

SUREFUSER+™

Portable disposable infusion device



Diabetes Care

Renal Care

Pathology Systems

Injection Systems

Infusion Care



NIPRO

Your Partner in Health Care

What is a portable disposable infusion device?



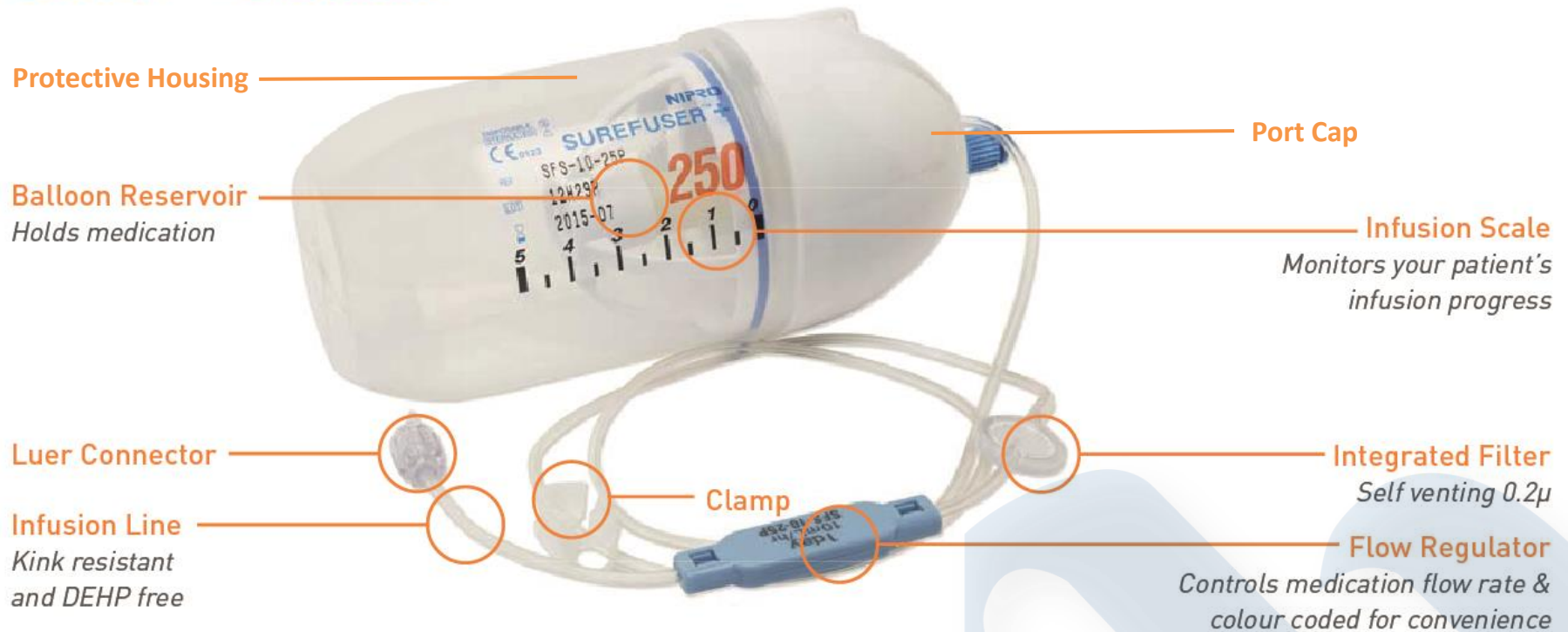
- An infusion system with non-electric power source (such as elastomeric balloon, atmospheric pressure, or spring)
- Is ambulatory, and delivers a fixed quantity of drug continuously
- Some pumps include a variable flow option or PCA (patient controlled analgesia)

Indications/Use

- Administration of analgesic (pain-killers) or local anesthetic; **epidural**
 - Post-operative pain control
 - Carcinomatous pain control
 - Labour pain control
 - **Anesthesiology**
- Continuous arterial injection of **anticancer drug** / continuous **intravenous infusion**
 - Cancer chemotherapy
 - **Internal Medicine, Surgery, Radiology**
- A very small amount of continuous infusion of other drugs (e.g. Heparin locks for in-dwelling catheter)

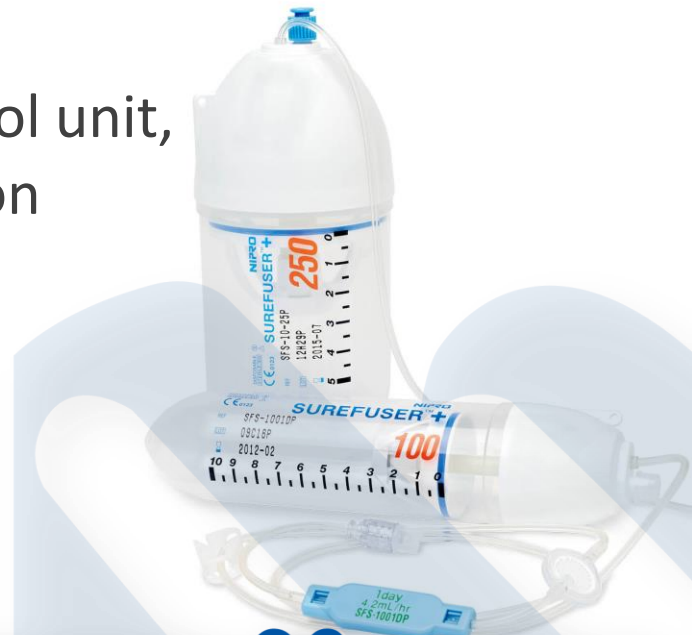
SUREFUSER™+ System Components

Surefuser™+ Components



How does SUREFUSER™ + work?

- The Surefuser™ + protective housing contains a balloon reservoir
- Filling the Surefuser™ + with drug expands the balloon reservoir
- The balloon reservoir contracts, discharging the medication
- Medication flows through a flow control unit, maintaining a consistent rate of infusion based on the Hagen-Poiseuille Law



Why SUREFUSER™ +?

SAFETY

- Bacteria, foreign substances and air bubbles are removed by the **0.2μ membrane filter** which is integrated into the infusion line

ACCURATE FLOW RATE

- The flow regulator calibrates to skin temperature to minimise any impact on flow rate by ambient/environmental temperature

CONSISTENT FLOW

- High balloon pressure (400-450mmHg) guards against pressure drop
 - *Ideal for arterial injection chemotherapy*

CONVENIENT – IN-HOSPITAL & HOME-CARE

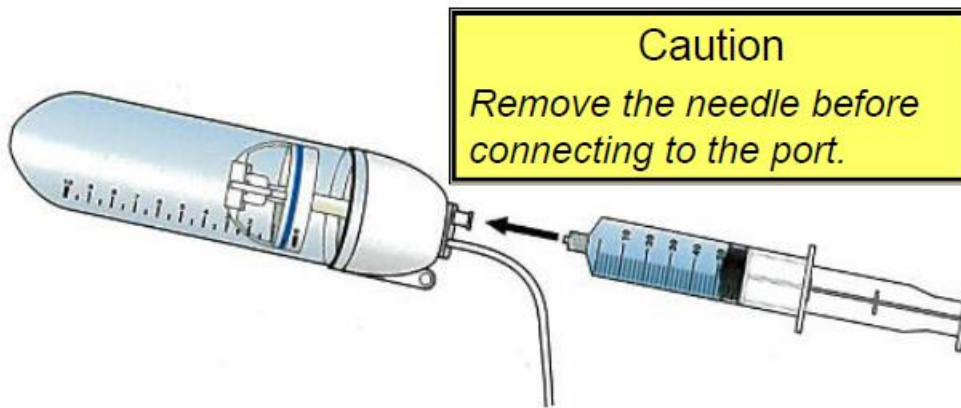
- Compact, discrete design – can be carried in breast pocket (50ml,100ml)



Operating Instructions (1)

Prepare medication

- Ensure you are working in sterile conditions
- Fill a luer lock syringe with medication. Remove all air bubbles from the syringe
- Remove the port cap and ensure the syringe is securely connected to the port

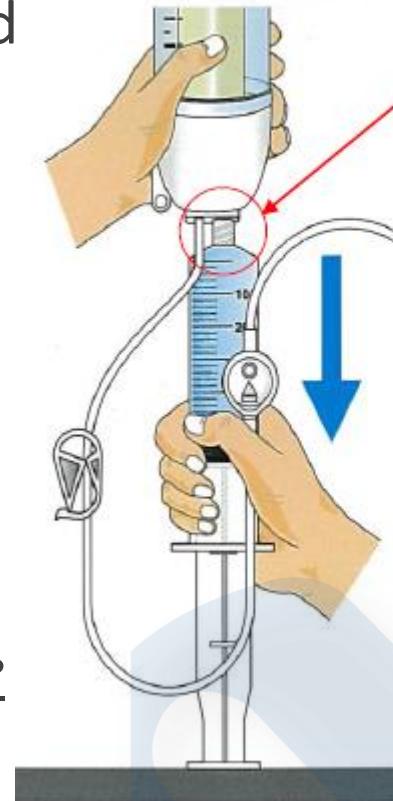


Please don't over tighten when connecting the syringe to the port. It may cause breakage of the syringe and/or port tip.

Operating Instructions (2)

Fill Surefuser™+

- Close clamp of the infusion line and fill the balloon with medication. Ensure syringe and port are in straight line (do not incline the syringe or Surefuser™+) during filling procedure
- Apply pressure on the syringe, not the Surefuser+
- After filling, close the port cap. Use the port cap which is included with the original product.



The a hand holding the Surefuser is only maintaining the position of the balloon body.

Do not apply downwards pressure of the balloon body

Operating Instructions (3)

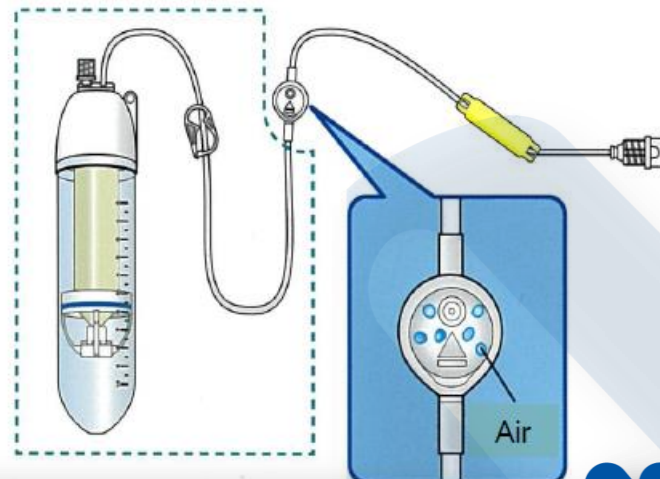
Priming

- Open the clamp holding the infusion line with the arrow on the **filter pointing upwards**.
- Priming of the infusion line starts automatically.
- When the filter is fully primed, you can release your hand from it's vertical position.
- When infusion line is fully primed, close the clamp.

Operating Instructions (3)

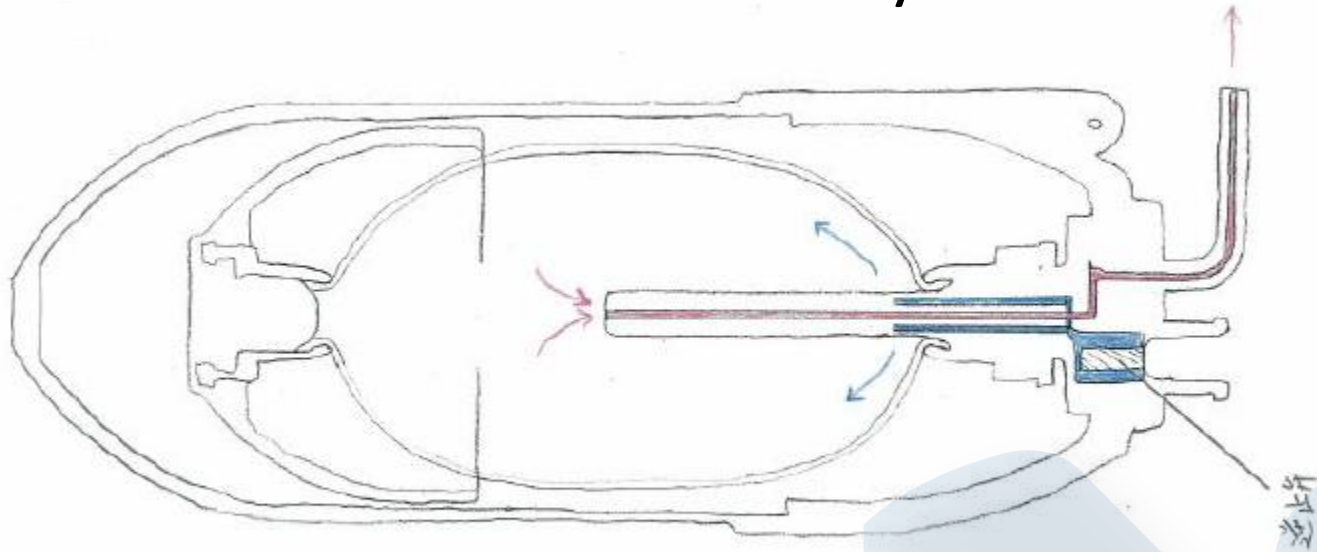
Check for air bubbles

- If there is an air bubble between filter and connector in the infusion line, open clamp to remove the air bubble, then close the clamp again.
- If there is an air bubble in the back of the filter (air vent side), the air is trapped at the filter and cannot flow to the patient.



Air in Balloon

Air left in a balloon is occasionally exhausted to the line - this air is removed by the filter.



Operating Instructions (4)

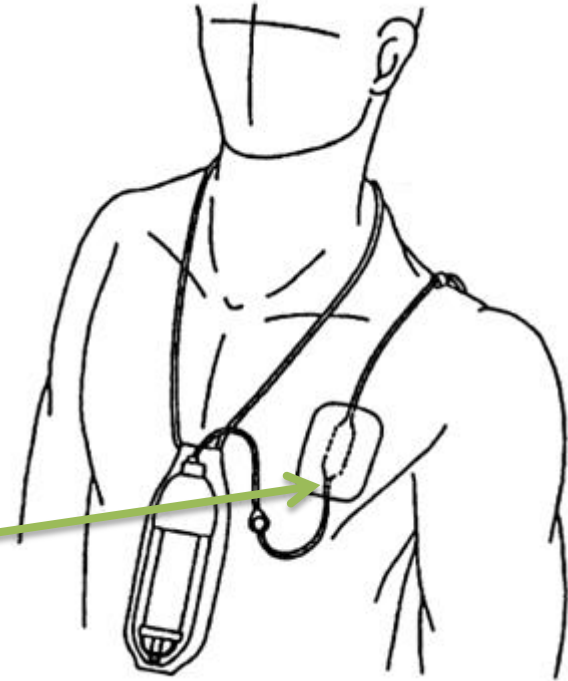
Cap the Connector

- To prevent slow leaks in transport, cap the connector with the **cap supplied in the packaging** with Surefuser+.

Operating Instructions (5)

Connect to patient

- Check again that there are no air bubbles between the filter and the infusion line, then connect the line to the patient.
- Use adhesive tape to **attach the regulator casing to patient's skin. Surefuser's flow regulator is calibrated to skin temperature. Must be taped to the skin, or flow rate may vary.**
- Make sure there are no bends and twists in the infusion line.
- Open the clamp and start the infusion.



TROUBLESHOOTING

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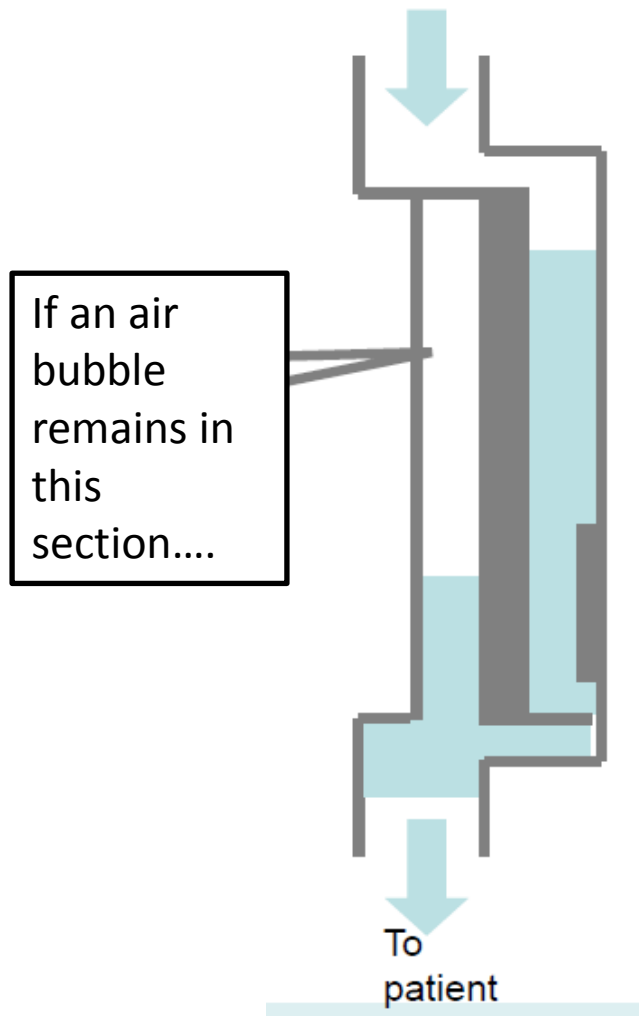
Infusion Care



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If the filter is incorrectly primed...

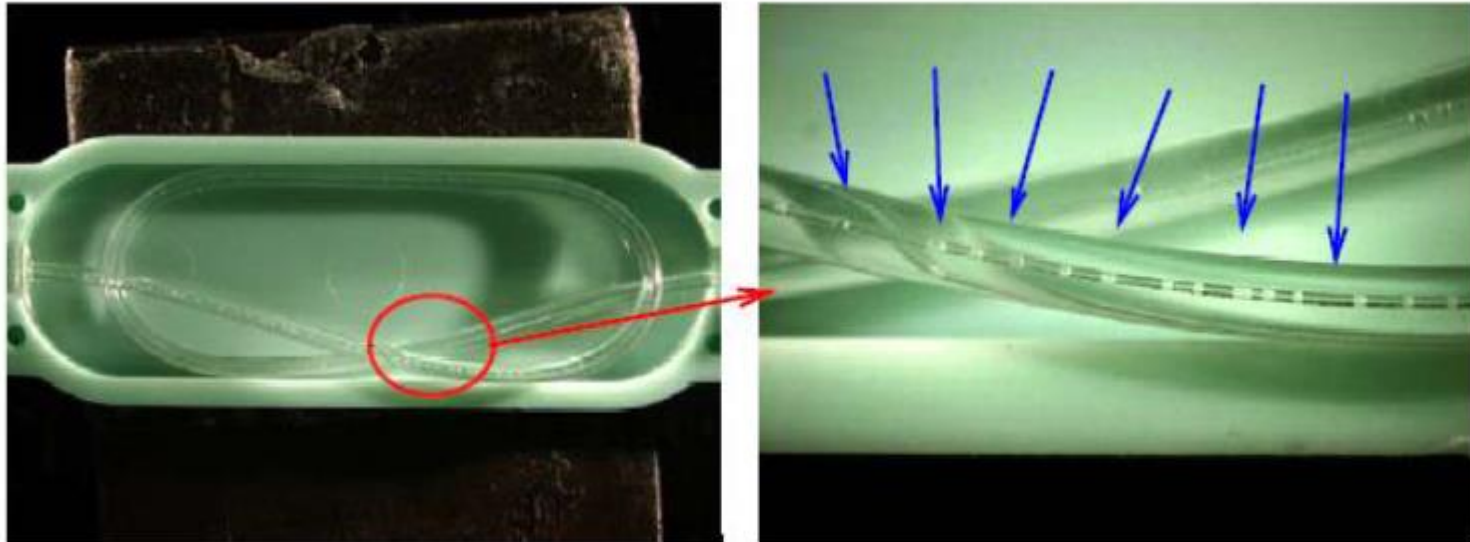


- May cause air-block and *flow may stop*
- Air bubbles remaining in the infusion line between filter and connector will move slowly - they need to pass through the regulator.



Arrow on the filter must be pointing upward during priming of the filter

Air-block in the flow regulator



Example of an air-block

- To remove air bubble, tap/flick the flow regulator with your finger. Verify flow of medication.
- If no medication flows, connect a syringe with a 3-way stopcock and pull/absorb the air bubble with the syringe.

Q1. Infusion end time has passed but considerable residual drug remains in Surefuser™+

A1. Three most common causes:

1. Flow regulator not in contact with patient's skin

- The flow regulator must contact the patient's chest/abdominal skin, as the Surefuser+ flow rate was set under **32 degree Celcius** conditions.

2. High drug viscosity

- When using a drug with higher viscosity than a saline (e.g. 5-FU, 5% glucose injection), regulate the filling gross weight. Flow rate of Surefuser+ was set with **saline**.

3. Use with arterial injection

- Flow rate of Surefuser+ was set under **no-load conditions**. When used in arterial injection, infusion speed slows under the influence of arterial blood pressure. Monitor the fill volume/qty.

Increase the quantity of a wash (e.g. saline) diluting drug in all of the above cases.

Q2. Drug solution has disappeared before scheduled end time.

A2. Three most common causes:

1. Patient's skin temperature is considerably higher than 32°C (e.g fever)
 2. Patient used an electric blanket
 3. The balloon appeared deflated, but a small amount of drug was still left in the balloon – can be difficult to see.
- In the case of 1 and 2, the infusion speed is significantly affected by temperature. For example, the infusion speed becomes approximately 10% faster when skin temperature is high, at 36-37°C.

Decrease the quantity of wash (e.g. saline) diluting drug.

Factors affecting infusion speed

1. *Temperature*

Infusion speed is affected by the temperature of a drug flowing through the flow regulator

Low temperature = high viscosity = low flow rate

High temperature = low viscosity = high flow rate

e.g. Starch syrup



High temperature → Low Viscosity



Low temperature → High Viscosity

Impact of temperature variance

Temperature (degrees)	Viscosity	Flow changing rate	Temperature (degrees)	Viscosity	Flow changing rate
23	0.936	-21.9%	31	0.784	-2.1%
24	0.914	-19.0%	32	0.768	0.0%
25	0.894	-16.4%	33	0.752	2.1%
26	0.874	-13.8%	34	0.737	4.0%
27	0.855	-11.3%	35	0.723	5.9%
28	0.836	-8.9%	36	0.709	7.7%
29	0.818	-6.5%	37	0.695	9.5%
30	0.801	-4.3%	38	0.681	11.3%

This table shows expected flow rate variance at a range of temperatures, with 32C being optimal.

Factors affecting infusion speed

2. *Viscosity of the drug*

Resistance of the drug via the flow regulator (orifice tube) can impact infusion speed.

Low viscosity = high flow rate

High viscosity (e.g. 5-FU, 5% glucose injection) = low flow rate

When 5-FU is used, volume of additional saline is often fixed by 5-FU dose conversion table.



Low Viscosity



High Viscosity

5-FU dose conversion table for FOLFOX (100ml/2days)

Balloon size	SUREFUSER+ Model	5-FU (mg)	5-FU (mL)	Saline(mL)	Total (mL)	Infusion Time (hr)
100mL	SFS-1002D	1500	30	55	85	46.0
		1600	32	53	85	46.5
		1700	34	50	84	46.2
		1800	36	47	83	46.1
		1900	38	44	82	46.0
		2000	40	42	82	46.4
		2100	42	39	81	46.3
		2200	44	36	80	46.1
		2300	46	33	79	46.0
		2400	48	30	78	46.0
		2500	50	28	78	46.3
		2600	52	25	77	46.3
		2700	54	22	76	46.1
		2800	56	19	75	46.1
		2900	58	16	74	46.0
		3000	60	13	73	46.0
		3100	62	11	73	46.4
		3200	64	8	72	46.4
		3300	66	5	71	46.4
		3400	68	1	69	46.1
3500	70	0	70	46.9		

5-FU dose conversion table for FOLFOX (250ml/2days)

Balloon size	SUREFUSER+ Model	5-FU (mg)	5-FU (mL)	Saline(mL)	Total (mL)	Infusion Time (hr)
250mL	SFS-5-25	3000	60	156	216	46.0
		3100	62	154	215	46.2
		3200	64	151	215	46.0
		3300	66	149	215	46.2
		3400	68	146	214	46.1
		3500	70	143	213	46.0
		3600	72	141	213	46.1
		3700	74	138	212	46.0
		3800	76	136	212	46.2
		3900	78	133	211	46.1
		4000	80	131	211	46.2
		4100	82	128	210	46.1
		4200	84	125	209	46.0
		4300	86	123	209	46.1
		4400	88	120	208	46.0
		4500	90	118	208	46.1
		4600	92	115	207	46.0
		4700	94	112	206	46.0
		4800	96	110	206	46.2
		4900	98	107	205	46.0
5000	100	105	205	46.2		

5-FU dose conversion table for FOLFOX (100ml/36hr)

Balloon size	SUREFUSER+ Model	5-FU (mg)	5-FU (mL)	Saline (mL)	Total (mL)	Infusion Time (hr)
100mL	SFS-1036H	2400	48	57	105	44.5
		2500	50	55	105	44.8
		2600	52	53	105	45.1
		2700	54	51	105	45.3
		2800	56	49	105	45.5
		2900	58	47	105	45.8
		3000	60	45	105	46.1
		3100	62	42	104	46.2
		3200	64	39	103	46.0
		3300	66	36	102	46.1
		3400	68	34	102	46.4
		3500	70	31	101	46.2
		3600	72	28	100	46.2
		3700	74	25	99	46.2
		3800	76	22	98	46.2
		3900	78	19	97	46.1
		4000	80	16	96	46.1
		4100	82	13	95	46.1
		4200	84	10	94	46.0
		4300	86	7	93	46.0
4400	88	4	92	46.2		
4500	90	1	91	46.2		

You can administer wide 5-FU levels at 100mL capacity.

Factors affecting infusion speed

3. *Pressure*

When there is pressure against the infusion flow, the infusion speed slows.

In the case of arterial injection in particular, flow speed is affected by the arterial blood pressure



No pressured



Pressured

Please report...

- **Leaking from infusion line around the flow regulator**
 - New flow regulator design avail early 2014
- **Foreign particle sighted in/on the elastomeric balloon**
 - Report as product fault



Product Range

Short Infusion Rate

	Colour of Flow Regulator	Infusion Time	Infusion Rate ml/hr	
			100ml	250ml
Short Infusion Range	Off White	30 mins	200	-
	Light Purple	1 hour	100	-
	Light Pink	2 hours	-	125
	Light Gray	4 hours	-	62.5



Product Range

Continuous Infusion Rate

	Colour of Flow Regulator	Infusion Time	Infusion Rate ml/hr	
			100ml	250ml
Continuous Infusion Range	Purple	5 hours	20	-
	Pink	12 hours	8.3	-
	Blue	1 day	4.2	10
	Green	2 days	2.1	5
	Crème	3 days	1.4	3.5
	Yellow	5 days	0.8	2
	Orange	1 week	0.6	1.5

Product Range

Variable Infusion Rate

	Colour of Flow Regulator	Infusion Time	100 ml Infusion Rates (ml/hr)
Variable Infusion Range	Green	n/a	0.5 / 1.5 / 2.5 / 3.5
	Green	n/a	2 / 3 / 4 / 5
	Green	n/a	0 / 1 / 2 / 3



Drug Stability Data

A range of medications including antibiotics , analgesics and anti-cancer drugs have been tested for stability in the Surefuser+™.

Tests are carried out by third party, fully accredited laboratories, using **High Performance Liquid Chromatography (HPLC)**.

Ask your representative for a full listing of tested drugs and the relevant stability durations.



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