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a werfen company

Clinician Guide

DOSI-FUSER[®]

Portable Elastomeric Infusion Pump





Product Overview

DOSI-FUSER® is a single-use, continuous-infusion pump for ambulatory patients that works without batteries or electricity. It consists of an elastomeric balloon inside a rigid, transparent container and an infusion line with the Capillary Element and a Luer-Lock connector that attaches to the patient.

After the balloon is inflated, the medication flows through the Capillary Element as a result of the pressure from the elastomeric balloon, which determines the flow rate.

The DOSI-FUSER® is designed for **safe ambulatory infusion therapy**; it promotes patient recovery and improves quality of life by increasing patient mobility and removing the inconvenience of electronic pumps.

INDICATIONS

- > Chemotherapy
- > Pain Management
- > Antibiotic therapy

ADMINISTRATION ROUTES

- > Intravenous
- > Intra-arterial
- > Epidural
- > Subcutaneous

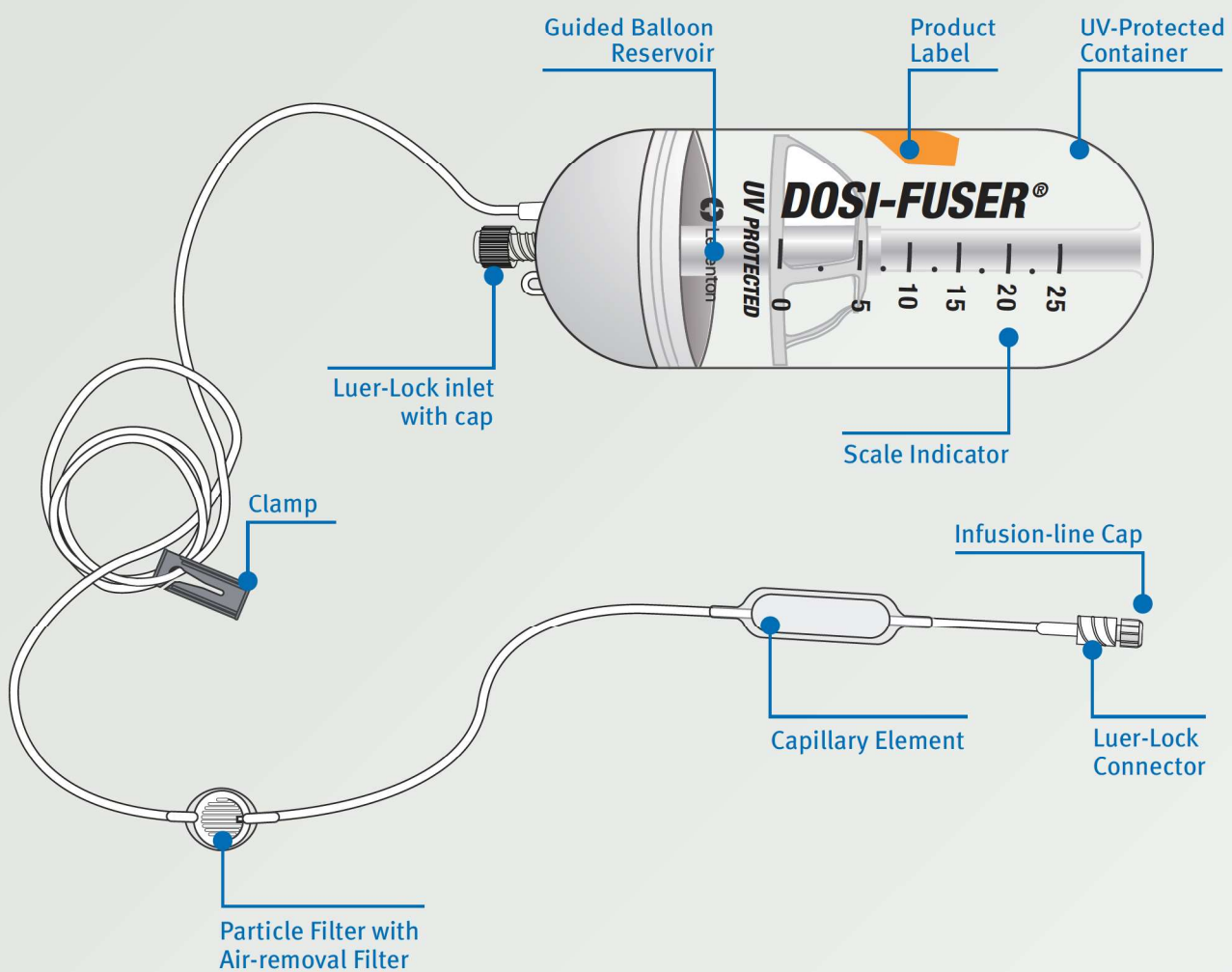
Advantages Over Electronic Pumps:

- 100% disposable device
- Easy to use
- Portable – lightweight and small
- Non-electronic device – no batteries or power source required
- No programming required - select from a wide range
- No calibration required
- No option to change the parameters – fixed flow
- No loud mechanism – silent
- No maintenance required
- No capital investment needed – profitable



Main Product Features:

- Unique DOSI-FUSER® - DESIGNED CAPILLARY
- Specially designed guided balloon with Scale Indicator
- Easy to fill, even by hand
- Full product range with easy identification by coloured labels



Features, Advantages & Benefits

RESERVOIR

- **Complete range:**
65, 100, 150 and 250 ml
- **Rigid plastic housing:**
Protects against external pressure on the balloon. In case of incidents, it ensures that the drug inside remains
- **UV-light protected:**
Protects light-sensitive drugs from UV radiation of up to 390 nm
- **Polyisoprene balloon reservoir:**
The best mechanical performance
Proven compatibility with drugs: does not absorb them
(DOSI-FUSER® drug stability table available on request)
- **Independent entry and exit points:**
Fills drug directly into the balloon
- **Guided balloon:**
Lower filling pressure
Accurate Scale Indicator: makes it possible to monitor development of the infusion
- **Lightweight and portable**
- **Shape- and colour-coded labels: simple and easy to understand**
- **Blue bag for transport and light protection**



INFUSION LINE

- **Infusion line to patient:**
DEHP-free, kink-resistant
- **Safety in-line filters:**
1.2-µm particle filter and 0.03-µm air-removal filter
- **Removable clamp**

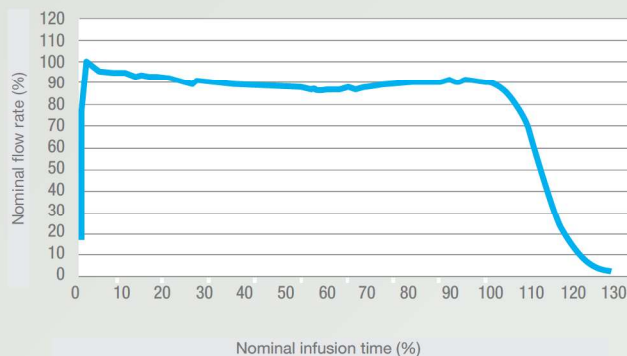


FLOW CONTROL

- **Complete range:**
Fast-Flow: from 30 minutes to 12 hours.
Slow-Flow: from 1 to 11 days.
- **Unique patented DOSI-FUSER® Capillary Element:**
 - Wider channel: reduces the risk of clogging due to drug crystallization
 - Longer channel: provides improved output flow stability
 - Flat design, optimal thermal stability on the skin. Calibrated at 32°C (89.6°F).
 - Located 10 cm (4 inch) from distal end for easier dressing and patient comfort.



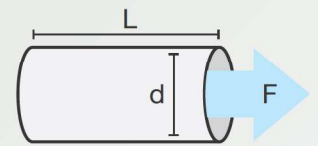
EVOLUTION GRAPH: DOSI-FUSER®
 INFUSION FLOW RATE OF 100D2 MODEL



HAGEN-POISEUILLE LAW

$$F = \frac{P\pi \left(\frac{d}{2}\right)^4}{8\eta L}$$

F: **Flow rate** (ml/h)
 P: **Pressure** (g/(cm·h²))
 d: **Diameter of tube** (cm)
 π : 3.1416
 L: **Length**(cm)
 η : **Liquid viscosity** (g/(cm·h))



INFUSION PARAMETERS

- **Precision ±15% of the Infusion Time. Operative accuracy ±10%*.**
- **The DOSI-FUSER® administers 90% of the nominal volume in the nominal delivery time.**

* This % is the accuracy of the average flow of the tested samples of each batch number, measured in delivery time.

SLOW-FLOW CONTINUOUS INFUSION

| Label Colour | Code A | Description | Nominal Volume | Residual Volume B | Nominal Flow Rate | Nomina Delivery Time | Maximum Volume | Units / Case |
|--------------|---------------|-------------------|----------------|-------------------|-------------------|----------------------|----------------|--------------|
| | L25915-065H12 | DOSI-FUSER 65H12 | 65 ml | 2.5 ml | 5.4 ml / hr | 12 horas | 80 ml | 10 |
| | L25915-065D1 | DOSI-FUSER 65D1 | | | 2.7 ml / hr | 1 día | | 10 |
| | L25915-065D2 | DOSI-FUSER 65D2 | | | 1.3 ml / hr | 2 días | | 10 |
| | L25915-065D3 | DOSI-FUSER 65D3 | | | 0.9 ml / hr | 3 días | | 10 |
| | L25915-065D5 | DOSI-FUSER 65D5 | | | 0.5 ml / hr | 5 días | | 10 |
| | L25915-100D1 | DOSI-FUSER 100D1 | 100 ml | 3.5 ml | 4.1 ml / hr | 1 día | 130 ml | 10 |
| | L25915-100D2 | DOSI-FUSER 100D2 | | | 2.0 ml / hr | 2 días | | 10 |
| | L25915-100D3 | DOSI-FUSER 100D3 | | | 1.4 ml / hr | 3 días | | 10 |
| | L25915-100D5 | DOSI-FUSER 100D5 | | | 0.8 ml / hr | 5 days | | 10 |
| | L25913-100D7 | DOSI-FUSER 150D7 | | | 0.6 ml / hr | 7 días | | 10 |
| | L25915-150D1 | DOSI-FUSER 150D1 | 150 ml | 4 ml | 6.2 ml / hr | 1 día | 180 ml | 10 |
| | L25915-150D2 | DOSI-FUSER 150D2 | | | 3.1 ml / hr | 2 días | | 10 |
| | L25915-150D3 | DOSI-FUSER 150D3 | | | 2.1 ml / hr | 3 días | | 10 |
| | L25915-150D5 | DOSI-FUSER 150D5 | | | 1.2 ml / hr | 5 días | | 10 |
| | L25915-150D7 | DOSI-FUSER 150D7 | | | 0.9 ml / hr | 7 días | | 10 |
| | L25915-250D1 | DOSI-FUSER 250D1 | 250 ml | 5 ml | 10.4 ml / hr | 1 día | 265/300 ml* | 10 |
| | L25915-250D2 | DOSI-FUSER 250D2 | | | 5.2 ml / hr | 2 días | | 10 |
| | L25915-250D3 | DOSI-FUSER 250D3 | | | 3.5 ml / hr | 3 días | | 10 |
| | L25915-250D5 | DOSI-FUSER 250D5 | | | 2.1 ml / hr | 5 días | | 10 |
| | L25915-250D7 | DOSI-FUSER 250D7 | | | 1.5 ml / hr | 7 días | | 10 |
| | L25915-250D11 | DOSI-FUSER 250D11 | | | 0.9 ml / hr | 11 días | | 10 |

A Master code. Different configurations for specific countries. Ask your distributor.

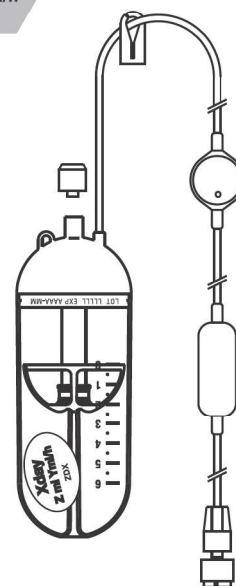
B Maximum value.

* Studies show that the operating parameters do not change up to 300 ml of filling volume.

SLOW-FLOW WITH CAPILLARY ELEMENT

| | 65ml | 100ml | 150ml | 250ml |
|----------|-------------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|
| 11 días | | | | 11days 250 ml 0,9 ml/h 250D11 |
| 7 días | | 7days 100 ml 0,6 ml/h 100D7 | 7days 150 ml 0,9 ml/h 150D7 | 7days 250 ml 1,5 ml/h 250D7 |
| 5 días | 5days 65 ml 0,5 ml/h 065D5 | 5days 100 ml 0,8 ml/h 100D5 | 5days 150 ml 1,2 ml/h 150D5 | 5days 250 ml 2,1 ml/h 250D5 |
| 3 días | 3days 65 ml 0,9 ml/h 065D3 | 3days 100 ml 1,4 ml/h 100D3 | 3days 150 ml 2,1 ml/h 150D3 | 3days 250 ml 3,5 ml/h 250D3 |
| 2 días | 2days 65 ml 1,3 ml/h 065D2 | 2days 100 ml 2,0 ml/h 100D2 | 2days 250 ml 3,1 ml/h 150D2 | 2days 250 ml 5,2 ml/h 250D2 |
| 1 día | 1day 65 ml 2,7 ml/h 065D1 | 1day 100 ml 4,1 ml/h 100D1 | 1day 250 ml 6,2 ml/h 150D1 | 1day 250 ml 10,4 ml/h 250D1 |
| 12 horas | 12hours 65 ml 5,4 ml/h 065H12 | | 12hours 150ml 12ml/h 150H12 | |

X days
Z ml Y ml/h
ZDX



FAST-FLOW CONTINUOUS INFUSION

| Label Colour | Code A | Description | Nominal Volume | Residual Volume B | Nominal Flow Rate | Nominal Delivery Time | Maximum Volume | Units / Case |
|--------------|---------------|-------------------|----------------|-------------------|-------------------|-----------------------|----------------|--------------|
| | L25915-065M30 | DOSI-FUSER 65M30 | 65 ml | 2.5 ml | 130 ml / hr | 30 minutes | 80 ml | 10 |
| | L25915-065H1 | DOSI-FUSER 65H1 | | | 65 ml / hr | 1 hour | | 10 |
| | L25915-065H2 | DOSI-FUSER 65H2 | | | 32 ml / hr | 2 hours | | 10 |
| | L25915-065H5 | DOSI-FUSER 65H5 | | | 13 ml / hr | 5 hours | | 10 |
| | L25915-100M30 | DOSI-FUSER 100M30 | 100 ml | 3.5 ml | 200 ml / hr | 30 minutes | 130 ml | 10 |
| | L25915-100H1 | DOSI-FUSER 100H1 | | | 100 ml / hr | 1 hour | | 10 |
| | L25915-100H2 | DOSI-FUSER 100H2 | | | 50 ml / hr | 2 hours | | 10 |
| | L25915-100H5 | DOSI-FUSER 100H5 | | | 20 ml / hr | 5 hours | | 10 |
| | L25915-100H12 | DOSI-FUSER 100H12 | | | 8.3 ml / hr | 12 hours | | 10 |
| | L25915-150M30 | DOSI-FUSER 150M30 | 150 ml | 4 ml | 300 ml / hr | 30 minutes | 180 ml | 10 |
| | L25915-150H1 | DOSI-FUSER 150H1 | | | 150 ml / hr | 1 hour | | 10 |
| | L25915-150H2 | DOSI-FUSER 150H2 | | | 75 ml / hr | 2 hours | | 10 |
| | L25915-150H5 | DOSI-FUSER 150H5 | | | 30 ml / hr | 5 hours | | 10 |
| | L25915-150H12 | DOSI-FUSER 150H12 | | | 12 ml / hr | 12 hours | | 10 |
| | L25915-250H1 | DOSI-FUSER 250H1 | 250 ml | 5 ml | 250 ml / hr | 1 hour | 265/300 ml* | 10 |
| | L25915-250H2 | DOSI-FUSER 250H2 | | | 125 ml / hr | 2 hours | | 10 |
| | L25913-250H5 | DOSI-FUSER 250H5 | | | 50 ml / hr | 5 hours | | 10 |
| | L25915-250H12 | DOSI-FUSER 250H12 | | | 20 ml / hr | 12 hours | | 10 |

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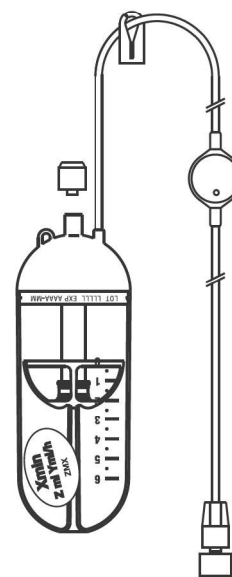
B Maximum value

* Studies show that the operating parameters do not change up to 300 ml of filling volume.

FAST-FLOW WITH CAPILLARY TUBE

| | 65ml | 100ml | 150ml | 250ml |
|----------|---|---|--|--|
| 12 hours | | 12hours 100ml 8.3ml/h 100H12 | | 12hours 250ml 20ml/h 250H12 |
| 5 hours | 5hours 65ml 13ml/h 065H5 | 5hours 100ml 20ml/h 100H5 | 5hours 150ml 30ml/h 150H5 | 5hours 250ml 50ml/h 250H5 |
| 2 hours | 2hours 65ml 32ml/h 065H2 | 2hours 100ml 50ml/h 100H2 | 2hours 150ml 75ml/h 150H2 | 2hours 250ml 125ml/h 250H2 |
| 1 hour | 1hour 65ml 65ml/h 065H1 | 1hour 100ml 100ml/h 100H1 | 1hour 150ml 150ml/h 150H1 | 1hour 250ml 250ml/h 250H1 |
| 30 min | 30 min 65ml 130ml/h 065M30 | 30 min 100ml 200ml/h 100M30 | 30 min 150ml 300ml/h 150M30 | |

Xday
Zml Yml/h
.....ZBX



Scale Indicator

ADVANTAGES OF CONTROLLING THE DELIVERY PROGRESSION REGARDING THE NOMINAL VOLUME:

- Confirmation that the balloon has filled up to the expected volume
- Monitoring of the development of the infusion by patient or nursing staff
- In case of an incident, identification of the undelivered volume
- Confirmation of the end of the infusion



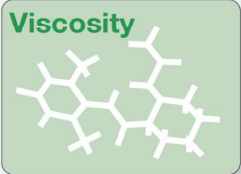
Note: The filling volume must be measured by the filling device (syringe...). The Scale Indicator only shows the approximated volume pending of delivery.

Clinical Information

CLINICAL INFORMATION

GUIDELINES

Viscosity

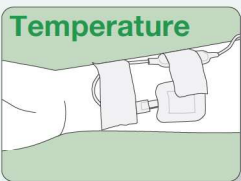


The DOSI-FUSER® is calibrated by filling it with sodium chloride 0.9%.

- Some drugs may increase solution viscosity, which results in a delay due to the reduced flow rate.
- 5% dextrose produces a delay of about 10% of the infusion time.

- The use of sodium chloride 0.9% is preferred.
- Note that there is a delay with 5% dextrose or more, or when infusing drugs with high viscosity.

Temperature



Capillary Elements are calibrated at a skin temperature of 32°C (89.6°F), as temperature affects the liquid viscosity.

- A 1°C (1.8°F) increase in temperature will speed up the infusion time by 2%.
- A 1°C (1.8°F) decrease in temperature will delay the infusion time by 2%.
- Keeping the flow control device at 22°C (71.6°F) will delay the infusion time by 20%.

- DOSI-FUSER®. Attach the Capillary Element to the skin (32°C) to keep the viscosity of the drugs constant.
- The reservoir should be kept at room temperature.
- Let the liquid in the reservoir thaw to room temperature.

Filling Volume



DOSI-FUSER® is most accurate when filled at nominal volume.

Filling the pump above nominal volume will:

- Increase the infusion time.
- Decrease the flow rate slightly.

- Choose the right DOSI-FUSER® model for your application.
- Fill DOSI-FUSER® with the nominal volume if possible.
- Do not fill it above the maximum volume.
- If 80% of the nominal volume is filled, an additional advance of less than 5% may occur. If it is filled between 60% (minimum volume) and 80% of the nominal volume it can suffer the additional advance of 10%.

Pump Height

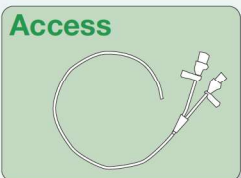


The infusion time depends on the height of the reservoir.

- Placing the reservoir 2.5 cm (1 inch) above the outlet connector will speed up the infusion time by 0.5%.
- Placing the reservoir 2.5 cm (1 inch) under the outlet connector will delay the infusion time by 0.5%.

- Instruct the patient to keep the reservoir near the thoracic trunk if the infusion is intravenous or epidural.
- Instruct the patient to keep the reservoir near the level of the catheter if the infusion is subcutaneous.

Access



Infusion time will not be affected by the access device if:

- A 22-gauge device or wider is used together with Slow-Flow devices.
- IV catheters, implantable ports or PICC catheters are used together with Slow-Flow devices.
- An 18-gauge device or wider is used together with Fast-Flow devices.

- Slow-Flow DOSI-FUSER®. Use a 22-gauge access device or wider.
- Fast-Flow DOSI-FUSER®. Use an 18-gauge access device or wider.
- Verify that there is no occlusion in the access device before connecting the DOSI-FUSER®.

Storage



DOSI-FUSER® is most accurate when the infusion is started immediately after it has been filled with solution at 22°C (71.6°F).

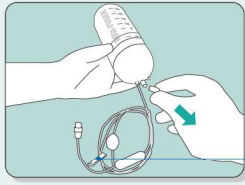
- Starting the infusion a few days after it has been filled will delay the infusion time: by 5% after one day and by 10% after one week.
- Starting the infusion when the liquid is below room temperature will also delay the infusion time.

- Be aware that some delay in the infusion time will be related to the storage of the prefilled product.
- Thaw the product at room temperature (16 hours for 65-ml and 100-ml models and 20 hours for 150-ml and 250-ml models) before the infusion.
- Leave the product at room temperature for 4 hours for 65-ml and 100-ml models and 6 hours for 150-ml and 250-ml models if it was stored in the refrigerator.

Pharmacy: Filling the DOSI-FUSER®

1 Verification

1



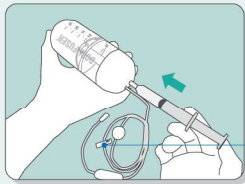
Once the packaging has been opened, check that all the components are in perfect condition and that the infusion line is properly closed with the infusion-line cap.

While holding the DOSI-FUSER®, clamp the infusion line and remove the container inlet cap.



2 Priming

2

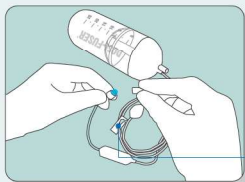


As a general procedure, first fill the DOSI-FUSER® with a syringe of 10 ml saline solution.

Unclamp the line and remove the distal cap. The liquid will then flush the line.



3



Wait for the first drop at the distal connector.

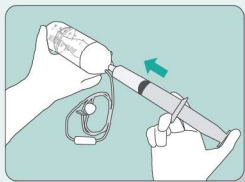
Close the connector with the cap.

Clamp the line to ensure it is primed only with saline solution.



4 Filling

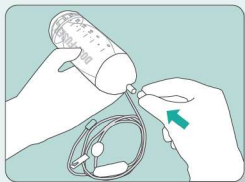
4



Fill a Luer-Lock syringe with the solution. Insert the syringe into the container inlet and push the solution into the balloon.

The solution should be introduced at a constant speed, without sudden spurts. The balloon will expand symmetrically along the inner guide and the indicator will move along the scale.

5



Remove the syringe once the required total volume has been introduced into the balloon (if more than one syringe is required, step 4 should be repeated). Close the container inlet with the inlet cap.

6 Identification

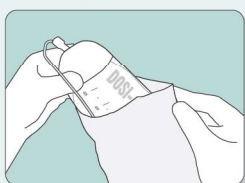
6



Complete the patient label (included with the product) with all necessary information and attach it to the container.

7 Transport

7

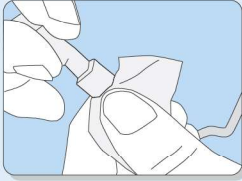


Insert the DOSI-FUSER® into the opaque blue bag (included with the product for transport and to protect the infusion set).

Nursing staff: Connecting the DOSI-FUSER®

Checking

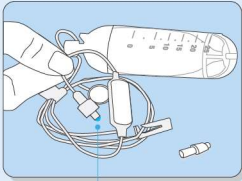
1



Before connecting the DOSI-FUSER® to the patient, check the patient access line in accordance with institution protocol and the instructions of the access device.

Check the patient label.

2



Verify that the DOSI-FUSER® line is primed.

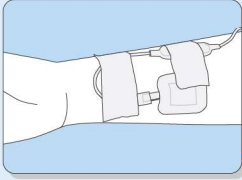
If not, then prime the infusion line before connecting to the patient. Unclamp the line, remove the infusion-line cap and make sure that the liquid flows through the infusion line to the output connection.

Wait for the first drop and verify that all air has been removed from the line.



Connection

3

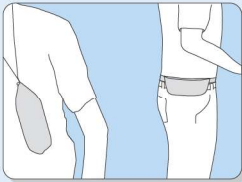


To connect the infusion line to the patient, remove the infusion-line cap, connect to the patient and unclamp the infusion-line.

Attach the Capillary Element to the patient's skin. Ensure that the air and particle filter is kept dry and that the air-filter hole is not obstructed.



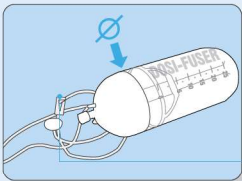
4



Hang the reservoir at the mid-axillary line level.

Disconnection

5

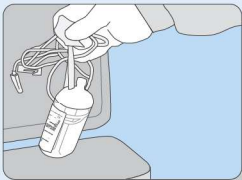


The infusion is finished when the level indicator is close to 0 and the balloon is empty and fully deflated.

Clamp the infusion line and disconnect it from the patient.



6



Dispose of the infuser in accordance with institution protocol.

Accessories



Mesh Bag

| | |
|-------------|------------------------|
| L25915-1020 | SMALL MESH BAG 65/100 |
| L25915-1065 | LARGE MESH BAG 150/250 |



Belt Bag

| | |
|-------------|---------------------------|
| L25915-1030 | LARGE BELT BAG 150/250 |
| L25915-1040 | SMALL BELT BAG 65/100 |
| L25915-1010 | VERTICAL BELT BAG 150/250 |



Support

| | |
|------------|--------------------------------------|
| L259000321 | SMALL SUPPORT FOR DOSI-FUSER 65/100 |
| L259000322 | LARGE SUPPORT FOR DOSI-FUSER 150/250 |



Alligator Clip

| | |
|-------------|----------------|
| L25915-1070 | ALLIGATOR CLIP |
|-------------|----------------|



Syringe 50ml

Available: Kits including syringe

Patient FAQs



Sleeping

Place your DOSI-FUSER® under your pillow or in another location at your level.
Do not hang from a bed post or IV pole.
Do not leave it on the floor..



Washing

The Capillary Element does not require washing, but if you do wash it, use water only. Do not use alcohol or other solvents for this purpose.
Do not wash the filter.



Shower/bath

If you have to take a shower/bath, protect your DOSI-FUSER® from direct water streams.
In particular, ensure that the filter hole on the line is protected from water, as it could block the air elimination membrane.



Exercise

You may exercise with DOSI-FUSER®, but consider the following:
The height of the reservoir.
The temperature.
Do not wet the filter on the line.
Do not let the product fall.



Temperature

Do not expose the reservoir to extreme temperatures.
Protect the reservoir from cold temperatures by carrying it under your clothes. Protect it from direct heat.
Keep the Capillary Element in contact with the skin at 32°C (89.6°F).



Travelling

You may travel by plane with your DOSI-FUSER®.



SAFETY AND TRUST

DOSI-FUSER[®]

Leventon's Quality Management System is certified by UL LLC according to ISO 13485:2016 and MDSAP additional regulatory requirements.

MANUFACTURED BY:

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