NIPRO

HOSPITAL PRODUCTS

SUREFUSER™+

PORTABLE INFUSION SYSTEM

PATIENT GUIDE

PATIENT GUIDE| SUREFUSER™+

Nipro's Surefuser™+ has been prescribed for your home infusion therapy and is designed to deliver your medication according to your personal treatment schedule as determined by your physician. This patient guide will help you become familiar with Surefuser™+ and how it works.

This patient guide is intended as general information only and does not replace the information provided to you by your healthcare provider. Please ask your healthcare provider if you have any questions about this patient guide.

WHAT IS SUREFUSER™+?

Surefuser™+ allows patients to receive intravenous (IV) treatment in the comfort of home without being confined to bed. It is a disposable and portable elastomeric infusion pump, also called an ambulatory balloon infuser.

Simply stated, Surefuser+

- is a self-powered pump that uses the force of a deflating medical-grade isoprene balloon to infuse medication via catheter
- does not require batteries or electricity
- ensure a silent operation withoun confusing alarms

HOW DOES IT WORK?

Before starting your treatment, always discuss with your healthcare provider the possible side effects of your treatment and what to do in case of complications or emergencies. Also make sure that you are aware of the safety precautions

Preparation

The hospital prepares the device for your therapy treatment. They load the prescribed medication by connecting a syringe to the pump. As they inject the medication, the balloon inflates, just like you would inflate a normal

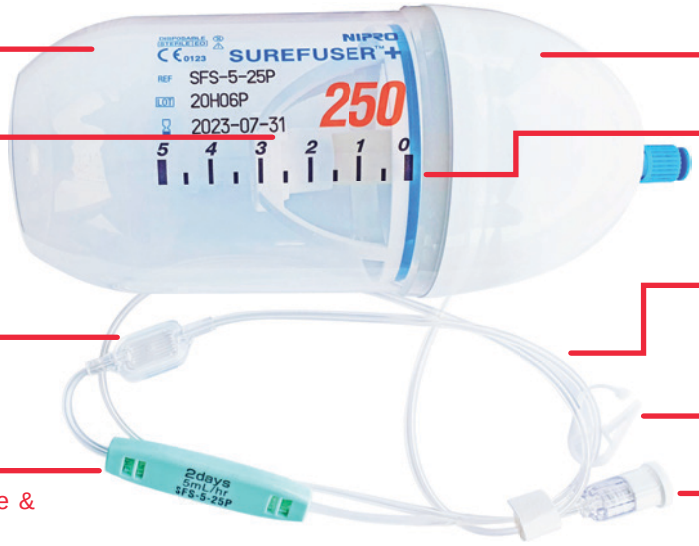
Administration

As the balloon inflates, it stores energy that is used to push out the medication from the balloon into the infusion line. To ensure the medication flows at a constant rate, a flow regulator is integrated in the infusion line. It is the flow regulator that determines how fast your medication will be administered. Based on the pump volume and speed of the flow regulator, your nurse will indicate to you when the balloon is expected to be empty. Connecting and disconnecting the device from your catheter should always be performed by a trained healthcare professional.

Disposal

Ask your healthcare provider regarding your country's disposal guidelines. The pump should never be disposed of in your regular waste bin at home.

Surefuser™+ Components



Protective Housing

Balloon Reservoir
Holds medication

Integrated Filter
Self venting 0.2µ

Flow Regulator
Controls medication flow rate & color coded for convenience

Port Cap

Infusion Scale
Monitors you patient's infusion progress

Infusion Line
Kink resitant and DEHP free

Clamp

Luer Connector

WHAT ARE THE DIFFERENT PARTS OF A SUREFUSER™+?

- **Balloon pump:** Contains the medication for your therapy
- **Housing:** Protects the balloon containing your medication
- **Balloon volume:** The volume of the balloon pump at 100% filling grade
- **Scaling:** Allows you to monitor infusion progress
- **Clamp:** Allows you to stop infusion if you must pause or cease treatment
- **Infusion line:** Carries the medication from the balloon pump to your catheter
- **Dual filter:** Removes air from the infusion line and prevents particles larger than 0.2 µm* from passing through
- **Flow regulator:** Determines the speed of infusion
  - Your doctor will have provided you a Surefuser™+ with the correct flow rate for your therapy
- **Port cap:** Protects the port for filling the balloon with medication
- **Hydrophobic filter:** Allows air to pass, but stops liquid

WHAT FACTORS MAY AFFECT INFUSION?

Although Surefuser™+ does not require any intervention during the treatment duration, there are some external factors that can influence the infusion speed. It is best to keep these external factors as constant as possible to ensure a predictable

TEMPERATURE

The flow regulator, which regulates how fast the medication flows, is calibrated at skin temperature. Therefore, it is important to keep the flow regulator attached to the body.

The device itself is best kept at room temperature. When inside, keep it away from heat sources, such as radiators or the stove. When going outside, keep it out of direct sunlight (especially in the summer) and protect it under your clothes when going outside during colder periods. We recommend using the Surefuser + carrying bag, as this bag is thermo-insulated.

BALLOON PUMP POSITION

The height position of the pump relative to the infusion point (your cathe-ter location) also affects the infusion speed. For the medication to flow at a normal flow rate, the pump should be positioned at the same level of height as the infusion point.

If the pump is kept in a higher position than the infusion point, the flow increases because of gravity. On the other hand, if the pump is below the position of the infusion point, the flow decreases.

MUST I DO ANYTHING DURING TREATMENT ?

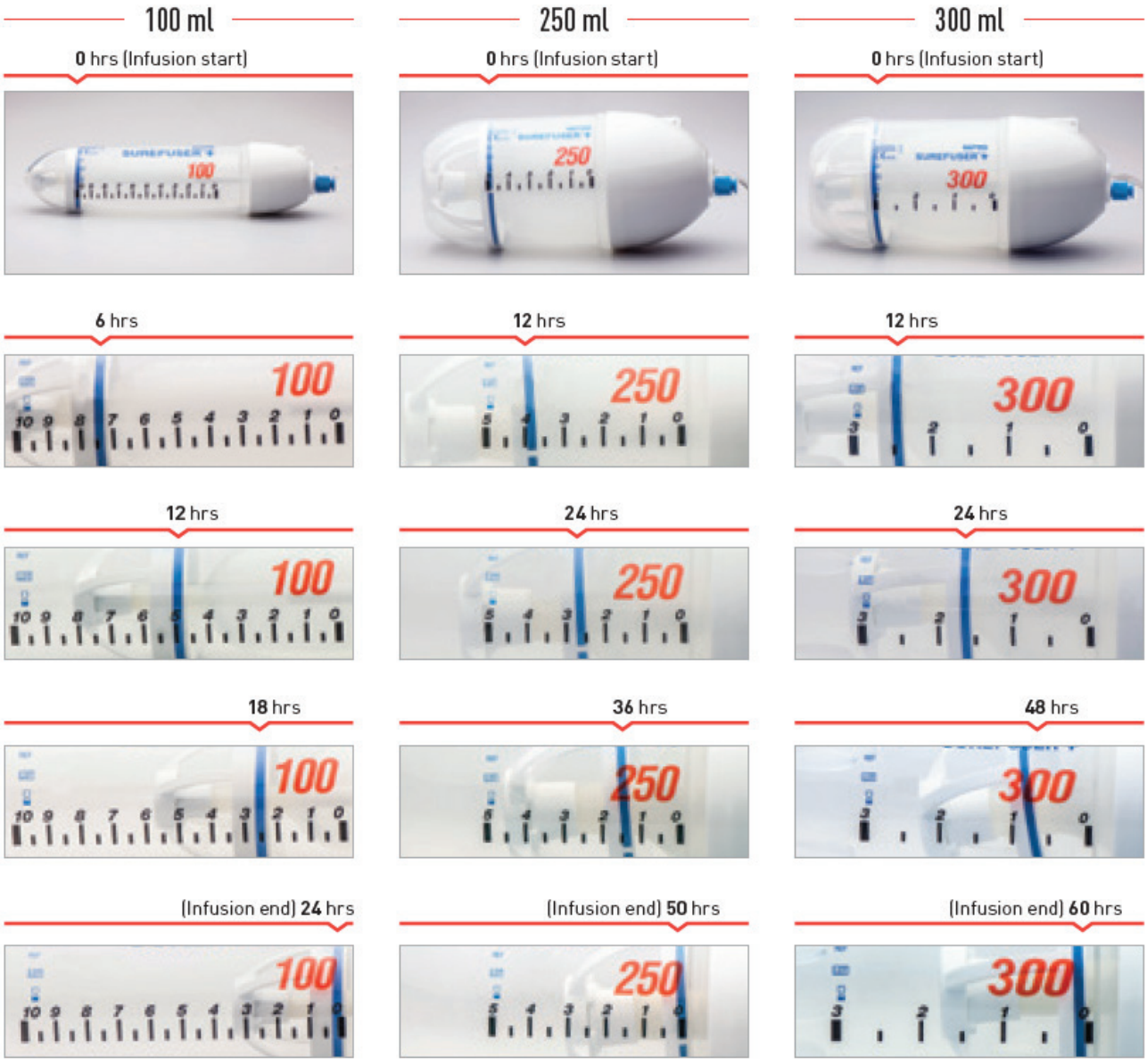
Surefuser™+ is self-powered, but we advise that you regu-larly verify that the medication is being infused at the expect-ed speed. Surefuser™+ does not require any Programming or adjusting once the therapy has begun. However, as explained above, infusion can be influenced by external factors. Check-ing if the balloon deflates as expected will give you a good indication of infusion progress. As the balloon deflates, the blue progression line moves along the scale, indicating the infusion progress.

Depending on the volume of the pump, the scaling goes from 0 – 3, 0 – 5 or 0 – 10 with intervals of 1.

- For volumes of 50 ml and 100 ml, each interval of 1 corresponds approximately to 10 ml.
- For volumes of 150 ml and 250 ml, each interval of 1 corresponds approximately to 50 ml.
- For the largest pump of 300 ml, each interval of 1 corresponds approximately to 100 ml.

Infusion progression examples

100 ml pumpwith 4.2 ml/hr flow rate		250 ml pump with 5 ml/hr flow rate		300ml pump with 5 ml/hr flow rate	
Infusion time	Blue line position	Infusion time	Blue line position	Infusion time	Blue line position
0 hr (start)	10	0 hr (start)	5	0 hr (start)	3
6 hrs	7-8	12 hrs	3-4	12 hrs	2-3
12 hrs	4-6	24 hrs	2-3	24 hrs	1-2
18 hrs	1-4	36 hrs	1-2	48 hrs	0-1
24 hrs	0-1	50 hrs	0-1	60 hrs	0-1



IS TREATMENT WITH SUREFUSER™+ SAFE?

Yes! Your health and safety are of primary importance at Nipro. Therefore, we incorporated a number of safety mechanisms into Surefuser™+ to ensure that you can receive your therapy safely and worry-free.

SOLID PROTECTION

The light, but sturdy housing protects the balloon that contains your medication. It also keeps the medication safely contained within the device in the unlikely event that the balloon would leak. The filter on the bottom of the pump allows air to pass through, which allows the balloon to expand and deflate without additional pressure, while preventing liquid from passing through. Remember, this filter should be kept dry.

BUILT-IN “EMERGENCY BRAKE”

The clamp on the infusion line will allow you to stop the infusion at any time if you must pause or cease treatment. Just press firmly on the clamp an it will close the infusion line. Since the clamp is integrated into the infusion line, you will always have it handy if needed.

PARTICLE AND AIR FILTRATION

The filter allows air to escape from the infusion line while also preventing any particles larger than 0,2 µm* from passing through. As a reference, the bacteria Staphylococcus aureus, a strain that most commonly causes hospital-acquired infections, is 0,5 – 1,5 µm in size and cannot pass the filter.[1,2] Remember, this filter should be kept dry.

CAREFULLY CHOSEN MATERIALS

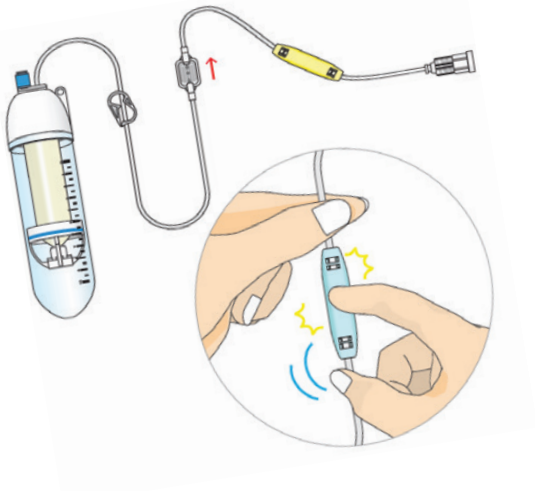
Nipro’s strong focus on safety and health is also reflected in our choice of materials. The materials used to produce Surefuser+ are not made with DEHP and latex. DEHP is a plasticizer that is known to be an endocrine disruptor, meaning this molecule can cause a disruption of normal hormonal balance.[3] Latex is known to induce latex allergies after repeated exposure to products containing natural rubbers.[4] Surefuser+ does not contain either material.

WHAT TO DO IN CASE OF...?

Nipro developed Surefuser™+ with the utmost care, making patient safety our number one priority. In rare cases, you may encounter an unexpected scenario during treatment. We present the following situations for general reference. Always follow the guidelines provided by your HCP.

AIR IN THE INFUSION LINE

Nipro's strong focus on safety and health is also reflected in our choice of materials. The materials used to produce Surefuser™+ are not made with DEHP and latex. DEHP is a plasticizer that is known to be an endocrine disruptor, meaning this molecule can cause a disruption of normal hormonal balance. [3] Latex is known to induce latex allergies after repeated exposure to products containing natural rubbers.[4] Surefuser™+ does not contain either material.



MEDICATION THAT NO LONGER FLOW

Verify that the clamp on the infusion line is open. Check the infusion line to make sure it is not twisted or kinked. If the clamp and infusion line are fine, try tapping the flow regulator with your fingertips while holding the filter vertically (see drawing). If the infusion still does
not start, close the clamp and call your hospital to understand how to proceed.

LEAKAGE

Close the clamp immediately. If leaking from the infusion line, close the clamp above the point where the leakage occurs. If leaking from one of the connections, check if they are closed tight. Remember to wear protective gloves while doing so. If leaking from the pump housing, place it in a plastic bag. Report all leakages to your hospital and follow their advice. If the medication came into contact with your skin, follow the guidelines provided by your hospital. In case of severe complications, call emergency services.

INFUSION PROGRESSION THAT IS SLOWER OR FASTER THAN EXPECTED

Call your hospital to determine if treatment can be continued or if it should be stopped. In the event treatment should be stopped, close the clamp on the infusion line and follow the guidelines provided to you by the hospital. In case of severe complications, call emergency services.

BURSTING OF THE BALLOON

Close the clamp to stop treatment. Place the pump housing in a plastic bag. Call your hospital to understand how to proceed. Do not disconnect the infusion line from your catheter unless advised by your healthcare provider.

FREQUENTLY ASKED QUESTIONS

Can I swim with SureFuser+?

No, swimming is not allowed because SureFuser™+ should not be submerged in water. Sauna or steam room visits are also not allowed.

Can I travel by air with SureFuser+?

Yes, Please consult with your doctor before taking Surefuser™+ on flight with you.

Can I go outside with Surefuser+?

Yes, however, Surefuser+ must stay out of direct sunlight and should not be exposed to high temperatures. Please ensure the flow regulator is securely attached to your skin. The pump should be kept in its carrying bag, as the device must remain at room temperature.

Can I sleep with Sure-fuser™+?

Yes. We recommend that you keep Surefuser™+ in a secured place on or near your bed and at the same “head height” as your sleeping position. Do not keep it under your bed covers, as the pump must remain at room temperature.

Can I take a shower/bath with SureFuser™+?

Please check with your healthcare provider if it is ok for you to shower or take a bath. Please make sure that the pump housing and the infusion line are not submerged or exposed to a direct stream of water. The filter should not come into contact with water or soap.

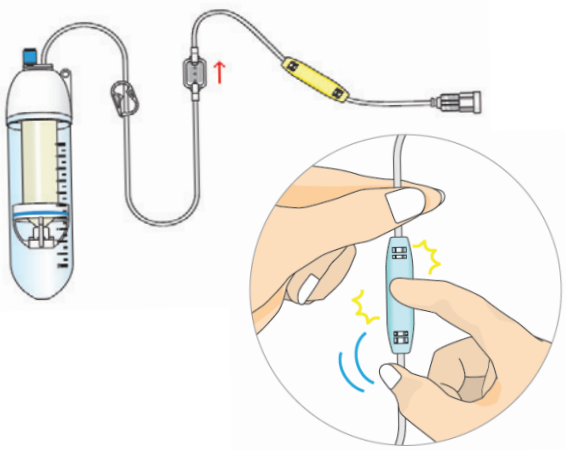
WHAT TO DO IF....

...there is a leak:

In the unlikely event of a leakage, close the clamp immediately. If leaking from the infusion line, close the clamp above the point where the leakage occurs. If leaking from one of the connections, check if they are closed tight. Remember to wear protective gloves while doing so. If leaking from the pump housing, place it in a plastic bag. Report all leakages to your hospital and follow their advice. If the medication came into contact with your skin, follow the guidelines provided by your hospital. In case of severe complications, call emergency services.

...infusion stopped before the balloon has emptied:

Verify that the clamp on the infusion line is open. Check the infusion line to make sure it is not twisted or kinked. If the clamp and infusion line are fine, try tapping the flow regulator with your fingertips while holding the filter vertically (see drawing). If the infusion still does not start, close the clamp and call your hospital to understand how to proceed.



...the infusion progression is slower or faster than expected:

Call your hospital to determine if treatment can be continued or if it should be stopped. In the event treatment should be stopped, close the clamp on the infusion line and follow the guidelines provided to you by your hospital. In case of severe complications, call emergency services.

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