DOSI-FUSER®

EN PORTABLE ELASTOMERIC INFUSER
ES INFUSOR ELASTOMÉRICO AMBULATORIO
FR DIFFUSEUR ELASTOMÈRE PORTABLE POUR PERFUSION
DE TRAGBARER ELASTOMERER INFUSOR
IT INFUSORE ELASTOMERICO AMBULATORIALE
PT PERFUSOR ELASTOMÉRICO PORTÁTIL
NL DRAAGBAAR ELASTOMEERINFUUS
SV PORTABEL INFUSIONSUTRUSTNING MED ELASTOMERBALLONG
DA BÆRBART ELASTOMERISK INFUSIONSAPPARAT
FI KANNETTAVA ELASTOMEERINEN INFUUSIOLAITE
HU HORDOZHATÓ ELASZTOMER INFÚZIÓS PUMPA
RO POMPĂ ELASTOMERICĂ, PORTABILĂ, PENTRU PERFUZIE
RU ПОРТАТИВНАЯ ЭЛАСТОМЕРНАЯ ИНФУЗИОННАЯ ПОМПА
EL ΦΟΡΗΤΗ ΕΛΑΣΤΟΜΕΡΙΚΗ ΑΝΤΛΙΑ ΕΓΧΥΣΗΣ
AR موزع التسريب المحمول المصنوع من المطاط الصناعي
ZH 便携式弹性输注泵
HR PRIJENOSNI ELASTOMERNI INFUZOR
SL PRENOSNI ELASTOMERNI INFUZOR
SK PRENOSNÝ INFUZÉR ELASTOMÉROV
PL PRZENOŚNY INFUZOR ELASTOMEROWY
CS PŘENOSNÝ ELASTOMERICKÝ INFUZOR
ID ALAT INFUS PORTABEL DARI BAHAN ELASTOMER

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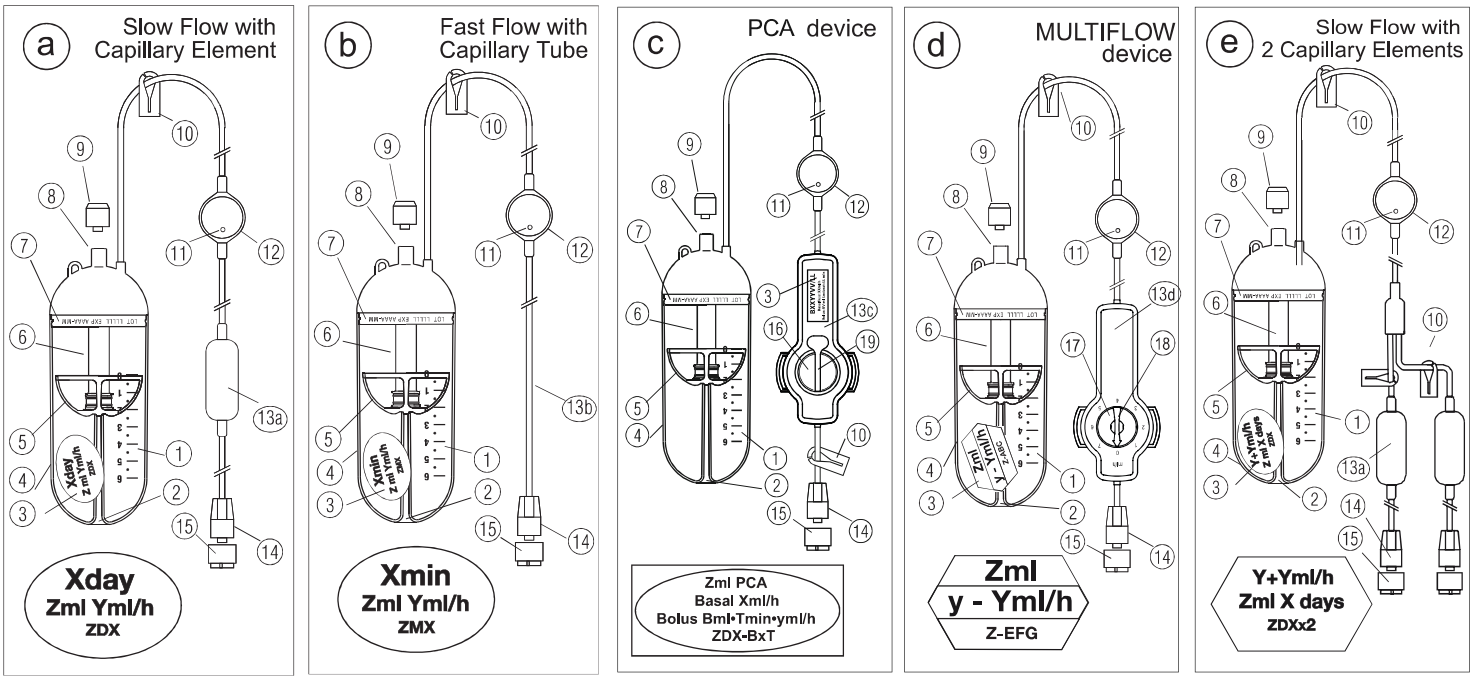
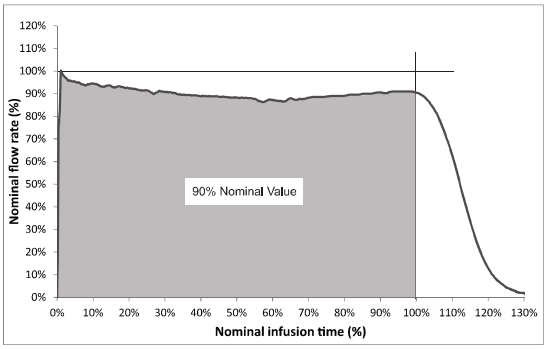
DOSI-FUSER®



	65ml	100ml	150ml	250ml	400ml	500ml	600ml
a	Xdays 65 ml Yml/h 65DX	Xdays 100ml Yml/h 100DX	Xdays 150ml Yml/h 150DX	Xdays 250ml Yml/h 250DX	Xdays 400ml Yml/h 400DX	Xdays 500ml Yml/h 500DX	Xdays 600ml Yml/h 600DX
a or b	Xhour 65ml Yml/h 65HX	Xhour 100ml Yml/h 100HX	Xhour 150ml Yml/h 150HX	Xhour 250ml Yml/h 250HX	Xhour 400ml Yml/h 400HX	Xhour 500ml Yml/h 500HX	Xhour 600ml Yml/h 600HX
b	Xmin 65ml Yml/h 65MX	Xmin 100ml Yml/h 100MX	Xmin 150ml Yml/h 150MX	Xmin 250ml Yml/h 250MX	Xmin 400ml Yml/h 400MX	Xmin 500ml Yml/h 500MX	Xmin 600 ml Yml/h 600MX
c	65ml PCA Basal Yml/h Bolus Bml•Tmin•yml/h 65DX-BxT	100ml PCA Basal Yml/h Bolus Bml•Tmin•yml/h 100DX-BxT		250ml PCA Basal Yml/h Bolus Bml•Tmin•yml/h 250DX-BxT			600ml PCA Basal Yml/h Bolus Bml•Tmin•yml/h 600DX-BxT
d		100ml y - Yml/h 100EFG		250ml y - Yml/h 250EFG	400ml y - Yml/h 400EFG		600ml y - Yml/h 600EFG
e				Y+Yml/h 250ml X days 250DXx2		Y+Yml/h 500ml X days 500 DXx2	Y+Yml/h 600ml X days 600Xx2



T1. Filling Volumes

Volume	65XX	100XX	150XX	250 XX	400 XX	500 XX	600 XX
Nominal	65ml	100ml	150ml	250ml	400 ml	500 ml	600 ml
Maximum	80ml	130ml	180ml	300ml	420 ml	525 ml	650 ml
Minimum	39ml	60ml	90ml	150ml	240ml	300ml	360ml
Residual	<2,5ml	<3,5ml	<4ml	<5ml	<7ml	<7ml	<7ml

T2. Flushing times

Flow rate	Flushing time
>50ml/h	<10 sec.
>10ml/h	<30 sec.
>4ml/h	<1 min.
>2ml/h	<2 min.
>1ml/h	<3 min.
>0.8ml/h	<4 min.
0,5ml/h	<6 min.
MULTIFLOW 1 - 7 ml/h	<2 min+1.5 min
MULTIFLOW 2 - 14 ml/h	<1 min+1.5 min

EN

PORTABLE ELASTOMERIC INFUSER

Description

DOSI-FUSER® is a single-use, elastomeric type, continuous and ambulatory infusion system. To its operation does not need batteries or electric current. It is composed of an elastomeric balloon located inside a rigid and transparent reservoir, and an infusion line with a Luer-Lock connection*.

Components

Item	Name	Item	Name	Item	Name
1	Scale	9	Inlet cap	13d	Multiflow system
2	Balloon guide	10	Clamp	14	Outlet connection
3	Identification label	11	Air outlet	15	Infusion line cap
4	Reservoir	12	Filter	16	PCA button
5	Level indicator	13a	Capillary element	17	Regulator
6	Elastomeric balloon	13b	Restrictor tube	18	Key
7	Lot label	13c	PCA system	19	Activator
8	Reservoir inlet	See sketches in back cover			

Intended Use

DOSI-FUSER® is a single-use sterile product intended for parenteral continuous infusion of drug, without hindering the mobility of the patient.

Indications

DOSI-FUSER® is indicated for multiple treatments, among which:
- Chemotherapy, anti-emetic and hydration treatments.
- Antibiotics, antivirals and antifungals treatments.
- Analgesics.
- Palliative care.

Routes of administration include intravenous, subcutaneous, intra-arterial, and perineural such as epidural, peripheral nerve block, and infiltration.

Trained health personnel such as nurses, pharmacists and anaesthesiologists are required for the tasks of filling, purging, connecting, adjusting the flow (according to reference) and disconnecting the product. Healthcare personnel must train caregivers, the patient or their family members in the correct use of the product.

DOSI-FUSER® is a medical device appropriate for any patient in need of an infusion therapy. Health professionals determine the suitability of its use according to the infusion treatment prescribed.

The DOSI-FUSER® Elastomeric Pump allows continuous and effective treatment in multiple contexts. Its use guarantees a safe, simple, versatile and comfortable technique that enables outpatient treatment, thus reducing the time of admission of the patient.

Contraindications

The elastomeric infusion pump DOSI-FUSER® is contra-indicated for use in the administration of blood or blood derivatives or substances containing lipids.

Instructions for Use

⚠ WARNINGS

1. Follow the Instructions for Use.
2. The medication to be infused into the patient must be established according to medical prescription.
3. Do not infuse medications that contain alcoholic solutions since this can cause leaks in the air filter and particles.
4. DOSI-FUSER® will work correctly so long as the indicated precautions are respected.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority indicating the information on the lot label (7).

Preparing the medication and the product

1. Use an aseptic technique throughout all the procedure.
2. To prepare the solution, follow the specific instructions for the medication in question. Choose the most suitable DOSI-FUSER® model for the volume and duration of the infusion, as indicates on the identification label (3).
3. To determine the volume of solution to be infused, it is important to factor in the residual volume (as indicated in Volume Table T1). The maximum volume of the DOSI-FUSER® indicated in Table T1 should never be exceeded.
4. If the solution to be administrated is a cytostatic drug, prime DOSI-FUSER® with 10 ml saline solution, following the instruction 5 to 8, before filling it with the medication. This avoids the risk of exposure.

CAUTIONS

a. Do not remove DOSI-FUSER® from its packaging until ready for use.
b. Do not use DOSI-FUSER® if the packaging is open or defective. Do not resterilize.
c. Do not reuse DOSI-FUSER® due to the risk of patient contamination. This product is intended for single use. This means that the patient's safety cannot be guaranteed if the product is used again.
d. Do not re-fill DOSI-FUSER® or mix with other medications during use.
e. DOSI-FUSER® is equipped with a filter (12) that keeps particles larger than 1.2 µm from entering the system and the ≤0.03 µm pore size removes air bubbles.

Filling Instructions

1. Use an aseptic technique throughout all the procedure.
2. 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 (15).
3. While holding the DOSI-FUSER® , clamp (10) the infusion line and remove the inlet cap (9) from the reservoir (4).
4. Connect the syringe or any other filling system with Luer-Lock* connection to the reservoir inlet (8) and fill the elastomeric balloon (6) (a needle or other sharp instrument should never be used).
5. The solution should be introduced at a constant speed, without sudden spurts. More force is required when the balloon (6) first starts filling.
6. Prime the infusion line. To do so, hold the reservoir (4) in a vertical position with the connections at the top. Unclamp (10) the line, remove the infusion line cap (15) and make sure that the liquid flow through the infusion line to the outlet connection (14). The time required to prime the line should not exceed the time indicated in Priming Time Table T2. If this occurs, the product should be discarded following verification.
   a. If the PCA system (13c) is used, in addition to what is contained in point 6, place the device in a vertical position with the activator (19) inserted in order to allow air to escape. When the liquid begins coming out of the device, remove the activator (19) and press the PCA button (16) all the way down in order to eliminate air from its bolus and release it for it to quickly regain its position. Wait until liquid comes out through the outlet connection (14).
   b. If the MULTIFLOW system (13d) is used, in addition to what is contained in point 6, make sure that the regulator (17) is set at maximum position. Wait 1.5 minutes after the first drop comes out to ensure complete priming.
7. Once all the air has been removed from the line, clamp (10) the infusion line and recap it (15) until connected to the patient. Continue with the filling procedure.
8. Check visually that the balloon (6) expands symmetrically along the inner guide of the reservoir (4). If it does not, the device may be defective and should be discarded. Remove the syringe. The liquid inside the balloon does not come out thanks to a check valve. If more than one syringe is required, steps 4, 5 and 8.
9. Once the balloon (6) filling is finished close the reservoir inlet (8) with the inlet cap (9) and verify that the clamp (10) is closing the line and the infusion line cap (15) is placed.
10. Fill out the patient label (included with the product) with all necessary information and attach it to the reservoir (4).
11. Insert the DOSI-FUSER® into the bag (included with the product) for transport and to protect the infusion set.

CAUTIONS

a. When using non-volumetric filling systems, the pressure of the balloon (6) can cause the expected filling volume to vary. It is recommended to check the volume introduced into the DOSI-FUSER® by weight.
b. The infusion time indicated on the identification label (3) will not be attained if anything other than the nominal volume of solution is introduced into the balloon (6).If the balloon is filled with 80% of the nominal volume, an additional advance of less than 5% may occur. If it filled with a volume between 60% (minimum volume) and 80% of the nominal volume, it may suffer an additional advance of 10%.

Infusion Instructions

1. Use an aseptic technique throughout all the procedure.
2. Before connecting the device to the patient, ensure that the connector is attached correctly and is compatible with the DOSI-FUSER® (Luer-Lock* system).
3. Make sure the DOSI-FUSER® infusion line is primed.
4. Proceed to connect the infusion line outlet connection (14) to the patient's line. In order to do so, remove the infusion line cap (15) form the infusion line and connect it to the patient. Unclamp (10) the infusion line. If the MULTIFLOW system (13d) is used, turn the regulator (17) to the desired flow rate position using the key (18) supplied. Once this operation is complete, remove the key from the regulator and retain it for future use. **Important:** If the regulator (17) is set to an intermediate position (between marks), the infusion will stop.
5. Attach the capillary element (13a), the restrictor tube (13b), the PCA system (13c) or the MULTIFLOW system (13d) to the patient´s skin. Ensure that the filter (12) is kept dry and the air outlet (11) is not obstructed.
6. Check the patient label.
7. The infusion is considered finish when the level indicator (5) is close to 0 and the balloon (6) is empty and fully deflated.
8. Visually inspect the infuser once the infusion has finished. Clamp (10) the infusion line and disconnect it from the patient. To avoid possible handling risks, connect the end of the outlet connection (14) to the Luer-Lock* reservoir inlet (8).

CAUTIONS

a. Make sure the infusion line is primed before use. Otherwise, air may be introduced into the patient.
b. The activator (19) on the PCA device must be removed during the priming process and before connecting the device to the patient. Otherwise its bolus's outlet will remain open and the flow used to fill it will be added to the infusion flow, causing an over-infusion for the patient.
c. The capillary element (13a), the PCA system (13c) and the MULTIFLOW system (13d) may deteriorate if placed in contact with solvents. Use water to clean them.
d. No components of the system should be changed or tampered.
e. DOSI-FUSER® should be protected from sunlight and UV rays. Keep dry and store between 0 ºC and 30ºC.
f. Infusion should be interrupted by clamping (10) the line in any of the following cases:
   - If the reservoir (4) or the balloon (6) breaks totally or partially or becomes detached.
   - If the capillary element (13a), PCA system (13c), MULTIFLOW system (13d), filter (12) or any section of the infusion line breaks.
   -If leaks are observed in any of the components, including the interior of the reservoir (4).
g. No elements should be introduced through the air-inlet hole (2) of the reservoir (4).
h. The DOSI-FUSER® can come into contact with water, but it must be ensured that no liquid enters the reservoir (4) through the air-inlet hole (2).
i. Visually check the progress of the level indicator (5) while the reservoir (4) gradually empties and ensure that infusion duly follows its course.
j. Do not set the regulator (17) of the MULTIFLOW system (13d) at intermediate positions because the infusion will stop.
k. The air outlet (11) on the filter (12) must not be covered and must be kept in dry and clean.
l. If accidentally dropped, the reservoir (4) could be subject to cracks or the Balloon (6) to leakages. It is recommended to check the integrity of both items.
m. A small amount of solution will be left in the DOSI-FUSER® after the infusion has finished (see Table T1). Any liquid remaining in the infusion line or the system should not be reused.

Safe disposal of the product

1. Dispose of the product following the protocol of the healthcare center or the instructions of healthcare personnel.

Infusion Time

DOSI-FUSER® is designed to supply 90% of the nominal volume in the infusion time indicated on the identification label (3). See cautions below. The accuracy of the infusion time is ±15%.
The PCA system (13c) makes it possible to release an additional volume of the infused drug by pressing the PCA button (16). Once this amount has been released, it takes a set amount of time, as shown on the identification label (3), to refill. If the PCA system (13c) is used, the infusion time will be reduced.
The MULTIFLOW system (13d) allows the user to select a specific flow rate, as shown on the identification label (3). When this is changed, the infusion time is modified.

CAUTIONS

a. The anticipated infusion time may increase if:
   - The DOSI-FUSER® is worn below the mid-axillary line. Infusion time is reduced if the set is worn above.
   - The capillary element (13a), restrictor tube (13b), PCA system (13c) or MULTIFLOW system (13d) is not in contact with the skin or is situated in a cold area.
   - The temperature of the liquid in the reservoir (4) is lower than 22ºC.
   - The DOSI-FUSER® is filled a long time before infusion is commenced.
   - The reservoir (4) air-inlet hole (2) is obstructed.
   - The solution to be infused is more viscous than the 0.9% saline solution used to calibrate the product.
   - The flow into the patient's blood stream is too restricted.
   - The patient has high blood pressure.
   - The infusion line is overly twisted.
   - Infusion is interrupted.
   - The DOSI-FUSER® with 2 outlets is used and either of the outlets is clamped.

In case of doubt about the operation of the product or symptoms of discomfort presumably associated with the product, consult your doctor.

Calibration Conditions

DOSI-FUSER® is calibrated under the following conditions:
- Infusion begins when the balloon (6) starts filling.
- Device filled to nominal capacity with 0.9% NaCl solution.
- Temperature of the solution in the reservoir is 22ºC.
- Temperature of the capillary element (13a), the restrictor tube (13b), the PCA system (13c) or the MULTIFLOW system (13d) is 32ºC, equivalent to its temperature when in contact with the skin.
- Restrictor tube (13b) is straight (i.e. not twisted).
- Reservoir (4) and outlet connection (14) are at the same level, with free output.

(*) Luer-Lock reservoir inlet (8) connection and outlet connection (14) in accordance with standard ISO 594-1.

Additional copies of the instructions for use can be ordered from Leventon free of charge.

The symbols used on the DOSI-FUSER® labelling are in accordance with ISO15223-1:2021