

insuflon™

One step closer to a normal life

insuflon™ makes injections more convenient & comfortable

Although some patients don't mind frequent daily injections, many worry about this extra discomfort or object to this painful inconvenience. For these people an alternative may be insuflon™, an indwelling subcutaneous soft cannula. insuflon™ can be used by adults and children (even infants) and was initially designed to help children and their families come to terms with diabetes. By virtually eliminating the needle pain associated with daily injections, insuflon™ can increase therapy compliance.

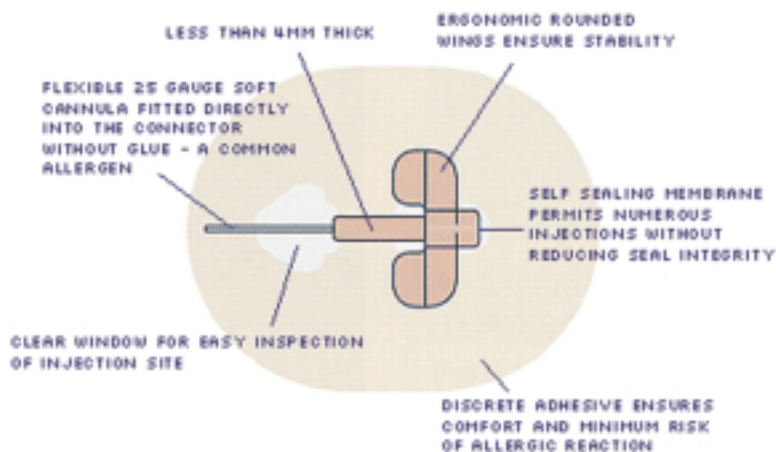
Currently, insuflon™ is being used successfully in many specialties throughout the hospital and also at home to administer medications, which can be given subcutaneously.

insuflon™ is gentle

insuflon™ consists of a soft cannula that is gentle to the tissues. It is small and easy to handle, only 18mm (0.71") long and 0.6mm (0.02") outer diameter.

Insertion of insuflon™ is simple. It is inserted subcutaneously into the fatty tissue of the body at a 20-45° angle. The steel needle, which is used to introduce insuflon™, is then removed, leaving the soft cannula in place.

insuflon™ has a small membrane through which medication can be injected painlessly. At least 75 injections can be made through this membrane. insuflon™ is held in place by a skin-friendly adhesive with a built-in see-through window to allow visual inspection of the injection site.



Injecting through insuflon™ is easy and painless. Small enough to be worn comfortably underneath tight clothing.

insuflon™ is safe to use

The adhesive material is soft and comfortable to the tissue with little risk that insuflon™ will scrape or cause any other irritation.

Leading hospitals are using insuflon™ to administer many medications, which are given subcutaneously: insulin, low molecular weight heparin, morphine, G-CSF, growth hormones and many more drugs.

insuflon™ works

Patients and medical staff have an excellent acceptance rate of insuflon™. Many patients and care givers enjoy the benefits of insuflon™ at home with the support of home care programs. insuflon™ improves patients' quality of life.

insuflon™: the cost effective solution

insuflon™ can be left in the subcutaneous fatty tissue of various sites up to 3 days depending on the type of medication. After a while, it will be possible to determine the length of time the insuflon™ can be left in place.

insuflon™ is manufactured to the highest hygienic and quality standards by Unomedical a/s, a leading supplier of single-use medical devices.

Distributed by:



920 Minters Chapel Rd, Suite 200
Grapevine, TX 76051
Toll Free: 866-211-7867 (PUMP)
Fax: 630-845-2768
www.intrapump.com
www.insuflon.com

Manufactured by:

Unomedical a/s
Åholmvej 1-3, Osted
4000 Roskilde, Denmark
www.infusion-set.com

insuflon™

Insertion, Removal and Maintenance of insuflon™, Subcutaneous Catheter

How to insert insuflon™

1. Collect all necessary equipment to insert the insuflon™ catheter (e.g. insuflon™ blister pack, alcohol swab and/or IV Prep). Wash hands with antibacterial soap.
2. Select a site for the catheter insertion. Outside of the arm, the front of the leg, top of buttocks and the abdomen are common sites of insertion. If using the abdomen, the catheter should be placed horizontally, avoiding skin folds or lines of clothes.
3. If desired, apply a topical anaesthetic (e.g. Emla cream or ice) to the insertion site for greater comfort.
4. Clean the injection site with an alcohol swab or IV Prep swab. Allow the injection site to dry for at least two minutes to ensure secure adhesion of the adhesive dressing.
5. insuflon™ is sterile if the package is undamaged. Check package and expiry date. Package must not be opened before use. To open pull lid from plastic blister.
6. Remove protective cap by gripping catheter hub and pulling cap off. The cap is then placed in the rear of insuflon™.
7. During insertion, hold insuflon™ like a pen in one hand. With the other hand, pinch the skin at site of insertion. Insert insuflon™ as far as possible in one smooth movement at a 20 - 45° angle.
8. Remove the inducer needle by holding catheter hub firmly and pulling the needle out slowly.

Care must be taken to prevent catheter withdrawing during placement. Use a new insuflon™ if catheter is damaged or withdrawn.

9. Attach insuflon™ by using the adhesive dressing provided. Apply adhesive dressing from catheter end first ensuring insertion site is clearly visible; smooth out dressing.
10. Dispose of the inducer needle safely.

Removing insuflon™

1. Always place a new insuflon™ before removing the old one to ensure rotation of sites.
2. Carefully peel off the adhesive dressing, beginning at the catheter end and then remove catheter.

Living with insuflon™

Injecting. Syringe needle must be between 27 – 31 gauge; Length of syringe needle should not exceed 3/8th inch (10.5 mm). Catheter dead space volume is 0.0075ml (dead space volume when injecting insulin: 0.5 unit of U100). If more than ten percent of the medication is lost in the catheter dead space volume, consult the physician and pharmacy before using the insuflon™. A small amount of compatible solution may be considered to flush the medication if necessary. A separate insuflon™ must be used for each drug injected. **DO NOT** deliver multiple drugs through a single insuflon™ without consulting with your Health Care Professionals. *An exception to this may occur if the insuflon™ is being used for delivery of insulin. Consult your Health Care Professionals before mixing insulins in the insuflon™.*

1. Collect necessary equipment to inject the subcutaneous medication (needle, syringe, alcohol swab). Fill syringe with drug to be injected.
2. Insert syringe needle into the insuflon™ hub. The needle must penetrate the membrane by at least 1/8th inch (3mm) and not more than 3/8th inch (8mm). A longer needle could possibly damage the catheter. Do not use excessive force to insert the needle.
3. Inject the medication slowly then remove the needle. A slow injection will help to reduce site irritation caused by the medication.
4. Check insuflon™ daily for skin irritations or other complications. If reasonable care is taken you can join in most activities including sports and swimming. In the shower or bath take a little extra care not to disturb insuflon™, particularly in very hot water.

Insuflon™ replacement

Be prepared to replace insuflon™ early if any irritation or other complications are noted. The following guidelines have been found to be safe and effective for using insuflon™. Learn the reasons why insuflon™ may be replaced early (See Problem Solution Guide below).

- Start by changing insuflon™ every 3 days. Place the next insuflon™ on the other side of the abdomen, buttocks, opposite arm or leg. When returning to the same side select a different insertion site to avoid the formation of lipohypertrophies.
- When using insulin, insuflon™ should be removed every 72 hours (every 3 days). Activity level, amounts of injections and medication type may vary how often insuflon™ needs to be changed.
- Always place the new insuflon™ before removing the old one to avoid contaminating the site and to ensure good site rotation.

Problems solution guide

1. Reasons for early replacement:
 - Pain, redness, discomfort or swelling at insertion site.
 - Kinked catheter or other obstructions.
 - Loose adhesive dressing. If the adhesive dressing is not secure there is a danger that insuflon™ will move, the cannula will withdraw and medication will not be delivered subcutaneously.
 - If used for insulin delivery, deterioration in blood glucose or urine tests without obvious cause (e.g. sick day, unusual food intake etc) indicates immediate replacement is required.
2. Catheter Peel Back
 - If insuflon™ insertion is too slow there is a risk of the catheter "crimping" or peeling back from the needle. If this occurs a new insuflon™ should be used. This is a typical "beginner's problem". Contact your Health Care Professional if you encounter this.
3. Withdrawn Catheter
 - If the catheter pulls out from the skin, no drug will be administered subcutaneously when injecting. Place new insuflon™.
4. Infection or Redness
 - Infection around the catheter in the subcutaneous tissue is recognized by redness or pain around the insertion site.
 - Redness outside the area covered by the adhesive tape is normally caused by a too superficial insertion of insuflon™. Contact your Health Care Professional if this happens.
5. Lipohypertrophy and/or Deteriorating Insulin-Effect
 - Lipohypertrophy or fat cushion at the catheter tip may occur after several days. Replace insuflon™ immediately and change insertion site if you notice deterioration in effect. Contact your Health Care Professional if this occurs often.
6. Haematoma or Bruise
 - A bruise or bleeding at the insertion site can occur when using insuflon™. It is normally nothing to worry about. If accompanied by other indications such as pain or discomfort bleeding then insuflon™ should be removed and replaced.

Revised 31/01/05

This document is intended as a guide only.

Consult Health Care Professionals for assistance with specific questions/details/problems.