box**	**Code No. (REF)**
	Cyto-Set®	with 3 needle-free valve		20	8250917SP
	Cyto-Set®	with 5 needle-free valve			8250817SP
	Cyto-Set®	with 3 needle-free valve	■		8250920SP
	Cyto-Set®	with 5 needle-free valve	■		8250820SP
	Cyto-Set®	with 5 needle-free valve, with 0.2 µm filter			8250414SP
	Cyto-Set® Pump Adapter	with 4 needle-free valve			A1673SO

Literature

1. For further information please refer to "Chemical Contamination" leaflet.
2. McDiarmid MA, Egan T. Acute occupational exposure to antineoplastic agents. J Occup Med 1988; 30(12): 984-987
3. Valanis GB, Vollmer WM, Labuhn KT, Glass AG. Association of antineoplastic drug handling with acute adverse effects in pharmacy personnel. Am J Hosp Pharm 1993b; 50; 455-462
4. For further information please refer to "Drug Incompatibility" leaflet.
5. For further information please refer to "Microbiological Contamination" leaflet.
6. Uslusoy E., Mete S.: Predisposing factors to phlebitis in patients with peripheral intravenous catheters: a descriptive study. J Am Acad Nurse Pract. 2008; 20(4): 172-80
7. Bouchoucha et al. Deep venous thrombosis associated with acute hematogenous osteomyelitis in children. Orthop Traumatol Surg Res. 2010 Dec; 96(8): 890-3., Boucher 2010
8. For further information please refer to "Particulate Contamination" leaflet.
9. Dewan et al. 1995b; publications ex Dewan et al. 2002; Ewan PA, Stefanek W, Byard RW. Long-term response to intravenously injected Teflon and Silicone in a rat model. Pediatric Surgery Interantional 1995b; 10(2,3): 129-133
10. Roth 2007, Lehr et al. 2002; Roth JV. How to enter a medication vial without coring. Anesth Analg 2007; 104(6): 1615
11. For further information please refer to "Medication Error" leaflet.
12. For further information please refer to "Sharps Injuries" leaflet.
13. Canadian Center for Occupational Health and Safety (CCOHS); Needlestick injuries. 2000. (www.ccohs.ca/oshanswers/diseases/needlestick_injuries.html)
14. For further information please refer to "DEHP-Exposure" leaflet.

For more information about risk prevention visit:

www.safeinfusiontherapy.com

Notes

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