DISPOSABLE PAIN MANAGEMENT SYSTEM FOR CONTINUOUS WOUND INFILTRATION (CWI)

200 mL, 400 mL & 650 mL

Ambu[®] ACTion™ Fuser Pain Pump

is a disposable pain pump that is mainly designed to give consistent and customized pain therapy through continuous wound infiltration (CWI).

The ability and simplicity with the cut-to-size catheter infusion to the actual incision length, together with the ability to set the infusion strategy parameters to gain efficient saturation along the entire incision, is a major benefit of Ambu ACTion Fuser Pain Pump.

Ambu ACTion Fuser is intended to be used in hospitals, ambulatory surgical centers, and at home. Ambu ACTion Fuser consists of three components; reservoir, ACTion Fuser Set (regulating set), and catheter, each in a separate sterile package.

Regulator

An innovative regulator providing consistent flow rates allowing for precision treatment; regulator maintains uniform consistent flow-rates regardless of changes to pressure made during use.

Ambu® ACTion™ Fuser Pain Pump



KEY BENEFITS

Disposable pain pump may reduce length of stay (LOS) by allowing patients recovering at home through a controlled medication delivery system.

Cut-to-size catheter reduces the need for stocking multiple lengths catheters.

Advanced technology of the flow regulator maintains flow consistency between +/- 5%.

Multiple layers of safeguards against contamination, including a 0.2 micron filter and an antimicrobial fixation dressing.

Each fuser pump contains Prosit antimicrobial wound dressing to further decrease the risk of infection.

NEW - Closed Pain Pump System



Ambu® ACTion™ Fuser Pain Pump package:

- Reservoir (available in 200 mL, 400 mL or 650 mL)
- Regulating set (available in 1-6 mL/hr or 5-15 mL/hr)
- Cut-to-size wound infiltration catheter set
- 50/60 mL luer lock disposable syringe
- Antimicrobial dressing and fixation dressings
- Medication and pump labels
- Carrying pouch and combination lock
- Physician and patient instructions
- Flow splitter (optional and included in items with dual catheter)



SPECIFICATIONS

| Reservoir | | |
|-------------------------------|--|--|
| Minimum Fill Volume | Fill all reservoirs sizes to minimum 50 mL | |
| Maximum Fill Volume | 200 mL can overfill to 330 mL 400 mL can overfill to 550 mL 650 mL fill to nominal value | |
| Refillable | The reservoir can be re-filled one time as needed during the duration of use | |
| Partial Filling | Reservoirs can be filled partially between 50 mL and its maximum value and still maintain +/- 5% consistent flow rate and +/- 15% accuracy. | |
| Flow Regulator | | |
| Flow Rate Range | 1-6 mL/hr or 5-15 mL/hr (depends on version) | |
| Flow Consistency | Consistency +/- 5% of actual average delivered flow-rate at a stable surrounding temperature (saline, at 22°C | |
| Flow Accuracy | racy +/- 15% of the nominal flow-rate (saline, at 22°C ±2°C) | |
| Volume Incremental | The resolution of the secured/locked flow rate is in incremental of: • 1-6 mL/hr Flow Regulator: About 0.05 mL • 5-15 mL/hr Flow Regulator: About 0.1 mL | |
| Operational Environment and | n of the Adjusting Ring) in between the printed digits is by tactile feel. | |
| Recommended Usage Temperature | +20° C (68° F) to +24° C (75° F) | |
| Transportation & Storage | Transport: Shouldn't be exposed to temp. over 50° C (120° F), Shouldn't be exposed to direct sunlight, Boxes with products shouldn't be in direct contact with the vehicle floor Storage: Temperature range -15° C to 40° C (5° F to 105° F), Avoid exposure to direct sunlight, Pest control, Boxes with products shouldn't be in contact with the floor | |
| Sterilization | EtO (Ethylene Oxide) | |

Ambu ACTion™ Fuser Pain Pump by Materials (fluid path)

| Reservoir | Synthetic Polyisoprene, Soft PVC (DEHP Free), Terlux, CYROLITE, ABS, PC, PE, Acrylic, |
|------------------|---|
| Pain Pump Set | PC, ABS, Silicon, PE, Rigid PVC ,Soft PVC (DEHP Free), Terlux, Acrylic |
| (Regulating Set) | |

Does Ambu ACTion™ Fuser Pain Pump Contain:

| Silicone | No (only the Regulator in the Pain Pump Set contains silicone) |
|-----------|--|
| Latex | No |
| DEHP | No |
| Pthalates | No |

Is the Ambu ACTion™ Fuser Pain Pump MRI compatible?

The Ambu ACTionTM Pain Pumps are MRI-compatible (the only non-MRI-compatible components are the carrying pouch and the combination lock).

Ambu recommends removing the carrying case and combination lock prior to MRI scanning.

Ambu ACTion™ Fuser Pain Pump Packaging Materials

| Sterile Packaging | Flexible pouch, Film: polyester, Paper: tested and validated according to EN 868-5 and ISO 11607-1 |
|-------------------|--|
| Air Bubble Sheet | t Low Density polyethylene |
| Internal Box | Laminated Cardboard (Internal Box only applicable for Ambu ACTion Reservoir Sets (separate accessory)) |
| Shipping Box | Reinforced Carton |

How to discard Ambu ACTion Fuser Pain Pump:

• Regular disposal, Single-use

ORDERING SPECIFICATIONS – Ambu ACTion™ Fuser Pain Pump (Closed System)

| Item No. | Description | Case QTY by PCS |
|--------------|--|-----------------|
| 418 103 200C | ACTion™ Fuser, 200 mL, 1-6 mL/hr Regulator, 140 mm catheter, 6" introducer, Prosit Fixation Dressing | 5 |
| 418 108 200C | ACTion™ Fuser, 200 mL, 1-6 mL/hr Regulator, Splitter, Dual: 140 mm catheter and 6" introducer, Prosit Fixation Dressing | 5 |
| 418 103 400C | ACTion™ Fuser, 400 mL, 1-6 mL/hr Regulatore, 140 mm Catheter, 6" Introducer, Prosit Fixation Dressing | 5 |
| 418 108 400C | ACTion™ Fuser, 400 mL, 1-6 mL/hr Regulator, Splitter, Dual: 140 mm catheter and 6" introducer, Prosit Fixation Dressing | 5 |
| 418 113 400C | ACTion™ Fuser, 400 mL, 1-6 mL/hr Dual Regulator, 190mm Catheter, 9"Introducer, Flow Splitter, Prosit Fixation Dressing | 5 |
| 418 106 400C | ACTion™ Fuser 400 mL, 5-15 mL/hr, Dual Cut to Size 190 mm, Prosit Fixation Dressing | 5 |
| 418 104 650C | ACTion™ Fuser, 650 mL, 5-15 mL/hr Regulator, 140 mm catheter, 6″ Introducer, Prosit Fixation Dressing | 5 |

ORDERING SPECIFICATIONS - Ambu ACTion™ Fuser Pain Pump (Modular System*)

| | | Case QTY by PCS |
|--------------|---|-----------------|
| 418 103 200M | ACTion™ Fuser, 200 mL, 1-6 mL/hr Regulator, 140 mm catheter, 6" introducer, Prosit Fixation Dressing | 5 |
| 418 108 200M | ACTion™ Fuser, 200 mL, 1-6 mL/hr Regulator, Splitter, Dual: 140 mm catheter and 6" introducer, Prosit Fixation Dressing | 5 |
| 418 103 400M | ACTion™ Fuser, 400 mL, 1-6 mL/hr Regulator, 140 mm Catheter, 6" Introducer, Prosit Fixation Dressing | 5 |
| 418 108 400M | ACTion™ Fuser, 400 mL, 1-6 mL/hr Regulator, Splitter, Dual: 140 mm catheter and 6" introducer, Prosit Fixation Dressing | 5 |
| 418 104 650M | ACTion™ Fuser, 650 mL, 5-15 mL/hr Regulator, 140 mm catheter, 6" Introducer, Prosit Fixation Dressing | 5 |

ORDERING SPECIFICATIONS – Ambu ACTion™ Reservoir Sets (Separate Accessory)

| Item No. | Description | Case QTY by PCS |
|-------------|--|-----------------|
| 418 000 200 | Reservoir Set - 200 mL reservoir and syringe | 8 |
| 418 000 400 | Reservoir Set - 400 mL reservoir and syringe | 8 |
| 418 000 650 | Reservoir Set - 650 mL reservoir and syringe | 8 |
| 418 000 515 | Reservoir Set - 1000 mL reservoir (2 x 500 mL) and syringe | 8 |

^{*} Make to Order: 6-8 weeks of delivery time



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