

INSTRUCTIONS FOR USE

Insignis-26G™ 26 Gauge Subcutaneous Needle Sets

Indications for Use

The Insignis-26G™ Subcutaneous Needle Sets are used for the subcutaneous infusion to administer fluids from a container or a syringe to a patient's subcutaneous tissues in the hospital, home, ambulatory, military, or clinic setting. The Insignis-26G™ Subcutaneous Needle Sets can be used with mechanical and electronic syringe driver systems as well as for manual push applications.

Maximum duration of use: < 24 hours

Contraindications

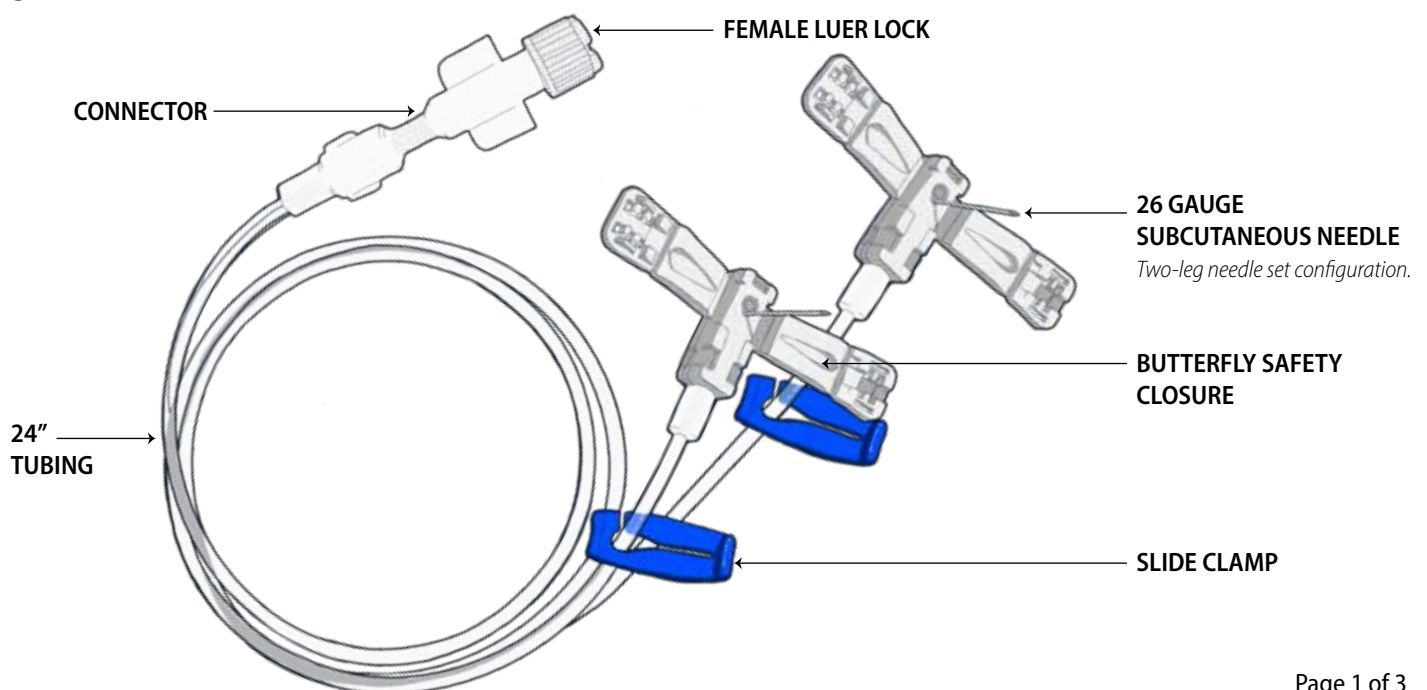
The Insignis™ Syringe Infusion System is not intended for the delivery of life sustaining medications, such as blood transfusion or the delivery of insulin.



Caution

- Use of the Insignis-26 G™ Subcutaneous Needle Sets are intended only for the patient for whom the device is prescribed.
- U.S. federal law restricts this device to sale by or on the order of a physician.
- Before use, carefully inspect the administration set package. Do not use if the package has been opened or is damaged.
- Do not re-sterilize administration sets.
- Do not stretch or kink the administration sets/ancillary devices.
- Always follow the infusion instructions located on the package insert of the manufactured drug.
- The Insignis-26G™ Subcutaneous Needle Sets are not intended to be used in a Magnetic Resonance (MR) Environment. The use of this device in an MR environment may cause serious injury or death and may also produce image artifacts that can lead to inaccurate clinical diagnosis.
- If using the infusions set for the first time, do so in the presence of a healthcare provider.
- Since individuals inherently have varying amounts of subcutaneous fat on the body, be sure to select the appropriate needle length to fit your needs or as instructed by a physician.
- If the infusion site becomes inflamed, replace the set, and choose a new infusion site until the first site has healed.
- Be sure to remove the needle guard prior to insertion.
- Ensure that the needle is not bent prior to insertion.
- Never attempt to free a clogged tubing line while the set is inserted.
- Store infusion sets in cool, dry place. Do not leave infusion sets in direct sunlight or inside a vehicle.
- When using multi-leg needle set configurations, over-infusion may occur to remaining sites if one or more of the needles is blocked.
- Inaccurate medication delivery, infection, and/or site irritation may result from improper needle insertion and maintenance of the infusion site.
- Always consult and comply with guidance provided by your healthcare providers, and drug manufacturers, regarding the location and the number of infusion sites.

Insignis-26G™ Subcutaneous Needle Set



INSTRUCTIONS FOR USE

Starting the Infusion for Subcutaneous Administration:

Insignis-26G™ 26 Gauge Subcutaneous Needle Sets

1

Ensure you have all supplies for your infusion.

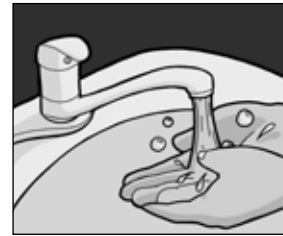
Verify that you are using the appropriate subcutaneous flow rate tubing set for your application per physician's order and have all of the required supplies to perform your infusion.



2

Wash hands

Wash hands thoroughly and if needed, wear disposable gloves. Prepare clean surface for set-up.



3

Remove End Cap

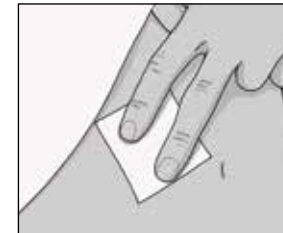
Remove the sterile caps from opposite end of tubing set and the Insignis-26G needle set. Attach male luer of fixed rate tubing to female luer on Subcutaneous Needle Set. When using a mechanical infusion pump, do not connect needle set directly to syringe. When using an electric infusion pump, the needle sets can be connected directly to the syringe.



4

Prep Infusion Site(s)

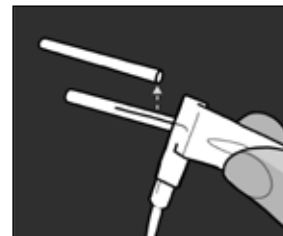
Using aseptic technique, prep infusion site(s) as directed by clinician. Remove rubber band from butterfly, fold wings back, and remove needle guard.



5

Remove Needle Guard

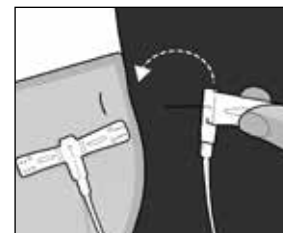
Remove rubber band from butterfly and fold wings back to expose needle guard; remove needle guard.



6

Insert Needle(s)

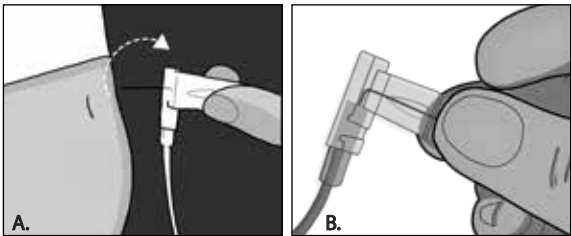
Insert needle(s) into appropriate locations in subcutaneous tissue at 90° angle. Lay butterfly wings flat on skin. Cover site with tape or adhesive dressing. If checking for blood return, after inserting the needles, pause, gently pull back on the syringe plunger. If blood is noted in the tubing, follow drug manufacturer's recommendations.



INSTRUCTIONS FOR USE

Ending the Infusion:

1 Remove Dressing
Pause before removing needles; allow site pressures to decrease naturally. Remove needle dressing. To minimize accidental risk of needle stick injury, use one hand to remove needle. Using the same hand, squeeze butterfly safety closure wings together to firmly encase needle.



2 Dispose of Needles
Once wings are closed, dispose of needle set in sharps container.



Storage

The Subcutaneous Needle Sets are recommended for storage in a dry place (humidity levels 15% - 90%) at room temperature (16-30°C; 61-86°F).

Technical Information

Length: 61.0 cm
Weight: 10.0 - 22.0g
Tubing Diameter: 2.3mm
Residual Volume:

1 site	0.61 ml
2 sites	1.12 ml
3 sites	1.60 ml
4 sites	2.10 ml

Part	Material
Tubing	Polyurethane
Connector	Polycarbonate
Needle	Stainless Steel

Part Numbers

Insignis-26G™ Subcutaneous Needle Set (box of 10)

Configuration	6mm	9mm	12mm	14mm
1 site	SC-NS-0106	SC-NS-0109	SC-NS-0112	SC-NS-0114
2 sites	SC-NS-0206	SC-NS-0209	SC-NS-0212	SC-NS-0214
3 sites	SC-NS-0306	SC-NS-0309	SC-NS-0312	SC-NS-0314
4 sites	SC-NS-0406	SC-NS-0409	SC-NS-0412	SC-NS-0414

Definition of Symbols

	Caution		Quantity		Do not reuse
	Consult Instructions for Use		Serial number		Catalog number
	Use by YYYY--MM-DD		Prescription only		Batch code
	Manufacturer		Sterilized using radiation		Volume
	Temperature		Humidity		Altitude
	Pressure device		Non-pyrogenic		European Conformity
	Latex Free		European Authorized Representative		Do not use if package is damaged
	Do not use in MRI setting		Do Not Resterilize		Medical Device
	Unique Device Identifier		Date of Manufacture		

CE 2797

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The Insignis-26G™ Subcutaneous Needle Sets are a trademark of Innovative Health Sciences LLC (IHS). IHS is ISO 13485 certified and abides by the quality policies as outlined in 21 CFR 820.

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