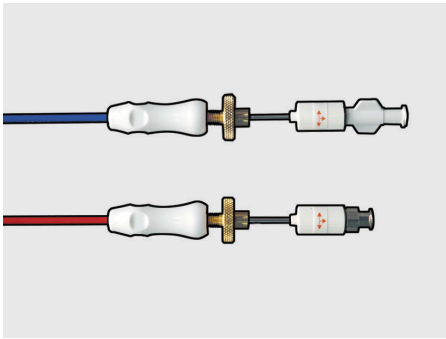


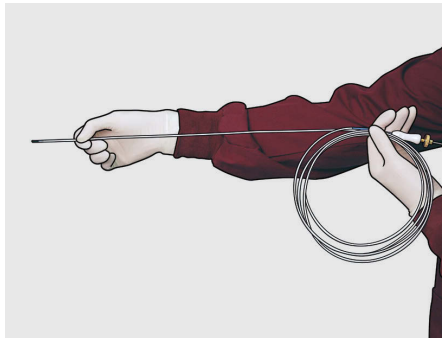
Variable Injection Needles

System Preparation



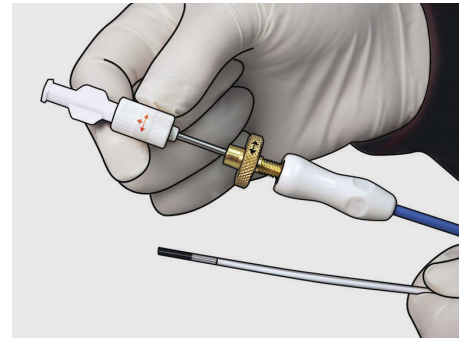
There are different styles of injection needles with identical functionality.

Step 1



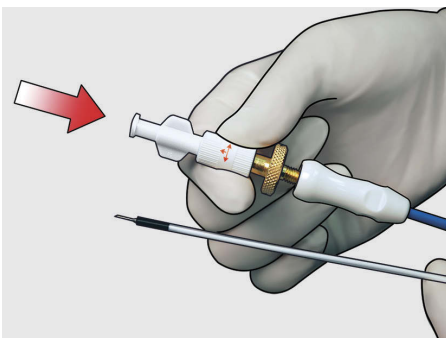
Uncoil the catheter and straighten it completely.

Step 2



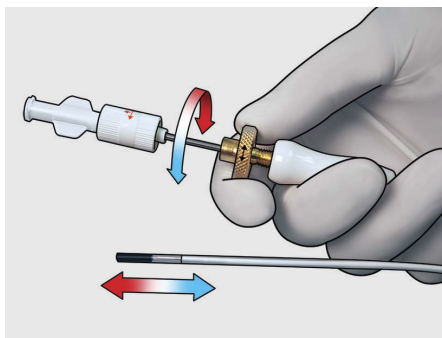
Disengage the Luer slip fitting from the adjustment wheel prior to adjusting the needle extension. **Caution:** Attempting to adjust the needle extension while the Luer slip fitting is engaged may result in damage to the device.

Step 3



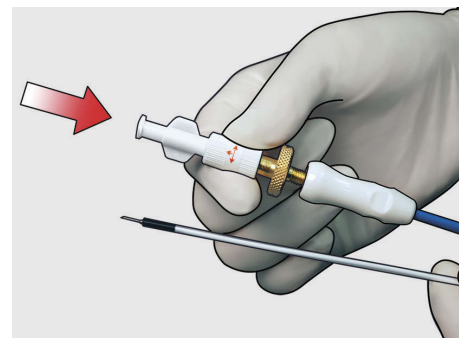
To ensure the desired needle extension, advance the Luer slip fitting and engage it firmly into the adjustment wheel.

Step 4



To adjust the needle, be sure to retract it back into the outer sheath before turning the adjustment wheel. Hold the device with the Luer lock fitting facing the operator and rotate the adjustment wheel clockwise to lengthen the needle extension, counterclockwise to shorten the needle extension.

Step 5



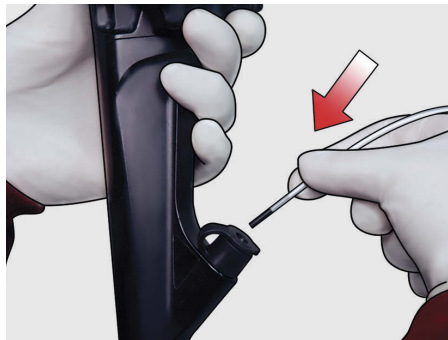
Verify the adjustment by advancing and engaging the Luer slip fitting again. The needle should move in and out of the outer sheath easily. Inspect the needle for breaks. **Caution:** Advancing and retracting the needle while the catheter is coiled may result in stretching of the catheter and damage to the device.

Instructions - Step 1



Securely attach a prefilled syringe to the Luer lock fitting on the device, then flush air from the needle. Check for patency and leaks.

Step 2



With the needle fully retracted into the sheath, introduce the device into the accessory channel of the endoscope and advance in short increments until it is visualized exiting the endoscope. Endoscopically visualize the desired injection site and maintain the position of the endoscope.

Step 3



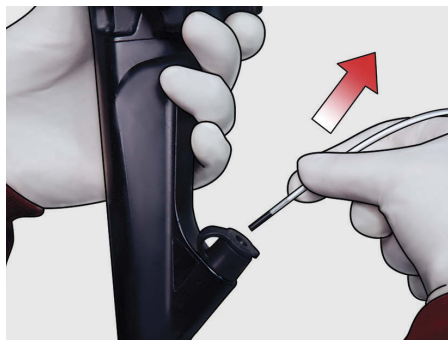
With the sheath in endoscopic view, advance and secure the needle by firmly engaging the Luer slip fitting into the adjustment wheel. **Note:** If desired, the needle extension may be adjusted by withdrawing the needle into the sheath and fine-tuning the needle extension using the adjustment wheel. **Caution:** During needle adjustment or advancement, ensure the sheath of the device has exited the endoscope completely and the sheath is in endoscopic view. (Refer to step 4 of system preparation for needle adjustment instructions.)

Step 4



Advance the needle into the mucosa. Using the attached syringe, perform the injection.

Step 5



Upon completion of the procedure, retract the needle into the sheath and remove the device from the endoscope.

Please refer to the product's Instructions for Use (IFU) for full prescribing information, warnings, precautions, contraindications, and potential adverse events.

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