INSTRUCTIONS FOR USE

Insignis-26G™
26 Gauge Subcutaneous Needle Sets

OBSOLETE

Indications for Use

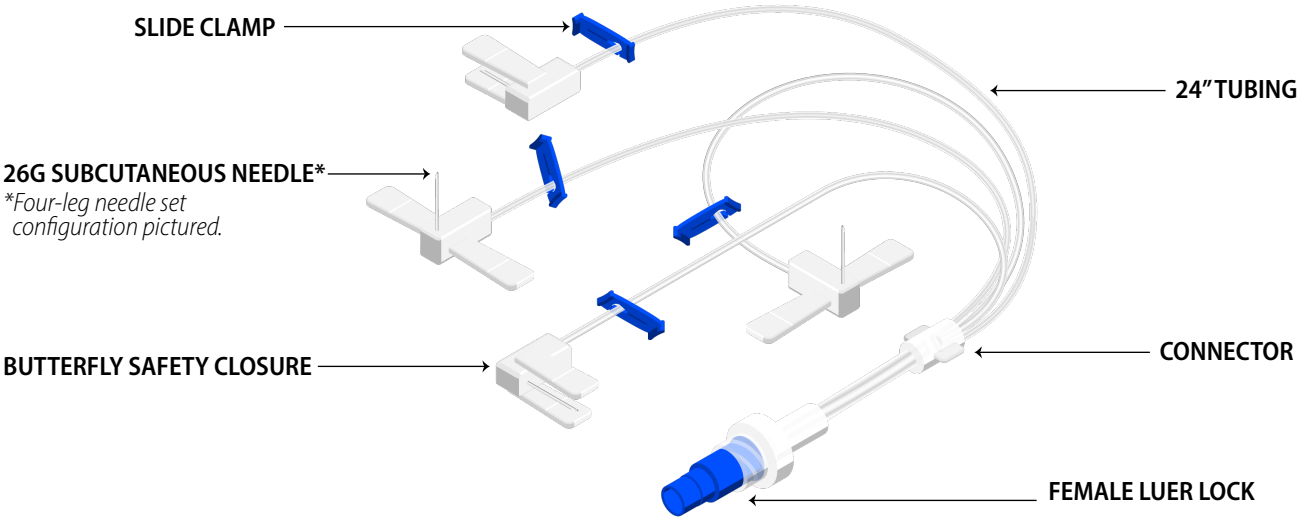
The Insignis-26G ™ Subcutaneous Needle Sets are used for the subcutaneous infusion to administer fluids from a container or a syringe to a patient's subcutaneous tissues.

Maximum duration of use: < 24 hours

⚠ Caution

- Use of the Insignis-26 ™ 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 adminstration 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.

Product Diagram



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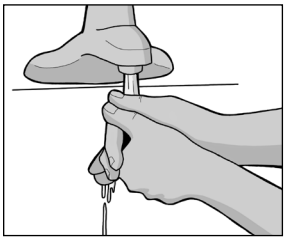
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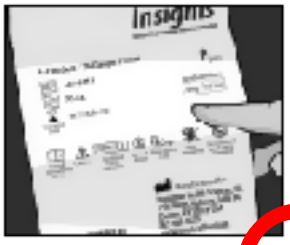
Starting the Infusion for Subcutaneous Administration:

1. Wash hands



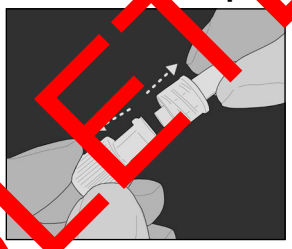
Wash hands thoroughly and if needed, wear disposable gloves.

2. Verify Packaging



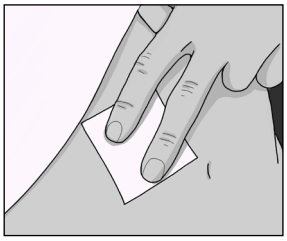
Verify that you have selected the appropriate needle set for your application.

3. Remove End Cap



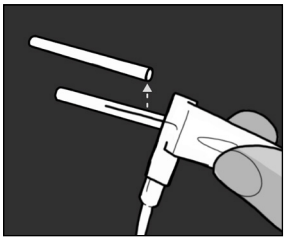
Remove end cap and connect to the infusion source.

4. Prepare Infusion Site(s)



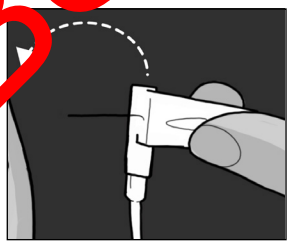
Using aseptic technique, prep infusion site(s) as directed by a clinician.

5. Remove Needle Guard



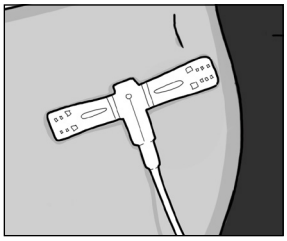
Remove rubber band from butterfly and fold wings back to expose needle guard; remove needle guard.

6. Insert Needles



Insert needle(s) dry into appropriate locations in subcutaneous tissue at 90° angle.

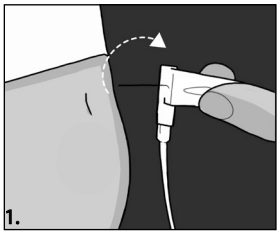
7. Lay Butterfly Wings Flat

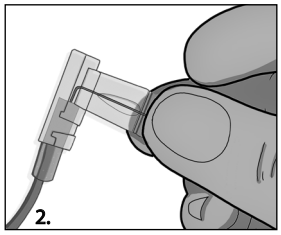


Lay butterfly wings flat on skin. Cover infusion site with needle dressing or adhesive tape. Start infusion as recommended by your provider.

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.

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Storage

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

Insignis Technical Information

Length: 24" (61cm)
Residual Volume:

1 site	0.04ml
2 sites	0.07ml
3 sites	0.10ml
4 sites	0.13ml

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	QTY	Quantity		Do not reuse
	Consult Instructions for Use	SN	Serial number	REF	Catalog number
	Use by YYYY--MM-DD	Rx Only	Prescription only	LOT	Batch code
	Manufacturer	STERILE R	Sterilized using radiation	VOL	Volume
	Temperature		Humidity		Altitude
P (psi)	Pressure device		Non-pyrogenic	CE	European Conformity
LATEX	Latex Free	EC REP	European Authorized Representative		Do not use if package is damaged
MR	Do not use in MRI setting	2 STERILIZE	Do Not Resterilize	MD	Medical Device
UDI	Unique Device Identifier		Date of Manufacture		

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Manufacturered for
Innovative Health Sciences
1108 Kings Highway Suite 4
Chester, NY 10918, USA
855-680-0630
innohealthsci.com
Made in China

EC REP
European Authorized Representative
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE 1282