

# Fleboflex<sup>®</sup> Luer

Partners in secure solutions

## Delivering an innovative, safe, and convenient IV solution

0.9% Sodium Chloride Injection,  
USP, in Fleboflex<sup>®</sup> Luer  
plastic container

Please see Important Safety Information  
on page 6 and full Prescribing Information  
on page 7 for 0.9% Sodium Chloride Injection, USP.

**GRIFOLS**



## Fleboflex® Luer is an innovative solution that combines safety and convenience when preparing and administering IV drugs

- ▶ Made of polypropylene: free of PVC, plasticizers, adhesives, and latex
- ▶ With a needle-free system that avoids the risk of accidental punctures
- ▶ Comes partially filled: large additive volume

## Fleboflex® Luer means safety

- ▶ **Prevention of accidental needle stick injuries**
- ▶ **No dripping** at the connection and disconnection of the syringe or vial adaptor
- ▶ **Avoids potential spike drops**
- ▶ **No potential risk** of microbiological contamination in the manipulation



## Fleboflex® Luer means convenience

- ▶ **Large additive volume**
- ▶ **Smooth and quick addition and removal** of medication that prevents RSI (repetitive strain injury) syndrome
- ▶ **High flow rate of the solution**
- ▶ **High resistance** to pressure cuffs, responding satisfactorily to 400 mmHg pressure for 72 hours



<i>Fleboflex® Luer</i>	<b>50/100 mL</b>	<b>100/250 mL</b>	<b>250/500 mL</b>	<b>500/1000 mL</b>
Max. additive volume in mL up to a pressure of 50 mL bar	136	289	422	639
Maximum removable volume (mL)	187	394	677	1139
Residual volume (mL)	0.3-1.8	0.3-1.5	0.2-1.9	0.2-2.6
Air volume (mL)	4-5	5-20	12-30	15-30

Data on file. In 2016, an R&D study was carried out to determine the overfill volume, residual volume, extractable volume and pressure resistance (LG\_ITEC\_I+D-16-0053).

## Fleboflex® Luer is totally collapsible, lightweight, and transparent

The container meets the Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system



### Designed for safe and easy handling

Integrated eyelet support for easy and safe handling of the container during the infusion.

### Product information

- Inclusion of the National Drug Code
- Inclusion of lot and expiration date
- Sequential number

### Highly compatible material

The solution is only in contact with polypropylene. Both the multilayer film and the inner membranes of the medication and outlet ports contain only polypropylene.

Polypropylene can be sterilized at a higher temperature because it resists heat better than other olefins.

### High sealing resistance

High resistance to pressure cuffs.

### Injection/extraction port

Luer-lock valve for automatic locking that allows easy, quick, and safe access to the interior of the bag through the connection of a needle-free syringe or a male vial adaptor.

### Infusion port

Hermetic twist-off made of polypropylene for the connection of the infusion equipment. It maintains sterility until opened.

**Individual overwrap of polypropylene that protects and maintains the sterility of the container and limits evaporative moisture loss from the primary solution container. It is transparent to allow visual inspection and has a peelable opening system.**



## Fleboflex® Luer for hazardous drug compounding

Fleboflex® Luer can be used with any **Closed System Transfer Device** on the market that comes with a luer system

Fleboflex® Luer has drug-container compatibility studies with a selected number of drugs <sup>1,2</sup>	Fleboflex® Luer
	25 °C (77 °F)
<b>Bleomycin sulfate</b> / 0.15 U/mL in 0.9% SC	7 days
<b>Carboplatin</b> / 0.5 mg/mL in 0.9% SC	7 days
<b>Cisplatin</b> / 0.5 mg/mL in 0.9% SC	7 days
<b>Cytarabine</b> / 13 mg/mL in 0.9% SC	7 days
<b>Dacarbazine</b> <sup>3</sup> / 3.4 mg/mL in 0.9% SC	1 day*
<b>Docetaxel</b> / 0.3 mg/mL in 0.9% SC	7 days
<b>Etoposide</b> / 0.3 mg/mL in 0.9% SC	7 days
<b>Epirubicin</b> / 2 mg/mL in 0.9% SC	7 days
<b>Fludarabine</b> / 6 mg/mL in 0.9% SC	7 days
<b>Gemcitabine</b> / 4 mg/mL in 0.9% SC	7 days
<b>Idarubicin</b> / 1 mg/mL in 0.9% SC	7 days
<b>Ifosfamide</b> / 1 mg/mL in SC	7 days
<b>Irinotecan</b> / 2.8 mg/mL in SC	7 days
<b>Methotrexate</b> / 1 mg/mL in 0.9% SC	7 days
<b>Mitoxantrone</b> / 0.2 mg/mL in 0.9% SC	7 days
<b>Oxaliplatin</b> / 0.6 mg/mL in 0.9% SC	7 days
<b>Paclitaxel</b> / 0.3 mg/mL in 0.9% SC	7 days
<b>Vinblastine</b> / 0.2 mg/mL in 0.9% SC	7 days
<b>Vincristine</b> / 0.04 mg/mL in 0.9% SC	7 days
<b>Vinorelbine</b> / 1 mg/mL in 0.9% SC	7 days

1. Data on file, Grifols.

2. Compatibility of additives with Sodium Chloride 0.9% must be checked before adding a medication.

3. DACARBAZINE - dacarbazine injection, powder, for solution. Fresenius Kabi USA, LLC.

\* Dacarbazine solutions should be protected from light and used within 8 hours of reconstitution.

Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus have been reported with 0.9% Sodium Chloride Injection, USP.

Please see Important Safety Information on page 6 and full Prescribing Information on page 7 for 0.9% Sodium Chloride Injection, USP.

## Important Safety Information

Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

### Warnings

#### Hypersensitivity

Hypersensitivity and infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus have been reported with 0.9% Sodium Chloride Injection, USP.

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

#### Electrolyte Imbalances

##### Fluid Overload

Depending on the volume and rate of infusion, and the patient's underlying clinical condition, the intravenous administration of Sodium Chloride Injection, USP can cause fluid disturbances such as overhydration/hypervolemia and congested states, including pulmonary congestion and edema.

Avoid 0.9% Sodium Chloride Injection, USP in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, and acid base balance, as needed and especially during prolonged use.

##### Hyponatremia

Sodium Chloride Injection, USP may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury. Avoid Sodium Chloride Injection, USP in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

##### Hypertatremia

Hypertatremia may occur with Sodium Chloride Injection, USP. Conditions that may increase the risk of hypertatremia, fluid overload and edema (central and peripheral), include patients with: primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia. Avoid Sodium Chloride Injection, USP in patients with, or at risk for, hypertatremia. If use cannot be avoided, monitor serum sodium concentrations.

### Precautions

#### Patients with Severe Renal Impairment

Administration of Sodium Chloride Injection, USP in patients with or at risk of severe renal impairment, may result in hypertatremia and/or fluid overload. Avoid Sodium Chloride Injection, USP in patients with severe renal impairment or conditions that may cause sodium and/or potassium retention, fluid overload, or edema. If use cannot be avoided, monitor patients with severe renal impairment for development of these adverse reactions.

#### Drug Interactions

##### Other Products that Affect Fluid and/or Electrolyte Balance

Administration of Sodium Chloride Injection, USP to patients treated concomitantly with drugs associated with sodium and fluid retention may increase the risk of

hypertatremia and volume overload. Avoid use of Sodium Chloride Injection, USP in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance and acid-base balance.

##### Lithium

Renal sodium and lithium clearance may be increased during administration of 0.9% Sodium Chloride Injection, USP. Monitor serum lithium concentrations during concomitant use.

##### Other Drugs that Increase the Risk of Hyponatremia

Administration of Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia.

Avoid use of Sodium Chloride Injection, USP in patients receiving products, such as diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. If use cannot be avoided, monitor serum sodium concentrations.

#### Pregnancy

Sodium Chloride Injection, USP should be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### Lactation

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing woman.

#### Pediatric Use

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Sodium Chloride Injection, USP may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy.

#### Geriatric Use

Geriatric patients are at increased risk of developing electrolyte imbalances. Sodium Chloride Injection, USP is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function.

### Adverse Reactions

The following adverse reactions have been reported in the post-marketing experience during use of 0.9% Sodium Chloride Injection, USP and include the following: General disorders and administration site conditions (Infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria), Hypersensitivity reactions: (Hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus), Metabolism and nutrition disorders (Hypertatremia, hyponatremia, hyperchloremic metabolic acidosis) and Nervous System Disorders (Hyponatremic encephalopathy).

**0.9% Sodium Chloride Injection, USP  
in FLEBOFLEX and FLEBOFLEX LUER Plastic Container**

**DESCRIPTION**

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. The pH ranges from 4.5 to 7.0. Composition, osmolarity, and ionic concentration are shown below:

**0.9% Sodium Chloride Injection, USP** contains 9 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 308 mOsmol/L (calc). It contains 154 mEq/L sodium and 154 mEq/L chloride.

The FLEBOFLEX and FLEBOFLEX LUER plastic containers are fabricated from latex-free polyolefins or polypropylene plastic materials. The solution contact materials do not contain PVC, DEHP, or other plasticizers. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. The suitability of the container materials has been established through biological evaluations, which have shown the containers pass Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container systems.

**CLINICAL PHARMACOLOGY**

Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

**INDICATIONS AND USAGE**

Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

**Hypersensitivity**

Hypersensitivity and infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus have been reported with 0.9% Sodium Chloride Injection, USP.

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

**Electrolyte Imbalances**

**Fluid Overload**

Depending on the volume and rate of infusion, and the patient's underlying clinical condition, the intravenous administration of Sodium Chloride Injection, USP can cause fluid disturbances such as overhydration/hypervolemia and congested states, including pulmonary congestion and edema.

Avoid 0.9% Sodium Chloride Injection, USP in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, and acid base balance, as needed and especially during prolonged use.

**Hyponatremia**

Sodium Chloride Injection, USP may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH) treated with high volume of Sodium Chloride Injection, USP.

The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). See **Drug Interactions**.

Patients at increased risk for developing complications of hyponatremia such as hyponatremic encephalopathy, include pediatric patients, women (in particular pre-menopausal women), patients with hypoxemia, and patients with underlying central nervous system disease. Avoid Sodium Chloride Injection, USP in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

**Hypernatremia**

Hypernatremia may occur with Sodium Chloride Injection, USP. Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral), include patients with: primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia.

Certain medications such as corticosteroids or corticotropin, may also increase risk of sodium and fluid retention, see **Drug Interactions**.

Avoid Sodium Chloride Injection, USP in patients with, or at risk for, hypernatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hypernatremia is potentially dangerous with risk of serious neurologic complications. Excessively rapid correction of hypernatremia is also associated with a risk for serious neurologic complications such as osmotic demyelination syndrome (ODS) with risk of seizures and cerebral edema.

**PRECAUTIONS**

**Patients with Severe Renal Impairment**

Administration of Sodium Chloride Injection, USP in patients with or at risk of severe renal impairment, may result in hypernatremia and/or fluid overload (see **WARNINGS**). Avoid Sodium Chloride Injection, USP in patients with severe renal impairment or conditions that may cause sodium and/or potassium retention, fluid overload, or edema. If use cannot be avoided, monitor patients with severe renal impairment for development of these adverse reactions.

**Drug Interactions**

**Other Products that Affect Fluid and/or Electrolyte Balance**

Administration of Sodium Chloride Injection, USP to patients treated concomitantly with drugs associated with sodium and fluid retention may increase the risk of hypernatremia and volume overload. Avoid use of Sodium Chloride Injection, USP in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance and acid-base balance.

**Lithium**

Renal sodium and lithium clearance may be increased during administration of 0.9% Sodium Chloride Injection, USP. Monitor serum lithium concentrations during concomitant use.

**Other Drugs that Increase the Risk of Hyponatremia**

Administration of Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia.

Avoid use of Sodium Chloride Injection, USP in patients receiving products, such as diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. If use cannot be avoided, monitor serum sodium concentrations.

**Pregnancy**

There are no adequate and well controlled studies with Sodium Chloride Injection, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman. Sodium Chloride Injection, USP should be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Lactation**

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing woman.

**Pediatric Use**

The use of Sodium Chloride Injection, USP in pediatric patients is based on clinical practice. (See **DOSAGE AND ADMINISTRATION**).

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Sodium Chloride Injection, USP may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy.

**Geriatric Use**

Geriatric patients are at increased risk of developing electrolyte imbalances. Sodium Chloride Injection, USP is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Therefore, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Consider monitoring renal function in elderly patients.

**ADVERSE REACTIONS**

**Post-Marketing Adverse Reactions**

The following adverse reactions have been identified during post approval use of Sodium Chloride Injection, USP. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported in the post-marketing experience during use of 0.9% Sodium Chloride Injection, USP and include the following:

**General disorders and administration site conditions:** Infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria.

**Hypersensitivity reactions:** Hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus.

**Metabolism and nutrition disorders:** Hyponatremia, hyponatremia, hyperchloremic metabolic acidosis. Nervous System Disorders: Hyponatremic encephalopathy.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

**OVERDOSAGE**

Excessive administration of 0.9% Sodium Chloride Injection, USP can cause hypernatremia. Hypernatremia can lead to CNS manifestations, including seizures, coma, cerebral edema and death.

Excessive administration of Sodium Chloride Injection, USP can cause fluid overload (which can lead to pulmonary and/or peripheral edema). See **WARNINGS** and **ADVERSE REACTIONS**.

When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment.

Interventions include discontinuation of Sodium Chloride Injection, USP administration, dose reduction, and other measures as indicated for the specific clinical constellation (e.g., monitoring of fluid balance, electrolyte concentrations and acid base balance).

**DOSAGE AND ADMINISTRATION**

**Important Preparation and Administration Instructions**

- Sodium Chloride Injection, USP is intended for intravenous administration using sterile equipment.
- Prior to infusion, visually inspect the solution for particulate matter and discoloration. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear, and container is undamaged.
- To reduce the risk of air embolism, adhere to the following preparation instructions for Sodium Chloride Injection, USP:
  1. Use a non-vented infusion set or close the vent on a vented set.
  2. Use a dedicated line without any connections (do not connect flexible containers in series).
  3. The use of pressure infusion is not recommended as a method to increase flow rates. However, if pressure infusion is required, ensure that all air within the bag is fully evacuated prior to initiation of infusion.
  4. If using a pumping device to administer Sodium Chloride Injection, turn off the pump before the container is empty.

**Dosing Information**

The choice of product, dosage, volume, rate, and duration of administration is dependent upon the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician experienced in intravenous fluid therapy.

**Introduction of Additives**

Additives may be incompatible.

Evaluate all additions to the plastic container for compatibility and stability of the resulting preparation. Consult with a pharmacist, if available.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Do not store solutions containing additives. Discard any unused portion.

**HOW SUPPLIED**

The available sizes of 0.9% Sodium Chloride Injection, USP are shown below:

Size (mL)	NDC	Size (mL)	NDC
<b>Fleboflex bags:</b>		<b>Fleboflex Luer bags:</b>	
50 (115 units in one carton)	76297-001-11	50 (90 units in one carton)	76297-001-51
100 (70 units in one carton)	76297-001-21	100 (50 units in one carton)	76297-001-61
250 (28 units in one carton)	76297-001-31	250 (32 units in one carton)	76297-001-71
500 (20 units in one carton)	76297-001-01	500 (24 units in one carton)	76297-001-81
1000 (10 units in one carton)	76297-001-41	1000 (10 units in one carton)	76297-001-91

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at 20° to 25°C (68° to 77°F); excursions are permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.] Store unit in moisture barrier overwrap. Brief exposure up to 40°C (104°F) does not adversely affect the product.

**DIRECTIONS FOR USE OF FLEBOFLEX and FLEBOFLEX LUER PLASTIC CONTAINER**

For Information on Risk of Air Embolism – see **DOSAGE AND ADMINISTRATION**.

**To Open**

Peel off the overwrap and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

**Preparation for Administration**

1. Suspend container from eyelet support.
2. Fleboflex bags: Remove plastic protector from outlet port at bottom of container. Fleboflex Luer bags: Break the twist-off administration port by means of torsion.
3. Attach administration set. Refer to complete directions accompanying set.

**To Add Medication**

Additives may be incompatible.

**To add medication before solution administration**

1. Prepare medication site.
2. Fleboflex bags: Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject. Fleboflex Luer bags: Using syringe or vial, connect to the needle-free medication port and inject.
3. Mix solution and medication thoroughly.

**To add medication during solution administration**

1. Close clamp on the set.
2. Prepare medication site.
3. Fleboflex bags: Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject. Fleboflex Luer bags: Using syringe or vial, connect to the needle-free medication port and inject.
4. Remove container from intravenous pole and/or turn to an upright position.
5. Mix solution and medication thoroughly.
6. Return container to in-use position and continue administration.

**Laboratorios Grifols, S.A.**

Murcia - SPAIN  
Printed in SPAIN  
Rev. 04/2025  
GRIFOLS and FLEBOFLEX are trademarks of Grifols, S.A.

**GRIFOLS**

Laboratorios Grifols, S.A. Calle Marte n 4 – Polígono Industrial Los Llanos  
30565 Las Torres de Cotillas- Murcia SPAIN

# Guidelines for Fleboflex® Luer use

## ► Overwrap removal

The overwrap serves as a moisture barrier. It is intended to limit evaporative moisture loss from the primary solution container.



**1.** The overwrap is designed to be opened by pulling apart the 2 sheets of the overwrap.



**2.** The recommended method to remove the overwrap is to peel off one sheet by the corner while holding the other sheet at one end and carefully remove the solution container.

**The overwrap should not be removed until product is to be used.**

## ► Container inspection

Visually inspect the container for particulate matter and discoloration.

Check for minute leaks by squeezing inner container firmly. **If leaks are found, discard solution as sterility may be impaired.** If the ports are damaged, detached, or not present, discard container as solution path sterility may be impaired.

**Do not administer unless the solution is clear and seal is intact.**

## ► Adding medications and solution removal with a needle-free syringe



**1.** Connect a syringe to the luer valve.



**2.** Secure the connection with a small rotational movement.



**3.** Add or remove solution.

**The compatibility of the additives with Sodium Chloride 0.9% must be checked before adding a medication.**

## ► Reconstitution of vials with vial adaptor



**1.** Remove the protective foil from the blister containing the vial adaptor. Do not remove the adaptor from the blister.



**2.** Without removing the blister, connect the vial adaptor in the vial by pressing vertically on the surface until the adaptor is fixed and the awl has penetrated the surface of the vial.



**3.** Remove the blister.



**4.** The vial with the vial adaptor is ready to reconstitute once connected to the luer valve of the bag.

Please see Important Safety Information on page 6 and full Prescribing Information on page 7 for 0.9% Sodium Chloride Injection, USP.