

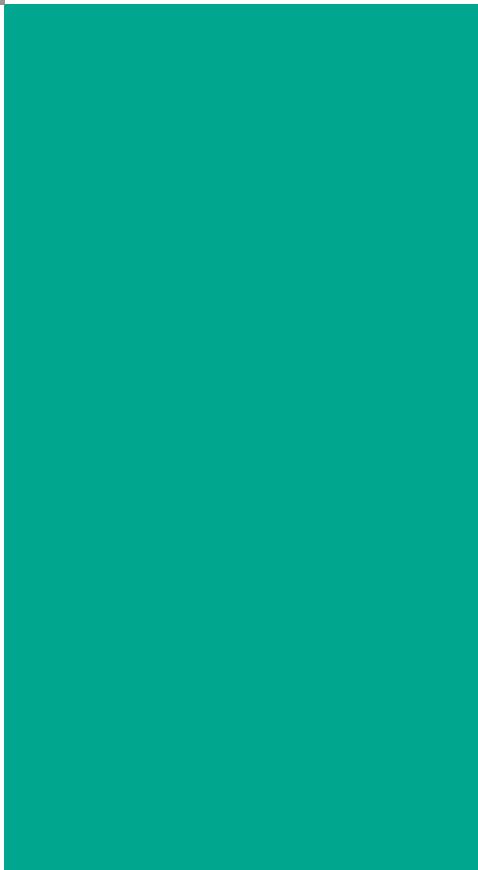


NEW WITH AIRSTOP



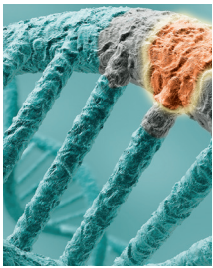
Cyto-Set®

Advanced preparation and application of hazardous drugs



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:

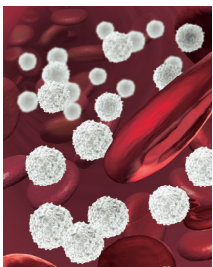


Chemical Contamination

- Unintended exposure of a healthcare professional to hazardous drugs.

Possible consequences

- 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).^{1, 2}

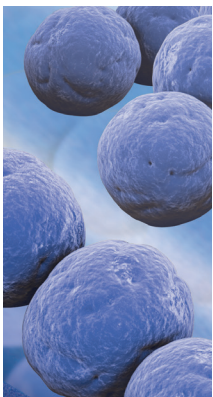


Drug Incompatibility

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

Possible consequences^{3, 4, 5}

- Damage from toxic drugs (e. g. dermatitis, antibiotics hypersensitivity)
- Particulate emboli from crystallization and separation (thrombophlebitis up to multi-organ failure)
- Tissue irritation due to major pH changes
- Therapeutic failure due to the reduction or elimination of the active drug



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.

Possible consequences

- 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}

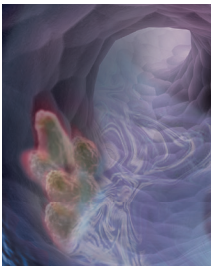


Particulate Contamination

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

Possible consequences

- Unfavorable effects (phlebitis, damage lungs⁸, kidneys, nodular fibrosis of the liver and spleen, granulomatous lung disease, myocarditis, occult pulmonary granulomas to local tissue infarction and pulmonary infarction)⁹



Medication Error

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

Possible consequences¹⁰

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

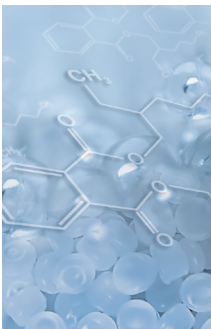


Sharp Injuries

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

Possible consequences

- 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.¹¹ 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.

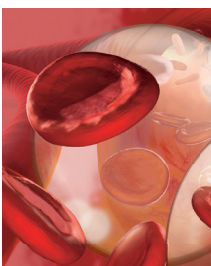


DEHP-Exposure

- 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.

Possible 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.¹²



Air Embolism

- Vascular air embolism is the entrainment of air (or exogenously delivered gas) from the operative field or other communications with the environment into the venous or arterial vasculature, producing systemic effects.

Possible consequences

- The symptoms and clonical signs of air embolism are related to the degree of air entry into the circulation system. They usually develop immediately after embolization.¹³
- Air embolism can have a broad range of consequences ranging from harmless to serious.

Risk Reduction with Cyto-Set®



The new and improved Cyto-Set® design is in line with our Safe Infusion Therapy concept to protect users and patients. In the field of drug preparation the wide spread portfolio of Cyto-Set® offers a high safety standard of each component. 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 solution for the application of cytostatic drugs in several situations. When used together Cyto-Set® Mix, Cyto-Set® Infusion and Cyto-Set® Infusomat® Space 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	<ul style="list-style-type: none"> Needle-free valve 	<ul style="list-style-type: none"> Helps to reduce the risk of chemical contamination as the valves are designed for preventing spillage / drug exposure.¹⁴
Microbiological Contamination	<ul style="list-style-type: none"> Finger stopper and finger grip PrimeStop Needle-free valve Air vent filter in the spike 	<ul style="list-style-type: none"> Reduction of microbial contamination due to the finger stopper and finger grip.¹⁵ Improved 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.^{16, 17} Provides easy access, while helping to reduce the chance of accidental touch contamination.¹⁸ The bacteria tight air vent filter in the spike reduces the contamination risk of the infusion solution.¹⁹
Drug Incompatibility	<ul style="list-style-type: none"> Grip plate with integrated back check valves 	<ul style="list-style-type: none"> Integrated back check valves enables an improved safety standard and less risk of unmeant mixture of drugs due to the prevention of reflux.²⁰
Particulate Contamination	<ul style="list-style-type: none"> 15 µm filter in the drip chamber 0.2 µm Sterifix® filter 	<ul style="list-style-type: none"> A particle filter in the drip chamber with pore size of 15 µm prevents the infusion of particles from the infusion container.²¹ The 0.2 µm Sterifix® filter retains bacteria, fungi, particles and air.
Sharps Injury	<ul style="list-style-type: none"> Needle-free valve 	<ul style="list-style-type: none"> Provides needle-free access, while eliminating the risk of needlestick injuries.^{22, 23}
Medication Error	<ul style="list-style-type: none"> Structure of the regime 	<ul style="list-style-type: none"> 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.
Air Embolism	<ul style="list-style-type: none"> AirStop 	<ul style="list-style-type: none"> AirStop function in drip chamber reduces the risk of air embolism.²⁴
DEHP Exposure	<ul style="list-style-type: none"> PVC / DEHP free tubing 	<ul style="list-style-type: none"> All lines are PVC-free, there is no risk of DEHP exposure.

A Proven Closed System*

INNOVATION IN DESIGN AND TECHNOLOGY

Improved design of Cyto-Set® offers a higher level of patient and user safety due to its new features. In addition to this, the features are supporting to increase the usability of the new portfolio due to 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.

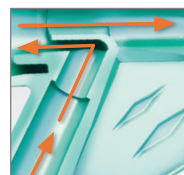
YOUR BENEFITS

- Cytostatic resistant material "Tritan™" is used for the needle-free valve to avoid the risk of chemical contamination caused by stress-cracking.
- Systematic arrangement of the needle-free valves supporting the user during application. This helps to reduce the risk of medication errors.
- Integrated back check valves to avoid drug incompatibilities and medication errors caused by unmeant reflux.
- Ergonomic design of grip plate and Y-site needle-free valve supports safe handling and helps to reduce risk of microbial contamination.
- Improved fluid flow leads to a reduced dead space volume of Y-site needle-free valve which is decreasing the risk of drug incompatibilities and air embolism.
- AirStop function in drip chamber prevents air entrainment into the infusion tubing and helps to reduce the risk of air embolism.

Cyto-Set® products details

PrimeStop Cap**

Proven bacteria tightness during storage and transportation.



- Improved fluid flow for reduced dead space volume.
- Finger plate & finger stopper are helping to reduce risk of touch contamination.



AirStop

Is available in Cyto-Set® Infusomat Space and Cyto-Set® Infusion protecting against air infusion by preventing the infusion line running dry.



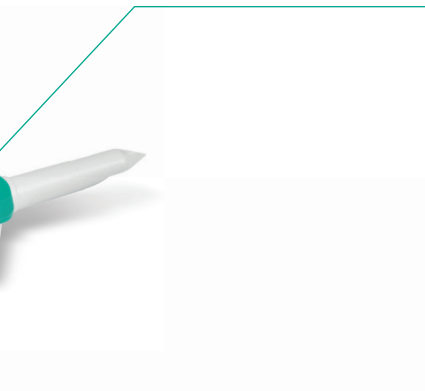
* Cyto-Set® is tested according to NIOSH guidelines as a closed system. Confirmation available.

** Bacteria tightness of PrimeStop Cap. Confirmation available.

*** Filter prevents the escape of any contamination into the adjacent environment. Confirmation available.

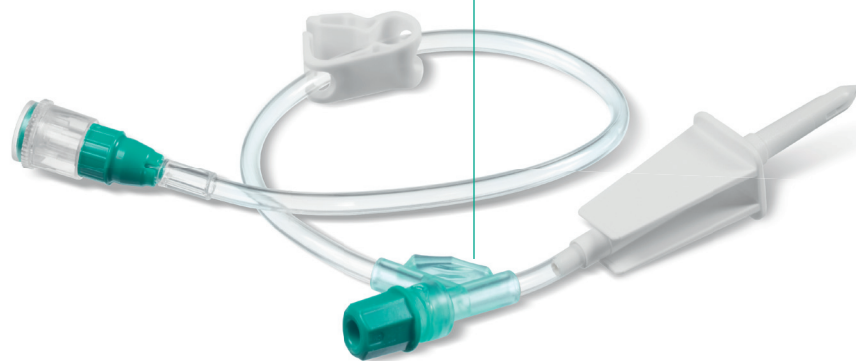
Vented Spike***

High filter performance! The bacterial and viral filter efficiency is higher than 99.99%! ¹⁹



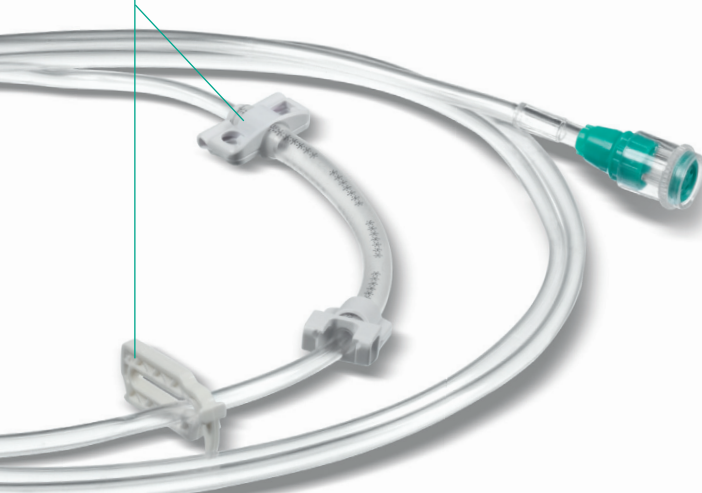
Needle-free valve

With finger stopper and finger grip helps to reduce the risk of microbial contamination.

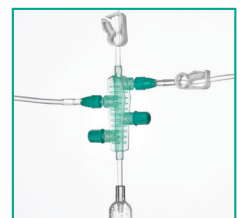
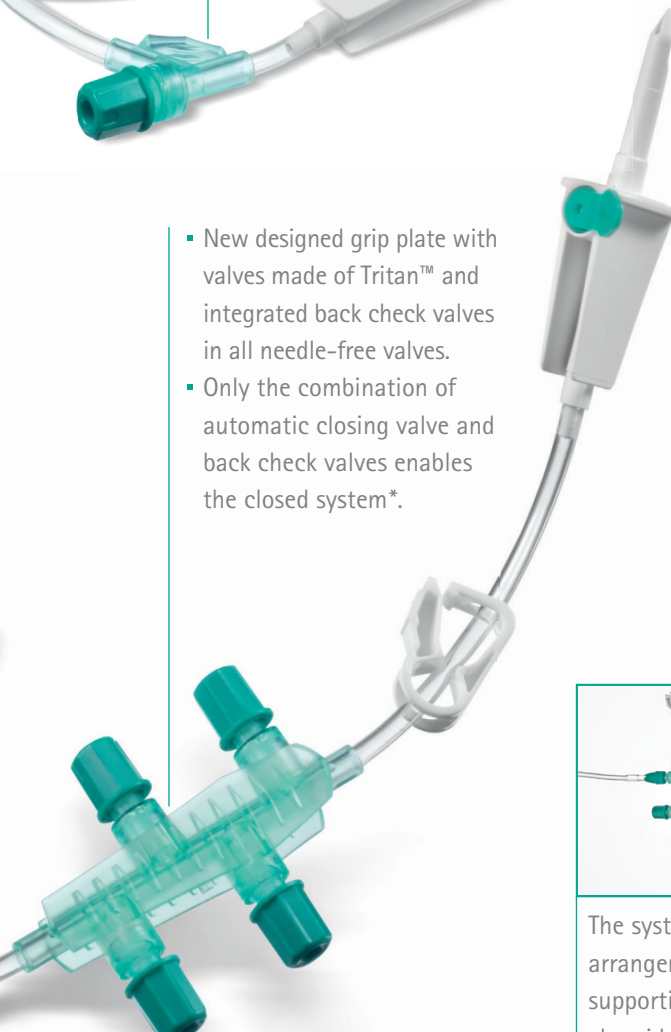


Design Assisted Loading

- 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 enables 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.

Drug Preparation in the Pharmacy



1 Handling Step
Close venting cap.

Safety Feature
Air vent filter in spike with integrated B.C.V. helps to avoid contamination during venting.

2 Handling Step
Spike the container.

Safety Feature
Container stability of Ecoflac® plus allows easy and convenient spiking while helping to reduce risks of sharps injuries.

3 Handling Step
Prime the filter.

Safety Feature
0.2 µm Sterifix® filters every particles larger than 0.2 µm to avoid particular contamination.

4 Handling Step
Prime the line completely.

Safety Feature
Hydrophobic, bacteria retentive cap maintaining a closed system until connection to the main line without spillages of fluid.

Priming of Cyto-Set® Mix in the pharmacy

Protect yourself and your environment 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 hazards, Cyto-Set® Mix is supporting the pharmacists reducing the risk of contamination and helps to increase the process efficiency of admixing drugs.



- 1 Handling Step**
Close white clamp close to the needle-free valve.

Safety Feature
Helps to avoid chemical contamination as only saline will remain at the connection site.
- 2 Handling Step**
Connect prepared syringe with diluted drug to the needle-free valve by using the finger plate.

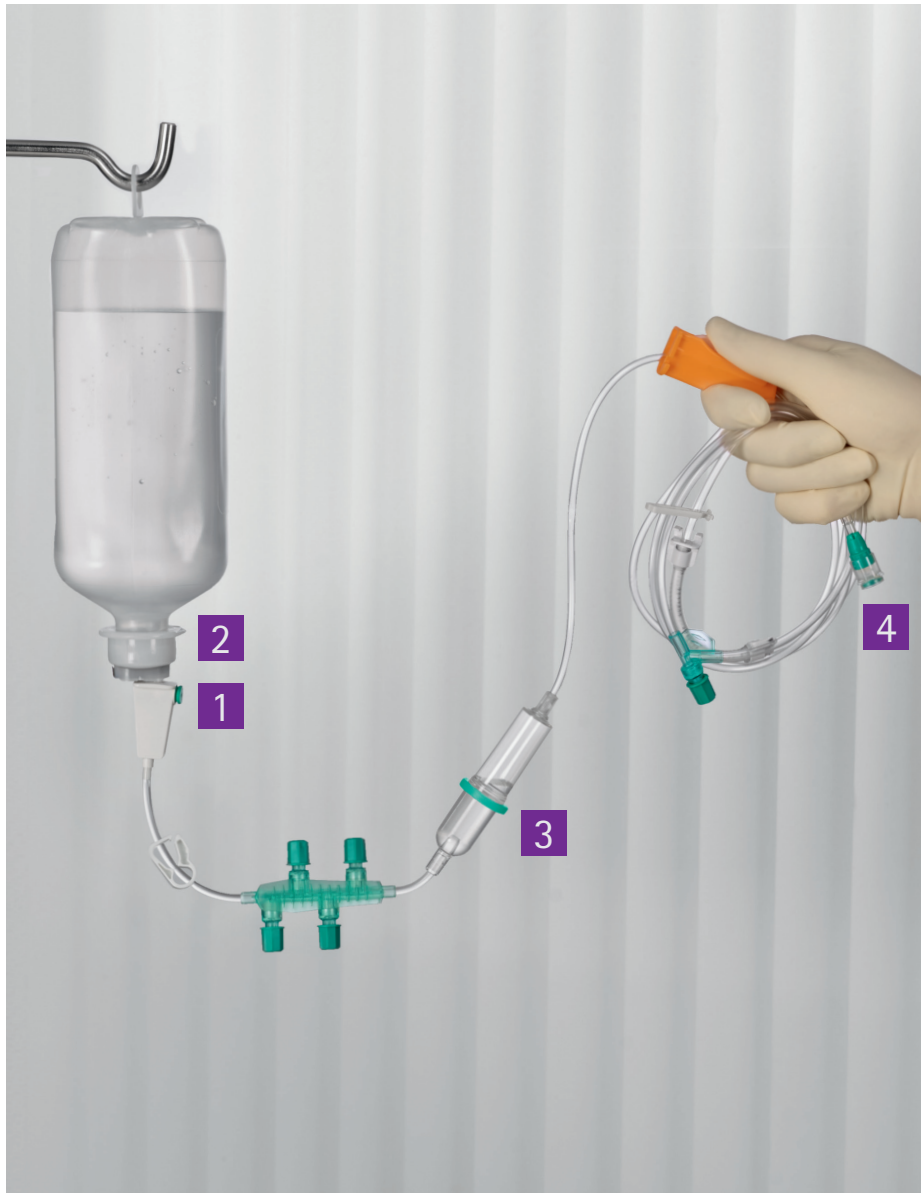
Safety Feature
Helping to reduce risk of microbiological contamination since no direct contact to the needle-free valve is needed. The needle-free valve is preventing needle-stick injuries.
- 3 Handling Step**
Inject drug into container and mix the high concentrated drug well by aspirating once or twice.

Safety Feature
Drug is administered in accordance with the prescribed concentration.

Drug preparation in the pharmacy with Cyto-Set® Mix

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

Application on the Ward



1 Handling Step
Close venting cap.

Safety Feature

Air vent filter in spike with integrated B.C.V. to avoid contamination during venting.

2 Handling Step
Spike the container.

Safety Feature

Tight connection. Once inserted the spike stays firmly connected to reduce the chance of being disconnected accidentally.

3 Handling Step
While allowing system to fill, hold the drip chamber upside down.

Safety Feature

Fluid filter in the drip chamber to avoid particular contamination.

4 Handling Step
Prime the line completely.

Safety Feature

Hydrophobic, bacteria retentive cap maintaining a closed system until connection to the main line without spillages of fluid.

Priming of Cyto-Set® main line on the ward

Cyto-Set® main line is designed for 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 environment of an oncology ward.

PRESCRIPTION

PATIENT ACCESS

PREPARATION



1 Handling Step
Close white clamp of main line.

Safety Feature
Closed clamp prevents a contamination of flushing solution to reduce the risk of drug incompatibilities.

2 Handling Step
Connect Cyto-Set® Mix to main line, open white clamp and start treatment.

Safety Feature
A tactile "click" will let the user know that the sets are connected.

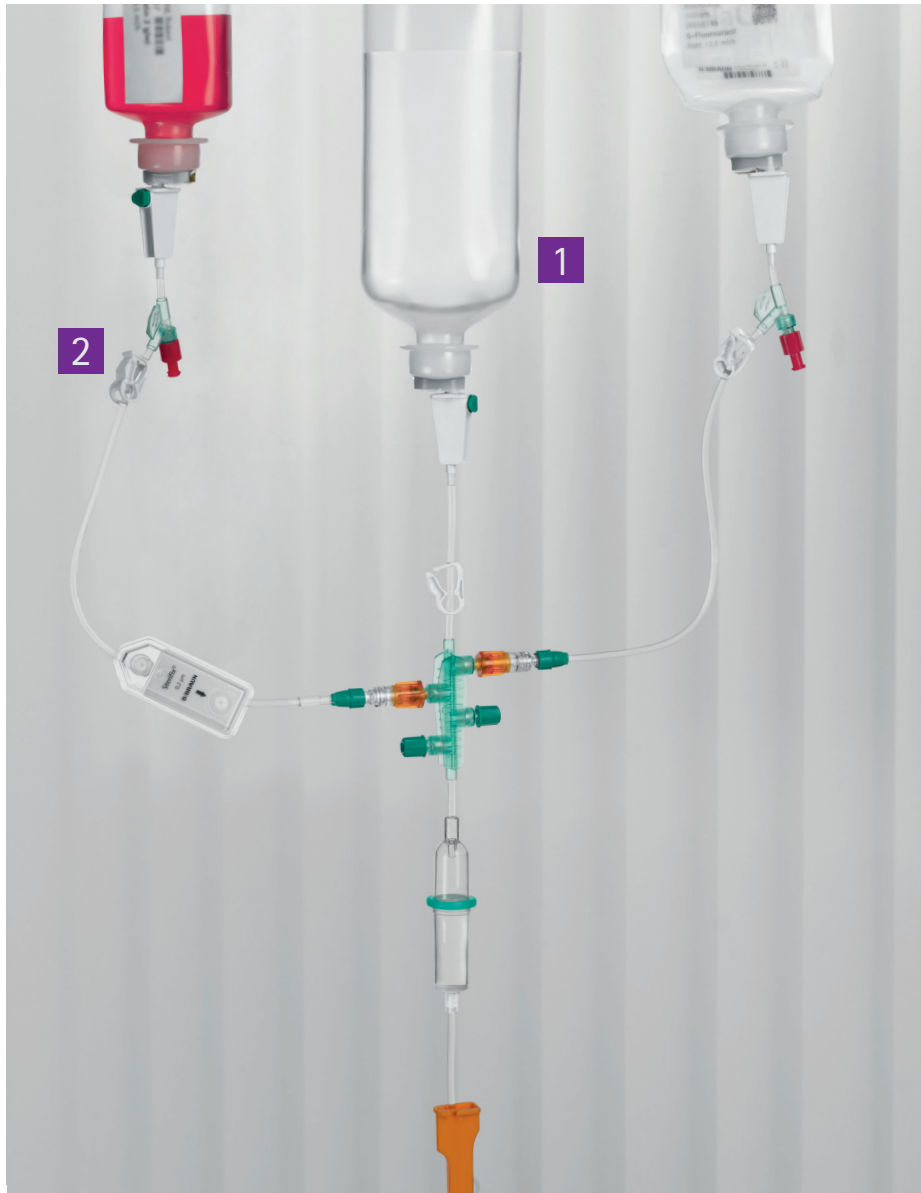
Drug application on the ward with Cyto-Set® & Cyto-Set® Mix

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 ineffective treatment or of an inefficient process. The concept of Cyto-Set® is supporting the process by helping to increase: efficiency, effectiveness and safety!

APPLICATION

DISCHARGE MANAGEMENT

Application on the Ward and Disposal



1 Handling Step
After each drug flush the line completely with flushing solution.

Safety Feature

The full amount of drug is given to the patient which helps to reduce the risk of medication errors.

Thanks to AirStop function the fluid level remains in the drip chamber after drug application. The line is not running dry which helps to prevent air embolism.

2 Handling Step
Open clamp of next Cyto-Set® Mix to start the next treatment.

Safety Feature

Flushing plus integrated back check valves helps to reduce the risk of drug incompatibilities.

Drug application on the ward with Cyto-Set® & Cyto-Set® Mix

In order to support the cancer treatment Cyto-Set® is enabling the user to flush the IV-Set after the treatment completely for the application of the whole medication in accordance with the prescription.

PRESCRIPTION

PATIENT ACCESS

PREPARATION



1 Handling Step
Dispose as a closed system.

Safety Feature
Helps to avoid the risk of chemical contamination because no disconnection is necessary.


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 environment. The whole Cyto-Set® portfolio is also supporting the healthcare worker afterwards to dispose the system in a convenient way.

APPLICATION

DISCHARGE MANAGEMENT

Product Portfolio

Cyto-Set®	Product	Type	Light protection	AirStop	Units per box	Code no. (REF)
	Preparation					
	Cyto-Set® Mix	with 1 needle-free valve	-	-	20	A2900N
		with 1 needle-free valve, with 0.2 µm filter	-	-		A2903N
		with 1 needle-free valve	■	-		A2906N
	Cyto-Set® Line	without needle-free valve	-	-	20	A2581NF
		without needle-free valve, with 0.2 µm filter	-	-		A2582NF
	Application (Gravity)					
	Cyto-Set® Infusion	with 3 needle-free valves	-	-	20	A1687
		with 5 needle-free valves	-	-		A1686SNF
		with 3 needle-free valves	-	■		A1688
		with 5 needle-free valves	-	■		A1687SNF
	Application (Pump)					
	Cyto-Set® Infusomat® Space	with 3 needle-free valves	-	-	20	8250917SP
		with 3 needle-free valves	-	■		835917SP
		with 5 needle-free valves	-	-		8250817SP
with 5 needle-free valves		-	■	835817SP		
with 3 needle-free valves		■	-	8250920SP		
with 3 needle-free valves		■	■	835920SP		
with 5 needle-free valves		■	-	8250820SP		
with 5 needle-free valves		■	■	835820SP		
with 5 needle-free valves, with 0.2 µm filter		-	-	8250414SP		
with 5 needle-free valves, with 0.2 µm filter		-	■	835414SP		
Cyto-Set® Pump Adapter	4 needle-free valves	-	-		A1673S0	

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For further information about Risk Prevention in Infusion Therapy, please refer to the Risk Prevention brochures or scan the QR-code and visit:

WWW.SAFEINFUSIONTHERAPY.COM

B. Braun Medical B.V. | +31 (0)412 67 24 11 | customer care.nl@bbraun.com | www.bbraun.nl
 B. Braun Medical N.V./S.A. | +32 (0)2 712 86 50 | customer care.be@bbraun.com | www.bbraun.be