

AQUABILITI™ Next Wave Healthcare



Below are upcoming advancements in flush syringes:

Aquastat SFR 5 mL Pre-Filled Flush Syringe: Ideal for the pediatric market, these syringes are easier and safer than attempting to use exactly half of a 10 mL syringe. This will be the only 5 mL sterile field ready syringe on the market.

Aquastat SFR 20 mL Pre-Filled Flush Syringe: While many emergency intravenous cardiac medications and contrast media should be immediately flushed with 20 mL of saline, there is currently no 20 mL syringe on the market. Nurses and paramedics must either use 2 10 mL syringes or draw from an IV bag. Both these methods are time-consuming, and often, only 10 mL is used. This product will be important to advance safety and convenience in patient outcomes.



Aquabiliti Quality

Aquabilliti maintains a class 100 manufacturing environment in which all of our pre-filled flush syringes are manufactured according to federally mandated good manufacturing practices and quality standards.

Maintaining the highest quality standards is part of the company's commitment to building long-term client relationships based on mutual trust and respect.

commitment to excellence is reflected in a robust Quality Management System (QMS) compliant with 21 CFR 820 FDA Quality System (QS) Regulation and <u>ISO</u>

13485:2016. This certification is a testimony to our commitment to providing the highest quality Design & Development services.



AQUABILITI"

Next Wave Healthcare

Aquastat Standard Flush Syringes



Affordable Care Without Compromise

Aquastat Flush Syringes offer clinicians and their patients the highest quality in a flush syringe at an economical price. Aquastat Flush Syringes are terminally sterilized using irradiation, a process that offers several advantages over conventional steam, heat or gas sterilization.

- Minimal breakforce means less waste and less mess
- Smooth operation gives clinicians greater control
- Better taste for improved patient experience

Aquastat Flush Syringes are packaged 400 syringes per case (4 inner cartons of 100).



Aquastat Flush Syringes

The Top Choice for Performance Satisfaction and Process Improvement

With state of the art manufacturing and terminal sterilization at a low temperature, Aquastat and Aquastat SFR Flush Syringes are revolutionizing the market.

- Low temperature, terminal sterilization offers numerous advantages over conventional steam.
 - Smooth operation yields greater control.
 - Less breakforce required means reduced waste and mess.
 - Better taste, improved patient experience.

All Aquastat Flush Syringes are manufactured in the United States, making them an excellent choice for US government and healthcare organizations.



AQUABILITI™ Next Wave Healthcare

Pre-filled Flush Syringes with 0.9% Sodium Chloride (Saline)

Code Number	2T0805	2T0806	2T0807	2S0706
510(k) Number	K111355	K111355	K111355	K120836
Device Listing Number	D218483	D218483	D218483	D218482
Volume (fill)	5mL	10mL	3mL	10mL
Packaging	Sterile Fluid & Path	Sterile Fluid & Path	Sterile Fluid & Path	100% Sterile*
				*sterile field
Syringe Information				
Capacity	12mL	12mL	12mL	12mL
Length (inches)	6.25"	6.25"	6.25"	6.25"
Width (inches)	1.25"	1.25"	1.25"	1.25"
Weight (lbs)	0.035	0.045	0.027	0.056

Case (shipper)

Information



Quantity (eaches)	400	400	400	240
Cartons* per case	4	4	4	4
Carton* quantity	100	100	100	60
* carton aka box				
Case Dimensions				
Length (inches)	22.5"	22.5"	22.5"	22.5"
Height (inches)	7.25"	7.25"	7.25"	7.25"
Width (inches)	15.25"	15.25"	15.25"	15.25"
Weight (lbs)	18	22	15.25	15.6
Carton Dimensions				
Length (inches)	11"	11"	11"	11"
Height (inches)	7.125"	7.125"	7.125"	7.125"
Width (inches)	7.5"	7.5"	7.5"	7.5"
Weight (lbs)	4.06	5.06	3.38	3.52





0.9% Sodium Chloride Injection, USP Aquastat ™ Saline Flush Syringe

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Description:

AquastatTM Saline Flush Syringe contains sterile, non-pyrogenic, preservative free 0.9% Sodium Chloride Injection, USP in a plastic, disposable single use syringe. No latex used in the manufacture of this device.

Fluid and Fluid Path are Sterile. Do NOT place on Sterile Field.

Indications and Usage:

AquastatTM Saline Flush Syringes are intended for the flushing of compatible intravenous administration sets and indwelling vascular access devices.

Contraindications: None

Symbol Legend:

;	Manufacturer	
REF	Catalog Number	
(i	Consult Instructions for Use	
Ω	Use by Date	

$P_{X_{only}}$	By Prescription Only	
(2)	Single Use Only	
®	Do not use if pack is opened or damaged	
8	Do not re-sterilize	

X	Temperature limitation	
<u>^</u>	Caution	
LOT	Lot Number	
STERILE R	Sterilized by Irradiation	

Caution! Caution statements describe conditions or actions that can result in damage to the product Cautions:

- 1. Do not use if package is not intact.
- 2. Do not use if tip cap is improperly affixed or dislodged from syringe tip or syringe is damaged exhibiting signs of leakage.
- 3. Do not use syringe if upon visual inspection solution is discolored, cloudy or hazy, contains a precipitate or has any type of particulate matter.
- 4. Verify expiration date. Do not use if product has expired.

Adverse Events: None.

Storage: Store at 20-25°C (68-77°F) excursions permitted to 15-30°C (59-86°F); Do not Freeze.

Directions for Use:

- 1. Utilize proper aseptic technique.
- 2. Open package by tearing pouch gently.
- 3. Remove syringe cap by twisting off.
- 4. If required, attach blunt cannula or needle to syringe following applicable manufacturer and institution guidelines.
- 5. Hold syringe upright and expel air if present.
- 6. Attach to needleless system or IV access device and flush adhering to institution's policies and indwelling device manufacturer's recommendations.
- 7. Discard unit after single use. Do not reuse.

How Supplied:

AquastatTM Saline Flush Syringes are provided in cartons containing individually packaged syringes. Scan QR code with appropriate scanner for a digital copy of the Direction Insert.

Reorder No. 2T0807 – 03mL in 12mL syringe – 400/case Reorder No. 2T0805 – 05mL in 12mL syringe – 400/case Reorder No. 2T0806 – 10mL in 12mL syringe – 400/case Reorder No. 2T0806-SP – 10mL in 12mL syringe – 120/case