INSTRUCTIONS FOR USE

Insignis™
Syringe Infusion System

Insignis™ Syringe Infusion System

The Insignis™ Syringe Infusion System is intended for the intravenous and subcutaneous administration of fluid medications. The System consists of a syringe based, non-electric, portable 13.5psi constant pressure Syringe Driver with carrying case; an intravenous or subcutaneous selectable rate flow control device (with needle(s) directly attached for subcutaneous use); intravenous or subcutaneous fixed rate flow control tubing, and 26 gauge subcutaneous needle sets.

For the intravenous administration of medication(s), the Insignis Intravenous (IV) Controller includes a selectable rate flow dial and tubing for direct connection to IV catheter tubing.* For the administration of subcutaneous immunoglobulin (SCIg), the OneSett™ and Q-Controller™ are pre assembled and include a selectable rate controller connected directly to an administration set comprised of one (1) to up to four (4) needle set configurations** (6mm, 9mm, 12 mm, and 14mm lengths), to meet the drug manufacturer's maximum flow rate limits. The Insignis-26G™ 26 Gauge Subcutaneous Needle Sets (6mm, 9mm, 12 mm, and 14mm lengths) are also available as an independent subcutaneous administration set that may be used for administering medications from syringes or the Insignis™ Syringe Driver. Fixed rate tubing is available.

When used under the supervision of a clinician, the Insignis™ Syringe Infusion System's IV Controller, OneSett™, and Q-Controller™ provide the user with the control to select, titrate, or modify the flow rate in real-time. For example, the OneSett™ enables a patient on subcutaneous immunoglobulin therapy to achieve maximum therapeutic benefit with minimal discomfort by simply turning the dial to modify the flow rate as indicated. To ensure safety, the system will automatically respond to increasing resistance at the infusion site, immediately decreasing the flow rate for patients experiencing tissue saturation. For intravenous applications, the system's ability to respond to site pressure minimizes infiltration and therefore may prevent overflow or overdose.[1]

Indications for Use

The Insignis™ Syringe Infusion System is indicated for the delivery of intravenous and subcutaneous medication from a syringe to a patient in the hospital, home, ambulatory, military, or clinic setting. This includes specific indications for intravenous antibiotics such as Vancomycin, 20% subcutaneous immunoglobulin solutions including Hizentra® Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring), Cuvitru® (manufactured by Takeda), and Xembify® (manufactured by Grifols) and 10% subcutaneous immunoglobulin solutions including HyQvia® (manufactured by Takeda). The system is intended for use in pediatric through adult clinician and caregiver populations and is to be operated under the supervision of an adult after instruction by a healthcare provider.

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.

Precautions and Warnings

- The administration sets are single use only. Do not re-sterilize.
- IHS advises against off-label use with the Insignis™ Syringe Infusion System.
- Carefully inspect the syringe driver before use to verify that it is in working condition. Do not use the driver if it is damaged.
- Do not use if any contaminants, debris, or fluids, including drug residue are encountered inside the syringe driver.
- Do not stretch or kink the delivery sets or fixed rate tubing.
- Ensure the syringe is empty before removing the syringe from the driver. If medication is still in the syringe, activate the lever once to infuse the remaining medication.
- For any drugs that require filtering, it is recommended to pre-filter the drug prior to beginning the infusion. Consult the drug manufacturer's instructions for use.
- Use of the Insignis Syringe Infusion System with narcotics or central nervous system depressants at temperatures above ambient temperature may cause a faster flow rate than indicated to be delivered to the patient. This expected increase in flow rate may be compensated for by decreasing the selectable rate flow controller in accordance with the well-known fluid principles of temperature and viscosity/flow rate compensation available from IHS (see page 17). In addition, patients should have adequate continuous vital signs monitoring, or consider using a volumetric pump for this patient.
- Use of other flow control devices and/or administration sets is not recommended as there can be no assurance that the specified performance is maintained and patient harm could occur.
- The IV Controller, OneSett™, Q-Controller™, and Insignis™ Fixed Rate Tubing are designed for accurate delivery with a 13.5psi constant pressure syringe driver, such as the Insignis™ syringe driver. IHS cannot assure the delivery of 13.5psi on other marketed devices besides the syringe driver specified in these instructions.
- Failure to store in correct storage conditions may lead to possible leak at the controller.
- Use caution when activating the syringe driver's lever to ensure that a finger does not get pinched between the lever and the body of the driver.

*Intravenous catheter not included. Consult your provider.

** The OneSett™ and Q-Controller™ is available in 1 and 2 needle site configurations; the OneSett™ is available in 1, 2, 3, and 4 needle site configurations.

INSTRUCTIONS FOR USE

Insignis™
Syringe Infusion System

⚠ Caution

- Use of the Insignis™ Syringe Infusion System is intended only for the patient for whom the device is prescribed.
- If using the infusion set for the first time, do so in the presence of a healthcare provider. Use this device only after receiving training from a healthcare provider.
- Use only recommended Becton Dickinson and Company® 50ml (#300865) or similar syringes with the Insignis™ Syringe Infusion System.
- Before use, carefully inspect the administration set package. Do not use if the package has been opened or is damaged.
- Always follow the infusion instructions located on the package insert of the manufactured drug.
- Verify the drug volume in the syringe(s) prior to beginning the infusion.
- The syringe driver's recommended operating temperature is room temperature (20°C- 25°C; 68°F - 77°F). If using the syringe driver outside of these temperatures, see page 17 for temperature sensitivity.
- Store infusion sets ina cool, dry place.
- Do not leave infusion sets in direct sunlight or inside a vehicle.
- Follow cleaning steps for the syringe driver after each use to thoroughly clean the device.
- If the safety lock tab is inadvertently released and the infusion is halted, return the safety tab to the locked position and activate the lever once for every 10ml (or less) of medication left in the syringe.
- If problems are encountered during use, see "Troubleshooting" section (p. 6 for IV use; p. 14 for SCIg).
- If for any reason you experience a medical emergency during use, call the local emergency number and/or your healthcare provider immediately.
- To stop the flow immediately, disengage the safety lock tab on the syringe driver by turning it to the left. You may also use the slide clamp on the tubing and/or turn the flow dial to 0ml/hr (for IV Controller , OneSett™, Q-Controller™).
- Overuse of the slide clamps on the administration sets may damage the tubing and affect the infusion flow rate.
- The Insignis™ Syringe Infusion System has not been tested in a Magnetic Resonance Imaging (MRI) environment and therefore cannot be recommended for use in such an environment.
- The Insignis™ Syringe Infusion System will run silently from beginning to end of the infusion; there are no alarms that will sound and no display of infusion status.
- The Insignis™ System is not suitable for use with medication where delay or under-infusion could result in serious injury.

Cautions Specific to Intravenous Use

- For intravenous applications, consult the manufacturer of the intravenous catheter set for specific instructions for use.
- If there is a problem with the catheter. Consult the catheter manufacturer and/or instructions for use.
- Prime the set before connecting to a patient's IV. Disconnect the administration set prior to attempting to free clogged tubing.

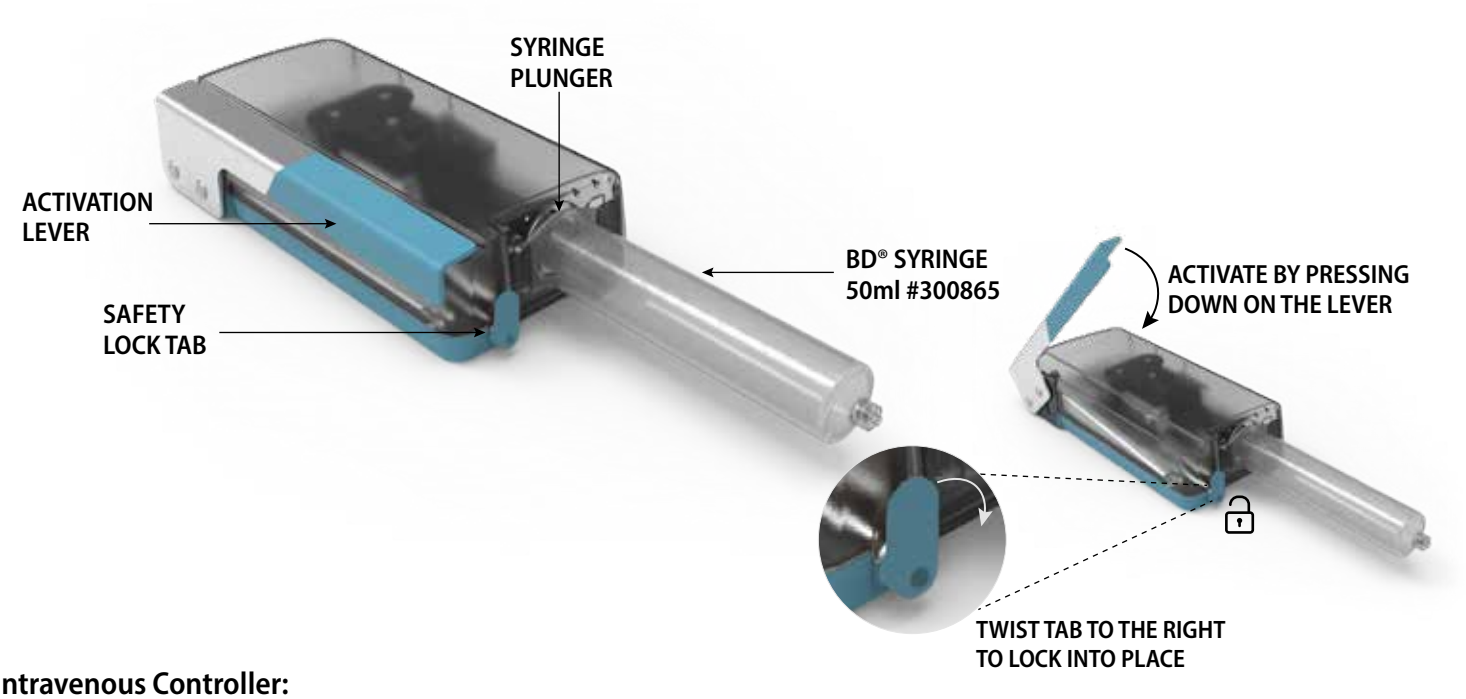
Cautions Specific to Subcutaneous Immunoglobulin Use

- Use of flow rate calculation software and/or computation documentation (tables, charts, graphs, etc.) may be unnecessary for use with the OneSett™ as the flow rate indications appears directly on the dial.
- Each OneSett is calibrated from 10-60ml/hr/site for the number of needles included. The OneSett enables the selection of flow rates between 10ml/hr up to 60ml/hr. A four-site needle configuration can provide a total flow rate of 240ml/hr (60ml/hr/site).
- Each Q-Controller™ is calibrated for 10-300ml/hr. Each needle site can deliver up to 300ml/hr of 3cP 10% immunoglobulin solution. A two site needle configuration can provide a total flow rate of 600ml/hr (300ml/hr/site).
- If a needle site is clamped-off while using a multi-needle set, the flow rate to the remaining needle site(s) will increase. To compensate for this increase, it is advised to manually decrease the flow rate on the flow dial. See page 17 for flow rate compensation recommendations.
- Always consult and comply with guidance provided by your healthcare providers and drug manufacturers regarding the location and the number of infusion sites.
- When using multi-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/or maintenance of the infusion site.
- Ensure that the needle is not bent beyond 90°.
- Be sure to remove the needle guard prior to insertion.
- Verify the correct needle length is used according to your healthcare provider's recommendations.
- For suspected site reactions, stop the infusion and consult your healthcare provider.
- Prime the set before inserting subcutaneous needles (can be primed within the syringe driver or manually - see page 13).

For Intravenous Infusions

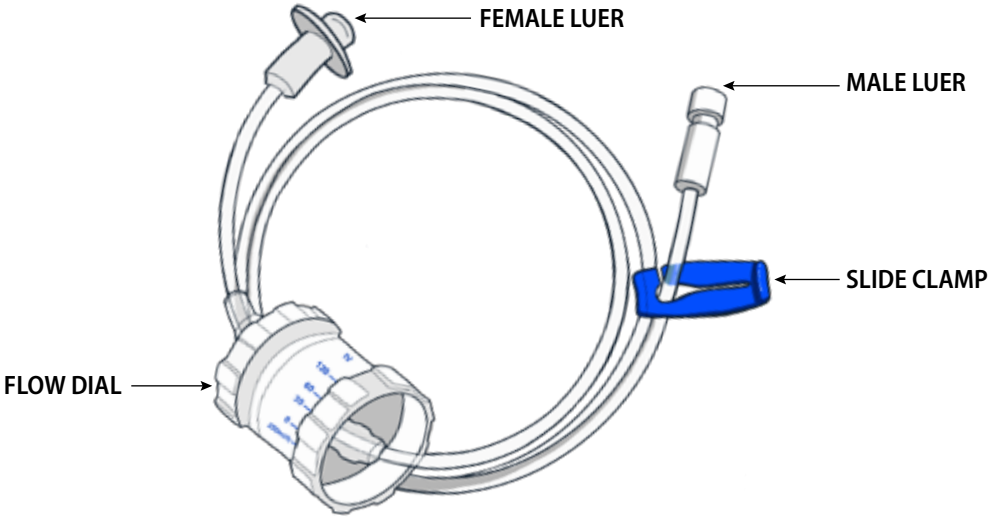
Syringe Driver : *13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*

Insignis™
Syringe Infusion System



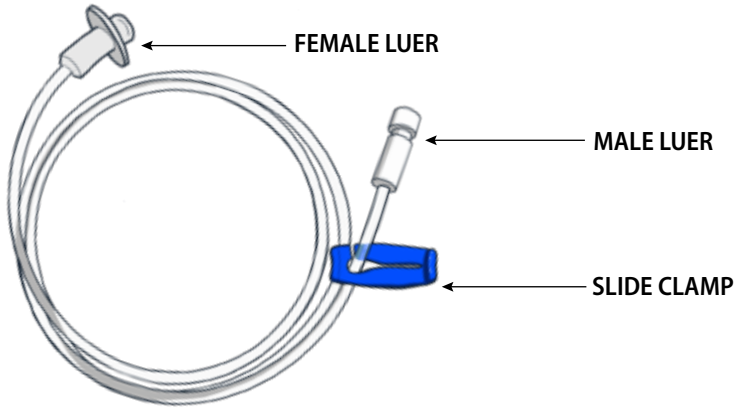
Intravenous Controller:

The IV Controller is calibrated from KVO (lowest flow rate on the dial) to 250ml/hr (highest flow rate on the dial). The IV Controller enables the continuous selection of flow rates between KVO (8ml/hr) up to 250 ml/hr.



Fixed Rate Tubing:

Available in 1ml/hr (IV-T1), 10m/hr (IV-T10), 50ml/hr (IV-T50), and 60ml/hr (IV-T60). The tubing is intended for the infusion of low viscosity medications intravenously (with appropriate intravenous ancillary products) or subcutaneously (with Insignis-26G™ Subcutaneous Needle Sets).



Intravenous Infusions Using the **Intravenous Controller:**

Syringe Driver : *13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*

Insignis™
Syringe Infusion System

Starting the Infusion for Intravenous Administration *using the Intravenous Controller (calibrated from 10ml/hr - 250ml/hr):*

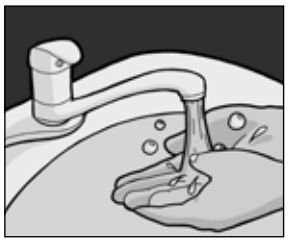
1 Ensure you have all supplies for your infusion.

Verify that you are using the correct administration set for intravenous use and have all of the required supplies to perform your infusion.

Supplies may include any of the following:
syringe driver and carrying case/pouch, IV Controller set, 50ml BD (#300865) or similar syringe, prefilled syringe(s) of medication with transfer device, and/or vials with dispensing pin/mini spike, antiseptic wipes, tape or securement device, gauze and or bandaid(s), bio hazard disposal container, gloves.

2 Wash hands

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



3 Fill Syringe

Make sure the drug product is at room temperature and fill 50ml BD® syringe to required dose. Refer to the drug manufacturer's instructions for complete filling directions.

4 Attach IV Controller

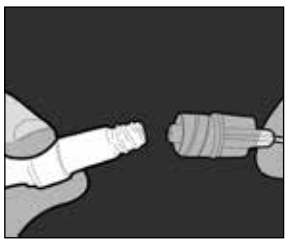
Using aseptic technique, remove the end cap on IV Controller and attach IV Controller to syringe by connecting female luer to mouth of syringe.

5 Prime IV Controller

Set IV Controller to OPEN (250ml/hr) for priming; gently press on syringe plunger and prime the set until one or two drops without air are noted; set dial to 0ml/hr (OFF).

6 Connect IV Controller to Catheter

Using aseptic technique, connect the IV Controller's male luer to the IV catheter. Follow healthcare provider instructions for line care. Clean the line with aseptic wipes for 20 seconds, unclamp the line, aspirate for blood return to ascertain patency. Flush with saline and lock solution per physician's order, clamp the IV line, remove cap from the IV Controller, and attach to the IV line.

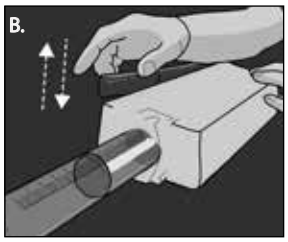


7 Load Syringe Driver

Turn the Insignis™ syringe driver's safety lock tab to the horizontal position (unlocked). Load syringe into driver, allowing plunger to move mechanism back to accommodate 50ml BD® syringe; rotate the syringe into place so that the syringe graduations are facing up.

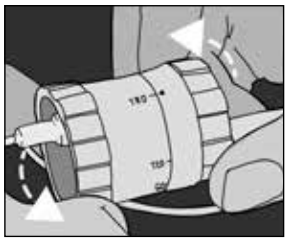
8 Activate Syringe Driver

Turn syringe driver safety lock tab to the vertical position (locked). Confirm the IV Controller is set to 0ml/hr (OFF). Depress the side lever fully one time for up to 10ml of fluid; for 50ml this is five times. Depress the lever one additional time to ensure the syringe plunger is fully engaged. Note that the driver will run silently from the beginning of the infusion to the end.



9 Set Flow Rate

Set the flow rate as prescribed by physician. If advised by clinician, change or set flow rate appropriately. Do not use any flow rate without instructions from your provider.



10 Check Progress

Check the infusion progress periodically by ensuring that the syringe plunger is moving and the volume is decreasing. The infusion may require an extra lever activation to ensure a complete infusion.

Intravenous Infusions Using **Fixed Rate Tubing**

Insignis™
Syringe Infusion System

Syringe Driver : *13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*

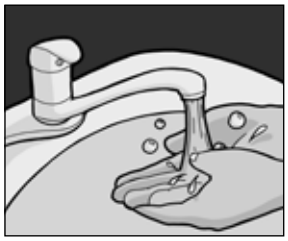
Starting the Infusion for Intravenous Administration *using Insignis™ Fixed Rate Tubing:*

1 Ensure you have all supplies for your infusion.

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

Supplies may include any of the following:
syringe driver and carrying case/pouch, intravenous or low-viscosity subcutaneous fixed rate tubing, 50ml BD (#300865) or similar syringe, prefilled syringe(s) of medication with transfer device, and/or vials with dispensing pin/mini spike, saline flush for pre and post medication, heparin flush or other lock solution (if ordered), antiseptic wipes, tape or securement device, gauze and/or bandaid(s), bio hazard disposal container, gloves.

2 Wash hands



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

3 Fill Syringe

Make sure the drug product is at room temperature and fill 50ml BD® syringe to required dose. Refer to the drug manufacturer's instructions for complete filling directions.

4 Attach Tubing

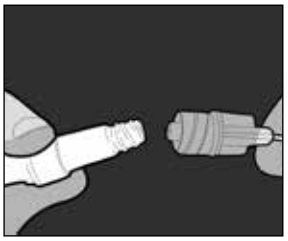
Using aseptic technique, attach female luer on fixed rate tubing to syringe.

5 Prime Tubing Set

Gently press on syringe plunger and prime tubing until one or two drops without air are noted.

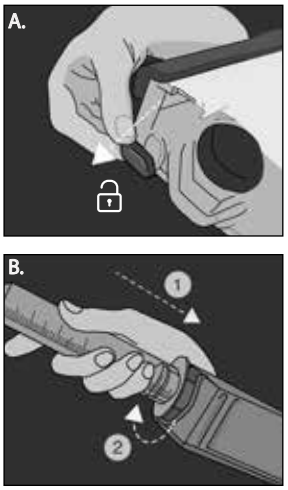
Note: If infusing low viscosity subcutaneous medication, skip step 6.

6 Connect Fixed Rate Tubing to Catheter



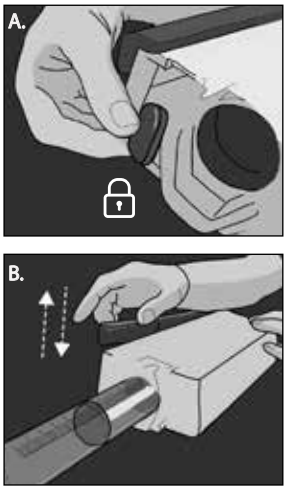
Follow healthcare provider instructions for line care. Clean the line with aseptic wipes for 20 seconds, unclamp the line, aspirate for blood return to ascertain patency. Flush with saline and lock solution per physician's order, clamp the IV line, remove cap from the IV Controller, and attach to the IV line.

7 Load Syringe Driver



Turn the Insignis™ syringe driver's safety lock tab to the horizontal position (unlocked). Load syringe into driver, allowing plunger to move mechanism back to accommodate 50ml BD® syringe; rotate the syringe into place so that the syringe graduations are facing up.

8 Activate Syringe Driver



Turn syringe driver safety lock tab to the vertical position (locked). Depress the side lever fully one time for up to 10ml of fluid; for 50ml this is five times. Depress the lever one additional time to ensure the syringe plunger is fully engaged. Note that the driver will run silently from the beginning of the infusion to the end.

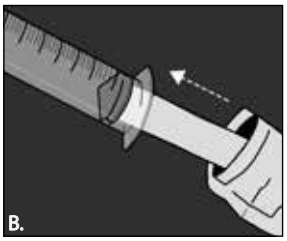
9 Check Progress

Check the infusion progress periodically by ensuring that the syringe plunger is moving and the volume is decreasing. The infusion may require an extra lever activation to ensure a complete infusion.

Ending the Infusion for Intravenous Administration:

1 Remove Syringe

When the syringe is empty, stop the infusion and clamp the IV line. Turn the safety lock tab to the horizontal position (unlocked) on the syringe driver and rotate the syringe to withdraw from the driver. Cleanse the hub with antiseptic wipes for 20 seconds and unclamp the IV line. Flush and lock line as prescribed by the physician. Flush the catheter with saline, flush with heparin or antibiotic if prescribed, clamp IV line.



2 Catheter Removal

Check the physician's orders for catheter care or removal.

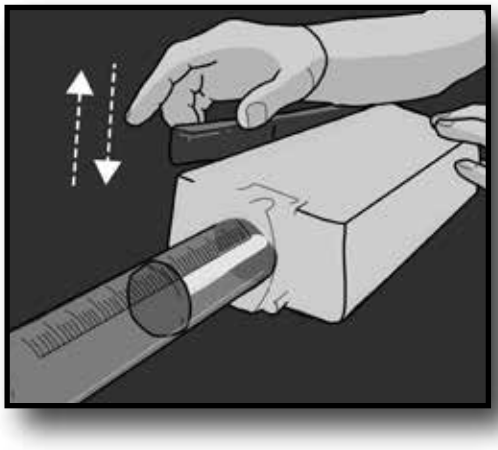
3 Dispose of Materials

Carefully dispose of materials in a sharps container per local regulations.

Intermittent Dosing *using the Insignis™ Syringe Driver and the Intravenous Controller*

The Insignis™ Syringe Driver can be used to infuse medication intermittently. This is especially advantageous when infusing smaller volumes of antibiotics over an extended period of time (for example, the delivery of 10ml of antibiotic medication every 6 hours over a 24-hour period).

1. Prepare infusion as instructed on page 3.
2. Instead of activating the pump for the a full 50ml of drug volume, using the lever on the side of the device, press down on the handle *only once* to deliver 10ml of drug.
3. Following the instructions on page 3, proceed with the infusion.
4. After the full 10ml of drug has been infused, activate the pump again by pressing down *once* to deliver another 10ml.
5. Continue this process until the desired drug volume has been infused.
6. Follow the instructions on above (page 6) to remove the syringe and dispose of the administration set.



Note: If using a piggy-back configuration, ensure that the Insignis™ system is placed into the higher-pressure port, so that continuous flow is maintained after each dose.

Troubleshooting

No Flow

- Ensure the slide clamps are open.
- Ensure that the syringe driver is engaged according to the syringe driver's instructions for use: Turn syringe driver safety lock tab to vertical position (locked). Depress the side lever fully one time for up to 10ml of fluid; for 50ml this is five times. Depress the lever one additional time to ensure the syringe plunger is fully engaged.
- While preserving the sterility of the male luer disc, disconnect the male luer from the indwelling catheter and note if a fluid drop occurs. If there is a fluid drop, then the system is operating properly and there is likely an issue with the indwelling catheter.
  Refer to the manufacturer's protocol for determining catheter patency.
- If medication fails to deliver, try replacing the IV Controller, prime again, and determine if the medication has been delivered.
- If medication is coming from the system but not passing through the catheter, the issue is likely due to the indwelling catheter. Contact healthcare provider for assessment.
- If no flow is experienced after the mitigation efforts outlined above, contact your healthcare provider or the device manufacturer.

Troubleshooting *(continued)*

Slow Flow

- If slow flow is experienced during the infusion, there may be a partial blockage in the IV Controller. Disconnect the IV Controller from the catheter to determine if there is a blockage. If there is an appropriate amount of fluid dripping from the IV Controller, the issue is likely due to the catheter. Contact the IV Catheter manufacturer to determine how to proceed.
- Check the syringe friction by pulling back on the syringe plunger and allow air to enter the syringe. With the syringe in a vertical position (locked), purge the air out, noting the level of difficulty required to perform this procedure. If the syringe plunger is difficult to move, this will result in a slower than normal infusion time. A replacement syringe with drug is recommended.
- If any slide clamp has been engaged for a period of time, it may cause a narrowing of the tubing, which could result in slower than normal performance. Replace tubing damaged by slide clamps that have been engaged for a long period of time.
- If the IV catheter infuses outside of the vein, infiltration may have occurred, which may result in a slower flow rate. Check for infiltration or extravasation. Follow IV catheter manufacturer's protocol for instances of infiltration or extravasation.
- The occurrence of a blood clot could also cause a slow flow rate. If you suspect a blood clot, stop infusion, and immediately contact your provider or your doctor.

Flow Rate Compensation

In a constant pressure infusion system, everything in the fluid path serves to decrease the flow rate. By design, resistance factors such as drug viscosity, central venous catheter tubing resistance, and venous back pressure are accounted for in the Insignis™ Syringe Infusion System in order to provide the patient with the expected flow rate, as indicated on the flow dial. When tested outside of patient use (free flow exiting to atmosphere with water), the flow rates will appear faster without those factors included. The table below shows the expected test flow rates when using water and collecting into a beaker.

Controller Dial Labeled Flow Rate (ml/hr)	Expected (Nominal) Water Flow Rate (ml/hr)
KVO (8 ml/hr)	8
30	32
60	65
120	130
180	192
240	255
250	265

Use of the Insignis™ System:

- For normal use and flow rates greater than 20ml/hr, the IV Controller is recommended. For slower flow rates below 20ml/hr or for situations that require a single flow rate only, the use of Insignis™ Fixed Rate Tubing is suggested.
- For longer delivery times, the IV Controller can be set at the lower end of the scale, which may be useful for Keep-Vein-Open (KVO) therapy. The use of Insignis™ Fixed Rate Tubing for slower flow rates is available: 10ml/hr (5 hour delivery) and 50ml/hr (1 hour delivery). Other fixed flow rates can be made available upon request.

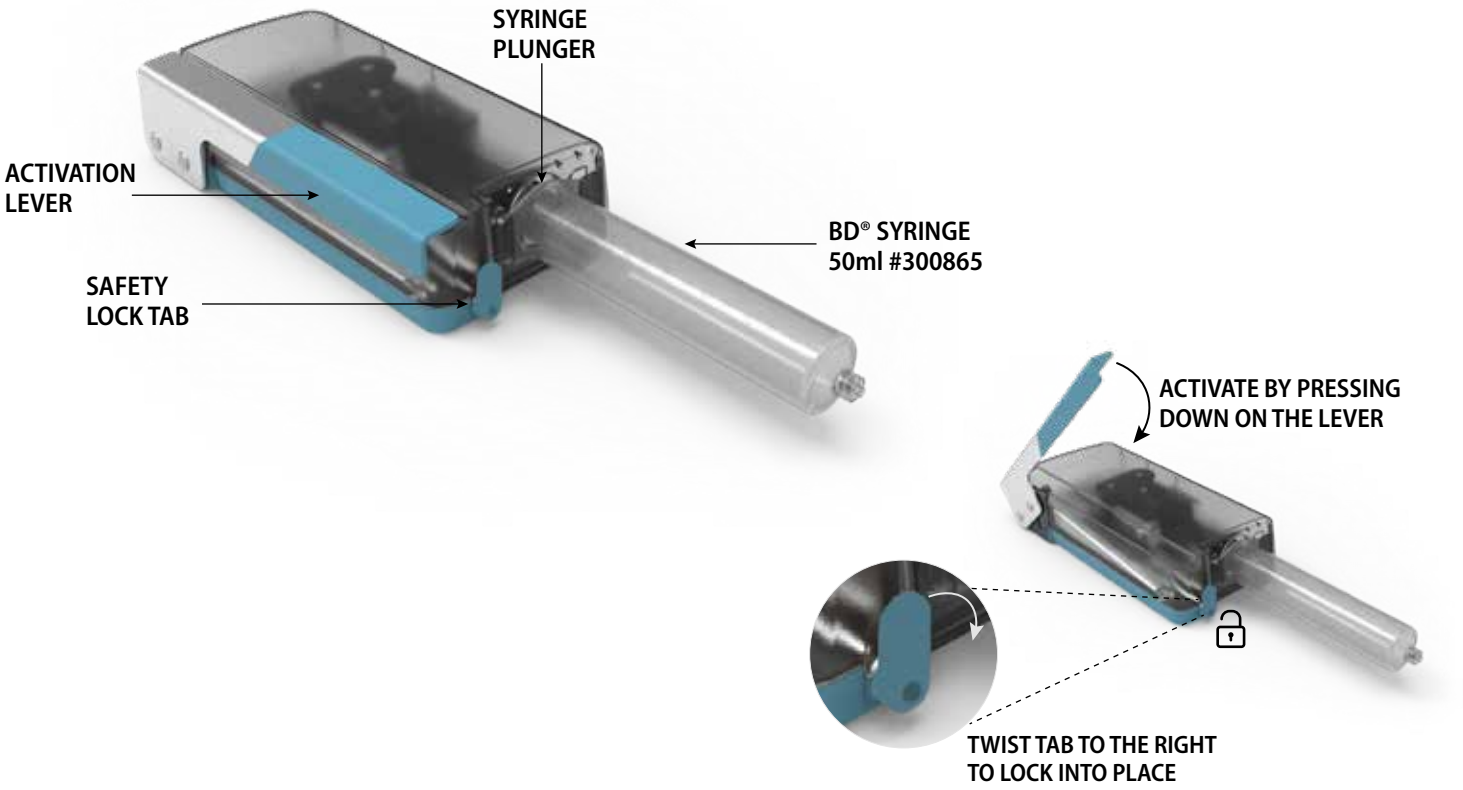
Testing and Calibration

To test the syringe driver:

1. Fill the 50ml BD® syringe with 10ml of 0.9 NaCl (Sodium Chloride).
2. Connect male luer lock on IV Controller to Insignis™ Syringe Driver by connecting female luer to syringe luer lock.
3. Set the IV Controller's dial to 250ml/hr (OPEN), purge air, set the IV Controller's dial to 0ml/hr (OFF).
4. Load the syringe into the driver; rotate the syringe into place so that the syringe graduations are facing up.
5. Turn syringe driver safety lock tab to the vertical position (locked). Pump lever on side of syringe driver once.
6. Set the IV Controller to 60ml/hr.
7. Measure the time for the fluid to be delivered; this should take between 8 - 11 minutes to confirm normal operation.

Note: the rate used for water is 65ml/hr, see flow compensation table above.

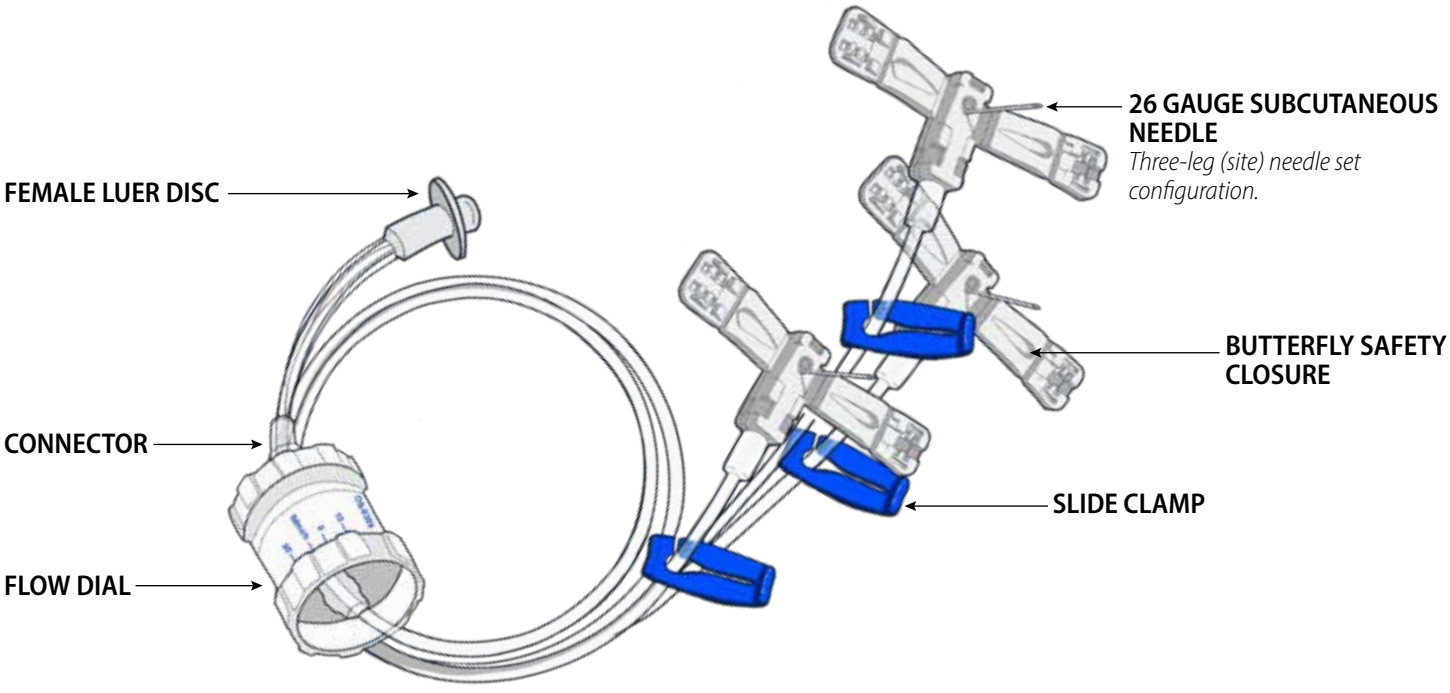
Syringe Driver : *13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*



OneSett™ Subcutaneous Administration Set *(Selectable Rate Flow Dial and Needle Administration Set - 24" tubing):*

Each OneSett is calibrated from 10-60ml/hr/site for the number of needles included. The OneSett enables the continuous selection of flow rates between 10ml/hr up to 60ml/hr. Each needle site can deliver up to 60ml/hr of 13-17cP 20% immunoglobulin solution. A four-site needle configuration can provide a total flow rate of 240ml/hr (60ml/hr/site).

Note: The OneSett™ is intended for use with 20% Immune Globulin (Human) Solutions. Consult the drug manufacturer's package insert for specific drug information.



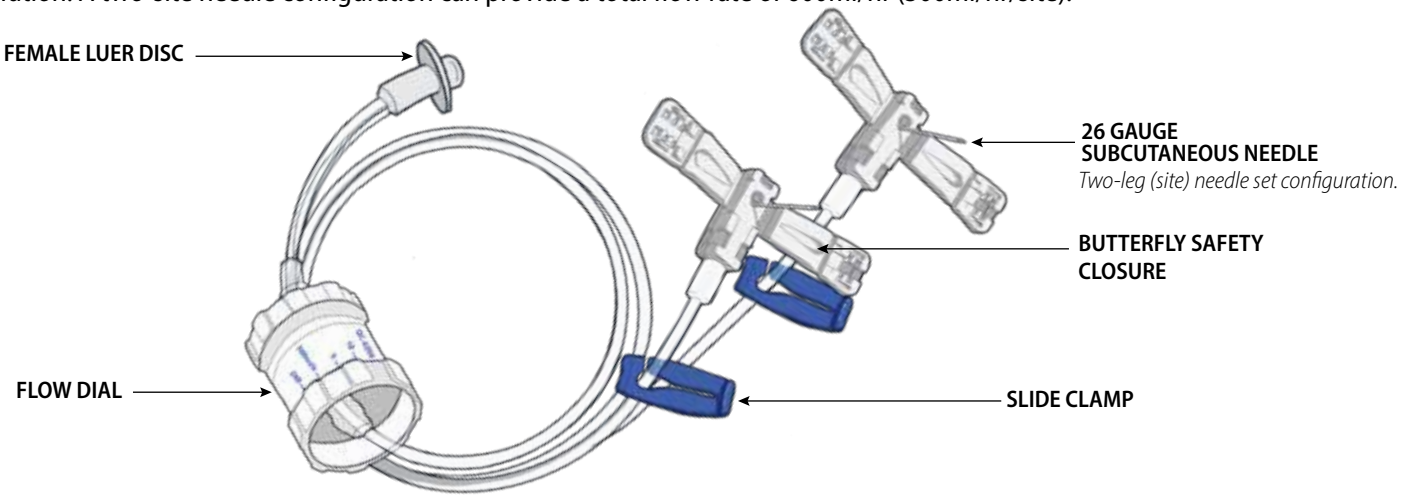
For Use with Subcutaneous Immunoglobulins

Insignis™
Syringe Infusion System

Q-Controller™ Subcutaneous Administration Set:

(Selectable Rate Flow Dial and Needle Administration Set - 24" tubing)

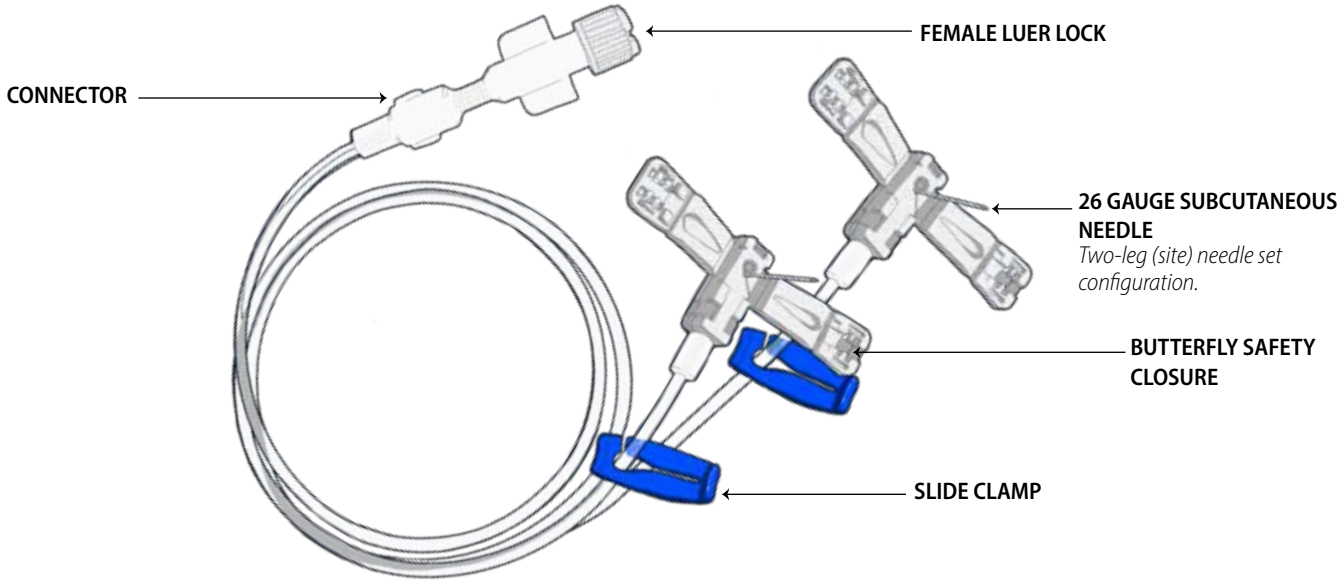
Each Q-Controller™ is calibrated from 10-300ml/hr/site for the number of needles included. The device enables the continuous selection of flow rates between 10ml/hr up to 300ml/hr. Each needle site can deliver up to 300ml/hr of 10% immunoglobulin solution. A two-site needle configuration can provide a total flow rate of 600ml/hr (300ml/hr/site).



Note: The Q-Controller™ is intended for use with 10% Immune Globulin (Human) Solutions. Consult the drug manufacturer's package insert for specific drug information. Consult the drug manufacturer's package insert for step-by-step instructions for infusing the Recombinant Human Hyaluronidase.

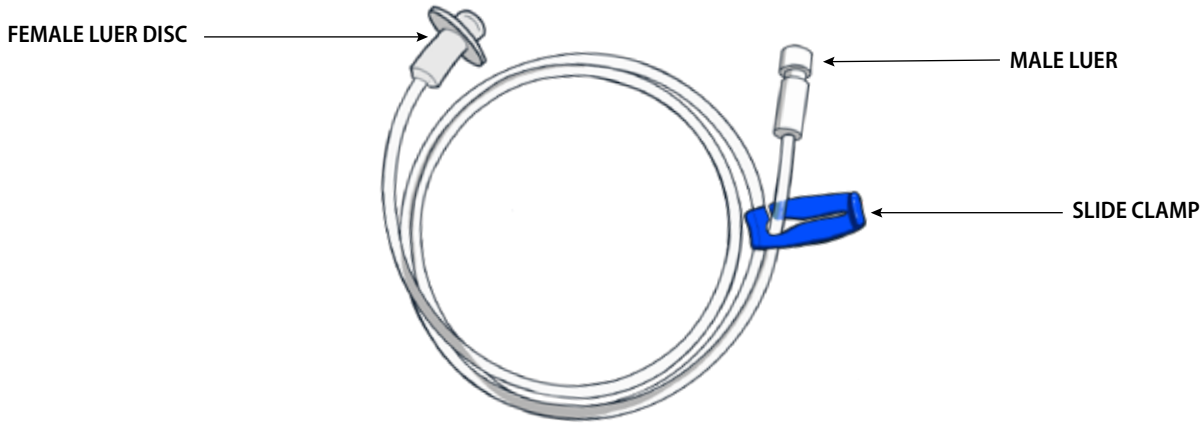
For General Subcutaneous Use

Insignis-26G™ Subcutaneous Needle Set: *Available in 1-4 needle sites and 6mm, 9mm, 12mm, 14mm needle length sizes.*



Insignis Fixed Rate Tubing for Subcutaneous Immunoglobulin (SCIg):

Available in 15ml/hr (SC-T15), 25ml/hr (SC-T25), and 50ml/hr (SC-T50) for 1-4 needle sites.



Note: Fixed rate tubing is also available for the subcutaneous infusion of low viscosity medications (T1, T10, T50, T60).

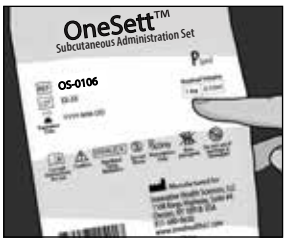
Subcutaneous Infusions Using the **OneSett™**

Syringe Driver : *13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*

Insignis™
Syringe Infusion System

Starting the Infusion for Subcutaneous Administration *using the OneSett™ (calibrated for 10-60ml/h/site):*

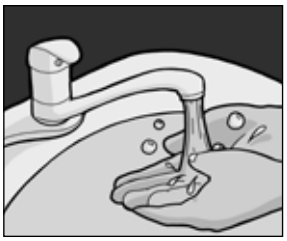
1 Ensure you have all supplies for your infusion.



Verify that you are using the correct administration set, making sure to check the number of sites and needle length on the packaging and that you have all required supplies to perform the infusion.

Supplies may include any of the following:
syringe driver and carrying case/pouch, OneSett™, 50ml BD (#300865) or similar syringe, prefilled syringe(s) of medication with transfer device, and/or vials with dispensing pin/mini spike, antiseptic wipes, tape or securement device, gauze and or bandaid(s), bio hazard disposal container, gloves.

2 Wash hands



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

3 Fill Syringe

Make sure the drug product is at room temperature and fill the 50ml BD® syringe(s) to your required dose. Refer to the drug manufacturer's instructions for complete filling directions.

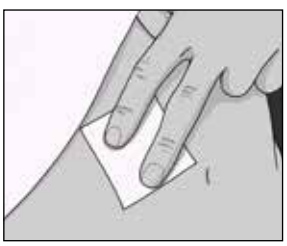
4 Attach OneSett™

Using aseptic technique, remove the OneSett™ end cap and attach to 50ml BD® syringe.

5 Prime OneSett™

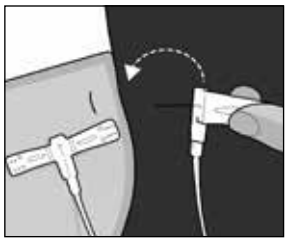
Set OneSett™ to OPEN (60ml/hr). Gently press on the syringe plunger and prime set, taking care to stop before medication reaches the needles. Set controller to 0ml/hr (OFF).

6 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.

7 Insert Needle(s)

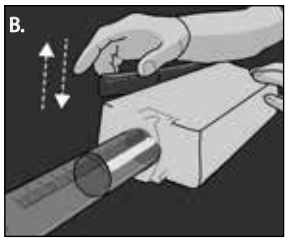


Insert needle(s) into appropriate locations in subcutaneous tissue at 90° angle. Lay butterfly wings flat on skin. Cover site with tape or adhesive dressing. If checking for blood return, after inserting the needles, pause, gently pull back on the syringe plunger. If blood is noted in the tubing, follow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

8 Load Syringe Driver

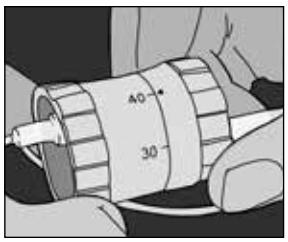
Turn the Insignis™ syringe driver's safety lock tab to the horizontal position (unlocked). Load syringe into driver, allowing plunger to move mechanism back to accommodate 50ml BD® syringe; rotate the syringe into place so that the syringe graduations are facing up.

9 Activate Syringe Driver



Turn syringe driver safety lock tab to vertical position (locked). Confirm OneSett™ is set to 0ml/hr (OFF). Depress the side lever fully one time for up to 10ml of fluid; for 50ml this is 5 times. Depress the lever one additional time to ensure the syringe plunger is fully engaged. Note that the driver will run silently from the beginning of the infusion to the end.

10 Set Flow Rate



As advised by your healthcare provider, set appropriate flow rate and begin administration. Do not exceed the maximum flow rate as indicated by your provider.

11 Check Progress

Check the infusion progress periodically by ensuring that the syringe plunger is moving and volume is decreasing. The infusion may require an extra lever activation of the syringe driver lever to ensure a complete infusion.

Subcutaneous Infusions Using the with Q-Controller™

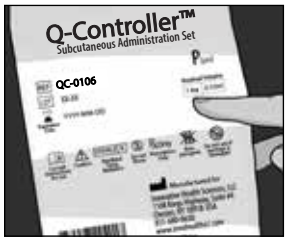
Insignis™
Syringe Infusion System

Syringe Driver : *13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*

Note: Before you begin, consult the drug manufacturer's package insert for step-by-step instructions for infusing the Recombinant Human Hyaluronidase.

Starting the Infusion for Subcutaneous Administration *using the Q-Controller™ (calibrated for :10-300ml/hr/site):*

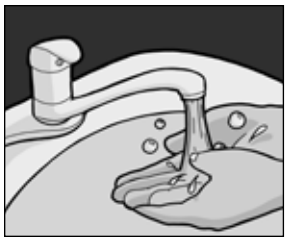
1 Ensure you have all supplies for your infusion.



Verify that you are using the correct administration set, making sure to check the number of sites and needle length on the packaging and that you have all required supplies to perform the infusion.

Supplies may include any of the following:
syringe driver and carrying case/pouch, Q-Controller, 50ml BD (#300865) or similar syringe, prefilled syringe(s) of medication with transfer device, and/or vials with dispensing pin/mini spike, antiseptic wipes, tape or securement device, gauze and or bandaid(s), bio hazard disposal container, gloves.

2 Wash hands



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

3 Fill Syringe

Make sure the drug product is at room temperature and fill the 50ml BD® syringe(s) to your required dose. Refer to the drug manufacturer's instructions for complete filling directions. Note: it may take several syringes to receive your prescribed dose.

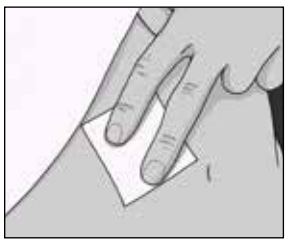
4 Attach Q-Controller™

Using aseptic technique, remove the Q-Controller ™ end cap and attach to 50ml BD® syringe.

5 Prime Q-Controller™

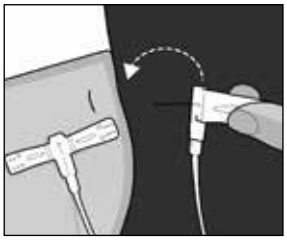
Set Q-Controller™ to OPEN (300ml/hr). Gently press on the syringe plunger and prime set, taking care to stop before medication reaches the needles. Set controller to 0ml/hr (OFF).

6 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.

7 Insert Needle(s)

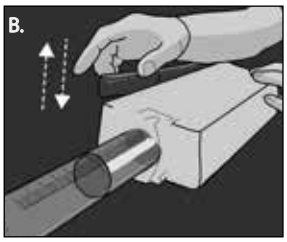


Insert needle(s) into appropriate locations in subcutaneous tissue at 90° angle. Lay butterfly wings flat on skin. Cover site with tape or adhesive dressing. If checking for blood return, after inserting the needles, pause, gently pull back on the syringe plunger. If blood is noted in the tubing, follow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

8 Load Syringe Driver

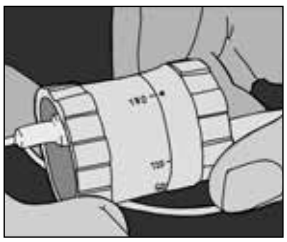
Turn the Insignis™ syringe driver's safety lock tab to the horizontal position (unlocked). Load syringe into driver, allowing plunger to move mechanism back to accommodate 50ml BD® syringe; rotate the syringe into place so that the syringe graduations are facing up.

9 Activate Syringe Driver



Turn syringe driver safety lock tab to vertical position (locked). Confirm Q-Controller™ is set to 0ml/hr (OFF). Depress the side lever fully one time for up to 10ml of fluid; for 50ml this is five times. Depress the lever one additional time to ensure the syringe plunger is fully engaged. Note that the driver will run silently from the beginning of the infusion to the end.

10 Set Flow Rate



As advised by your healthcare provider, set appropriate flow rate and begin administration. Do not exceed the maximum flow rate as indicated by your provider.

11 Check Progress

Check the infusion progress periodically by ensuring that the syringe plunger is moving and volume is decreasing. The infusion may require an extra lever activation of the syringe driver lever to ensure a complete infusion.

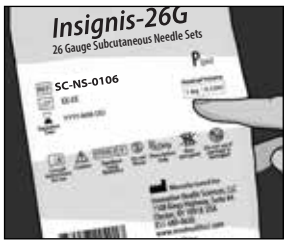
Subcutaneous Infusions Using **Fixed Rate Tubing and Insignis-26G™ Needles**

Insignis™
Syringe Infusion System

Syringe Driver *:13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*

Starting the Infusion for Subcutaneous Administration *using Insignis™ Fixed Rate Tubing and Insignis-26G™ Subcutaneous Needle Sets:*

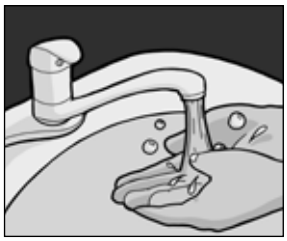
1 Ensure you have all supplies for your infusion.



Verify that you are using the correct administration set, making sure to check the number of sites, needle length, and appropriate flow rate tubing on the packaging and that you have all required supplies to perform your infusion.

Supplies may include any of the following:
syringe driver and carrying case/pouch, Insignis™ fixed rate tubing and Insignis-26G™ Subcutaneous Needle Sets, 50ml BD (#300865) or similar syringe, prefilled syringe(s) of medication with transfer device, and/or vials with dispensing pin/mini spike, antiseptic wipes, tape or securement device, gauze and or bandaid(s), bio hazard disposal container, gloves.

2 Wash hands



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

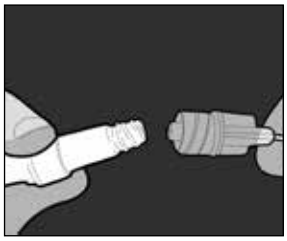
3 Fill Syringe

Make sure the drug product is at room temperature and fill the 50ml BD® syringe(s) to your required dose. Refer to the drug manufacturer's instructions for complete filling directions.

4 Attach Tubing to Syringe

Remove the sterile end cap from the fixed rate tubing and connect to the syringe.

5 Attach Fixed Rate Tubing to Needle Set

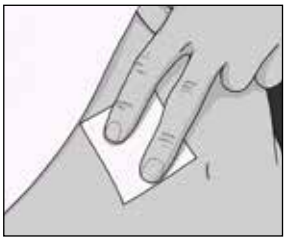


Remove the sterile caps from opposite end of tubing set and the Insignis-26G needle set. Attach male luer of fixed rate tubing to female luer on Subcutaneous Needle Set. When using a mechanical infusion pump, do not connect needle set directly to syringe. When using an electric infusion pump, the needle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

6 Prime Tubing

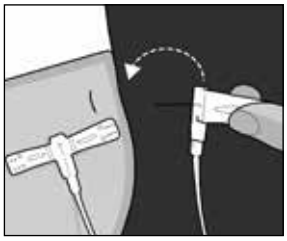
Gently press on syringe plunger and prime tubing set, taking care to stop before medication reaches the needles.

7 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.

8 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.

9 Load Syringe Driver

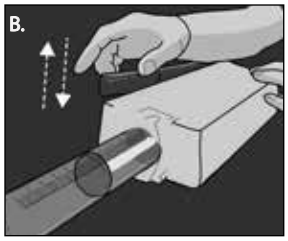
Turn the Insignis™ syringe driver's safety lock tab to the horizontal position (unlocked). Load syringe into driver, allowing plunger to move mechanism back to accommodate 50ml BD® syringe; rotate the syringe into place so that the syringe graduations are facing up.

Syringe Driver: *13.5psi Constant Pressure Syringe Driver, such as the Insignis Infusion Pump.*

Starting the Infusion for Subcutaneous Administration *using Insignis™ Fixed Rate Tubing and Insignis-26G™ Subcutaneous Needle Sets:*

10 Activate Syringe Driver

Turn syringe driver safety lock tab to vertical position (locked). Depress the side lever fully one time for up to 10ml of fluid; for 50ml this is 5 times. Depress the lever one additional time to ensure the syringe plunger is fully engaged. Note that the driver will run silently from the beginning of the infusion to the end.



11 Check Progress

Check the infusion progress periodically by ensuring that the syringe plunger is moving and volume is decreasing. The infusion may require an extra lever activation of the syringe driver lever to ensure a complete infusion.

For Use with Subcutaneous Immunoglobulins

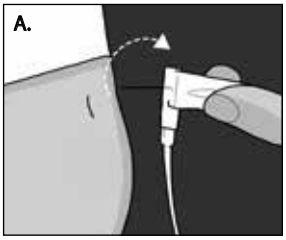
Ending the Infusion for Subcutaneous Administration:

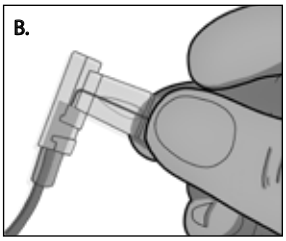
1 End Infusion

When the syringe is empty, stop the infusion by turning the safety lock tab to the horizontal position (unlocked). Ensure the syringe is empty before removing the syringe from the driver. If medication is still in the syringe, activate the lever once to infuse the remaining medication.

2 Remove Dressing

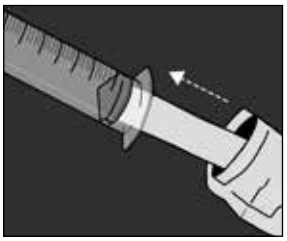
Pause before removing needles; allow site pressures to decrease naturally. Remove dressing from insertion site(s). To minimize accidental risk of needle stick injury, use one hand to remove needle(s). Using the same hand, squeeze butterfly safety closure wings together to firmly encase needle. This will produce an audible "click" with tactile feedback.





3 Remove Syringe

Remove syringe from driver by rotating syringe until tabs are clear and withdraw syringe.



4 Dispose of Materials

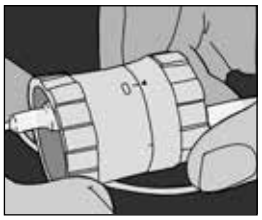
Carefully dispose of materials in a sharps container per local regulations.

Priming the Administration Set *Using the Insignis™ Syringe Driver:*

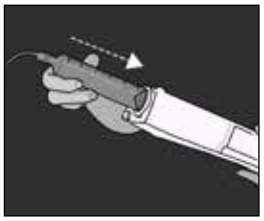
It may be easier for some patients to prime their administration set(s) using the Insignis™ Syringe Driver.

1 Attach Set to Syringe
Using aseptic technique, connect the administration set to the filled syringe.

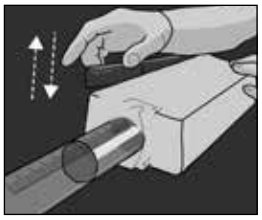
2 Set dial to 0ml/hr, OFF.
Set the flow dial to 0ml/hr, OFF.



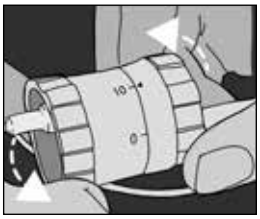
3 Load Syringe Driver
Place the syringe into the syringe driver.



4 Activate Syringe Driver
Activate the syringe driver by pressing down on the lever.

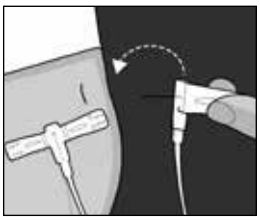


5 Increase Flow Rate
With the administration set tubing in view, slowly increase the flow rate on the flow dial to about 10ml/hr (slow) and carefully monitor the drug filling the tubing.

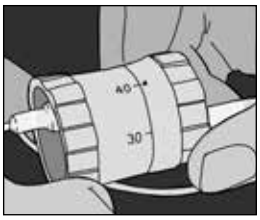


6 Check Progress
Observe the fluid in the tubing and stop before the drug reaches the needles (dry-prime).

7 Insert Needles
Insert needles into subcutaneous tissue.



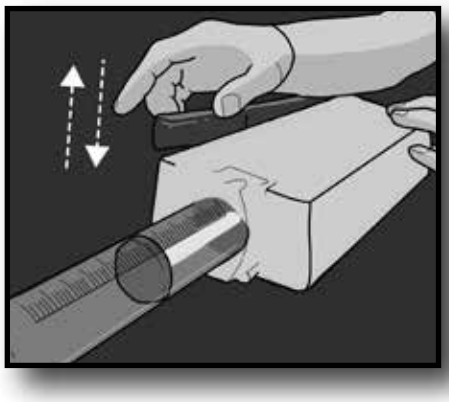
8 Set Flow Rate
Set the initial flow rate on the flow dial as indicated by your healthcare provider.



Intermittent Dosing *using the Insignis™ Syringe Driver and the OneSett™:*

The Insignis™ Syringe Driver intermittent dosing can be used to deliver the required dose in controlled intervals. Intermittent dosing is a safe and effective way to test and deliver medication at a fast flow rate without causing injury to the patient. This method allows the patient to safely maximize therapeutic benefit while minimizing discomfort. The patient should consult their provider prior to beginning intermittent dosing.

1. Prepare infusion as instructed in steps 1-8 on page 10.
2. Instead of activating the syringe driver for the full 50ml of drug volume, activate the driver using the lever and press down on the handle only *once* to deliver 10ml of drug.
3. Proceed with the infusion as indicated on page 10.
4. After the full 10ml of drug has been infused, the driver will stop, giving the patient the option to evaluate and assess the infusion site (for any reaction(s)) before proceeding. The patient may proceed immediately or wait a few minutes to assess the site before another dose is administered.
5. Modify the flow rate on the flow dial according to speed and comfort preference.
6. Activate the syringe driver again by pressing down *once* to deliver another 10ml.
7. Continue this process until the desired drug volume has been infused.
8. Follow the instructions on page 12 to remove the syringe and dispose of the administration set.



The health care provider will advise the patient of the maximum flow rate for the OneSett™. At no time should the patient exceed this rate. Intermittent dosing, by definition, must be slower than the continuous flow at the approved maximum flow rate. This is an option for patient comfort. Note: Each lever activation will deliver 10ml of fluid. Five lever activations will deliver 50ml continuously.

Troubleshooting

No Flow

- Check to ensure the slide clamps are open.
- Ensure that the syringe driver is engaged according to the syringe driver's instructions for use: Turn syringe driver safety lock tab to vertical position (locked). Depress the side lever fully one time for up to 10ml of fluid; for 50ml this is 5 times. Depress the lever one additional time to ensure the syringe plunger is fully engaged
- Try replacing the OneSett™, Fixed Rate Tubing, or Subcutaneous Needle Sets, prime again, and determine if the medication has been delivered.
- If no flow is still experienced after the troubleshooting efforts outlined above, contact your healthcare provider or the device manufacturer.

Slow Flow

- The absorption of medication into the patient's tissues may cause slow flow. After a few infusions, the body may create pockets or "depots," which help facilitate the medication's absorption. Therefore, the first few infusions may take longer than anticipated as the depots are not yet formed.
- Assure that the correct needle length is used. The medication may not be reaching below the dermal layer of the skin if the needle is not the optimal length for the patient.
- Check the syringe friction by pulling back on the syringe plunger and allowing air to enter the syringe. With the syringe in a vertical position, purge the air out, noting the level of difficulty required to perform this procedure. If the syringe plunger is difficult to move, this will result in a slower than normal infusion time. A replacement syringe with drug is recommended.

Site Reactions

Should you experience pain during the infusion, pause the infusion and consult your health care provider for instructions on how to minimize the possibility of site reactions. With the correct guidance, site reactions can be successfully avoided and/or reduced.*

Site complications have many causes and vary depending on the patient's level of experience with infusion therapy. Pain, redness, blanching, itching, and leaking are side effects that may be caused by:

- Inappropriate needle length
- Flow rate is too fast
- Volume is too much per infusion site
- Failure to use dry needle insertion, not allowing alcohol to dry, or angle of needle insertion.
- Site location

*For patients who benefit from pausing the dose, the Insignis has the ability to deliver up to 10ml for each full stroke of the lever. This pause can give patients the ability to review the status of the infusion before proceeding.

Flow Rate Compensation Tables

If a needle is clamped-off while using a multi-needle OneSett™ or Q-Controller™, the flow rate to the remaining needle site(s) will increase. To compensate for this increase, the user may manually decrease the flow rate on the flow dial. See below table for recommendations.

OneSett™ Flow Rate Compensation Table

# of Needles	Decrease by	Multiply by
2	50%	50%
3	30%	70%
4	25%	75%

Q-Controller™ Flow Rate Compensation Table

# of Needles	Decrease by	Multiply by
2	28%	72%

The example below using the OneSett™ demonstrates the calculation used to compensate for one clamped-off needle while using a four-needle site configuration.

METHOD	CALCULATION
Decrease by:	50ml/hr x 25% (.25) = 12.5 ; 50ml/hr – 12.5 = 37.5ml/hr
Multiply by:	50ml/hr x 75% (.75) = 37.5ml/hr
FLOW RATE:	Set the new flow rate to 37.5ml/hr

Checking Infusion Progress

If desired, a patient may choose to check the infusion progress by noting the volume in the syringe prior to starting the infusion. After waiting five minutes, a patient will note the new volume in the syringe, which now represents the defined flow rate. A patient may continue the infusion for another five minutes and then note the volume remaining in the syringe. A simple calculation will demonstrate whether the flow rate is increasing or decreasing. If the flow rate is decreasing, it may be an indication of tissue saturation at the infusion site(s). This allows the use of the flow dial on the OneSett™ to be decreased to minimize or prevent any site reactions. This timing and tapering process may prove beneficial to the patient and can be continued throughout infusion.

Stopping the Infusion

In the event it is necessary to stop the infusion mid-cycle (before complete), simply turn the safety lock tab to the side position to unlock (counter-clockwise), which will immediately stop the infusion. The mechanism will rapidly move rearward and the syringe wings will release, enabling them to be rotated clockwise until clear of the holder. At this point the syringe can be gently removed from the syringe driver.

Care and Maintenance of the Syringe Driver

Perform the manual cleaning procedure as follows:

- Prepare a mixture of mild detergent (soap) and warm water (1 part detergent or soap to 50 parts water by volume).
- Using a clean lint-free cloth, wipe the device with the detergent solution. Additional wipes may be used as needed. Actuate or manipulate the device during wiping.
- Using a new clean lint-free cloth, dry the device.

Perform the visual inspection as follows:

- Inspect each test article with the naked eye under normal lighting conditions to determine if all adherent visible soil has been removed from surfaces, lumens, crevices and serrations, if applicable. Actuate or manipulate moveable parts during the visual inspection. **Note:** Devices that are not soiled and positive control devices are not required to have a visual inspection.
- The Insignis Syringe Infusion System is designed to work as a complete system. Flow control is determined by the flow control device, not the syringe driver. Insignis products do not require any calibration or testing on the part of the user or the provider.
- Since the Insignis Syringe Infusion System may be used in many different environments and exposed to many different elements, care should be exercised to prevent foreign materials, debris, fluids, and other contaminants from entering the mechanism of the driver.
- The mechanism used in the syringe driver is designed such that the impact of contamination is minimized. Do not clean any part of the syringe driver that is not easily accessible (i.e. internal working mechanisms). Do not use the driver if it has been internally exposed to or immersed in fluid.
- Note: The use of alcohol is not recommended to clean the plastic as it may harm the cover materials.
- Under normal operation, the expected life-cycle of the Insignis™ Syringe Driver is approximately 3,000 uses.

Storage & Use

- The Syringe Driver, IV Controller, OneSett™ Subcutaneous Administration Set, Fixed Rate Tubing, and the Subcutaneous Needle Sets are recommended for storage in a dry place (humidity levels 15% - 90%) at room temperature (20-25°C; 68-77°F).
- The Syringe Driver, IV Controller, OneSett™ Subcutaneous Administration Set, Fixed Rate Tubing, and the Subcutaneous Needle Sets are recommended for use at or less than 10,000 feet or 4,267 meters altitude.

Flow Rate vs. Time Chart

This chart is used to determinethe relationship between volume, time, and flow rate.

Note: These times may vary based on the viscosity of the drug infused. Refer to the drug manufacturer's package insert for minimum and maximum flow rate guidelines.

At the slowest flowrate offered, 1ml/hr, a single fully loaded syringe will have an expected infusion duration of 60 hours (for IV only).
At the fastest flowrate offered, 250ml/hr, a single fully loaded syringe will have an expected infusion duration of 14 minutes and 24 seconds.

		Flow Rate								
		1ml/hr	**2.5ml/hr**	**10ml/hr**	**20ml/hr**	**60ml/hr**	**100ml/hr**	**150ml/hr**	**200ml/hr**	**250ml/hr**
Volume ml	**5**	1:00	2:00	0:30	0:15	0:05	03:00	02:00	01:30	<1:00
	10	5:00	4:00	1:00	0:30	0:10	06:00	04:00	03:00	02:24
	15	10:00	6:00	1:30	0:45	0:15	09:00	06:00	04:30	03:36
	20	20:00	8:00	2:00	1:00	0:20	12:00	08:00	06:00	04:48
	25	25:00	10:00	2:30	1:15	0:25	15:00	10:00	07:30	06:00
	30	30:00	12:00	3:00	1:30	0:30	18:00	12:00	09:00	07:12
	35	35:00	14:00	3:30	1:45	0:35	21:00	14:00	10:30	08:24
	40	40:00	16:00	4:00	2:00	0:40	24:00	16:00	12:00	09:36
	45	45:00	18:00	4:30	2:15	0:45	27:00	18:00	13:30	10:48
	50	50:00	20:00	5:00	2:30	0:50	30:00	20:00	15:00	12:00
	55	55:00	22:00	5:30	2:45	0:55	33:00	22:00	16:30	13:12
	60	60:00	24:00	6:00	3:00	1:00	36:00	24:00	18:00	14:24
		Hours:Minutes ([h]h:mm)					Minutes:Seconds (mm:ss)			

As noted in the Caution statements (page 2), it is recommended to use Becton Dickinson and Company® 50ml (#300865) or similar syringe with the Insignis™ Syringe Infusion System.

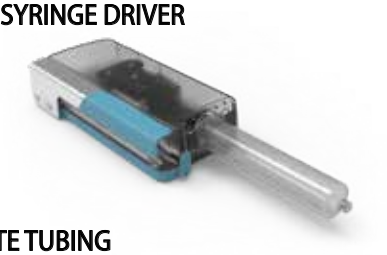
INSTRUCTIONS FOR USE

Insignis™ Product Identifiers

Insignis™
Syringe Infusion System

INSIGNIS SYRINGE DRIVER

Part #
D10021



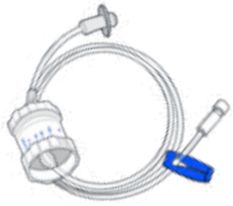
SYRINGE DRIVER CARRYING CASE

(Included with Syringe Driver)

INTRAVENOUS CONTROLLER

(box of 10)

Part #
C10031



FIXED RATE TUBING

SUBCUTANEOUS IMMUNOGLOBULIN (SCIg) (box of 10)

Rate (ml/hr)	1 site	2 sites	3 sites	4 sites
	Part #			
15	SC-T15-01	SC-T15-02	SC-T15-03	SC-T15-04
25	SC-T25-01	SC-T25-02	SC-T25-03	SC-T25-04
50	SC-T50-01	SC-T50-02	SC-T50-03	SC-T50-04

INTRAVENOUS FIXED RATE TUBING AND LOW VISCOSITY SUBCUTANEOUS MEDICATIONS

(box of 10)

Rate (ml/hr)	Part #
1	IV-T1
10	IV-T10
50	IV-T50
60	IV-T60

INSIGNIS-26G™ SUBCUTANEOUS NEEDLE SETS

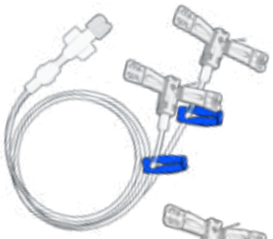
26 Gauge Needle Sets (box of 10)

Single Needle Set

Length	Part #
6mm	SC-NS-0106
9mm	SC-NS-0109
12mm	SC-NS-0112
14mm	SC-NS-0114

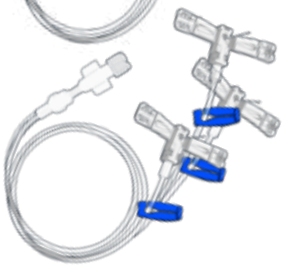
Two-Needle Set

Length	Part #
6mm	SC-NS-0206
9mm	SC-NS-0209
12mm	SC-NS-0212
14mm	SC-NS-0214



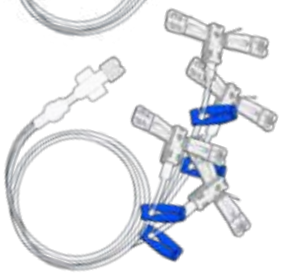
Three-Needle Set

Length	Part #
6mm	SC-NS-0306
9mm	SC-NS-0309
12mm	SC-NS-0312
14mm	SC-NS-0314



Four-Needle Set

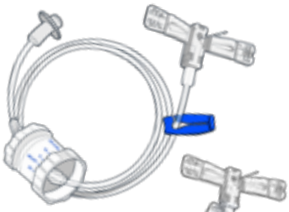
Length	Part #
6mm	SC-NS-0406
9mm	SC-NS-0409
12mm	SC-NS-0412
14mm	SC-NS-0414



ONESETT™ SUBCUTANEOUS ADMINISTRATION SET (box of 10)

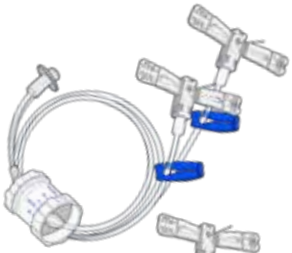
Single Needle Set

Length	Part #
6mm	OS-0106
9mm	OS-0109
12mm	OS-0112
14mm	OS-0114



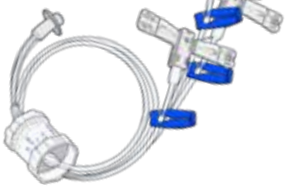
Two-Needle Set

Length	Part #
6mm	OS-0206
9mm	OS-0209
12mm	OS-0212
14mm	OS-0214



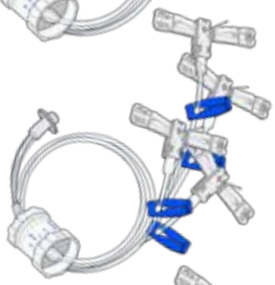
Three-Needle Set

Length	Part #
6mm	OS-0306
9mm	OS-0309
12mm	OS-0312
14mm	OS-0314



Four-Needle Set

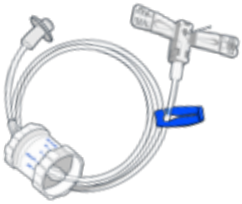
Length	Part #
6mm	OS-0406
9mm	OS-0409
12mm	OS-0412
14mm	OS-0414



Q-CONTROLLER™ SUBCUTANEOUS ADMINISTRATION SET (box of 10)

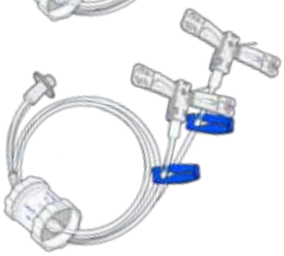
Single Needle Set

Length	Part #
6mm	QC-0106
9mm	QC-0109
12mm	QC-0112
14mm	QC-0114

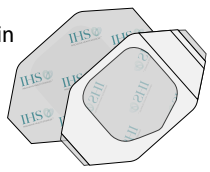


Two-Needle Set

Length	Part #
6mm	QC-0206
9mm	QC-0209
12mm	QC-0212
14mm	QC-0214



Sterile dressing/adhesive is included in subcutaneous needle administration set boxes.



INSTRUCTIONS FOR USE

Insignis™
Syringe Infusion System

Insignis™ Technical Information

Syringe Driver

Weight: 0.6 kg
Length: 23.0 cm
Width: 7.6 cm
Height: 5.0 cm

Note:

- At the slowest flowrate offered, 1ml/hr, a single fully loaded syringe will have an expected infusion duration of 60 hours.
- At the fastest flowrate offered, 250ml/hr, a single fully loaded syringe will have an expected infusion duration of 14 minutes and 24 seconds.

System

Reservoir volume: 50ml
Accuracy: ±7% (See table)
Height Sensitivity: 1%/10cm
Temperature Sensitivity: 3ml/hr/C°
Operating Pressure: 13.5psi Nominal
14.2psi Max
Altitude: Tested to 3,048m altitude with no impact to performance.

Accuracy Table* - OneSett™ with Insignis™ Syringe Driver

Site(s)	20ml/hr	30ml/hr	40ml/hr	50ml/hr	55ml/hr	Average
1	13%	11%	12%	9%	6%	10%
2	9%	8%	6%	6%	5%	7%
3	6%	6%	6%	6%	4%	6%
4	5%	5%	5%	4%	5%	5%
Average	8%	8%	7%	6%	5%	7%

*At 10ml/hr, the average flow rate varies from 8.3 – 11.7ml/hr (17%).

Fixed Rate Tubing

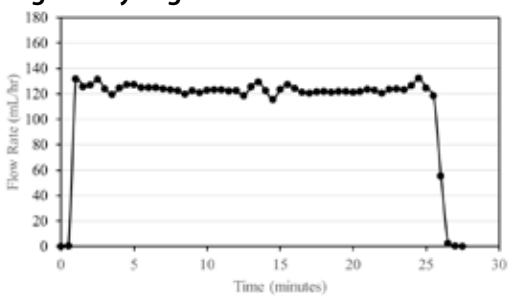
Length: 99.0 - 180.0 cm
Weight: 5.6 - 8.5g
Tubing Diameter: 1.7mm
Residual volume: *Intravenous (IV)/low viscosity subcutaneous medications*

IV-T1	0.03 ml
IV-T1	0.04 ml
IV-T50	0.09 ml
IV-T60	0.08 ml

Subcutaneous Immunoglobulin (SCIg)

Rate (ml/hr)	Configuration			
	1 site	2 sites	3 sites	4 sites
15	0.03	0.05	0.03	0.03
25	0.05	0.03	0.05	0.04
50	0.06	0.12	0.08	0.05

Insignis™ Syringe Driver Profile



Intravenous Controller

Length: 61.0 cm
Weight: 22.0g
Tubing Diameter: 1.7mm
Accuracy: 3.20% (See table)
Residual volume: 0.35 ml

Accuracy Table - Intravenous Controller with Insignis™ Syringe Driver

Flowrate	Accuracy	Flowrate range ml/hr
KVO	55%	4-12
30ml/hr	15%	27.2 - 36.8
60ml/hr	13%	56.4 - 73.5
120ml/hr	7%	120.9 - 139.1
180ml/hr	5%	182.4 - 201.6
240ml/hr	5%	242.2 - 267.8
250ml/hr	5%	251.7 - 278.3

OneSett™ Subcutaneous Administration Set

Length: 61.0cm
Weight: 20 - 32g
Tubing Diameter: 2.3mm
Residual volume:

1 site	0.86 ml
2 sites	1.41 ml
3 sites	1.87 ml
4 sites	2.35 ml

Q-Controller™ Subcutaneous Administration Set

Length: 93.0cm
Weight: 20 - 24g
Tubing Diameter: 2.3mm
Residual Volume:

1 site	0.84 ml
2 sites	1.38 ml

Insignis-26G™ Subcutaneous Needle Set

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
Controller	Polycarbonate, ABS
Needle	Stainless Steel

INSTRUCTIONS FOR USE

Insignis™
Syringe Infusion System

Syringe for Use with the Insignis™ Syringe Infusion System

Becton Dickinson and Company BD® Luer-Lok 50ml *(Sold Separately- Contact your provider)*
EU Reference: 300865

Warranty Information

Limited Warranty: Innovative Health Sciences LLC ("Manufacturer") guarantees the Insignis™ Syringe Infusion System free from defects in performance under normal use. This warranty is limited to the Original Purchaser and is valid for a period of three (3) years from purchase date. This warranty does not cover for damage caused by the use of non-proprietary ancillary products.
The Manufacturer agrees to repair or replace the Insignis™ Syringe Driver or ancillary products associated with the Insignis product line, provided that the device is received by the Manufacturer within the three year time period from date of purchase. Replacement parts and/or complete devices are warrantied for the warranty period from the purchase date by the Original Purchaser.

Innovative Health Sciences LLC abides by the quality policies as described in ISO 13485 and CFR 820 so as to confirm and document the product's extensive and rigorous testing procedures. The Insignis™ warranty does not cover third-party products or third-party products used in conjunction with any or all Insignis products.

Performance Procedure: All warranty submissions must be submitted in writing (via electronic mail (info@innohealthsci.com) or U.S. Postal Service) to:

IHS Customer Support and Service
Innovative Health Sciences LLC
1108 Kings Highway, Suite #4 Chester, N.Y. 10918

A detailed description of the defect is required in order to commence the reporting. The device of concern must be packaged and returned to the Manufacturer; any loss or damage experienced during shipment is incurred by the Original Purchaser.

This warranty and the associated rights and obligations shall be governed by the laws of the State of New York, USA.

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		Do not insert fingers into device
	Pinch point	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	CE	European Conformity		Date of Manufacture

References:

[1] The Insignis™ Syringe Infusion System's ability to respond to resistance at the infusion site by automatically decreasing the flow rate can be explained by the Hagen-Pouiseuille law, which states that the flow rate is directly proportional to the differential pressure (the pressure difference between the syringe driver (13.5psi and the patient's infusion site). Thus, during the course of an infusion, as the patient's tissues become increasingly saturated with medication, the pressure at the site also increases. As the infusion system uses a constant force mechanism of 13.5psi, the pressure differential decreases, slowing down the flow rate as a natural and immediate response. Dynamic equilibrium works to sense site irritation and the selectable rate flow control ability enables the patient to decrease the flow rate in real-time to help eliminate site reaction occurrence.

Baker, Mark Paul, Bullock, M., Sealfon A. *A Novel Approach to Customizing the Flow Profile for the Administration of Subcutaneous Immunoglobulins for Individual Infusions with Benefits to Minimize or Eliminate Site Reactions— CASE STUDY*. International Primary Immunodeficiencies Congress; April 2022; Vilamoura, Portugal.

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