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.

Apply even pressure at the safety closure circles, located

at the tip of the wings, to squeeze closed.

- · 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.



Store at room temperature.



Instructions

For Use

wings as an option, but not necessary.



Irradiation



Reuse

Only



Resterilize

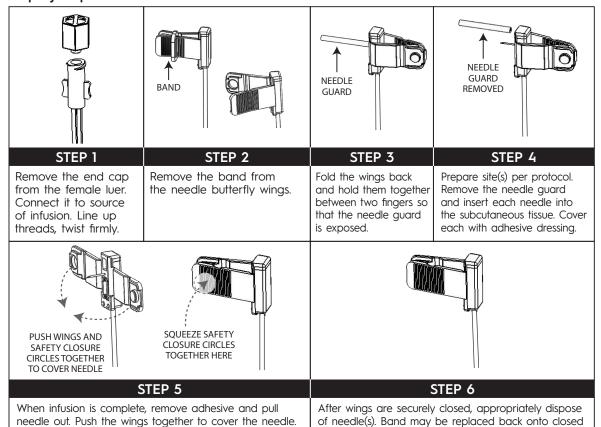






HIgH-Flo Subcutaneous Safety Needle Sets™, FREEDOM60® and FreedomEdge® Syringe Infusion Systems, and Precision Flow Rate Tubing™ are trademarks of KORU Medical Systems and are compliant with Medical Device Directive 93/42/EEC. KORU Medical Systems is ISO 13485 certified. ©2020 KORU Medical Systems; All Rights Reserved. 342108vA

Step-by-step instructions:



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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