

## TECHNICAL DATA SHEET

### MEDICAL DEVICE REFERENCE SYR-XXS Enteral ENFit® Syringe (ISO 80369-3)

CE  
0123

#### PRODUCT DESCRIPTION

AVANOS\* Enteral ENFit® syringe (ISO 80369-3) is indicated for use as a dispenser, a measuring device, and/or a fluid transfer device. It is used to enterally deliver/remove fluids into or from the body.

**Brand name** AVANOS\*

#### FEATURES

- Polypropylene
- Silicone lubricant
- mL scale
- Sterilized with Ethylene Oxide
- Single use
- Available from 1 to 60 mL, low dose from 1 to 5mL
- ISO 80369-3 ENFit® Compatible Connector\*\*



#### SPECIFICATIONS

Product Code	SYR-01S	SYR-03S	SYR-05S	SYR-10S	SYR-20S	SYR-60S
Description	Enteral Low Dose Tip Syringe with ENFit® Compatible Connector	Enteral Low Dose Tip Syringe with ENFit® Compatible Connector	Enteral Low Dose Tip Syringe with ENFit® Connector	Enteral Syringe with ENFit® Connector	Enteral Syringe with ENFit® Connector	Enteral Syringe ENFit® Connector
Capacity	1 mL	3 mL	5 mL	10 mL	20 mL	60 mL
Scale (mL)	0.01 mL	0.1 mL	0.2 mL	0.2 mL	1 mL	1 mL

#### COMPOSITION

- Product NOT made with natural rubber latex
- Product NOT made with Bisphenol A (BPA)
- Product NOT made with DEHP as a plasticizer

Component	Raw Material
Syringe Barrel and Plunger	Polypropylene
Piston	Polyisoprene synthetic rubber
Silicone Lubricant	Polydimethylsiloxane
Colorant Resin Blend	Acrylonitrile butadiene styrene blend
Printing Ink	Carbon black pigment blend

## PACKAGING, PRESERVATION, AND STORAGE

- Individually blister packaged sterile
- Store in a clean, dry place at room temperature

Product Code	SYR-01S	SYR-03S	SYR-05S	SYR-10S	SYR-20S	SYR-60S
Sell Unit	100	100	100	100	50	50
Size (Inches) (OD)	8.465 (L) x 5.315 (W) x 5.118 (D)	8.465 (L) x 5.315 (W) x 5.118 (D)	9.252 (L) x 5.512 (W) x 6.890 (D)	9.764 (L) x 6.102 (W) x 9.449 (D)	9.843 (L) x 6.299 (W) x 6.693 (D)	16.732 (L) x 8.858 (W) x 7.008 (D)
Case Cubic Feet	0.133 (ft3)	0.133 (ft3)	0.203 (ft3)	0.326 (ft3)	0.240 (ft3)	0.601 (ft3)
Size (mm) (OD)	215.000 (L) x 135.000 (W) x 130.000 (D)	215.000 (L) x 135.000 (W) x 130.000 (D)	235.000 (L) x 140.000 (W) x 175.000 (D)	248.000 (L) x 155.000 (W) x 240.000 (D)	250.000 (L) x 160.000 (W) x 170.000 (D)	425.000 (L) x 225.000 (W) x 178.000 (D)
Case Cubic Meters	0.004 (m3)	0.004 (m3)	0.006 (m3)	0.009 (m3)	0.007 (m3)	0.017 (m3)
Case Weight	1.00 (lbs)	1.10 (lbs)	1.75 (lbs)	3.70 (lbs)	1.65 (lbs)	4.13 (lbs)
Stack Pattern	RB41E20	RB41E20	RB36E14	RB32E10	RB30E15	C10E14
Cases/Layer	41	41	36	32	30	10
Layers/Unit OR Pallet	20	20	14	10	15	14
Cases/Unit OR Pallet	820	820	504	320	450	140
Weight excluding pallet	820.00 (lbs)	902.00 (lbs)	882.00 (lbs)	1184.00 (lbs)	742.50 (lbs)	578.20 (lbs)
Order Unit	Box of 1	Box of 1	Box of 1	Box of 1	Box of 1	Box of 1
Packaging Unit	Case of 8	Case of 8	Case of 8	Case of 8	Case of 6	Case of 4
Minimum Quantity	Box of 1	Box of 1	Box of 1	Box of 1	Box of 1	Box of 1

## INDICATIONS FOR USE

**Indications** AVANOS\* Enteral Syringe with ENFit® Compatible Connector is indicated for use as a dispenser, a measuring device, and/or a fluid transfer device. It is used to enterally deliver/remove fluids into or from the body. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

**Technical Safety** see instructions for use ref 15-M1-345-02

**Precautions** see instructions for use ref 15-M1-345-02

**Contraindications** see instructions for use ref 15-M1-345-02

## REGULATORY INFORMATION

Applicable European Union directive	CE marked according to MDD93/42/EEC Annex IX
DM Class	Class I-s – Rule 2 of Annex IX
Notified Body	TÜV SÜD – CE 0123
First market launch in the EU	July 2019
Manufacturer of DM per Directive	Avanos Medical, Inc. - 5405 Windward Parkway - Alpharetta, GA 30004 USA.
Country of Origin (COO)	Product of China
Biological Safety	ISO 10993-12018
Expiration	5 years from the date of manufacturing

Last Updated: July 17, 2019

\*\*The barrel dimensions of 1mL and 3mL syringes are smaller than specified in ISO 80369-3 and may pose an increased risk of misconnection with other medical devices.

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.