

FreedomEDGE® Infusion System

A Simple and Cost-Effective Infusion Solution for RYSTIGGO®

KORU Medical Systems' FreedomEDGE® is a mechanical syringe infusion pump indicated for the subcutaneous infusion of RYSTIGGO® (rozanolixizumab-noli) by a healthcare provider when administered according to the approved drug labeling. FreedomEDGE® offers specialty pharmacies and healthcare providers a **cost-effective alternative to electronic pumps**¹, eliminating the need for batteries, electricity, or complex programming.

The FreedomEDGE® Infusion System is a practical solution for subcutaneous administration of RYSTIGGO®, supporting quality care while improving operational efficiency and managing costs. Designed for **ease of use**, the pump uses a constant force spring mechanism designed to produce an accurate flow rate when used together with the High-Flo™ SubQ Needle Sets and the Precision™ Flow Rate Tubing. The FreedomEDGE® **reduces setup time** and significantly **minimizes patient and staff training requirements** in comparison to electronic pumps¹, streamlining the patient onboarding process.

FreedomEDGE® Infusion System Introduction

The FreedomEDGE® Infusion System consists of the following components:

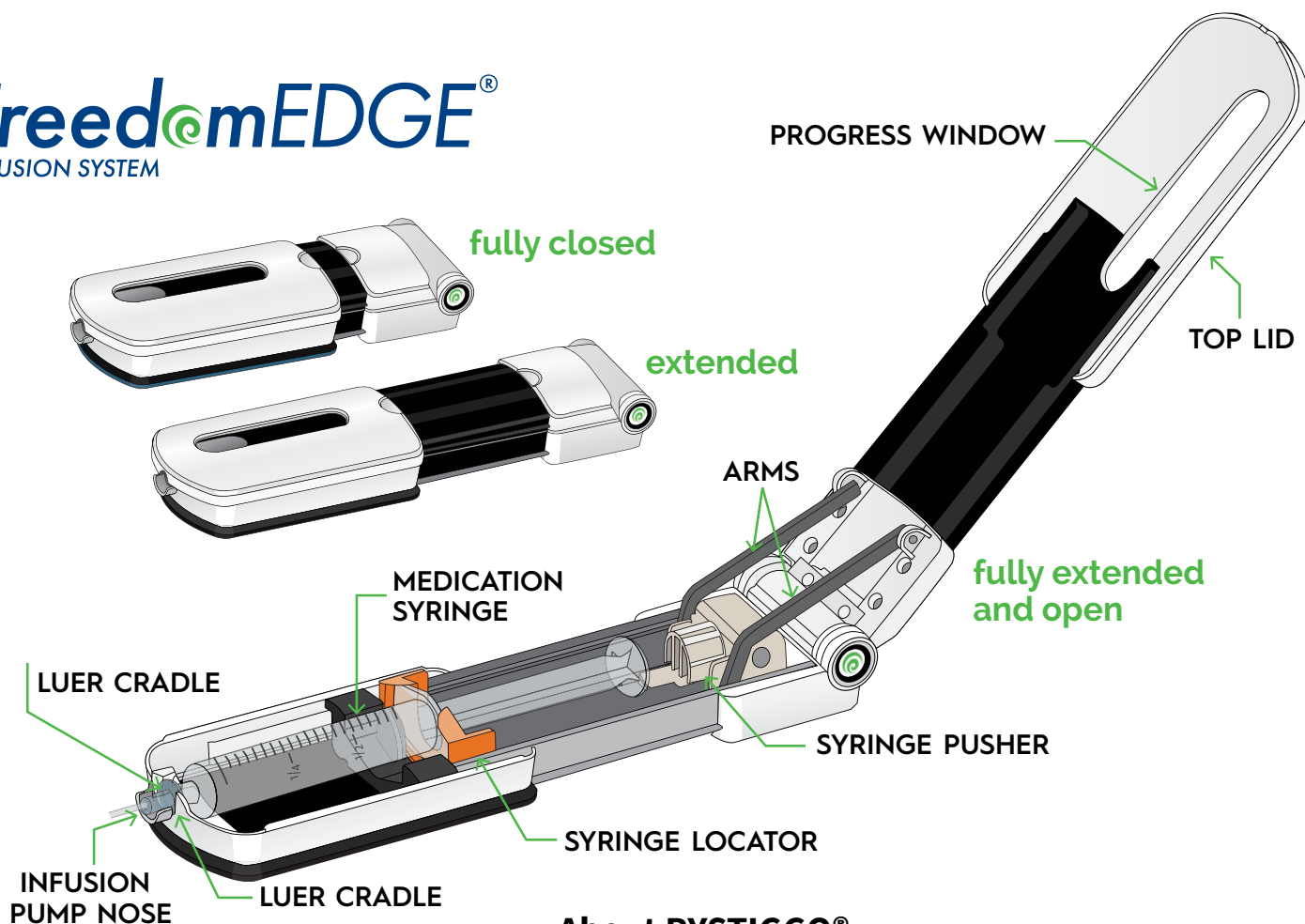
- FreedomEDGE® Infusion Pump
- Precision™ Flow Rate Tubing
- 26G High-Flo™ SubQ Needle Sets

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About RYSTIGGO®

RYSTIGGO® is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive².

Recommended Dose Based on Body Weight*²

Body Weight of Patient	Dose	Volume to be Infused
Less than 50 kg	420 mg	3 mL
50 kg to less than 100 kg	560 mg	4 mL
100 kg and above	840 mg	6 mL

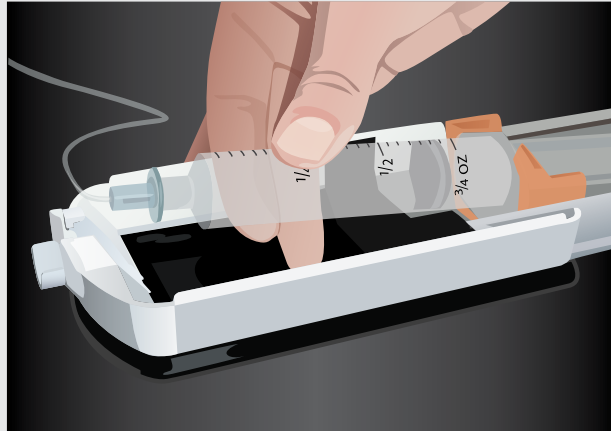
*Refer to the RYSTIGGO® prescribing information for more information on dosage and administration.

FreedomEDGE® Step-by-step Instructions

- Just 3 Steps – load, close and go
- Travel pouch included for easy transport
- No alarms or calibration

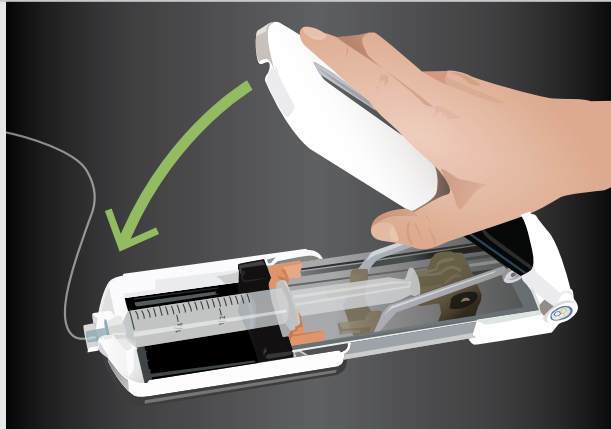
1 Load Syringe

Load prepared 20 mL syringe.



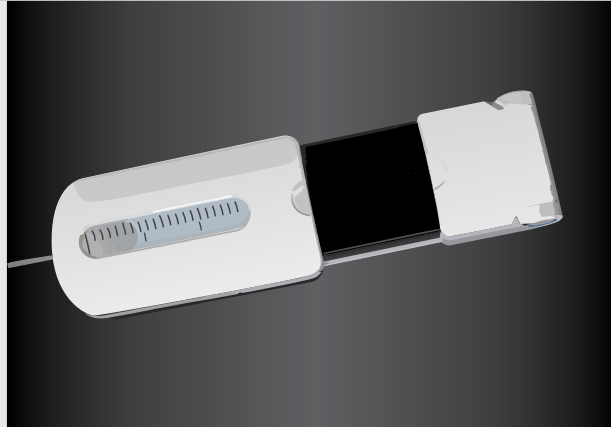
2 Close the Top Lid

The infusion will begin immediately.



3 Begin Infusion

Check the progress window.



Important: This brochure summarizes key steps for using the FreedomEDGE® Infusion System. Refer to the full Instructions for Use (IFU) for complete directions, warnings, and precautions.

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Administer the recommended dosage as a subcutaneous infusion using an infusion pump at a rate of up to 20 mL/hour once weekly for 6 weeks. RYSTIGGO® should only be prepared and infused by a healthcare provider. Refer to the RYSTIGGO® prescribing information for infusion

parameters and instructions on preparing the dose.²

Refer to the FreedomEDGE® Infusion System Instructions for Use for detailed step by step instructions on setting up and using the FreedomEDGE® Infusion Pump.

FreedomEDGE® INFUSION SYSTEM

This section provides ordering information for the FreedomEDGE® Syringe Infusion System and the necessary components for administering RYSTIGGO®.

Product	Item #
FreedomEDGE® Infusion Pump	F10020
Becton Dickinson & Co. BD® Luer-Lok® 20 ml*	US Ref. Number: 302830

*Not supplied by KORU

26G High-Flo™ SubQ Needle Sets

Single Needle Sets

Length	Item #	Residual Vol.	p/Box
4 mm	RMS12604	0.1 ml	20
6 mm	RMS12606	0.1 ml	20
9 mm	RMS12609	0.1 ml	20
12 mm	RMS12612	0.1 ml	20
14 mm	RMS12614	0.1 ml	20

Precision™ Flow Rate Tubing

Product	Item #	Average Flow Rate Per Site (mL/hr/site) (Min-Max)	p/Box
F180 Precision™ Infusion Tubing Set	F180	9.2 (5.3-13.1)	50
F275 Precision™ Infusion Tubing Set	F275	12.5 (7.0-18.1)	50

FreedomEDGE® Infusion Pump Product Specifications

Weight	12 oz (0.34 kg)
Length	Closed: 9" (229 mm), Extended: 11.75" (299 mm)
Width	3.25" (83 mm)
Height	1.5" (38 mm)
Target Operating Temperature	68-77°F (20-25°C)

REFERENCES:

1. Rutland B. Enhancing efficiency and cost-effectiveness in subcutaneous immunoglobulin replacement therapy home training: insights from a study on infusion pump choices and training protocols. KORU Medical Systems, Mahwah, NJ.
2. U.S. Prescribing Information: UCB, Inc. RYSTIGGO® (rozanolixizumab-noli) injection, for subcutaneous use – Prescribing Information. UCB, Inc.; Revised June 2023. Available at: <https://www.ucb-usa.com/rystiggo-prescribing-information.pdf>. Accessed July 28, 2025.