

## AquaFlate Pre-Filled Sterile Water Syringe 10mL Instructions for Use

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner



### MANUFACTURER:

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### PRODUCT:

REF #	Product Description	Sterile	Use	Package Size
250-400	AquaFlate Pre-Filled Sterile Water Syringe	Yes	Single-Use	10mL

### INDICATIONS FOR USE:

The AquaFlate Pre-Filled Sterile Water Syringe is intended to be used for inflating a Foley catheter balloon.

### DEFINITIONS:

None.

### DESCRIPTION:

The AquaFlate Pre-Filled Sterile Water Syringe is a 10mL syringe pre-filled with USP purified water and sterilized via gamma irradiation. The syringe consists of a polypropylene barrel and plunger and latex free rubber for both the plunger gasket and syringe tip cover.

### CONTRAINDICATIONS:

None known.

### WARNINGS:

- The prefilled syringe containing sterile water is intended to inflate the catheter ONLY and is NOT intended for injection.
- Syringes are for single use only and are not to be reused or re-sterilized.

### PRECAUTIONS

- Do not use product if package is damaged or opened.
- If cap is not present, do not use syringe.
- Syringes should be correctly disposed of after being used once only.
- Read the Instructions for Use and keep them in a safe place.



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- Use the product only in accordance with its intended use, see INDICATIONS FOR USE.
- Refer to the Instructions for Use of the Foley catheter manufacturer for specific catheter placement and inflation instructions, including selection of the appropriate volume of sterile water required to inflate the catheter balloon.

**PRE-USE, HANDLING, AND INSPECTION:**

The product must be thoroughly inspected upon receipt and prior to use to ensure packaging is not damaged or defective.

**INSTRUCTIONS FOR USE:**

1. Thoroughly read and follow the Foley catheter manufacturer's instructions for use.
2. When ready to use, remove syringe cap and follow Foley catheter manufacturer's instructions for use and inflation.
3. Upon completion of the catheterization, properly discard the syringe.

**STORAGE CONDITIONS:**

- To preserve product performance, store away from direct sunlight.
- Store in a clean, dry place.