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DOSI-FUSER®

PORTABLE ELASTOMERIC INFUSER

Description

The DOSI-FUSER® is a single-use, continuous-infusion system for ambulatory patients that works without batteries or electricity, the medication circulates through the capillary element or the capillary tube as a result of the pressure from the elastomeric balloon, which determines the flow rate regardless of the atmospheric pressure. It consists of an elastomeric balloon inside a rigid, transparent container and an infusion line with a LuerLock* connector.

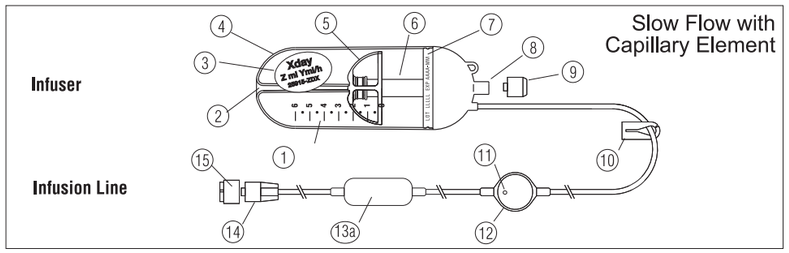
Indications

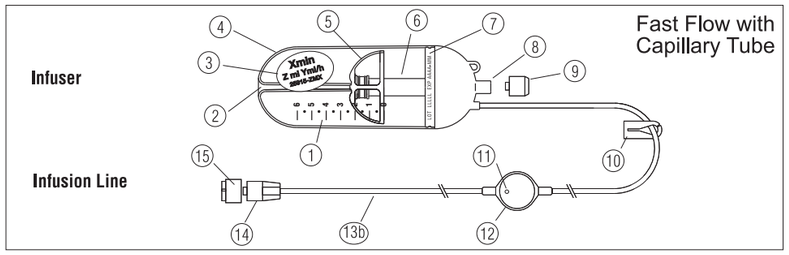
The DOSI-FUSER® is designed to provide parenteral drug infusions at a constant flow without impeding patient mobility. It is indicated for patients requiring slow infusion of medication, which may be administered intravenously or via intra-arterial, epidural or subcutaneous routes. The device allows patients to be mobile, thus making it suitable for ambulatory use.

Infusion time

The DOSI-FUSER® is thought to administrate the 90% of the introduced volume (nominal) in the infusion time indicated on the label. See flow evolution graphic and point 17 of the precautions.
Precision in infusion time is ±15%.

CAUTION: In the USA Federal law restricts this device to sale by or on order of a physician.





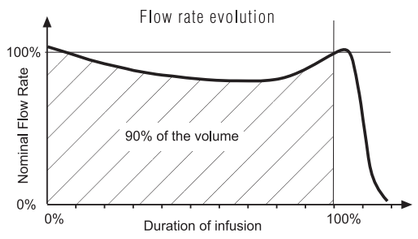


Table of volumes

T1	65XX	100XX	150XX	250XX
Nominal	65ml	100ml	150ml	250ml
Maximum	80ml	130ml	180ml	265ml
Residual	<2,5ml	<3,5ml	<4ml	<5ml

Table of flushing times

T2	65XX	100XX	150XX	250XX
<10 sec.	M30	M30	M30,H1	H1, H2
<20 sec.	H1	H1	H2	H5
<30 sec.	H2, H5	H2, H5	H5, H12	H12, D1
<1 min.	H12	H12	D1	D2, D3
<2min 30".	D1	D1, D2	D2, D3	D5
<5 min.	D2, D3	D3,D5	D5	D7
<6 min.	D5	D7	D7	D11

Conditions of Calibration

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DOSI-FUSER® is adjusted to the follwing conditions of calibration:

1. Beginning of the infusion at the moment of the inflation of the balloon.
2. Filling up to the nominal capacity with saline serum at Nacl 0.9%.

3. Serum temperature inside the deposit has to be 22ºC equal to 71,6 ºF.
4. The temperature of the capillary element (13a), capillary tubing (13b) has to be at 32ºC equal to 89,6ºF, euivalent to the temperature of the skin.
5. Capillary tubing (13b) streched.
6. Container (4) and conection LuerLock to the patient (14) at the same level, with free exit.

Instructions for Use

Preparing the Medication

1. The medication to be infused must be prescribed by the patient's doctor.
2. To prepare the solution, follow the specific instructions for the medication in question, using aseptic techniques.
3. Choose the most suitable DOSI-FUSER® model for the volume and duration of the infusion, as indicated on the label(3).

N.B.: The DOSI-FUSER® is calibrated with a 0.9% NaCl solution at 32ºC (89.6ºF).

Filling Instructions

1. Aseptic techniques must be used throughout the procedure.
2. Do not remove the DOSI-FUSER® from its packaging until ready for use. Once the packaging has been opened, check that all the components are in perfect condition and that the infusion-line cap (15) is properly closed.
3. Hold the DOSI-FUSER®, remove the container-inlet cap (9) and clamp (10) the infusion line at a point between the container (4) and the filter (12).
4. Fill a LuerLock* syringe with the solution. Insert the syringe into the container inlet (8) using a LuerLock* connector (a needle or other sharp instrument should never be used) and fill the elastomeric balloon (6). To determine the volume of solution to be introduced, the residual volume of DOSI-FUSER® (indicated on the volume table) should be taken into account. See attached table T1.
5. The solution should be introduced at a constant speed, without sudden spurts. More force is required when the elastomeric balloon (6) starts filling up.
6. Check visually that the balloon expands symmetrically along the inner guidelines of the container. If it does not, the DOSI-FUSER® may be defective and should be rejected.
7. The maximum volume of the DOSI-FUSER® (indicated in the volume table) should never be exceeded. See table T1.
8. Remove the syringe once the required total volume has been introduced into the balloon (if more than one syringe is required, steps 4 to 7 should be repeated). Close the container inlet (8) with the inlet cap (9).

Infusion Instructions

1. Aseptic techniques must be used throughout the procedure.
2. Check that the patient-administration connector is suitable and compatible with the DOSI-FUSER® (LuerLock* system).
3. Flush the infusion line before connecting to the patient. To do so, hold the container in a vertical position, with the connectors at the top. Unclamp (10) the line, remove the infusion-line cap (15) and make sure that the liquid flows through the infusion line to the output connection (14). The time required to flush the line should not exceed the time indicated in the Flushing Time Table T2. If it takes longer, the assembly should be checked and, if necessary, rejected.
4. Once the air has been flushed out of the system, clamp (10) the infusion line and close it with the infusion-line cap (15) until connecting it to the patient.
5. To connect the infusion line (14) to the patient, remove the DOSI-FUSER® infusion-line cap (15), connect to the patient-administration tubing system and unclamp (10) the infusion line.
6. Attach the capillary element (13a) or the capillary tube (13b) to the patient's skin. Ensure that the air filter (12) is kept dry and the air-filter hole (11) is not obstructed.
7. The infusion is finished when the balloon (6) is empty and is once more tube-shaped.
8. Check the condition of the DOSI-FUSER® when the infusion has finished. Clamp (10) the infusion line and disconnect from the patient-administration tubing system. To avoid any handling risks, connect the end of the LuerLock conection to the patient (14) to the LuerLock* inlet (8).
9. Destroy the DOSI-FUSER® following the medical centre's protocol.

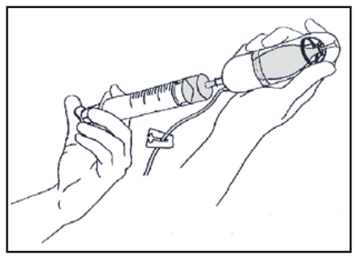
(*) LuerLock in accordance with Standard ISO 594-1

Precautions

1. The DOSI-FUSER® will work correctly so long as the following precautions are respected.
2. Follow the Instructions for Use.
3. Do not use the DOSI-FUSER® if the packaging is open or defective. Do not sterilize again.
4. The DOSI-FUSER® is a single-use product. Its correct functioning is therefore not guaranteed if reused or refilled once infusion has commenced.
5. Follow aseptic techniques throughout the procedure.
6. The capillary element (13a) could be damaged in contact with solvents, use water to clean it.
7. Be sure to purge the infusion line, in otherwise air could be introduced to the patient.
8. Visually check the progress of the infusion while the container (4) gradually empties, and ensure that infusion duly follows its course.
9. The air-filter hole (11) must not be covered and must be kept in a dry, clean area.
10. The indicated infusion time will not be applicable if less than the nominal volume of solution is introduced in the balloon (6).
11. A small amount of solution will be left in the DOSI-FUSER® after the infusion has finished (see volume table T1). Any liquid remaining in the infusion line or the system should not be reused.
12. No components of the system should be changed or tampered with.
13. The DOSI-FUSER® should be protected from sunlight and UV rays. Keep dry and store at between 0º and 30ºC (32ºF and 86,6ºF).
14. Infusion should be interrupted by clamping (10) the line in any of the following cases:
    - If the container (4) or the elastomeric balloon (6) breaks totally or partially or becomes detached.
    - If the capillary element (13a), air filter (12) or any section of the infusion line breaks.
    - If leaks are observed in any of the components, including the interior of the container.
15. No elements should be introduced through the hole of the container air inlet (2).
16. The DOSI-FUSER® can be worn while taking a shower, but it must be ensured that no liquid enters the container through the air-inlet hole (2).
17. The anticipated infusion time may be increased if:
    - The Infuser is worn below the mid-axillary line; infusion time is reduced if the set is worn above.
    - The capillary element (13a)or the capillary tube (13b) is not in contact with the skin or is situated in a cold area.
    - The temperature of the liquid in the container is lower than 22ºC equal to 71,6ºF.
    - The DOSI-FUSER® is filled more than 1 day before infusion is commenced.
    - The container air inlet is obstructed (2).
    - The solution to be infused is more viscous than the 0.9% saline solution used to calibrate the product.
    - The restriction of the patient inlet device is bigger than the offered by a tube with internal diameter of 0.3mm (0.012") and 50cm (19.7") length.
    - The patient has hypertension or the arterial via is used (approximately 5%).
18. DOSI-FUSER® includes a filter (12) in the line to avoid the pass of particles larger than 1.2µm. There's also a filter to remove air with a pore size of 0.02µm.
19. The average pressure inside the elastomeric balloon (6) during the infusion is approximately 0,5bar (50Kpa, 0.493Atm). This pressure can get up to 1bar (100KPa, 0.987Atm) during the inflating procedure, this is why we recommend to clamp the infusion line during this operation.

Wearing the DOSI-FUSER®

Filling the DOSI-FUSER®



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