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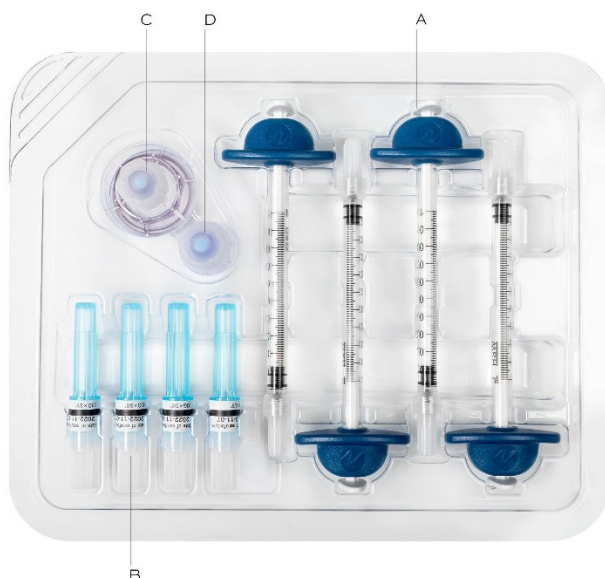
NavaClick™ Injection System

REF NBK20

**Manufacturer:**

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INSTRUCTIONS FOR USE

**PRODUCT DESCRIPTION**

The NavaClick™ Injection System is a kit of components designed to enhance the efficiency and precision of neurotoxin injections. All components are sterile, single-use, and utilize standard luer-lock connections. Each kit consists of the following:

A	Four (4) NavaClick™ Injectors, 1mL	Provide audible and tactile feedback/click upon delivery of each 0.02 mL of fluid for precise, metered delivery of neurotoxin
B	Four (4) LDS Needles, 0.24 x 9mm	Ultra-fine gauge, sharp low dead space needles for reduced pain, enhanced patient comfort, and reduced neurotoxin waste
C	One (1) Vial Adapter, 20mm	Provides needle-free access to drug vial for easy, safe reconstitution and withdrawal of neurotoxin without dulling injection needles
D	One (1) Vial Adapter, 13mm	Provides needle-free access to drug vial for easy, safe reconstitution and withdrawal of neurotoxin without dulling injection needles

INTENDED USE

The NavaClick Injection System is intended for injection of fluids into the body. It is specifically indicated for injection of botulinum neurotoxin, consistent with the neurotoxin's approved labeling.

WARNINGS



- For single use. Do not re-use. Re-use may lead to device failure, create a risk of contamination of the device, and/or cause patient infection or cross-infection.
- Do not re-sterilize. Re-sterilization may lead to device failure, create a risk of contamination of the device, and/or cause patient infection or cross-infection.

PRECAUTIONS



Rx ONLY

- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Do not use if package has been damaged or opened.
- Use standard aseptic technique when removing and handling components. Only access the vial adapter with unused NavaClick Injectors.
- All system components utilize standard luer-lock connections. Twist clockwise to connect components and counter-clockwise to disconnect.
- When withdrawing fluid into the NavaClick Injector: a) Ensure the injector is in Free Mode (no audible/tactile feedback/click), b) refer to the printed graduations for volume accuracy, and c) ensure no air bubbles remain in the injector to prevent dripping during injection.
- When injecting using the NavaClick Injector: a) Select operating mode (Feedback/Click or Free Mode), b) ensure that a needle is locked on the syringe barrel, and c) when using Feedback/Click Mode (Fig.2), each incremental click indicates that 0.02 mL of fluid has been delivered.
- After use, dispose as biohazardous waste.

How to Use the NavaClick Injection System

1. Connect Vial Adapter

- Place the neurotoxin vial on a firm, non-skid surface.
- Holding the adapter by its protective cap, remove the adapter from the package.
- Place over the adapter over the neurotoxin vial and firmly press down (Fig. 1a). The adapter will snap over the vial.
- Remove the protective cap from the adapter by holding the adapter in place and pulling the cap straight off.
- Load a luer-lock syringe with diluent (not provided) for neurotoxin reconstitution.
- To reconstitute the neurotoxin per approved labeling, connect the luer-lock syringe containing diluent to the adapter. Internal vacuum pressure within the neurotoxin vial will draw diluent into the neurotoxin vial (Fig. 1b). Use diluent syringe to inject additional air as needed to equalize remaining vacuum. Disconnect diluent syringe from adapter.



1a



1b

2. Withdraw

- Remove a sterile NavaClick Injector from the kit. Remove protective cap from syringe barrel.
- Connect the injector to the adapter by pushing straight into the valve using a clockwise, twisting motion.
- Ensure the injector is in Free Mode: long side of plunger thumb rest is perpendicular to long side of grips (Fig 2).
 - Feedback/Click Mode: the long axis of thumb rest aligns with the long axis of grips.
 - Free Mode: the long axis of thumb rest is rotated 90 degrees to the long axis of grips.
- With the vial inverted, withdraw neurotoxin into the injector by pulling back on the plunger (Fig. 3a). Refer to the graduations on the syringe barrel for fill volume accuracy. Ensure that there are no air bubbles (Fig 3b) in the injector by pushing air bubble back into the vial. Residual air bubbles can result in dripping during injection.
- Twist the plunger 90 degrees to lock it into Feedback/Click mode.
- Disconnect the injector from the vial adapter. Replace protective cap on vial adapter.



2



3a



3b

3. Attach Needle, Select Mode

- Remove a needle from the kit and separate the plastic hub cover to expose the needle hub.
- Insert and tighten the hub of the needle onto the luer-lock tip of the NavaClick Injector. Tighten the needle by turning it firmly in a clockwise direction.

- Select operating mode (Free or Feedback/Click) by twisting the plunger by 90 degrees in either direction (Fig. 2).
- In Feedback/Click Mode, audible, a tactile feedback or click indicates delivery of each 0.02 mL of fluid.
- In Free Mode, no injection feedback is provided and the operator must visually monitor the volume of fluid delivered using graduations.

For preparation of additional injectors with neurotoxin, Repeat steps 2-3. Swabable valve on vial adapter can be cleansed with a sterile alcohol wipe. Allow surface to air dry.

4. **Inject**

- Follow all instructions provided with the specific drug.
- Immediately prior to injection, remove needle cap. Hold the NavaClick Injector body in one hand and the needle cap in the other. Without twisting, pull apart to remove the cap.
- To inject, push plunger forward (Fig. 4). In Feedback/Click Mode, each click indicates when 0.02 mL of fluid has been injected. Five clicks indicate when 0.1 mL of fluid have been injected.
- Before removing the syringe from each injection site, lift thumb pressure off the plunger and pause to prevent dripping.



NOTE: The dose (Units) of neurotoxin injected depends on the volume and concentration. Examples are provided.



EXAMPLE A

A **100 Unit (U)** vial of botulinum neurotoxin is reconstituted with **2 mL** of diluent.

For the given concentration, 0.02 mL volume is equivalent to 1U of botulinum neurotoxin.

0.02 mL = 1 Unit

To inject 1 Unit of botulinum neurotoxin, the injector must be advanced by 1 click.

1 Click = 1 Unit 5 Clicks = 5 Units

Example A. Volume / Dose Equivalence

Vol. (mL)	Dose (Units)
0	0
0.1	5
0.2	10
0.3	15
0.4	20
0.5	25
0.6	30
0.7	35
0.8	40
0.9	45
1.0	50

EXAMPLE B

A **300 Unit (U)** vial of botulinum neurotoxin is reconstituted with **2 mL** of diluent.

For the given concentration, 0.02 mL volume is equivalent to 3U of botulinum neurotoxin.

0.02 mL = 3 Unit














To inject 3 Units of botulinum neurotoxin, the injector must be advanced by 1 click.

1 Click = 3 Unit 5 Clicks = 15 Units

Example B. Volume / Dose Equivalence

Vol. (mL)	Dose (Units)
0	0
0.1	15
0.2	30
0.3	45
0.4	60
0.5	75
0.6	90
0.7	105
0.8	120
0.9	135
1.0	150

TABLE OF SYMBOLS

SYMBOL	DESIGNATION
	Use-by Date (YYYY-MM-DD)
	Lot Number
	Catalog Number
	Single-Use
	Do Not Re-sterilize
	Do Not Use if Package is Damaged or Open
	Non-pyrogenic
	Not Manufactured with Natural Rubber Latex
	Sterilized Using Irradiation
	U.S. Federal Law restricts this device to sale by or on the order of a licensed physician
	Caution
	Consult Instructions for Use. For electronic copy scan QR code, or go to www.lineagebiomedical.com/ifu . For printed copy, call Customer Service
	Manufacturer