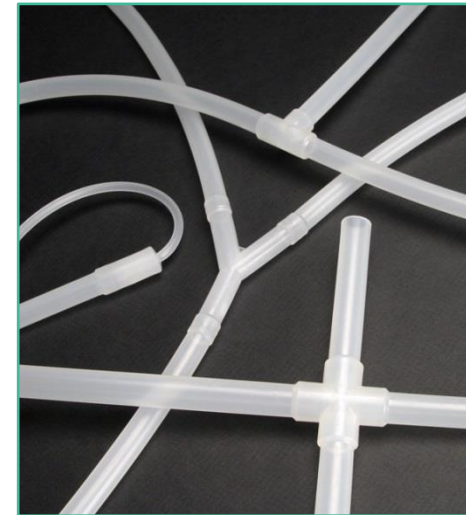
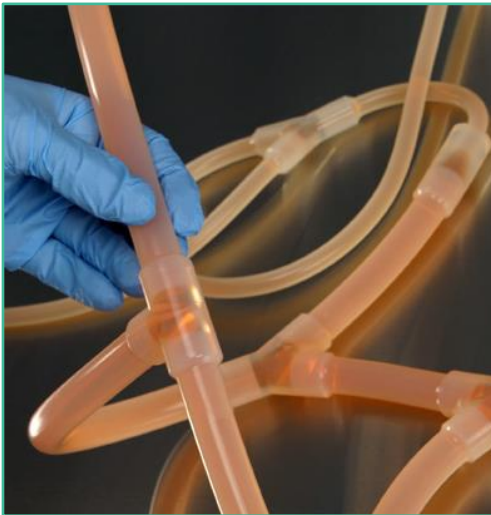


# NewAge® Industries/AdvantaPure®

Purity in Fluid Flow Systems®





**A View of NAI/AdvantaPure**

**Our Partners/Our Commitment**

**AP Quality**

**Our Technologies**





# AdvantaPure®

## **Be a Premier Supplier of Fluid Flow Products for Sanitary and High Purity Applications**

- Privately held company
- Family Company – 2<sup>nd</sup> Generation
- NewAge has a 60 year history in tubing, hose & molded products leadership
- **ESOP** (Employee Stock Ownership Plan)

## Our Facility in Southampton, PA



- ❑ ISO 9001:2008 Certified
- ❑ Controlled Warehouse Storage
- ❑ Class 10,000/ISO 7 Cleanrooms

- ❑ Currently 244,000 square feet
- ❑ 50,000 ft<sup>2</sup> Cleanroom Expansion in 2016
- ❑ 4,082 solar panels = 1MW system



**A View of NAI/AdvantaPure**



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# Our Customers



## Our Commitment

### **Be a Premier Supplier of Fluid Flow Products for Sanitary and High Purity Applications**

- Provide high quality products
- Excellent customer service
- Manufacturing operational excellence and clean environment
- Knowledgeable sales and applications support
- Innovation and new product development



## Our Industry Involvement



- Member of BPSA BoD and Quality Matrix Committee
- Co-Authored White Papers on E/L, Particulate & SUS
- ISPE reviewer for submitted articles and content
- Chaired ASME task group on E/L
- Participated in ASME task groups on particulate, hygienic seals and polymeric fittings

# World Wide Partners



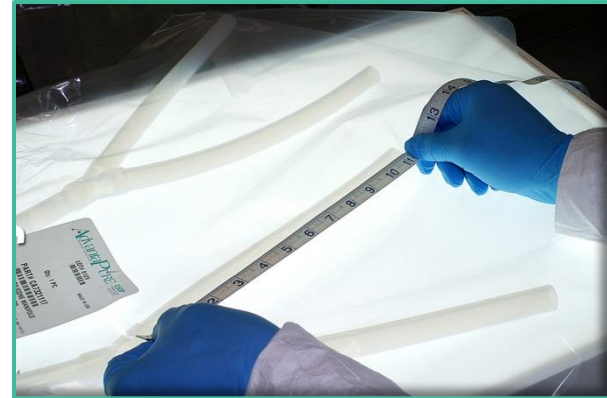
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## Validation of Products

- Meets USP Class VI
- Extensive extractables testing portfolio
- FDA CFR 177.2600
- ISO 10993
- 3A 18-03
- European Pharmacopoeia 3.1.9
- Full Validation package available upon request



## Validated Sterility

- Certified Sterility to ISO 11137 using VDmax method
- Gamma irradiation performed by 3<sup>rd</sup> party processor
- Configurations must fit within validation study – consult with plant
- Quarterly dose auditing to monitor bioburden levels and compliance

## Warehousing

- Temperature controlled
- Product stored in totes
- No cardboard or wood



## QC Inspection



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# Silicone Tubing

- APST Platinum Silicone Unreinforced Tubing
- APSH Platinum Silicone Braid Reinforced Tubing



- Multiple sizes and lengths available
- Autoclavable and gamma sterilizable
- Lot and batch traceable

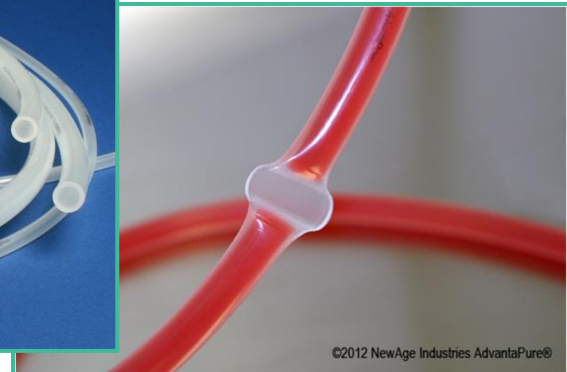
## Silicone Extrusion Lines



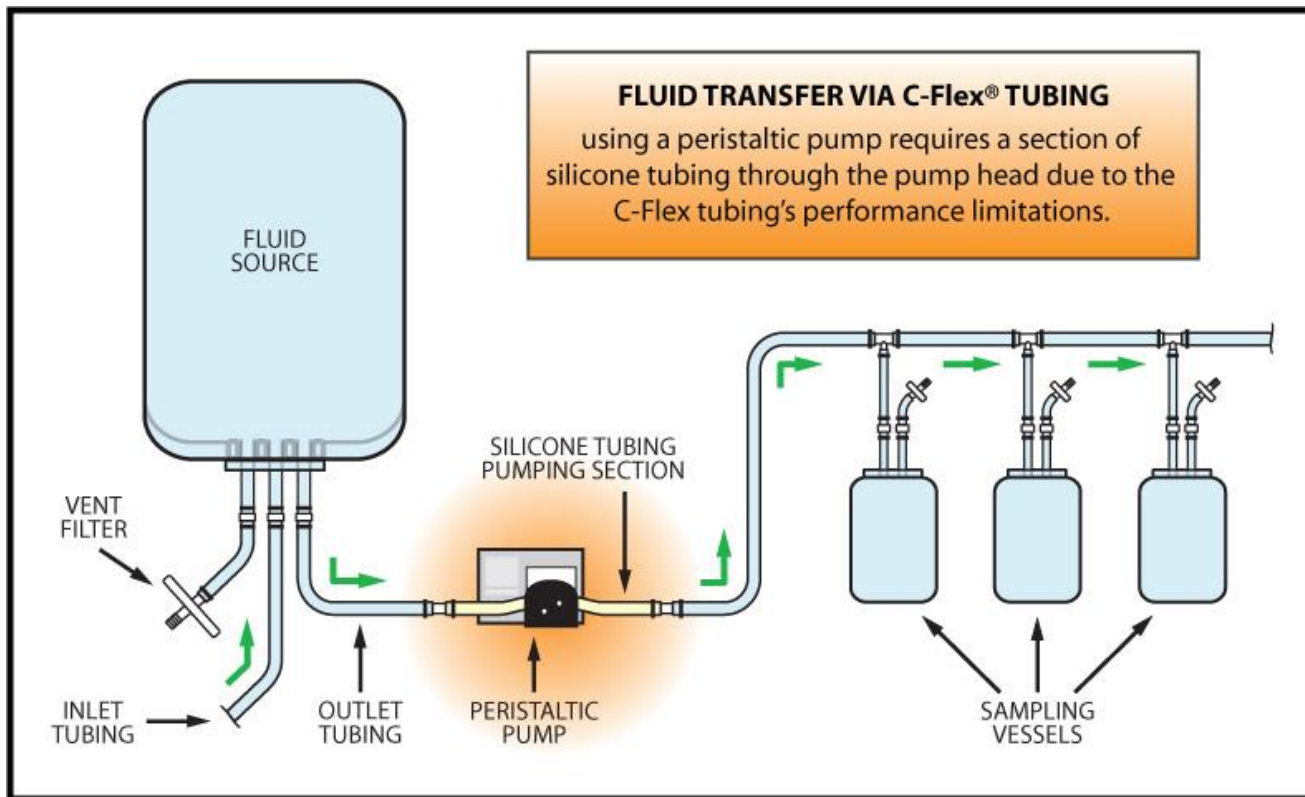
# AdvantaFlex TPE Tubing



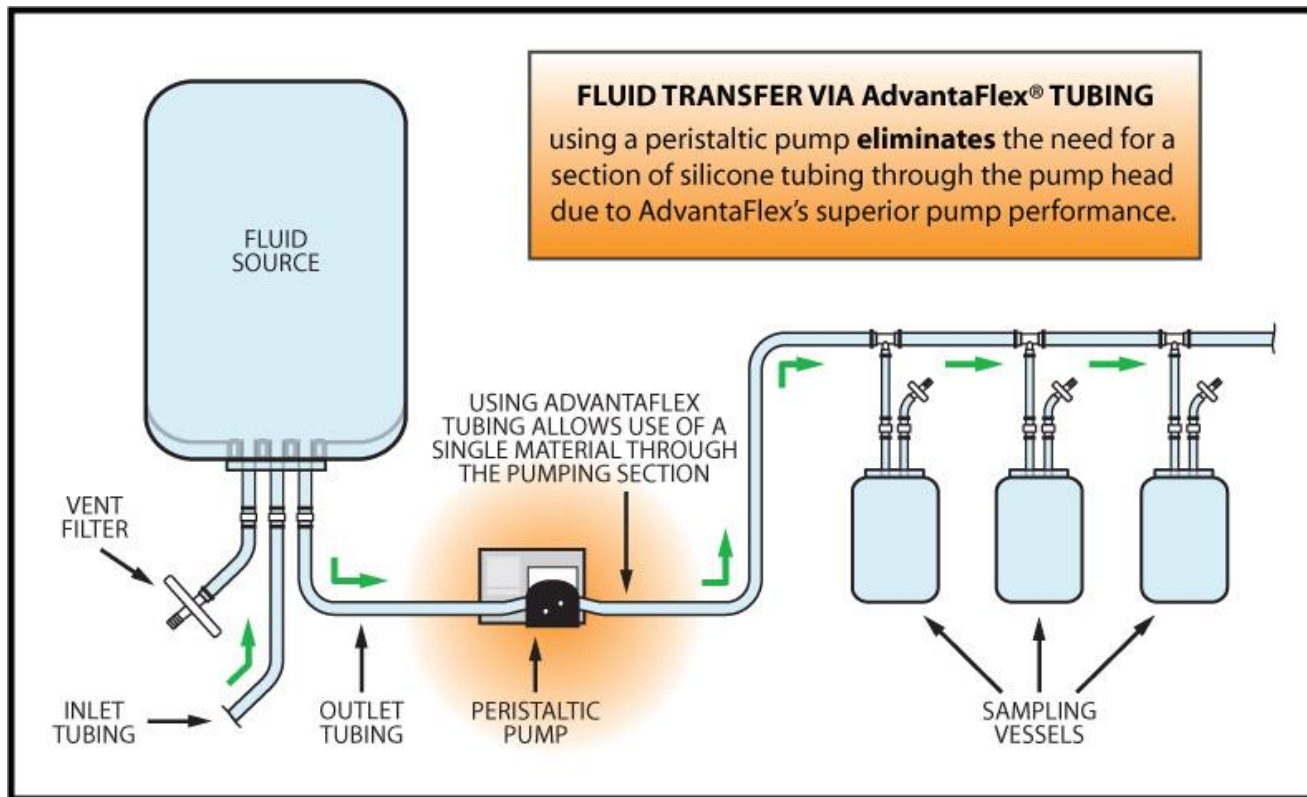
- Weldable and heat sealable
- Suitable for pump applications
- Newer formulation made with no silicone oils
- Better alternative to C-Flex; superior weld strength
- Available printed or unprinted



# AdvantaFlex: Superior Pumpability



# AdvantaFlex: Superior Pumpability

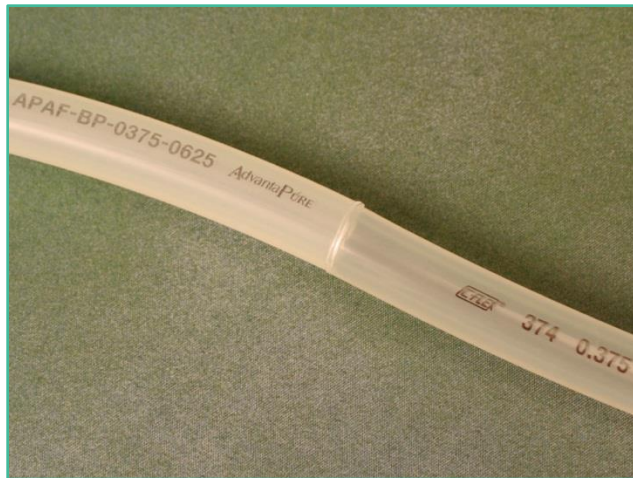




# AdvantaTube<sup>®</sup>

## Sterile Welder

- Welds sizes 0.375" to 0.750" OD tubing
- Cycle time is 3 minutes
- Easy two button control process
- Small footprint, easily transportable



# AdvantaTube<sup>®</sup> Sealer

- Seals sizes 0.250" to 1.0" OD tubing
- Remote sealing head for flexibility
- Easy two button control process on sealing head
- Capacity for user programmed recipes

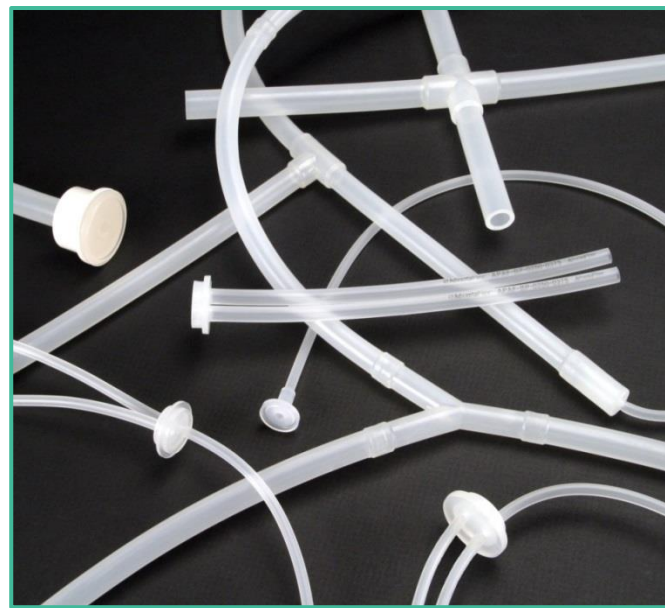


## Molded Products and Assemblies

Silicone



AdvantaFlex





## Molded Products and Assemblies

- Molded junctions (tees, wyes, reducers, crosses)
- Hygienic fittings
- Closures (GL45, 38-430, 53B, 83B, Stoppers, Tru-Union)





# SUS Integrity: Molded vs Barbed?

- Understand CPPs and the risks associated with batch failure

## Closure and Stopper Systems: Getting Big Benefits from Small Components

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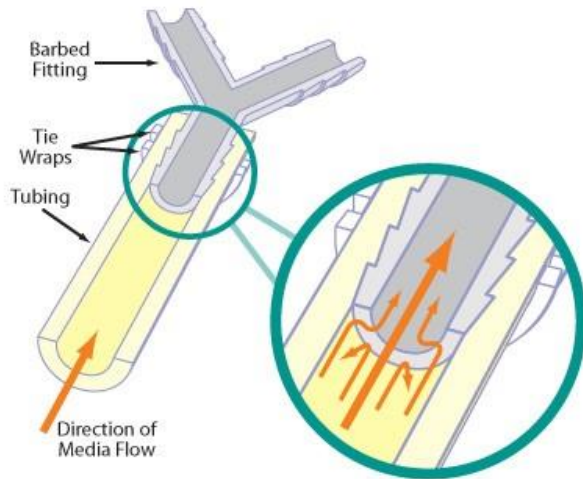
*by Tony Butler, ASQ CSSBB  
Manager, Single-Use Systems  
AdvantaPure<sup>®</sup>*



# SUS Integrity: Molded vs Barbed?

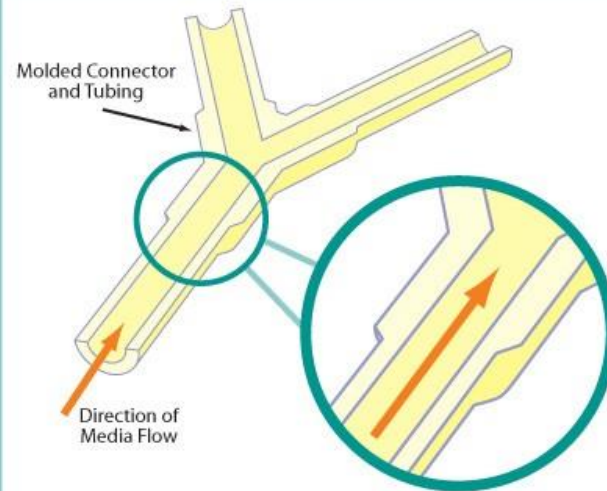
## Comparative Advantages of Molded Manifolds

**TUBING SET ASSEMBLY USING BARBED FITTINGS**



Edge of fitting may disrupt the flow or create an area of entrapment and potential leakage.

**SINGLE MOLDED MANIFOLD WITH MOLDED CONNECTIONS**



Molded interior provides a seamless transition for a continuous, unrestricted, leak-proof flow.

# DocuLink<sup>®</sup>

*Traceability and Document Retrieval Just Got Easier*

- Easily identify SUS by label on product and not just on bag from which it was removed
- Electronically lookup documents, such as CoCs and CoAs
- Suitable for autoclaving and gamma irradiation



## Process Hose

- APSH Braide/Double Braided Silicone
- APSM 4 Ply Mandrel Wrapped
- APSW Mandrel Wrapped, Wire Reinforced
- APSW-PC Mandrel Wrapped, Wire Reinforced, Convoluted
- APFRC FEP Lined w/ EPDM Cover
- APEWF Wire Reinforced EPDM Rubber
- APFOS-W Stainless Steel Overbraid, PTFE Lined
- APFOS- WC Stainless Steel Overbraid, PTFE Lined, Convoluted
- APFOSJ-W/WC Stainless Steel Overbraid, PTFE Lined, Silicone Jacket

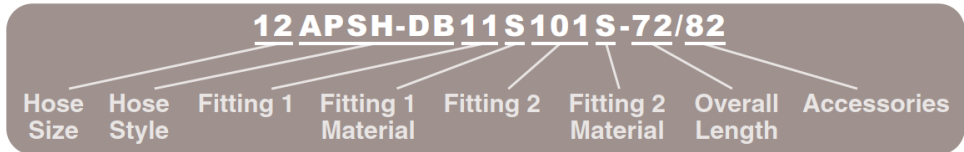


# Fittings and Connectors



## How to Order an AdvantaPure Hose Assembly

Example:



This assembly consists of a 3/4" I.D. double-braided silicone hose with a 3/4" mini sanitary Tri-Clamp® fitting (316L stainless steel) on one end and a 1-1/2" sanitary Tri-Clamp step up fitting (316L stainless steel) on the other. The assembly is 72" in length and uses an AdvantaLabel® for hose identification.

## Identification Solutions

- **AdvantaLABEL™** : Identification labels and color stripes permanently vulcanized to the O.D of silicone tubing and hose
- **Color Tracer Braid Silicone**: Braid material available in several colors
- **Color Four-Ply Silicone**: Permanent solid color on outside of hose
- **Laser Etched Collars**: Permanent identification that's more legible than acid etched or handwritten labels





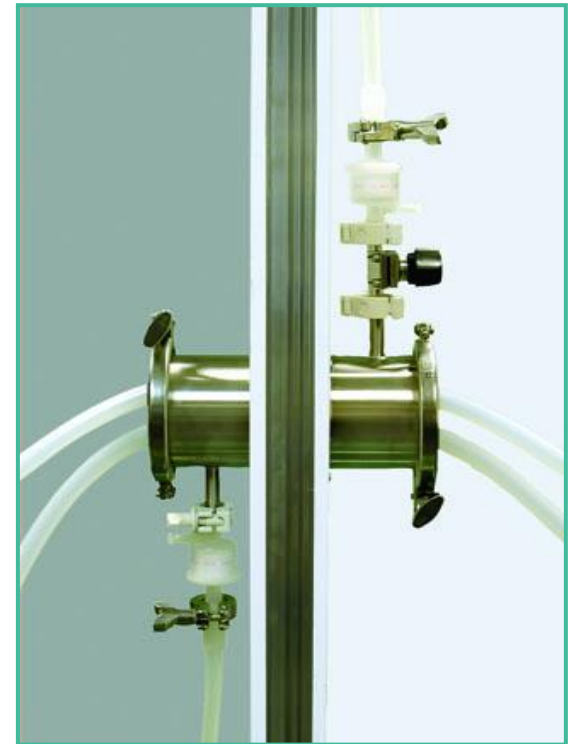
# AdvantaPure<sup>®</sup> Hose Shop



# AdvantaPass™

## *Wall and Bulk-head Pass Through Technology*

- Permits single-use aseptic transfer between walls & floors
- Fluid handling between different clean rooms
- New construction or retrofit
- Utilizes single-use process components in silicone or TPE
- Customized yet cost effective
- Single or multiple transfer lines



# AdvantaPass™

*Wall and Bulk-head Pass Through Technology*

## **Applying Single-Use Efficiencies to Room-to-Room Fluid Transfer**

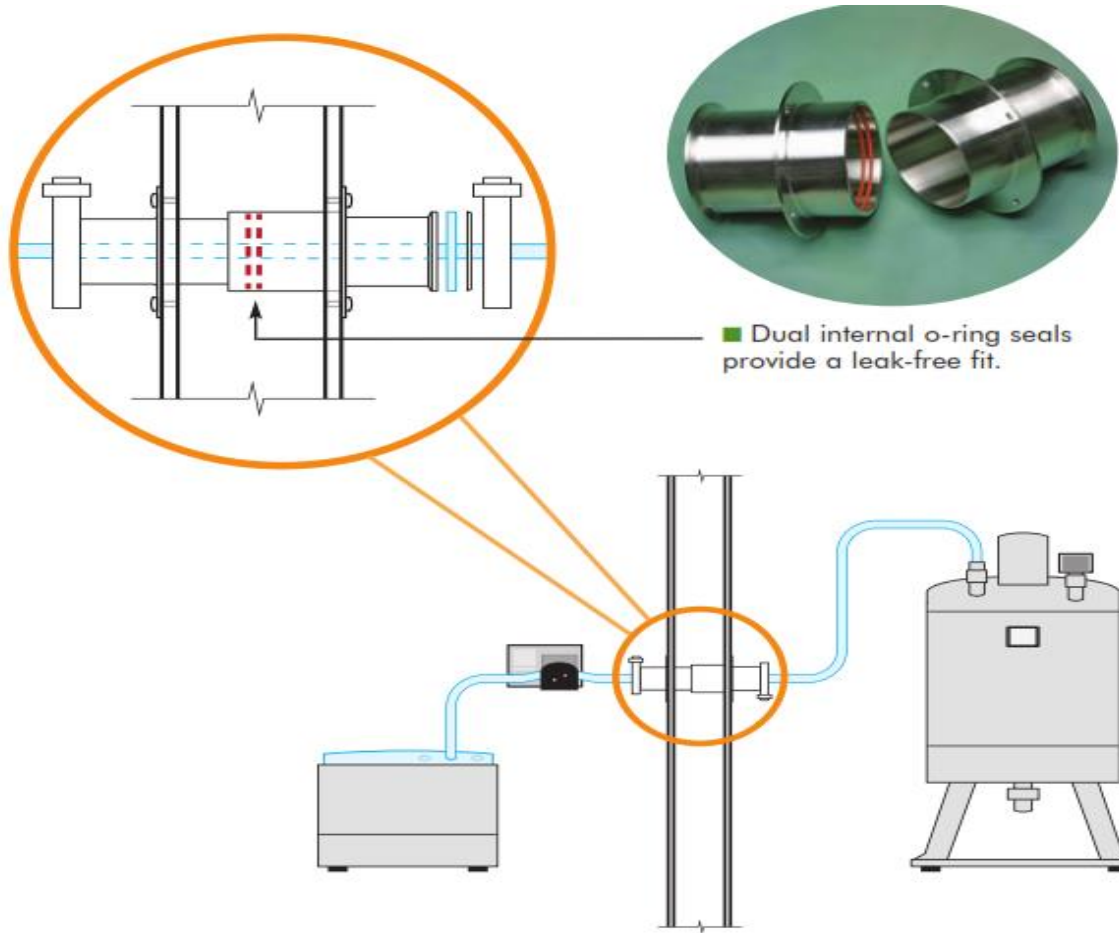
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*by Tony Butler, ASQ CSSBB  
Manager, Single-Use Systems  
AdvantaPure®*



# AdvantaPass™

## Wall and Bulk-head Pass Through Technology



# AdvantaPass™

## *Wall and Bulk-head Pass Through Technology*

- AdvantaPass can be used for:
  - Clean room to dirty hallway – Eliminates storage tank traffic into and out of clean room, storage tank staged outside of clean room.
  - Dirty hallway into Clean room – opposite of above.
  - Hood to production suite – APass allows for passing into production suite from hood area.
  - Clean room to Cold storage – Eliminates storage tank traffic into and out of clean room.



# **NewAge® Industries/AdvantaPure®**

**Purity in Fluid Flow Systems®**

Thank You

Lawrence Morano  
Global Sales Manager, AdvantaPure

