

High-Flo Subcutaneous Safety Needle Sets™

Instructions for Use

Indications for Use:

KORU High-Flo Subcutaneous Safety Needle Sets™ are intended for the delivery of medication to the subcutaneous tissue.

Caution:

- U.S. Federal Law restricts this device to sale by or on the order of a physician.
- Refer to the Prescribing Information for each immunoglobulin product to ensure that the maximum volume per infusion site is not exceeded.
- Only use subcutaneous needle sets for the patient for whom the device is prescribed and only for its intended use.
- Subcutaneous needle sets are only sterile and non-pyrogenic if the packaging is unopened and undamaged. Do not use a needle set from an open or damaged package.
- When infusing through multiple needles, over infusion may occur to remaining sites if one or more of the needles are occluded.
- Inaccurate medication delivery, infection and/or site irritation may result from improper needle insertion and maintenance of the infusion site.
- Always follow infusion instructions found in labelling of medications.
- **Warning:** Do not install more than one extension set per needle set.

Precautions:

- Never prime the infusion set or attempt to free a clogged tube while the needle is inserted. You may accidentally inject too much medication.
- Check the infusion set periodically to ensure that the needle remains firmly in place. If the needle is not in place, remove it and use a new needle set.
- Subcutaneous needle sets are single use items which should be disposed of after use. Please contact your healthcare provider for available sharps disposal containers.
- Be sure that the needle guard is removed before insertion.
- Assure that the needle is not bent prior to insertion.
- Do not re-sterilize needle sets.
- When using needle sets for the first time, do so in the presence of a trained healthcare provider.
- Do not exceed drug package insert specifications for total number of needle sites permitted.
- Comply with guidance provided by your healthcare providers, and drug manufacturers, regarding location and number of infusion sites.


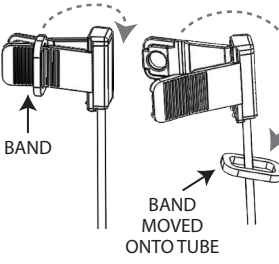
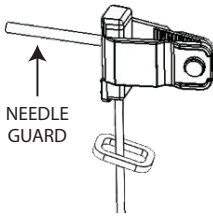
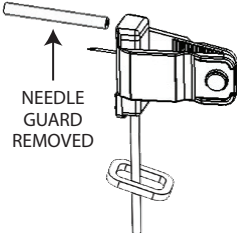
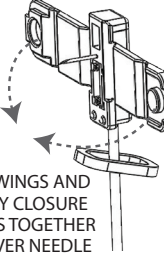
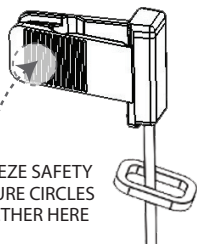
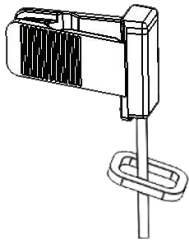
KORU Medical Systems  Manufacturer
24 Carpenter Road | 800-624-9600 toll free
Chester, NY 10918 USA | 845-469-2042 local

CE 2797 Store at room temperature.

 Caution  Consult Instructions For Use **STERILE R** Sterilized Using Irradiation **Rx ONLY** Prescription Only  Do Not Reuse  Do Not Resterilize  Do Not Use if Package is Damaged  Latex Free

High-Flo Subcutaneous Safety Needle Sets™, FREEDOM60® and FreedomEdge® Syringe Infusion Systems, and Precision Flow Rate Tubing™ are trademarks of KORU Medical Systems and are compliant with Medical Device Directive 93/42/EEC. KORU Medical Systems is ISO 13485 certified. ©2020 KORU Medical Systems; All Rights Reserved. 342104vL

Step-by-step instructions:

| | | | |
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| <p>STEP 1</p> <p>Remove the end cap from the female luer. Connect it to source of infusion. Line up threads, twist firmly.</p> | <p>STEP 2</p> <p>Slide the band back across the butterfly and down onto the tube.</p> | <p>STEP 3</p> <p>Fold the wings back and hold them together between two fingers so that the needle guard is exposed.</p> | <p>STEP 4</p> <p>Prepare site(s) per protocol. Remove the needle guard and insert each needle into the subcutaneous tissue. Cover each with adhesive dressing.</p> |
|  |  |  | |
| <p>STEP 5</p> <p>When infusion is complete, remove adhesive and pull needle out. Push the wings together to cover the needle. Apply even pressure at the safety closure circles, located at the tip of the wings, to squeeze closed.</p> | <p>STEP 6</p> <p>After wings are securely closed, appropriately dispose of needle(s). Band may be replaced back onto closed wings as an option, but not necessary.</p> | | |

| 26 Gauge Sets Residual Volume | |
|-------------------------------|--------|
| 1 needle | .1 ml |
| 2 needles | .2 ml |
| 3 needles | .3 ml |
| 4 needles | .4 ml |
| 5 needles | .5 ml |
| 6 needles | .6 ml |
| with Y-Connector | |
| 7 needles | .9 ml |
| 8 needles | 1.0 ml |

| 24 Gauge Sets Residual Volume | |
|-------------------------------|--------|
| 1 needle | .4 ml |
| 2 needles | .7 ml |
| 3 needles | 1.1 ml |
| 4 needles | 1.4 ml |

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