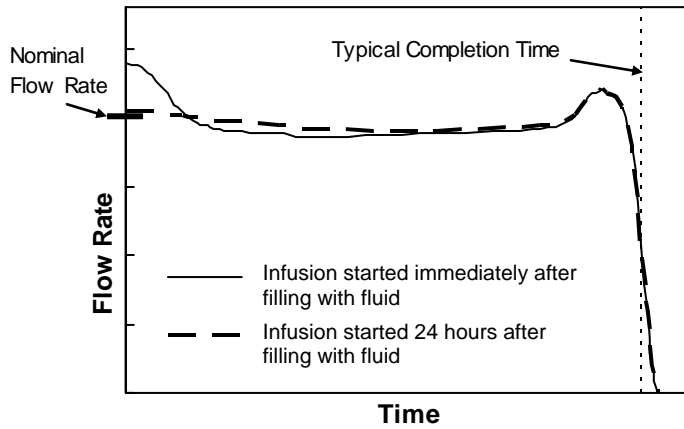




**Post-Operative Pain Relief Infusion System**

**LATEX-FREE**

**Figure 11: Flow Rate Profile**



**Definitions of Symbols**



Do not use if package is damaged or open



Latex-free

**MODELS**

S021	S022	S023	S024	S025	S026	S027	S028	S029
S031	S032	S033	S034	S035	S036	S037	S038	S039
S041	S042	S043	S044	S045	S046	S047	S048	S049
S051	S052	S053	S054	S055	S056	S057	S058	S059
S061	S062	S063	S064	S065	S066	S067	S068	S069

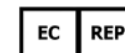
**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

U.S. Patents: 6,329,444; 6,569,375; 6,920,643  
 Patents Pending

Solace® is a registered trademark of Apex Medical Technologies, Inc.



Apex Medical Technologies, Inc.  
 San Diego, CA 92121  
 U.S.A.  
[www.solacepainrelief.com](http://www.solacepainrelief.com)



EMERGO EUROPE  
 Molenstraat 15  
 2513 BH, The Hague  
 The Netherlands  
 Phone: +31.70.345.8570  
 Fax: +31.70.346.7299

## INDICATIONS FOR USE

The Solace Infusion System is intended for continuous infusion of medications directly into an intraoperative site for post-operative pain relief. Infusions may also be administered percutaneously.

## CONTRAINDICATIONS

- The Solace Infusion System is not intended for intravenous, intra-arterial or epidural drug delivery.
- The Solace Infusion System is not intended for the delivery of blood, blood products, lipids or fat emulsions.
- The Solace Infusion System is not intended for use in joint spaces.

## LATEX-FREE

**THE SOLACE INFUSION SYSTEM IS STERILE. THE FLUID PATH IS NON-PYROGENIC.**

**SINGLE USE ONLY. DO NOT RESTERILIZE, REFILL OR REUSE.**

**DO NOT USE IF PACKAGE HAS BEEN OPENED OR DAMAGED.**

**The complete Solace Post-Operative Pain Relief Infusion System consists of a pump kit, catheter kit and introducer. Replacement components may be procured separately but are only intended to be used as part of the complete Solace system.**

## CAUTIONS

- Do not exceed maximum fill volume of pump.
- Caution should be used when selecting appropriate volumes and flow rates keeping in mind potential fluid build up in a restricted space that may lead to complications, particularly with hand and/or foot surgery.
- Use of vasoconstrictors such as epinephrine or adrenaline is not necessary and may not be recommended for continuous infusions.
- Medication used with this system should be administered in accordance with instructions provided by the drug manufacturer.
- Do not withdraw catheter through needle because of the possible danger of shearing.
- Use only smooth-edged atraumatic clamps or forceps.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice. (Dispose of introducer needle(s) or tunneler(s) in suitable sharps container.)
- Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.
- Store protected from light at room temperature (10° - 40°C, 10-90% relative humidity).
- Avoid placing sharp objects near the infusion system.
- Avoid contacting the filter with cleaning agents such as alcohol or soap to prevent leakage.
- Do not alter the infusion system.
  - Do not remove or disable the clamp(s).
  - Do not cut the catheter(s).

## WARNINGS

- Assure that the catheter is not in a vein or artery. Even if aspirations for blood are negative, intravascular penetration is still possible. Visual inspection, test dosing and patient monitoring are recommended - refer to drug manufacturer's package insert.
- It is recommended that the catheter be placed under direct visualization to ensure proper placement.

## REMOVING THE CATHETER

- Remove the dressing covering and loosen the adhesive skin closure strips at the catheter site.
- Grasp the catheter tubing close to the skin and gently pull to remove. Only pull on the catheter tubing, not the luer fitting at the end of the catheter. The catheter should be easy to remove and not painful. Do not tug or quickly pull on the catheter during removal.

## CAUTIONS

- If significant resistance is felt or catheter begins to stretch or tear, STOP. Continued pulling could break the catheter. Wait and try again after 30-60 minutes.
  - If the catheter is still difficult to remove, an X-ray is recommended (catheter is radiopaque).
  - Do not cut or forcefully remove the catheter.
  - Do not apply additional tension if the catheter begins to stretch.
  - After removal, check the distal end of the catheter for the black marking to ensure the entire catheter was removed.
  - Remove promptly after infusion is completed to reduce the risk of infection.
- Cover the puncture site with an appropriate dressing.

**Table 1: Delivery Information for the Solace Infusion System**

1" Zone Catheter (2.5cm)	S051	S052	S053	S054	S055	S056	S057	S058	S059
2.5" Zone Catheter (6.5cm)	S021	S022	S023	S024	S025	S026	S027	S028	S029
5" Zone Catheter (12.5cm)	S031	S032	S033	S034	S035	S036	S037	S038	S039
7.5" Zone Catheter (19cm)	S061	S062	S063	S064	S065	S066	S067	S068	S069
10" Zone Catheter (25cm)	S041	S042	S043	S044	S045	S046	S047	S048	S049
Nominal Total Flow Rate (ml/hr)	0.5	2	2	4 (2 sites)	5	4 (2 sites)	5	10	5 (2 sites)
Nominal Fill Volume (ml)	65	100	270	270	270	400	400	500	500
Maximum Fill Volume (ml)	75	125	295	295	295	500	500	525	525
Retained Volume (ml)	<8	<8	<12	<12	<12	<12	<12	<15	<15
Approximate Delivery Time	5 days	2 days	5½ days	2½ days	2 days	4 days	3 days	2 days	4 days

When filled to nominal volume, delivery accuracy is +/- 15% of the labeled infusion rate when delivering normal saline at 72°F (22°C) against no back pressure. See Figure 11.

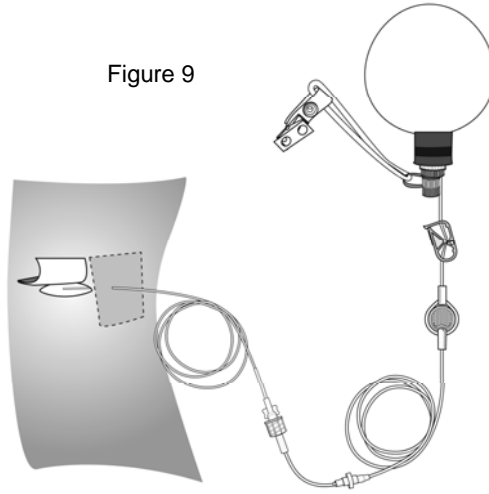
## CAUTIONS

- Actual infusion times vary due to viscosity, drug concentration, position of pump relative to catheter site, and temperature.
  - Filling the pump less than nominal may result in faster flow.
  - Filling the pump more than nominal may result in slower flow.
- This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

## BEGIN INFUSION

- After the catheter is placed in the wound site, use 5mL syringe to prime catheter again. This will ensure good flow distribution.
- Attach the catheter connector to the pump tubing (Figure 9).
- Open the tubing clamp to begin infusion.
- Secure catheter with Steri-Strips about 1" from the catheter insertion site. For suitable results, wrap at least one Steri-Strip around the catheter, then secure free adhesive ends to skin. Cover both insertion site and Steri-Strips with a Tegaderm or other suitable dressing.
- Do not bend, coil or stress the 3 inches of tubing on either side of the catheter connector.
- Do not cover the filter.
- The Infusion System must not be in contact with cold therapy pads.

Figure 9

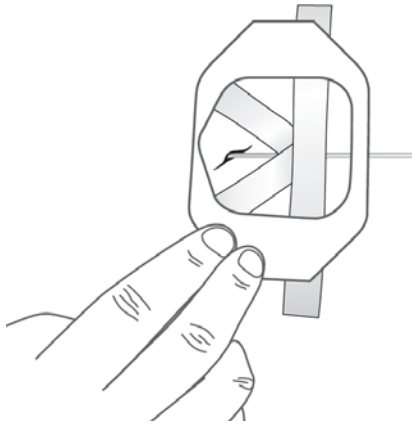


- The healthcare provider has the responsibility of ensuring that the patient is educated in the proper use of the pump and catheter(s) and that they are given the patient guidelines.
- The physician has the responsibility of prescribing drug(s) on the basis of each patient's individual clinical status (including age, weight, disease state, etc.).
- To avoid complications in restrictive spaces, use the lowest flow rate, drug concentration and volume necessary to create the desired outcome.
  - Catheter should not be placed in the distal end of extremities (including toes, fingers, ears, nose, penis, etc.) where build up of fluid can cause necrosis or ischemic injury.
  - Avoid tight wrappings which potentially limit blood supply or fluid diffusion.
- Do not suture catheter.
- Check the distal end of the catheter for black marking to ensure the entire catheter was removed.
- Infusion of certain medications to intra-articular spaces appears highly associated with joint damage including but not limited to postarthroscopic glenohumeral chondrolysis. Do not use the Solace Infusion System in joint spaces.
- See informational insert for important information.

## CATHETER MAINTENANCE

- The catheter should be maintained in accordance with standard hospital protocols.

Figure 10



## NOTE

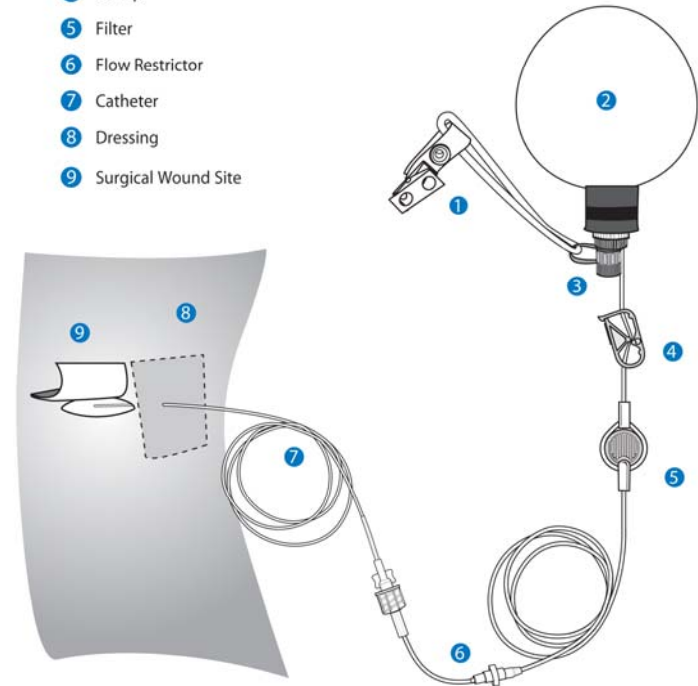
- For dual-site models, repeat *Priming the Catheter* and *Placing the Catheter* steps for the other wound site. Attach primed catheters to the two luer connectors at the end of the pump tubing. Open the tubing clamps to begin infusion.
- If tubing has been clamped for an extended period of time, roll tubing with fingers to help flow. If the pump is still not flowing, lay the tubing on a flat surface and roll a cylindrical object such as a pen 1" – 5" up the set tubing, away from the pump. Avoid rolling over set components and do not roll within the distal 5" of the set. Repeat as necessary.

## USE

- Attach to clothing using the supplied clip (attached through fill port cap strap) or place in a carrying case.
- Infusion is complete when pump is no longer inflated and a hard plastic ball can be felt in direct contact with the elastomeric bladder inside the deflated pump. Refer to Table 1 for approximate delivery time.

- 1 Clip
- 2 Solace Pump
- 3 Fill Port
- 4 Clamp
- 5 Filter
- 6 Flow Restrictor
- 7 Catheter
- 8 Dressing
- 9 Surgical Wound Site

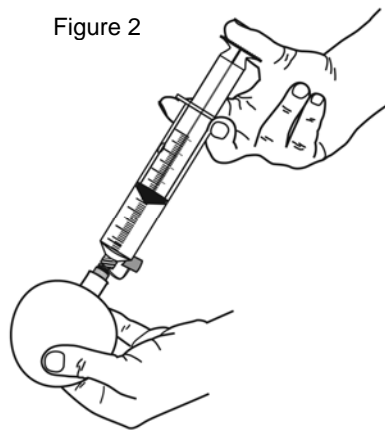
Figure 1



**DIRECTIONS FOR USE**  
Use Aseptic Technique

**FILLING THE SOLACE INFUSION SYSTEM PUMP (Figure 2)**

- Close tubing clamp.
- Un-cap the fill port, leaving cap attached to pump.
- Attach medication-filled syringe to the fill port.
- Inject medication into pump, repeating if necessary to fill pump to specific volume.
- DO NOT push down on the pump while filling as the syringe and/or pump may break.
- Do not exceed maximum fill volume (see Table 1).
- Replace the fill port cap.
- Label with the appropriate pharmaceutical and patient information.



**PRIMING THE PUMP**

- Open the tubing clamp and remove the cap(s) from the luer connector(s) at the end of the tubing. Allow the medication to fill the tubing and luer connector(s), priming for up to 5 minutes.
- Wait for all air to exit the tubing and then close the clamp until ready to use.

**PRIMING THE CATHETER**

- Proper priming of the catheter and pump tubing is very important since any trapped air in the catheter may affect proper catheter performance.
- Attach medication-filled syringe to the catheter connector and slowly prime the catheter such that it is filled with medication and contains no entrapped air (Figure 3). Medication should be observed infusing out along the entire marked infusion segment of the Zone Catheter® or near the tip of the standard catheter.



**PLACING THE CATHETER**

**WARNING:** It is recommended that the catheter be placed under direct visualization to ensure proper placement.

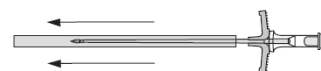


Figure 4

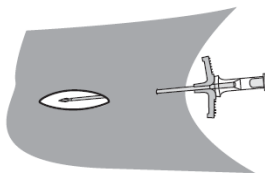


Figure 5

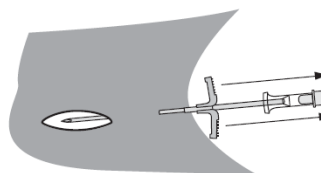


Figure 6

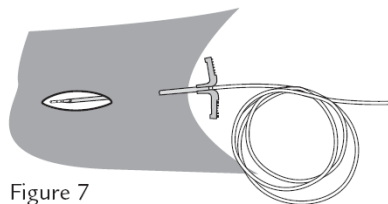


Figure 7

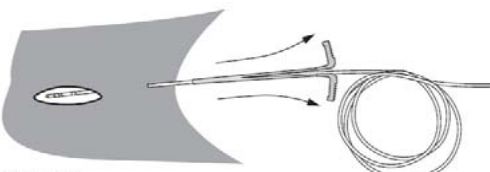


Figure 8

- Insert supplied introducer needle or tunneler through opening of T-handle introducer sheath and remove needle guard from introducer (if applicable) (Figure 4). Do not apply excessive pressure to T-handle. Grip only the introducer needle or tunneler hub during insertion.

- Insert the introducer through the skin (approximately 3-5 cm away from the wound site) then push introducer into the wound site (Figure 5).

- While holding the introducer sheath in place, withdraw the introducer needle or tunneler (Figure 6).

- Insert the marked end of the catheter through the opening of the introducer sheath such that it extends into the wound site (Figure 7). Advance catheter until entire infusion segment is visible.

- While holding the catheter tip in place, withdraw the introducer sheath from the insertion site, then split the sheath and peel it away from the catheter. (Figure 8). CAUTION: Introducer sheath must be completely removed from the body before peeling it away from the catheter to prevent sheath from breaking off in patient. Dispose of introducer sheath and needle or tunneler in accordance with accepted medical practice.

- Place the catheter to desired position within wound site. Ensure that entire infusion segment is within wound site.

**WARNINGS**

- Assume that the catheter is not in a vein or artery. Even if aspirations for blood are negative, intravascular penetration is still possible. Perform visual inspection, test dosing and patient monitoring. Refer to drug manufacturer's package insert.
- Avoid reinserting a withdrawn or partially withdrawn introducer needle or tunneler. This may damage or tear the sheath and leave material in the patient after removing the sheath.
- Handle catheter carefully to prevent kinking.
- Do not bend, coil or stress the 3 inches of tubing on either side of the catheter connector.

**NOTE**

- Care should be taken during catheter placement to assure that occlusion will not occur during use and that catheter removal will not be impeded.
- Drug infusion occurs between black tip and black band on catheter closest to tip.