GO MEDICAL INDUSTRIES PTY LTD

Innovative Products to Improve Common Medical Procedures

O'NEIL® SPRINGFUSOR® 50/60
Syringe Infusion Pump
REF SF 5060
Instructions for Use

DESCRIPTION

The Springfusor 50/60 is a spring driven syringe infusion pump. The Springfusor is a non-sterile, reusable pump that requires no programming or external power source. The Springfusor is to be used exclusively with Go Medical Flow Control Tubing (FCT) to deliver the required infusion rate. Different infusion rates can be achieved using a range of calibrated FCT's, which are currently available in 50 mL/15 min to 50 mL/2 hr. Other flow rates are possible and may be developed upon request.

INTENDED USE

The Springfusor is a reusable spring driven pump for intermittent and continuous controlled infusion of medication via subcutaneous or intravenous administration when used exclusively with Go Medical Flow Control Tubing (FCT) and approved syringe. It can be used for ambulatory or immobile patients in clinical or home settings

CONTRAINDICATIONS

The following conditions would preclude the use of the Springfusor:

- Intramuscular (IM) injection.

CONSUMABLES

Flow Control Tubing (FCT)

Tubing: Available in 50 mL/15 min to 50 mL/2 hr range. Priming volume is approximately 0.5 mL.

Syringe (supplied): B. Braun Omnifix® 50 mL luer lock syringe (REF: 4617509F) only. The use of unapproved syringes is not recommended as it may result in unacceptable performance characteristics.

WARNINGS

- Only to be used with Go Medical FCT and B. Braun Omnifix® 50 mL luer lock syringe (REF: 4617509F).
- **Do not** disconnect Tubing from a Syringe that is still loaded in Springfusor as contents of the Syringe will be immediately expelled.
- **Do not** use fingers to depress the spring-loaded platform to avoid injury.
- **Do not** immerse in water / solvents to avoid damaging the product.
- **Do not** sterilize as sterilization process may damage product.
- **Do not** expose to temperatures above 60°C as plastic components may deform.
- **Do not** use if contaminated or damaged.
- **Drop warning** – When the Syringe is filled it is at risk of damage when dropped, unless the Syringe has been secured to the Springfusor and patient.

CAUTION

- Not recommended where infusion accuracy better than ±20% is required.
- Use recommended Syringe and do not fill beyond nominal capacity.
- Select the correct FCT for the infusion rate required.
- Device is not suitable where frequent flow rate adjustment is necessary (e.g. dose titration).
- Device does not have audio / visual alarms to alert users of fault. Device does not provide print outs of flow rate information.
- Ensure the medication is fully dissolved prior to starting infusion to prevent blockages.
- Maintain temperature of infusate at approximately 20°C or ensure its influence has been considered (Refer to 'Accuracy and External Factors').
- Place Springfusor close to the injection site to maintain flow rate accuracy (Refer to 'Accuracy and External Factors').
- Protect the Springfusor from extremes of temperatures, pressures, moisture, solvents and other environmental conditions during storage and use.

OPERATING INSTRUCTIONS

Pre-use requirements

1. Select appropriate FCT flow rate for the desired clinical use.
2. Prepare Tubing and Syringe as per FCT Instructions For Use.

Springfusor Operating Instructions

1. Hold Springfusor on a firm surface, hold the filled Syringe in other hand near the luer lock tip and push Syringe into Springfusor.
2. Turn syringe 90° in the Springfusor to secure Syringe flange (wings).
3. Remove white cap, check drop formation and connect to patient. Operate as per FCT Instructions For Use.
4. The Springfusor can be strapped to the arm (over the Springfusor, not the Syringe), hung around the neck using the lanyard, placed in a pouch, or left beside patient ensuring that FCT is not compressed.
5. To stop the infusion or at the end of the infusion, the Syringe may be removed from the Springfusor by turning the syringe 90° in the Springfusor to disconnect the Syringe.
6. If the Syringe and Tubing is to be disconnected from the cannula, the Tubing can be removed by unscrewing the Tubing from the cannula and the cannula capped as per standard clinical protocols.

Post-use requirements

1. Clean the Springfusor by wiping exterior of Springfusor with detergent and / or disinfectant before re-use. **Do not** attempt to clean interior or disassemble the device. **Do not** use solvents or immerse device in liquid.

ACCURACY AND EXTERNAL FACTORS

The accuracy of the device is within ±20% when using the recommended syringe at the above conditions. The nominal flow rates of 50 mL FCT sets are calibrated using normal saline at 20°C. The flow rate driven by Springfusor 50 during infusion remains constant.

The following external factors could affect the accuracy of the infusion rate:

- **Selection of syringe.** The flow rate is highly dependent on the syringe used. The use of unapproved syringes is not recommended.
- **Viscosity, as influenced by drug type, drug concentration and diluent.** For example, the infusion time for Tobramycin 80 mg/50 mL is 20% longer than that of normal saline. Refer to 'Viscosity Correction Factor Table' section for more details.
- **Temperature.** Each 1°C (1.8°F) above or below 20°C (68°F) increases or decreases the flow rate, respectively, by approximately 2.5%.
- **Elevation of the Springfusor relative to the injection site.** The flow rate will be increased or decreased by approximately 4.6% if the Springfusor is placed 30 cm above or below, respectively, the injection site.

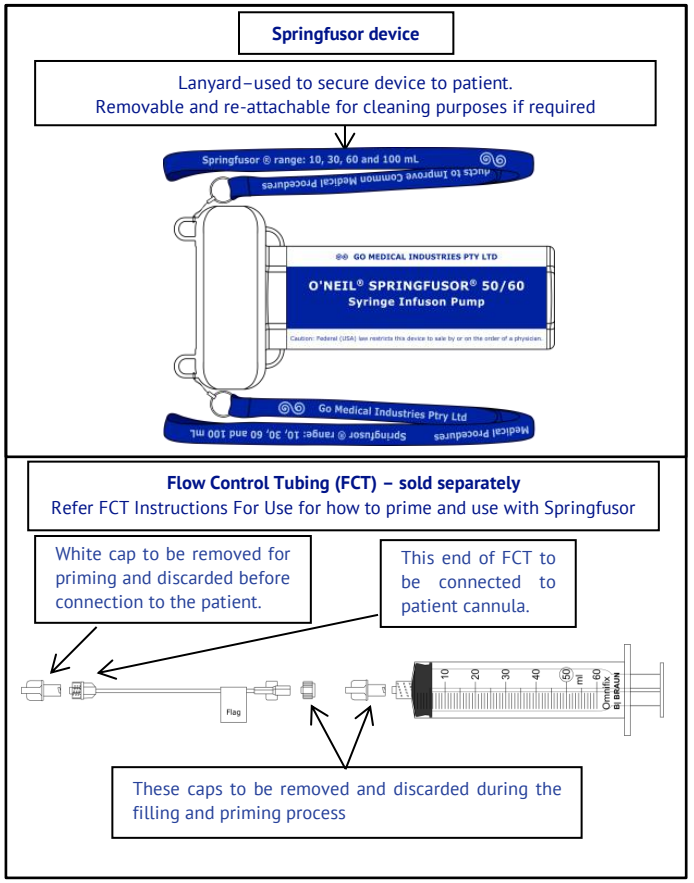
STORAGE & DISPOSAL

- Store below 30°C to maintain shelf life.
- Keep dry.
- Discard if contaminated, damaged or at end of expiry.
- Can be disposed in general waste.

WEIGHT & DIMENSIONS

Dimensions: 207 mm x 96 mm x 58 mm, nominal weight: 203 g.

SPRINGFUSOR COMPONENTS



REPORTING

In case of any serious incident that has occurred in relation to the device, this should be reported to the manufacturer and the competent authority of the Member State in which the user is established

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VISCOSITY CORRECTION FACTOR

Viscosity of drug solutions

The FCT is calibrated with normal saline (NS), unless otherwise labelled. Therefore, the viscosity of a drug solution needs to be taken into account as it will affect the infusion time.

Viscosity is dependent on the drug type, drug concentration, diluent and temperature. A table of Viscosity Correction Factors is provided here for reference. These correction factors represent the ratio of viscosity of the drug solution to water, and can be used to estimate the infusion time of the intended drug solution.

What is the purpose of the table?

The table provides a list of Viscosity Correction Factors for drug solutions commonly used with syringe infusion pumps. The correction factors provided here have been measured according to the method of the European Pharmacopoeia.

How to use the table?

Find the drug and concentration you want to use and note the Viscosity Correction Factor. Then, calculate the infusion time as:

Infusion time for drug = Labelled time on FCT x Viscosity Correction Factor

If necessary, correction should also be made for temperature.

Example 1: Viscosity Correction

Tobramycin 80 mg was diluted in 50 mL of normal saline (NS) to be infused via a 50 mL/15 min FCT.

From the Viscosity Correction Factor Table, the Viscosity Correction Factor for Tobramycin 80 mg/50 mL in NS is 1.2.

Therefore, the expected infusion time is calculated as:

Infusion Time = 15 minutes x 1.2
= **18 minutes**

Example 2: Temperature Correction

After correcting for viscosity, one must check if temperature correction is required based on surrounding temperature. Each 1°C above or below the FCT calibration temperature (20°C) increases or decreases, respectively, the flow rate by ~2.5%. In terms of infusion time, the higher the temperature, the less time is required for an infusion to complete.

Using Example 1, if the actual infusate temperature is 24°C and the FCT has been calibrated at 20°C, the expected temperature correction factor is:

1 – [(Infusate Temperature – Calibration Temperature) * 0.025]
= 1 – [(24 – 20) * 0.025]
= 0.9

Therefore, the final expected infusion time is calculated as:

Infusion Time = 18 minutes x 0.9
= **16.2 minutes (16 min 12 sec)**

What if the drugs are not listed?

For drugs not listed, the infusion time can be estimated by doing a bench test using the drug of interest and a fast-flow FCT, e.g. 15-minute variant. The full syringe volume as labelled on the FCT shall be run to get an accurate estimate. The Viscosity Correction Factor can then be calculated as:

Viscosity Correction Factor = Infusion time for drug / Labelled time on FCT

Using the Viscosity Correction Factor measured from the bench test, the infusion time for any FCT flow rate variant can now be estimated for the drug by following Examples 1 and 2.

VISCOSITY CORRECTION FACTOR TABLE

Drug	Concentration	Diluent	Correction Factor
Amoxycillin (Amoxil®)	2 g/10 mL	WFI	3.0
	1 g/10 mL	WFI	1.6
	500 mg/10 mL	WFI	1.2
Ampicillin (Austrapen®)	1 g/10 mL	WFI	1.4
	500 mg/10 mL	WFI	1.2
	1 g/30 mL	WFI	1.2
	100 mg/10 mL	U	1.1
Ampicillin / Sulbactum	3 g/50 mL	NS	1.2
(Unasyn®)	4.5 g/100 mL	NS	1.2
	3 g/100 mL	NS	1.1
Benzylpenicillin (CSL)	2.4 g/10 mL	WFI	3.0
	1.2 g/10 mL	WFI	1.5
	600 mg/10 mL	WFI	1.2
Cefazolin (Kefzol®)	2 g/10 mL	WFI	2.0
	1 g/10 mL	WFI	1.3
	500 mg/10 mL	WFI	1.1
(AFT Pharmaceuticals)	1 g/50 mL	NS	1.1
Cefepime (Omegapharm)	1 g/50 mL	NS	1.1
Cefotaxime (Claforan®)	2 g/10 mL	WFI	2.1
	1 g/10 mL	WFI	1.4
	500 mg/10 mL	WFI	1.2
Ceftazidime (Fortum®)	2 g/10 mL	WFI	2.3
	1 g/10 mL	WFI	1.4
	500 mg/10 mL	WFI	1.2
	1 g/50 mL	NS	1.1
Ceftriaxone (Rocephin®)	2 g/10 mL	WFI	2.1
	1 g/10 mL	WFI	1.4
	500 mg/10 mL	WFI	1.2
(Sandoz®)	2 g/50 mL	NS	1.3
	1 g/50 mL	NS	1.1
Cefuroxime (Flynn Pharma)	750 mg/50 mL	NS	1.1
	1.5 g/50 mL	NS	1.1
Cephalotin (Keflin®)	2g/10 mL	WFI	2.0
	1 g/10 mL	WFI	1.3
	500 mg/10 mL	WFI	1.1
Cephamandole (Mandol®)	2 g/10 mL	WFI	2.3
	1 g/10 mL	WFI	1.4
	500 mg/10 mL	WFI	1.2
	1 g/30 mL	WFI	1.2
Clindamycin (Dalacin®)	1.5 g/10 mL	U	2.3
	1.2 g/10 mL	WFI	1.9
	600 mg/10 mL	WFI	1.3
Cloxacillin (Austrastaph®)	1 g/10 mL	WFI	1.4
	1 g/30 mL	WFI	1.2
(Coly-Mycin® M Parenteral)	300 mg/10 mL	NS	1.3
	150 mg/10 mL	NS	1.1
Daptomycin (Cubicin®)	500 mg/50 mL	NS	1.1
Desferrioxamine (Desferal®)	2.5 g/10 mL	WFI	3.3
	2 g/10 mL	WFI	2.5
	1 g/10 mL	WFI	1.5
	500 mg/10 mL	WFI	1.2
Flucloxacillin (Floppen®)	2 g/10 mL	WFI	2.4
	1 g/10 mL	WFI	1.4
	500 mg/10 mL	WFI	1.2
Gentamicin (DBL)	160 mg/10 mL	NS	1.1
	80 mg/10 mL	NS	1.0
Glucose	5%	WFI	1.1
Heparin (DBL)	25,000U/5 mL	U	2.0
Meropenem (DBL)	2 g/50 mL	NS	1.3
	1 g/50 mL	NS	1.2
Phenytoin (Dilantin®)	500 mg/10 mL	U	6.4
Piperacillin (Pipril®)	2 g/10 mL	WFI	2.4
	1 g/10 mL	WFI	1.4
Piperacillin / Tazobactum	4 g/50 mL	NS	1.4
(Pipertaz Sandoz®)	3 g/50 mL	NS	1.3
Ranitidine (Zantac®)	250 mg/10 mL	U	1.1
Sodium Chloride	0.9%	WFI	1.0
Ticarcillin (Tarcil®)	3 g/10 mL	WFI	4.2
	1 g/10 mL	WFI	1.5
	500 mg/10 mL	WFI	1.2
Tobramycin (DBL)	80 mg/50 mL	NS	1.2
Vancomycin	1 g/10 mL	WFI	1.5
	500 mg/10 mL	WFI	1.2
	1 g/100 mL	NS	1.1

Footnotes: WFI = Water for Injection; NS = Normal Saline; U = Undiluted

Disclaimer: Diluents and concentrations used for measuring the Viscosity Correction Factors are intended as guidance in calculating the expected infusion time, but are not to be taken as the recommended diluents and concentrations. Always refer to the drug manufacturer's instruction for use.