



PRESCRIPTION

PATIENT ACCESS

PREPARATION

APPLICATION

DISCHARGE  
MANAGEMENT

## Cyto-Set<sup>®</sup>

Advanced preparation and administration of hazardous drugs

NOW FEATURING AIRSTOP TECHNOLOGY

# Challenges in Chemotherapy

Intravenous chemotherapy is one of the most challenging processes within the infusion therapy field. 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 patients are at risk of adverse consequences. International guidelines stipulate the special handling of cytostatic drugs to reduce risks during the process. In line with the regulatory requirements Cyto-Set supports the healthcare provider to prevent the following risks:

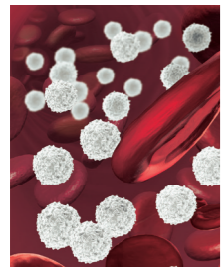


## Chemical Contamination

- 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).<sup>1, 2</sup>

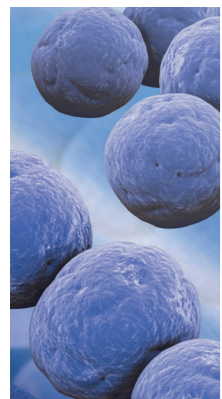


## Drug Incompatibility

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

### Possible consequences<sup>3, 4, 5</sup>

- 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<sup>6, 7</sup>

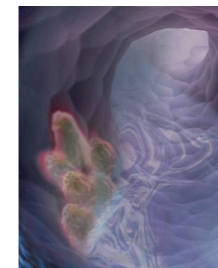


## Particulate Contamination

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

### Possible consequences

- Unfavorable effects (phlebitis, damage lungs<sup>8</sup>, kidneys, nodular fibrosis of the liver and spleen, granulomatous lung disease, myocarditis, occult pulmonary granulomas to local tissue infarction and pulmonary infarction)<sup>9</sup>



## Medication Error

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

### Possible consequences<sup>10</sup>

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

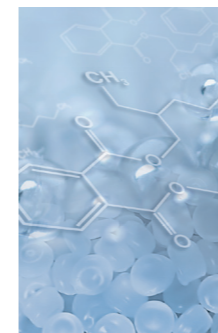


## Sharp Injuries

- 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 the physical trauma itself, but rather the percutaneous exposure to a patient's blood and body fluids (BBF) which may carry infectious diseases.<sup>11</sup> 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.

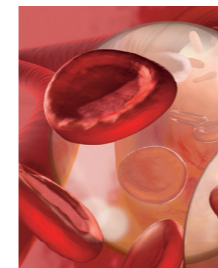


## DEHP-Exposure

- 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.<sup>12</sup>



## 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 clinical signs of air embolism are related to the degree of air entry into the circulation system. They usually develop immediately after embolization.<sup>13</sup>
- 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 clinicians and patients in the field of drug preparation.

The comprehensive portfolio of Cyto-Set® offers a high safety standard of each component. During administration on the ward the new Cyto-Set® portfolio not only improves handling but also increases safety.

The flexibility of Cyto-Set® offers convenient solutions for the application of cytostatic drugs across different clinical requirements. When used together Cyto-Set® Mix, Cyto-Set® Infusion and Cyto-Set® Infusomat® Space provide a closed system from preparation in the pharmacy to administration to the patient, all the way to the disposal of the Cyto-Set® system after treatment.



Risk	Safety Feature	Safety Benefits
Chemical Contamination	<ul style="list-style-type: none"> <li>Needle-free valve</li> </ul>	<ul style="list-style-type: none"> <li>Helps to reduce the risk of chemical contamination as the valves are designed for preventing spillage / drug exposure.<sup>14</sup></li> </ul>
Microbiological Contamination	<ul style="list-style-type: none"> <li>Finger stopper and finger grip</li> <li>PrimeStop</li> <li>Needle-free valve</li> <li>Air vent filter in the spike</li> </ul>	<ul style="list-style-type: none"> <li>Reduction of microbial contamination due to the finger stopper and finger grip.<sup>15</sup></li> <li>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.<sup>16, 17</sup></li> <li>Provides easy access, while helping to reduce the chance of accidental touch contamination.<sup>18</sup></li> <li>The bacteria tight air vent filter in the spike reduces the contamination risk of the infusion solution.<sup>19</sup></li> </ul>
Drug Incompatibility	<ul style="list-style-type: none"> <li>Grip plate with integrated back check valves</li> </ul>	<ul style="list-style-type: none"> <li>Integrated back check valves improve safety by reducing risk of unintended mixture of drugs.<sup>20</sup></li> </ul>
Particulate Contamination	<ul style="list-style-type: none"> <li>15 µm filter in the drip chamber</li> <li>0.2 µm Sterifix® filter</li> </ul>	<ul style="list-style-type: none"> <li>A particle filter in the drip chamber with pore size of 15 µm prevents the infusion of particles from the infusion container.<sup>21</sup></li> <li>The 0.2 µm Sterifix® filter (where fitted) retains bacteria, fungi, particles and air.</li> </ul>
Sharps Injury	<ul style="list-style-type: none"> <li>Needle-free valve</li> </ul>	<ul style="list-style-type: none"> <li>Provides needle-free access, eliminating the risk of needlestick injuries.<sup>22, 23</sup></li> </ul>
Medication Error	<ul style="list-style-type: none"> <li>Structure of the regime</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> </ul>
Air Embolism	<ul style="list-style-type: none"> <li>AirStop</li> </ul>	<ul style="list-style-type: none"> <li>AirStop function in drip chamber reduces the risk of air embolism.<sup>24</sup></li> </ul>
DEHP Exposure	<ul style="list-style-type: none"> <li>PVC / DEHP free tubing</li> </ul>	<ul style="list-style-type: none"> <li>All lines are PVC-free, there is no risk of DEHP exposure.</li> </ul>

# 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, these features support the usability of the new portfolio due to the intuitive handling of the IV-Set.

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 help to reduce the risk of medication errors.
- Integrated back check valves to avoid drug incompatibilities and medication errors caused by 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 decreases the risk of drug in compatibilities 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

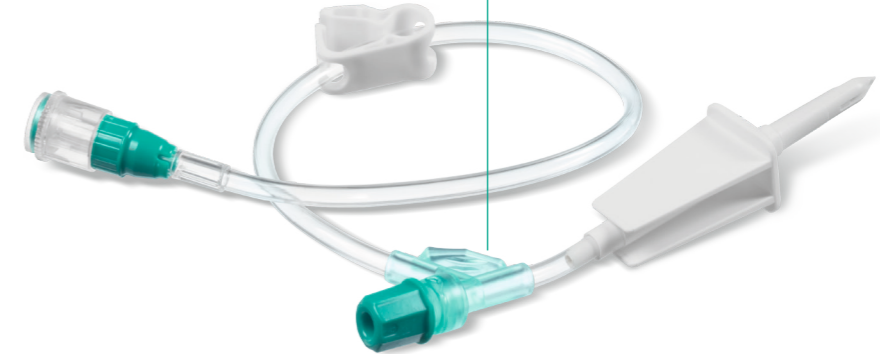
### PrimeStop Cap\*\*

Proven bacteria tightness during storage and transportation.



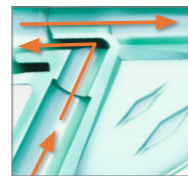
### Vented Spike\*\*\*

High filter performance! The bacterial and viral filter efficiency is higher than 99.99%! <sup>19</sup>



### Needle-free valve

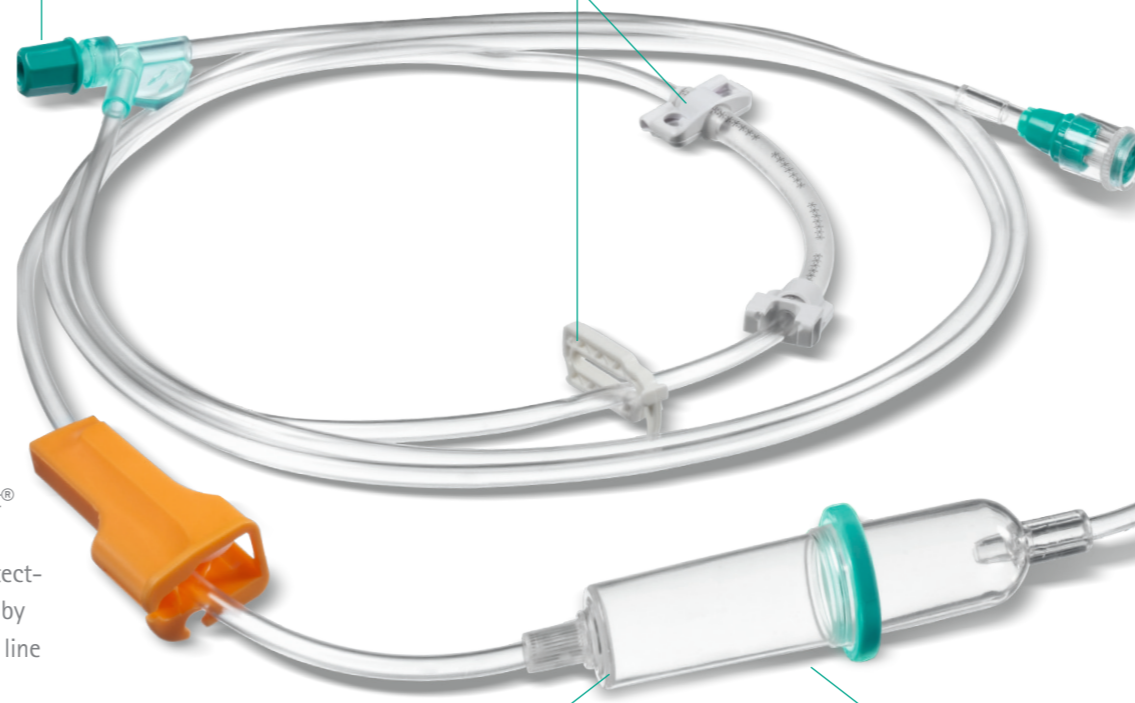
With finger stopper and finger grip helps to reduce the risk of microbial contamination.



- Improved fluid flow for reduced dead space volume.
- Finger plate & finger stopper help to reduce 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.

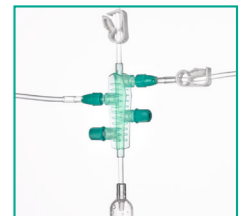


- New designed grip plate with valves made of Tritan™ and integrated back check valves in all needle-free valves.
- Only the combination of automatic closing valve and back check valves enables the closed system\*.

### AirStop

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

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



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



\* 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.

# 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 particles larger than 0.2 µm which reduces the risk of particulate 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. Since cytostatic drugs can pose serious health hazards, Cyto-Set® Mix supports pharmacists by reducing the risk of contamination and helping to increase the process efficiency of drug admixture.



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

**Safety Feature**  
Helps to avoid chemical contamination as the line will only contain inert carrier solution..
- 2 Handling Step**  
Connect prepared syringe with diluted drug to the needle-free valve by using the finger plate.

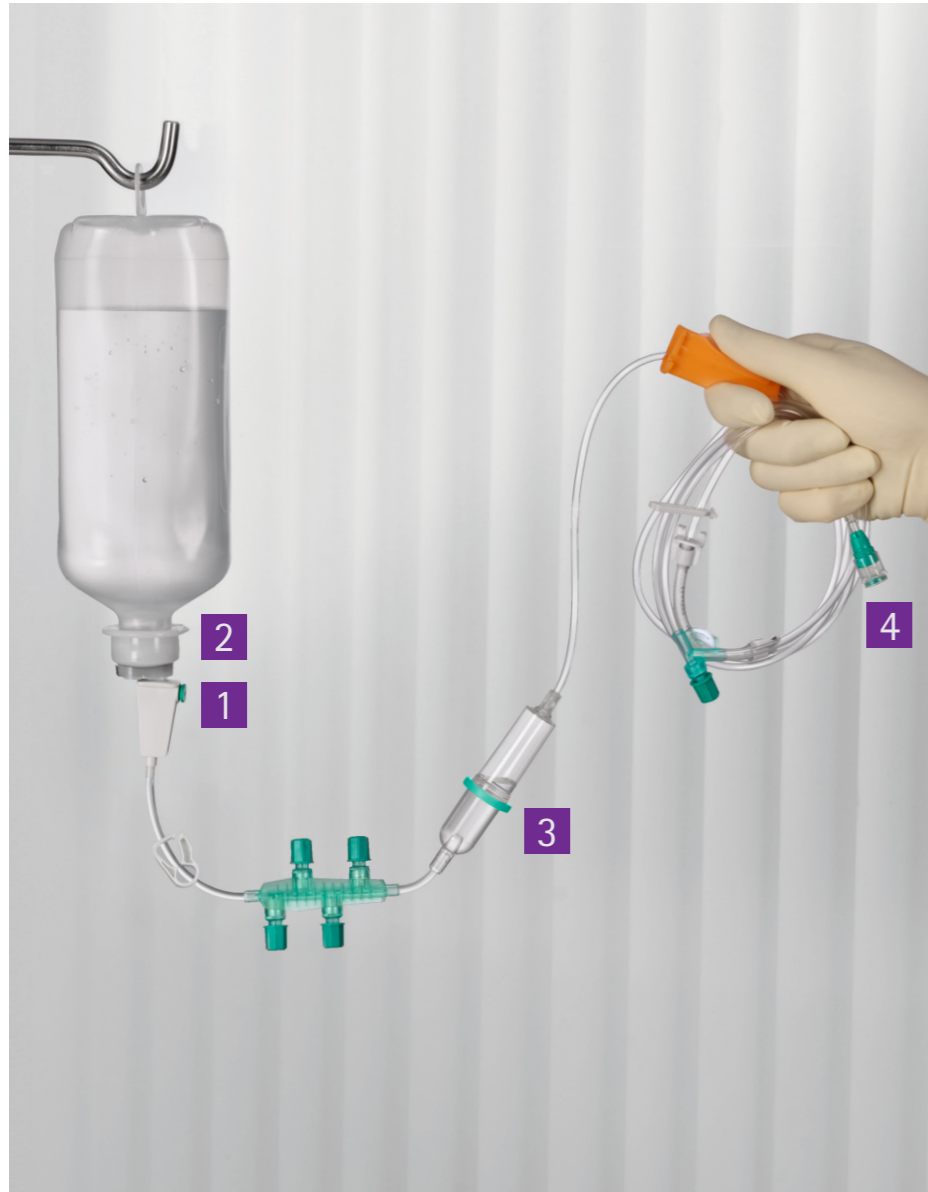
**Safety Feature**  
Helps to reduce risk of microbiological contamination since no direct contact to the needle-free valve is needed. The needle-free valve prevents needle-stick injuries.
- 3 Handling Step**  
Inject drug into container and mix the solution well by aspirating once or twice.

**Safety Feature**  
Drug is administered in accordance with the medical prescription..

## Drug preparation in the pharmacy with Cyto-Set® Mix

During the admixture process, as well as Cyto-Set® Mix, other products from B. Braun's comprehensive portfolio can be utilised; such as the closed male connector PureSite, the semi-rigid container Ecoflac®plus and the luer-lock Omnifix® syringe.

# Application on the Ward



## Priming of Cyto-Set® main line on the ward

Cyto-Set® main line is designed for safer drug administration on the ward by supporting the concept of a safer handling process before, during and after the treatment. Cyto-Set® supports the process with features dedicated to the environment of an oncology 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 particulate 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.



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

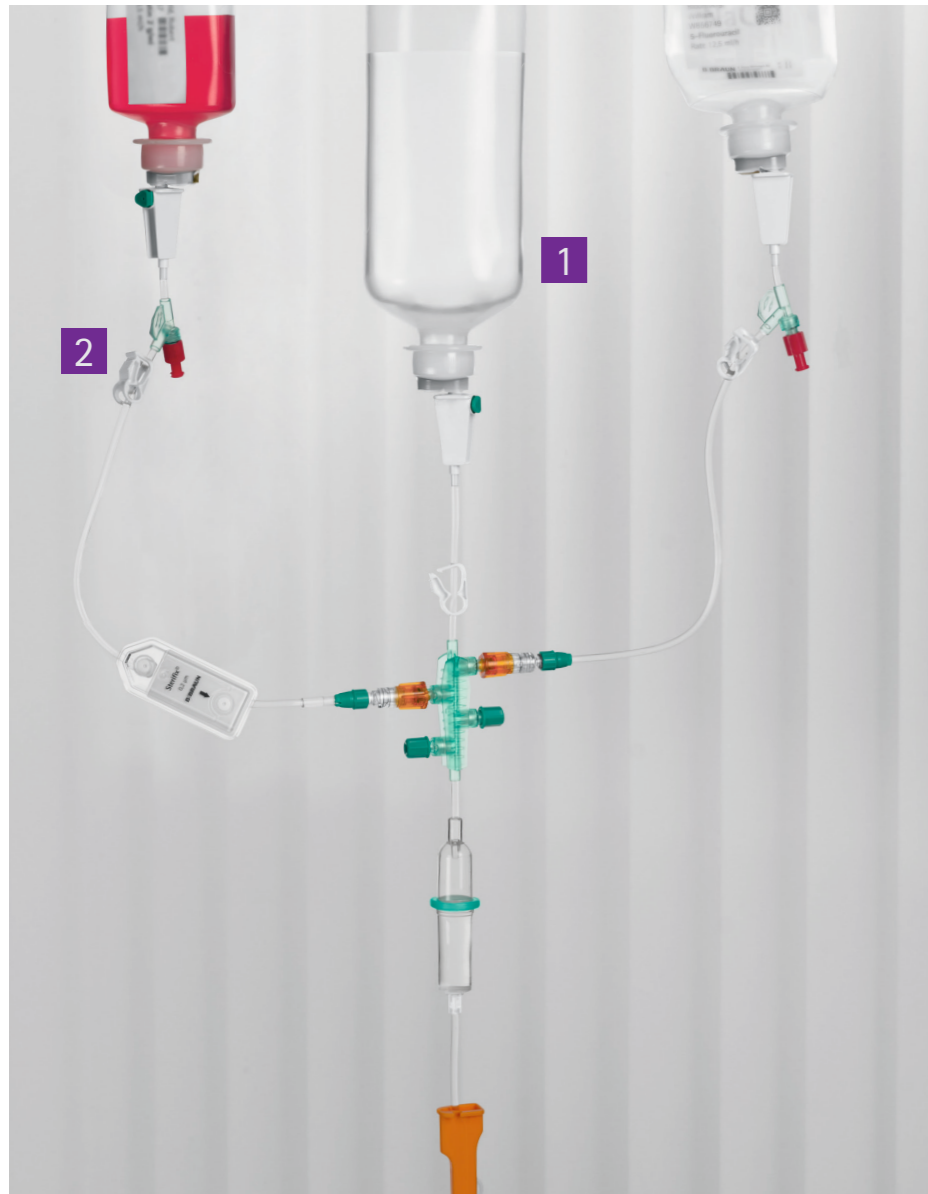
The numbers of cytostatic drugs available on the market are increasing and their cost remains high. Residual volume left in the IV-Set, as well as drug incompatibilities, increases the risk of an ineffective treatment or of an inefficient process. The concept of Cyto-Set® supports the process by helping to increase efficiency, effectiveness and safety!

- 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.

# Application on the Ward and Disposal



**Drug application on the ward with Cyto-Set® & Cyto-Set® Mix**  
In order to support effective treatment, Cyto-Set® enables the user to flush the IV-Set completely, delivering the whole dose in accordance with the medical prescription.

**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 does not run 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.



**Disposal as a complete system**  
Even after the treatment is finished, protection of staff, patients and the environment is vital. Cyto-Set® is disposed of easily and conveniently without any disconnection of the component parts and remains a closed system throughout.

**1 Handling Step**  
Dispose as a closed system.

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

# Product Portfolio

Cyto-Set®	Product	Type	Light protection	AirStop	Units per box	Code no. (REF)
	<b>Preparation</b>					
	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	-	-	A2581NF	
		without needle-free valve, with 0.2 µm filter	-	-	A2582NF	
	<b>Application (Pump) Infusomat® Space</b>					
	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	-		-

# Literature

## Literature

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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](http://WWW.SAFEINFUSIONTHERAPY.COM)