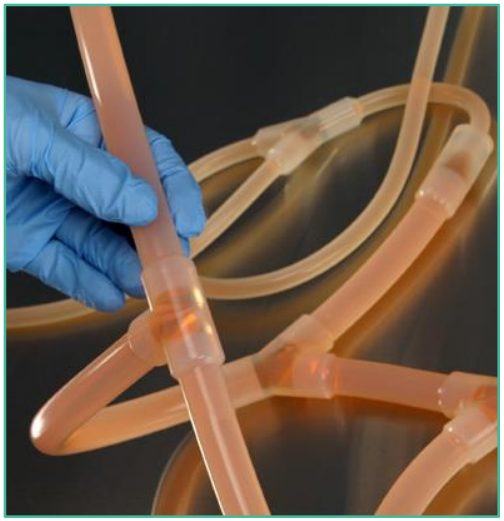
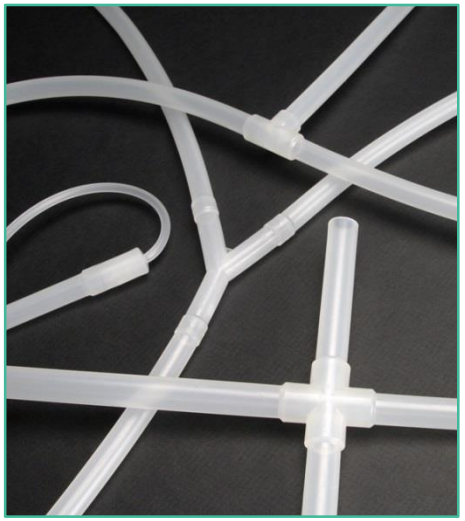
NewAge® Industries/AdvantaPure®

Purity in Fluid Flow SystemsSM





A View of NAI/AdvantaPure

Our Quality/Our Commitment

The BPOG Extractables Protocol

Our Technologies/Case Studies

Our Facility in Southampton,PA

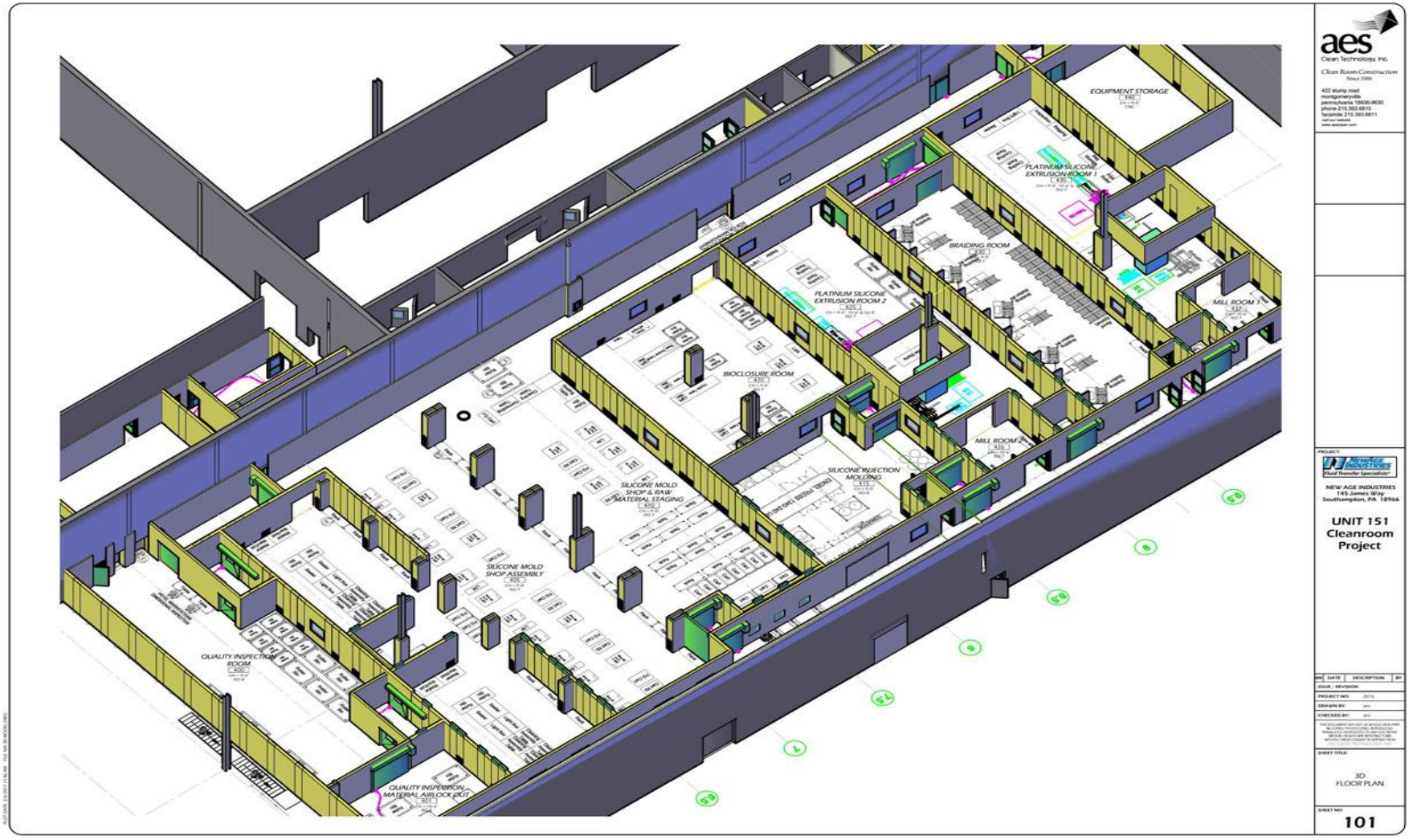
- 244,000 square feet
- 50,000 ft^2 Expansion in 2017
- 4,082 solar panels = 1MW system

- ISO 9001:2015 Certified
- Controlled Warehouse Storage
- Class 10,000/ISO 7 Cleanrooms

Environmentally Responsible

Over 4,000 panels on the building’s rooftop power half our annual electricity needs

Facility Expansion 2017



- A View of NAI/AdvantaPure
- Our Quality/Our Commitment
- AP Quality
- Our Technologies

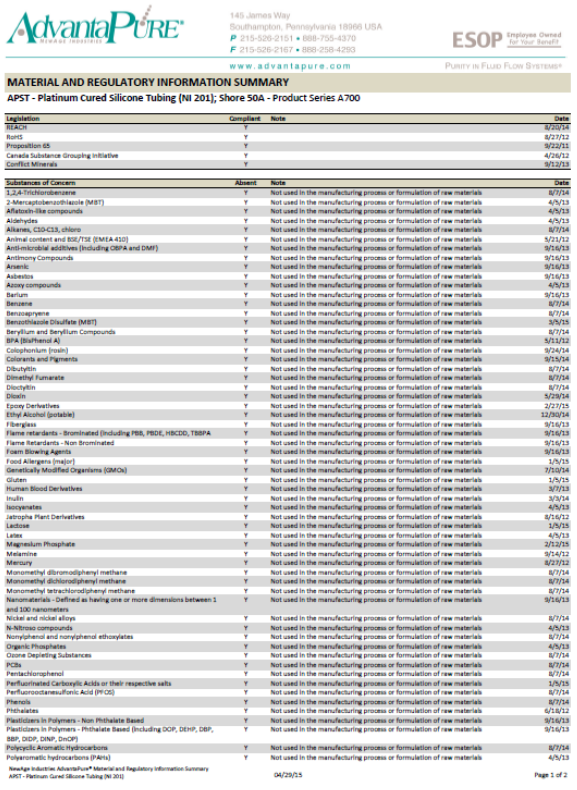
Our Customers

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, hygenic seals and polymeric fittings
- ASME Bioprocessing Equipment standard committee
- Member of BPOG on sterility sub-committee

Validation of Products

- Meets USP 88 (Class VI)
- Meets USP 85, 87, 661, 381
- Extractables testing portfolio to BPOG (2017)
- FDA CFR 177.2600
- ISO 10993
- European Pharmacopoeia 3.1.9
- DMF with FDA for Platinum Silicone: #26598
- DMF with FDA for AdvantaFlex: #28810
- Full Validation package available upon request



AdvantaPURE NewAge Industries

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ESOP Employee Owned

Purity in Fluid Flow Systems®

MATERIAL AND REGULATORY INFORMATION SUMMARY

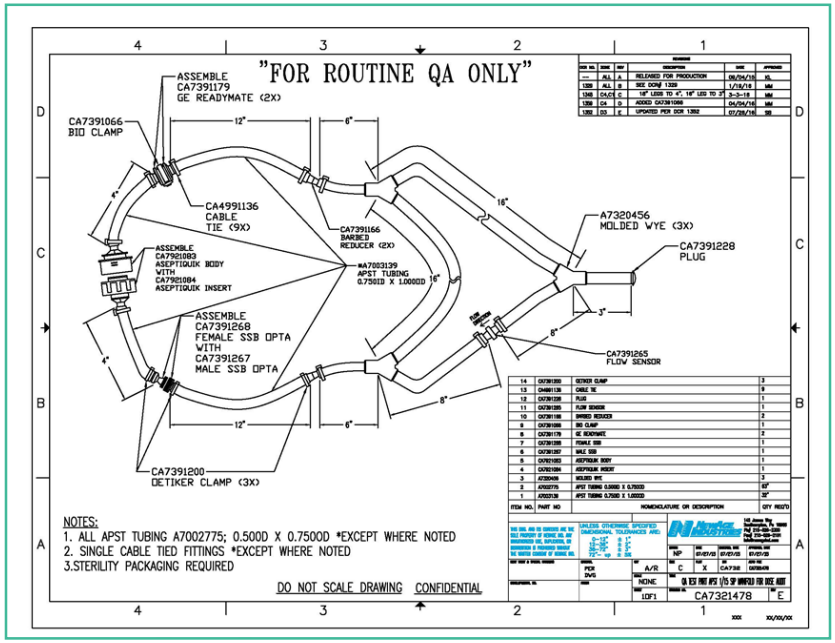
APST - Platinum Cured Silicone Tubing (NI 201); Shore 50A - Product Series A700

Legislation	Compliant	Note	Date
REACH	Y		8/20/14
RoHS	Y		8/27/12
Proposition 65	Y		9/22/11
Canada Substance Grouping Initiative	Y		4/26/12
Conflict Minerals	Y		9/13/13

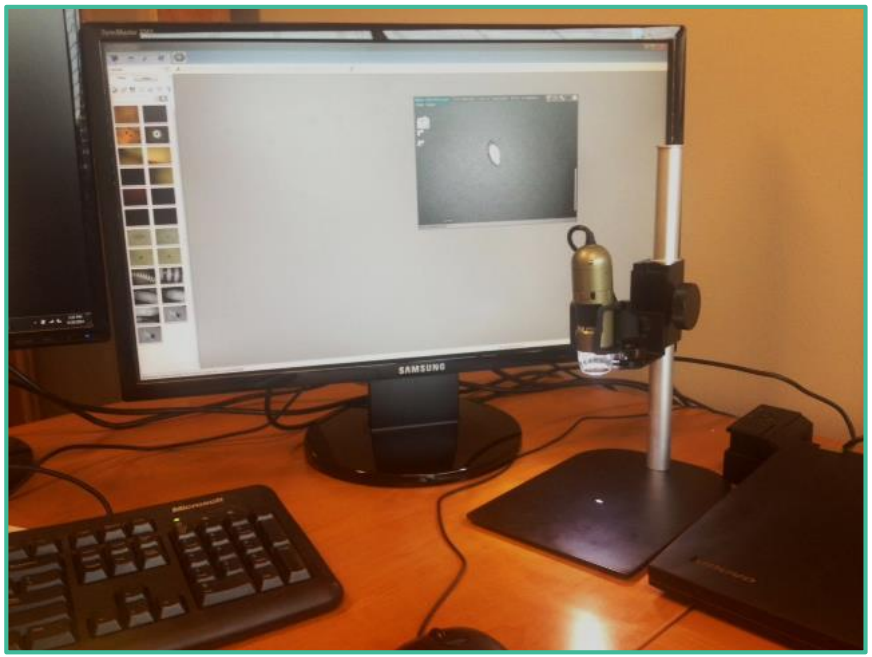
Substances of Concern	Absent	Note	Date
1,2,4-Trichlorobenzene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
2-Mercaptobenzothiazole (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Aflatoxin-like compounds	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Aldehydes	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Alkanes, C10-C13, chloro	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Animal content and BSE/TSE (EMEA 410)	Y	Not used in the manufacturing process or formulation of raw materials	5/21/12
Anti-microbial additives (including OBPA and DMF)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Antimony Compounds	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Arsenic	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Asbestos	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Azoxy compounds	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Barium	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Benzene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Benzopyrene	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Benzothiazole Disulfate (MBT)	Y	Not used in the manufacturing process or formulation of raw materials	3/5/15
Beryllium and Beryllium Compounds	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
BPA (BisPhenol A)	Y	Not used in the manufacturing process or formulation of raw materials	5/11/12
Colophonium (rosin)	Y	Not used in the manufacturing process or formulation of raw materials	9/24/14
Colorants and Pigments	Y	Not used in the manufacturing process or formulation of raw materials	9/13/14
Dibutyltin	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Dimethyl Fumarate	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Dioctyltin	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Diosin	Y	Not used in the manufacturing process or formulation of raw materials	5/29/14
Epoxy Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	2/27/15
Ethyl Alcohol (potable)	Y	Not used in the manufacturing process or formulation of raw materials	12/30/14
Fiberglass	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Flame retardants - Brominated (including PBB, PBDE, HBCDD, TBBPA	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Flame Retardants - Non Brominated	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Foam Blowing Agents	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Food Allergens (major)	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Genetically Modified Organisms (GMOs)	Y	Not used in the manufacturing process or formulation of raw materials	7/10/14
Gluten	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Human Blood Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	3/7/13
Inulin	Y	Not used in the manufacturing process or formulation of raw materials	3/3/14
Isocyanates	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Jatropha Plant Derivatives	Y	Not used in the manufacturing process or formulation of raw materials	8/16/12
Lactose	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Latex	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Magnesium Phosphate	Y	Not used in the manufacturing process or formulation of raw materials	2/12/15
Melamine	Y	Not used in the manufacturing process or formulation of raw materials	9/14/12
Mercury	Y	Not used in the manufacturing process or formulation of raw materials	8/27/12
Monomethyl dibromodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Monomethyl dichlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Monomethyl tetrachlorodiphenyl methane	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Nanomaterials - Defined as having one or more dimensions between 1 and 100 nanometers	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Nickel and nickel alloys	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
N-Nitroso compounds	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Nonylphenol and nonylphenol ethoxylates	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Organic Phosphates	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13
Ozone Depleting Substances	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
PCBs	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Pentachlorophenol	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Perfluorinated Carboxylic Acids or their respective salts	Y	Not used in the manufacturing process or formulation of raw materials	1/5/15
Perfluorooctanesulfonic Acid (PFOS)	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Phenols	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Phthalates	Y	Not used in the manufacturing process or formulation of raw materials	6/18/12
Plasticizers in Polymers - Non Phthalate Based	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Plasticizers in Polymers - Phthalate Based (including DOP, DEHP, DBP, BBP, DIDP, DINP, DnOP)	Y	Not used in the manufacturing process or formulation of raw materials	9/16/13
Polycyclic Aromatic Hydrocarbons	Y	Not used in the manufacturing process or formulation of raw materials	8/7/14
Polyaromatic hydrocarbons (PAHs)	Y	Not used in the manufacturing process or formulation of raw materials	4/5/13

Validated Sterility

- Certified sterility assurance of 10^{-6} per ISO 11137 using Vdmax 25 method
- Gamma irradiation performed by 3rd party processor
- Configurations must fit within validation study – consult with plant
- Quarterly dose auditing to monitor bioburden levels and ensure compliance



Contamination Control



- Full lot traceability of incoming raw materials
- Particulate testing per USP 788 performed quarterly on representative product from each product line
- EM Monitoring for non-viable monitored monthly and viable from air and surfaces monitored quarterly
- Particulates detected are categorized by microscopy and identified through FTIR

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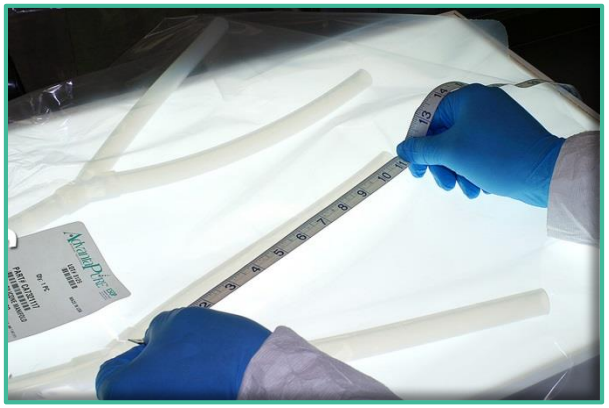
Our Technologies/Case Studies



Our members - leaders of the industry

We are privileged to have as our members, the most influential leaders of the Biopharmaceutical industry, whose representatives come together to deepen the level of collaboration and competitiveness of BioPharma operations.

	Solvents						Time				
	50% Ethanol	1% PS-80	5M NaCl	0.5N NaOH	0.1 M Phosphoric acid	WFI[a]	Time 0 (≤ 30 min)	24 hours	7 days	21 days	70 days
							Temperature				
							Ambient (25°C)	40°C			
Storage, Mixing, and Bioreactor Bags	X	X	X	X	X	X	X	X		X	X[b]
Tubing	X	X	X	X	X	X	X	X		X	X[b,c]
Tubing Connectors and Disconnectors	X	X	X	X	X	X	X	X		X	
Aseptic Connectors and Disconnectors	X	X	X	X	X	X	X	X	X		
Sterilizing-grade Filters/Process Filters	X	X	X	X	X	X	X	X	X		
Tangential-flow Filtration Cassettes	X	X	X	X	X	X	X	X		X	
Sensors and Valves	X	X	X	X	X	X	X	X		X[d]	
Chromatography Columns; Elastomeric Parts (gaskets, O-rings, diaphragms, and septum); Wetted Polymeric Surfaces of Positive Displacement Pumps	X	X	X	X	X	X	X	X			
Molded Parts of Mixers	X	X	X	X	X	X	X	X		X	
Filling Needles	X	X	X	X	X	X	X	X			

Abbreviations: PS-80 = Polysorbate-80; WFI = water for injection; min = minute.
[a] Deionized water can be used for this purpose if WFI is not available.
[b] Duration, specified for testing storage bags and tubing, is necessary to support 3-year storage time at 0°C.
[c] Tubing is included because tubing sections are typically integrated with bags during storage.
[d] The 21-day time-point applies only to sensors used with bioreactors (e.g. for dissolved oxygen and pH).

Table B. Extraction solvents, exposure times, and exposure temperatures by SUS component type.

- A View of NAI/AdvantaPure
- Our Quality/Our Commitment
- The BPOG Extractables Protocol
- Our Technologies/Case Studies

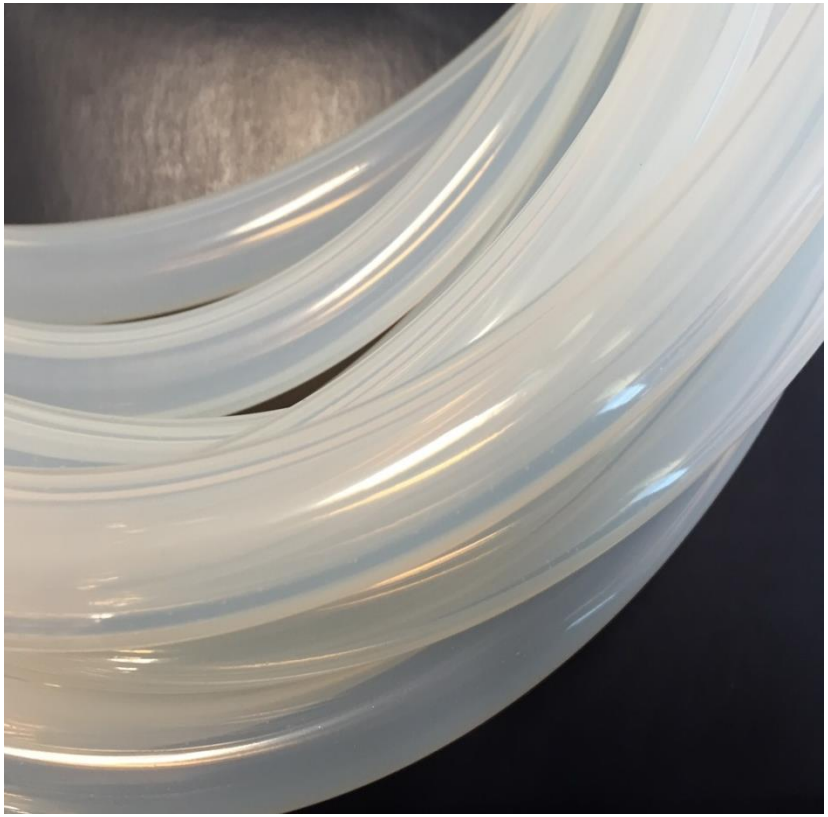
Silicone Tubing

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

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

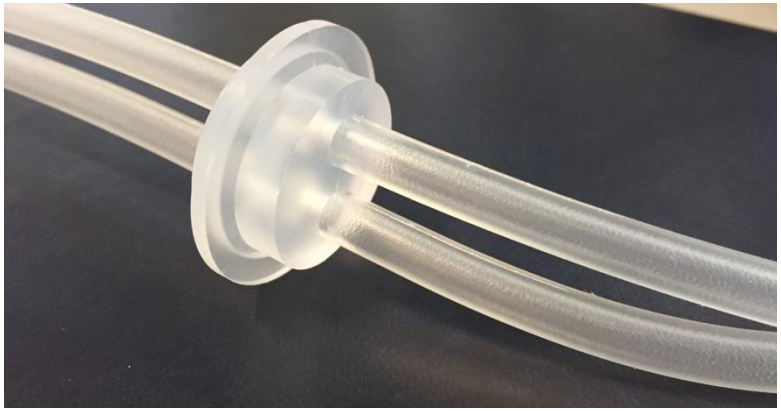
APHP High Pressure Silicone Tubing

- Designed for increased flow rates to reduce processing time
- Can withstand pressures up to ~ 4x greater than standard platinum silicone tubing
- Full vacuum rated on most sizes
- Optimal for TFF, inline integrity testing of SUS and high volume fluid transfer



Ultra Low Temperature Resistant Silicone

- An ultra low temperature compatible tubing and LIM designed to withstand static and dynamic conditions at -90C
- Brittle point is ~ -110C based on DMA/DSC analysis
- Can be used as a closure system for long term storage and shipping transport of bulk drug substance (such as Biotainer or LVV) or on a bag/shell system



AdvantaFlex TPE Tubing

AdvantaFlex™
BioPharmaceutical Grade 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

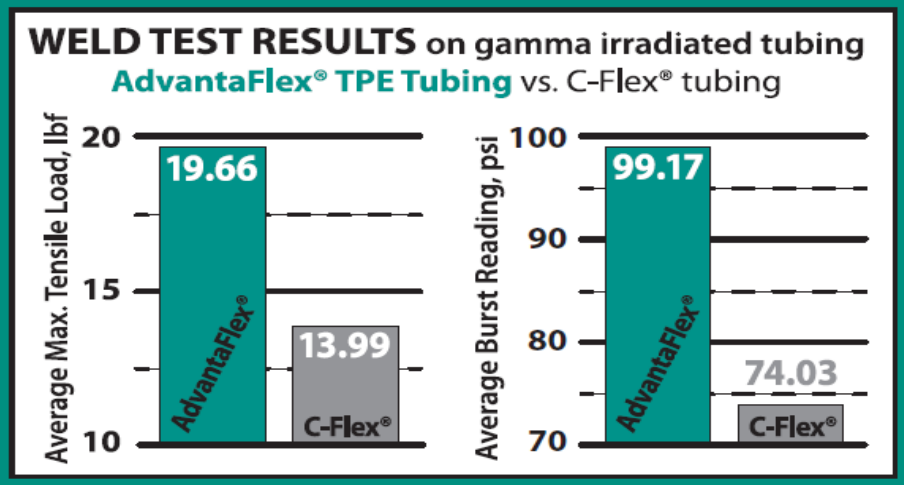
AdvantaFlex TPE Tubing

Get Better Weld Strength

with **AdvantaFlex®** tubing

Up to **40% stronger** than C-Flex® 374

Increase your **process security** by reducing the risk of failure at the weld. AdvantaFlex welds hold stronger than C-Flex® welds, providing a secure, **sterile boundary** to protect your investment.

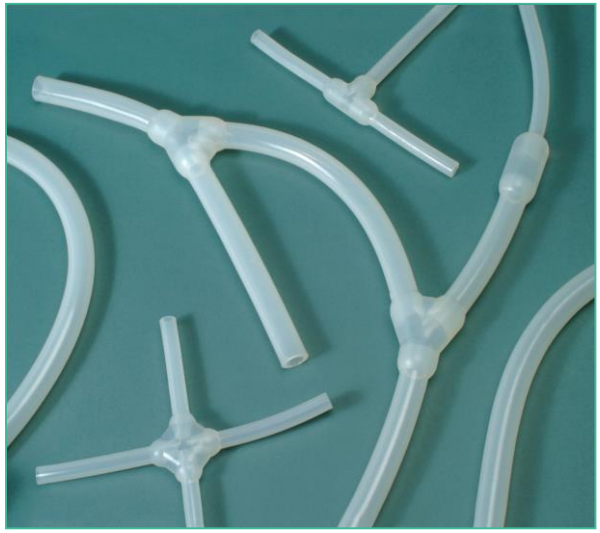


talk with us

AdvantaPURE® NEWAGE INDUSTRIES

Molded Products and Assemblies

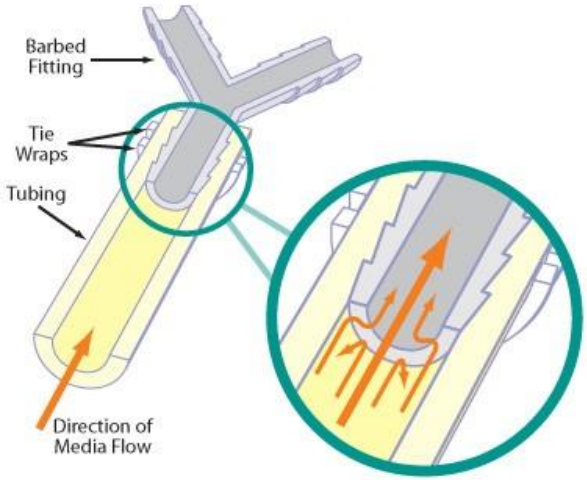
- Molded junctions (tees, wyes, reducers, crosses)
- Tri-Clamp Ends
- Closures (GL45, 38-430, 83B, Stoppers, Tru-Union)



SUS Integrity: Molded vs Barbed?

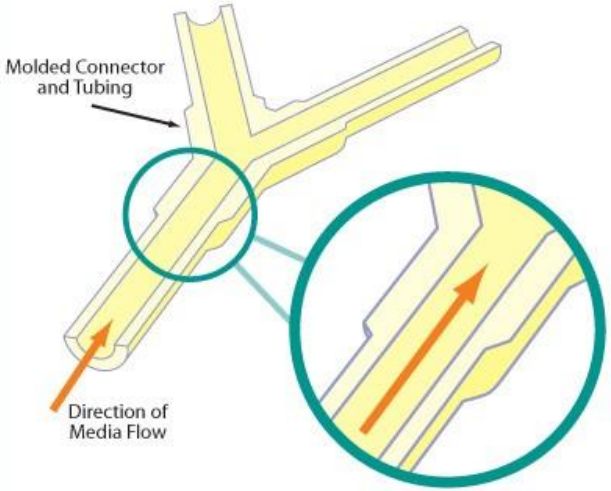
Comparative Advantages of Molded Manifolds

TUBING SET ASSEMBLY
USING BARBED FITTINGS



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

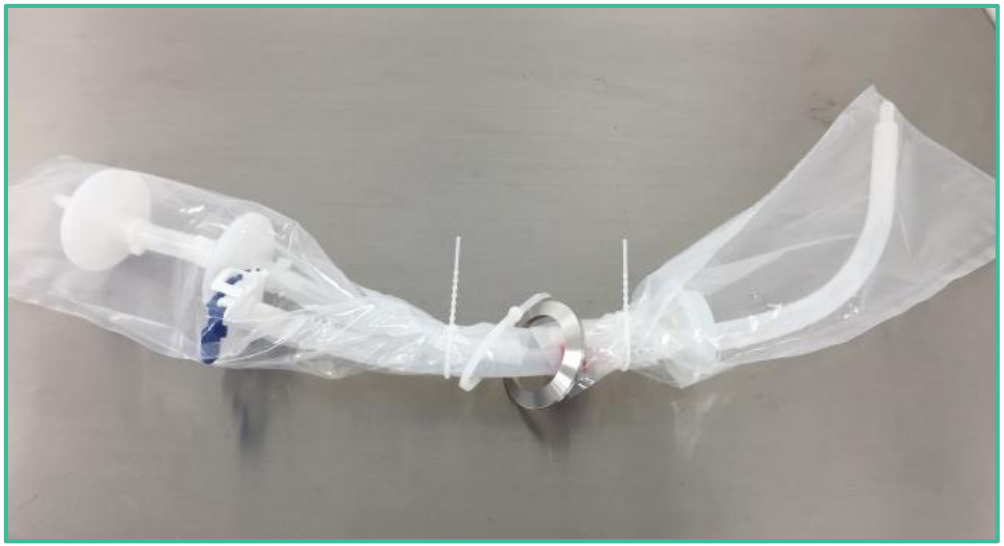
SINGLE MOLDED MANIFOLD
WITH MOLDED CONNECTIONS



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

Container Closure Case Study

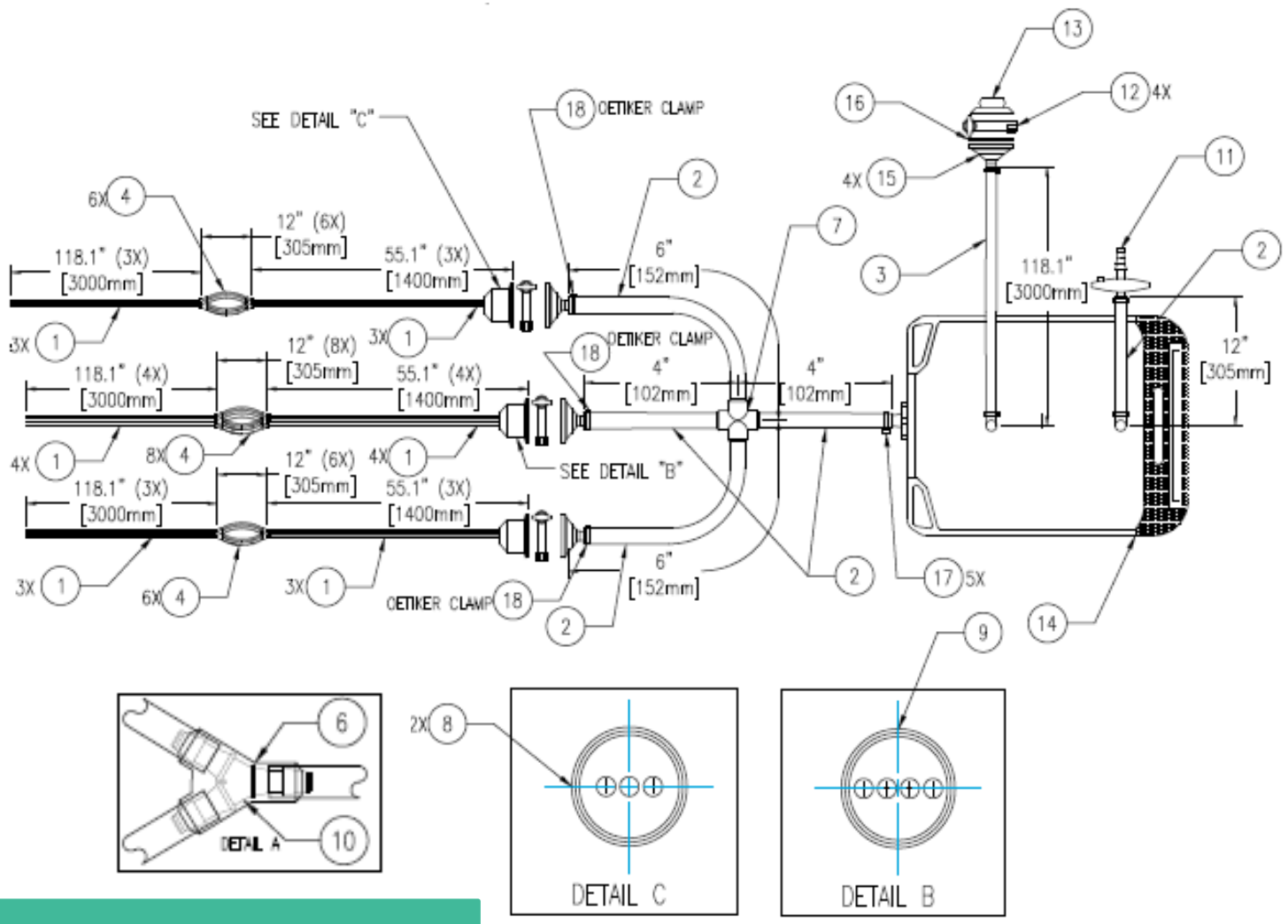
- **Facility**: Single Use Filling Line for Vaccines
- **Needs**: Single use fluid path assemblies and container closures for use in isolator environment. Closures necessary in 5L, 10L and 20L sizes and packaging must withstand VHP.
- **Solution**: AdvantaPure designed a custom closure and assemblies with specialized packaging that required sourcing of unique components to meet the customer's processing requirements.



Vial Filling Assembly Case Study

- **Facility**: Single Use Filling Line for Biologics
- **Needs**: 10 needle single use fluid path assembly for OPTIMA vial filler; tubing must be chemically compatible with product and m-Cresol
- **Solution**: AdvantaPure designed a custom bag and multiport tri-clamp assembly with overmolded pump elements out of AdvantaFlex TPE tubing that was chemically compatible

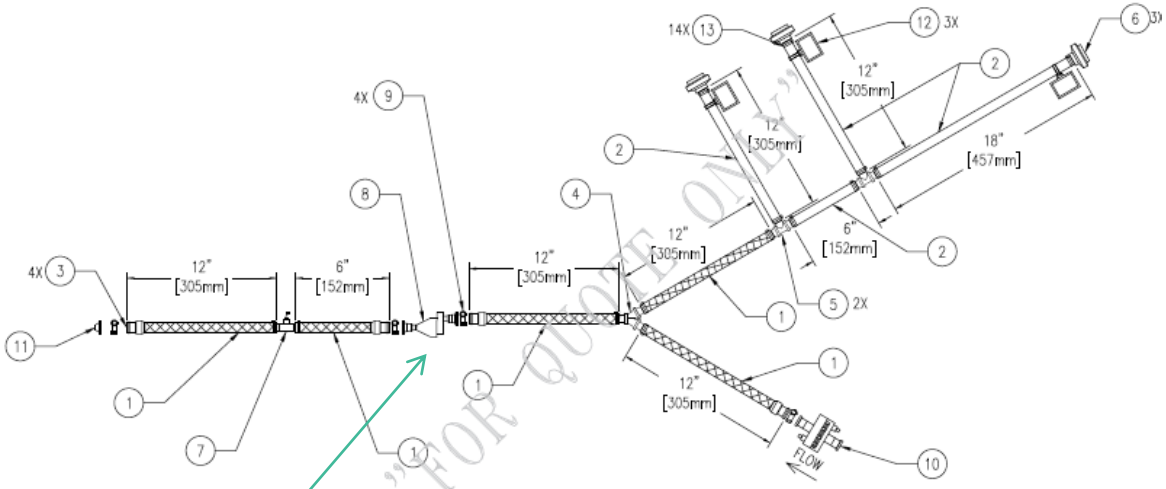
Vial Filling Assembly Case Study

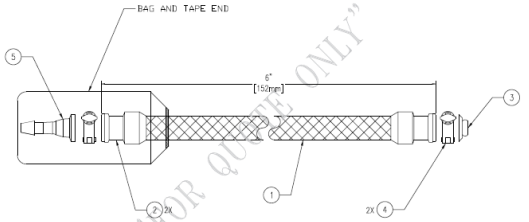


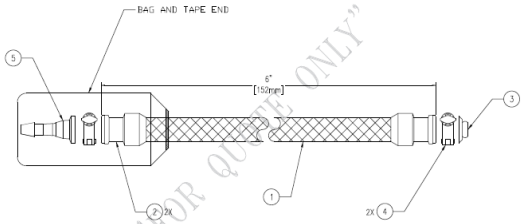
Sensor/Pump Kit Assembly Case Study

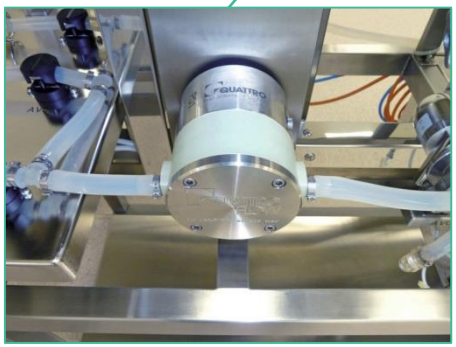
- **Facility**: Single Use Virus Filtration Kit for Biologics
- **Needs**: Single use assembly kit for 1m^2 and 4m^2 virus filtration system (Planova™)
- **Solution**: AdvantaPure designed a single use kit with flow meters, pressure sensors and pump head. Each assembly was labeled for easy identification and operator installation

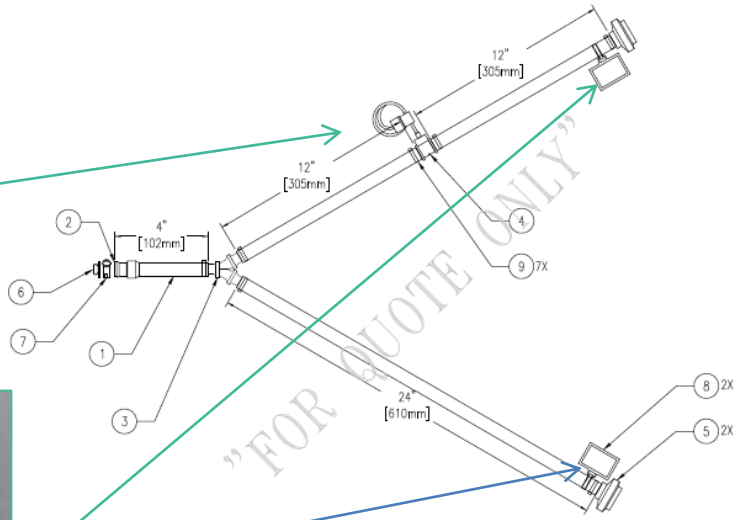
Sensor/Pump Kit Assembly Case Study





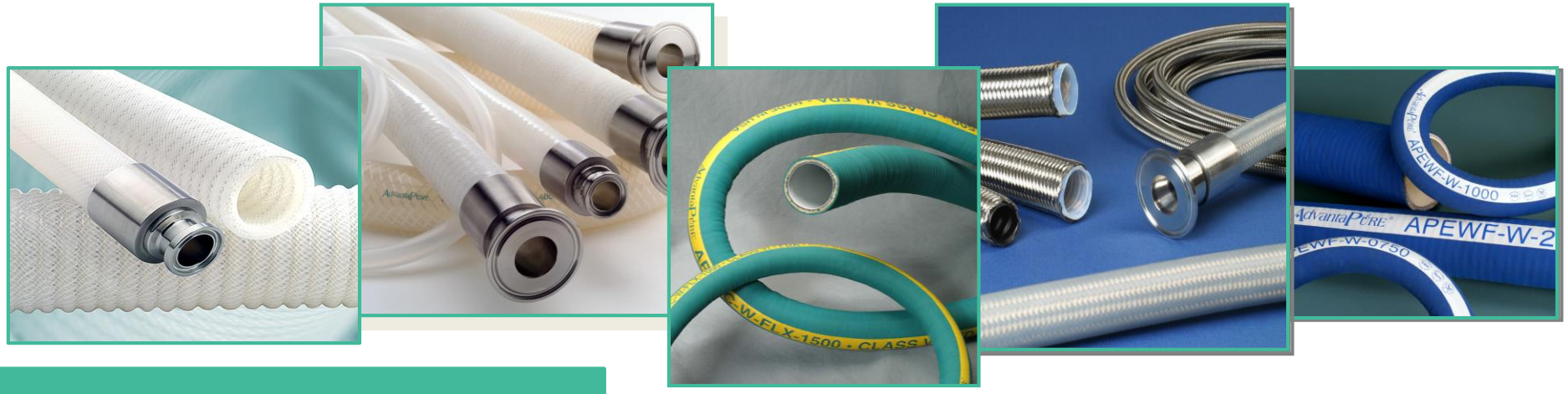






Process Hose

- APSH 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

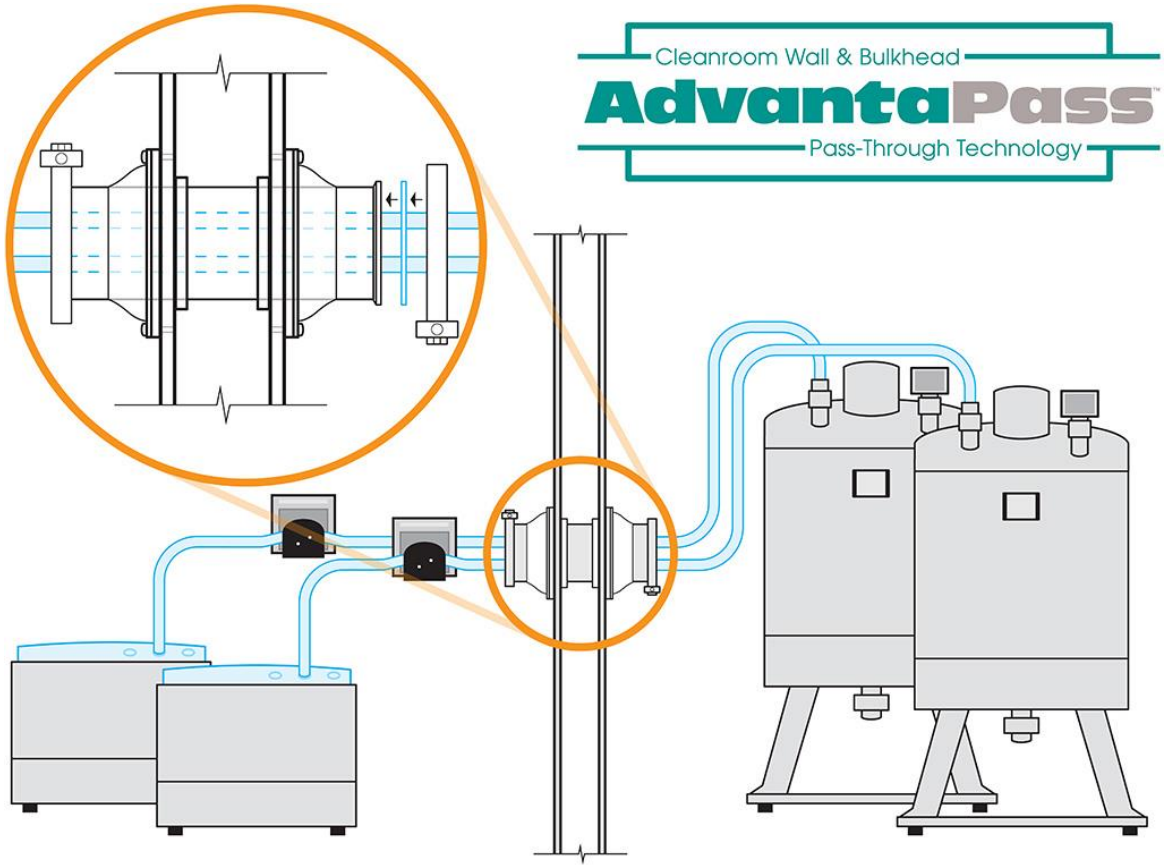


Identification Solutions

- **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

AdvantaPass™

Wall and Bulk-head Pass Through Technology



AdvantaPass™

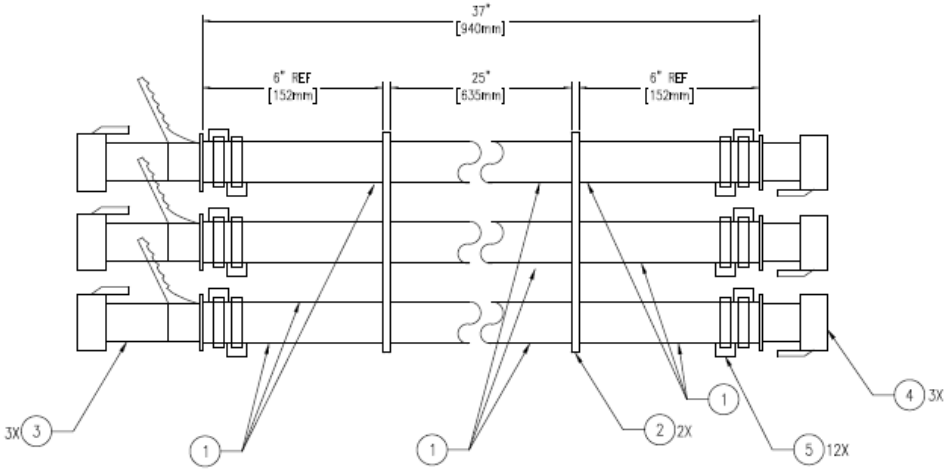
Wall and Bulk-head Pass Through Technology

- 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
- Portals available up to 8” in size

AdvantaPass™ Case Study

- Facility : Transfer Pass Through for Gene Therapy
- Problem: Looking for solution that maximized design flexibility, minimized transfer of bins, and could be used with multiple wall thicknesses in all unit operations.
- Solution: AdvantaPass 8” portal with 0.5” and 1” transfer lines
- Where: Used for fluid transfer in 3 areas,
  - Media Prep to Cell Culture
  - Buffer Prep to Chromatography
  - Chromatography to Viral Inactivation

AdvantaPass™ Case Study



NewAge® Industries/AdvantaPure®

Purity in Fluid Flow Systems℠

Thank You