



aSURE™ Instrument Tee Datasheet

SaniSure's aSURE™ Instrument Tees are designed specifically to enable the use of traditional reusable pressure gauges and transmitters in single-use applications while maintaining closed systems and isolating the reusable components from the fluid path. They are ideal for the most demanding process applications where accurate measurement is critical, and contamination cannot be tolerated. Better by design, aSURE™ Instrument Tees offer superior accuracy and ease of integration than other single-use pressure sensor solutions.

Simple, elegant and robust with industry-leading accuracy, aSURE™ Instrument Tees are the best pressure sensor solution for your process.

- Enables use of reusable pressure gauges
- Welded diaphragm isolates gauge from fluid path/ simple system closure
- Industry-leading accuracy from -30 in Hg to +60 PSI
- Standard calibration procedures
- Pressure gauge agnostic
- 100% leak tested
- Simplified integration
- Reduced environmental footprint
- Manufactured and packaged in ISO 7

Key Features & Benefits

Enables use of reusable pressure gauges:

- Industry-leading accuracy proven by NIST Qualified +/-X% accuracy—you can trust in aSURE™ Instrument Tees for your process control
- In-house calibration and recalibration eliminates dependency on supplier calibration certificates with expiration dates and allows the use of traditional in-house metrology with no new procedures.
- Works with any standard reusable pressure gauge or transmitter reducing change control.
- Standard pressure transmitters enable proven strategies for conformance to GMPs, 21CFR Part 11 and UL without signal drift or interference.
- Compress and de-risk project timelines by decoupling the process control decision from the single-use component decision.

Simple component with no embedded electronics.

- Simple design, made from well-known and well-characterized materials: Flint Hill P5M6K PP Body with SaniSure Cellgyn® or Pharma-line™ | diaphragm, simplifies implementation.
- Exempt from WEEE and RoHS regulations
- No electronics disposal reduces environmental impact.
- Robust, widely used, and well-known hose barb design for easy implementation by single-use integrators.
- Qualified operating temperature ranges from 0-135°C for use in any process.

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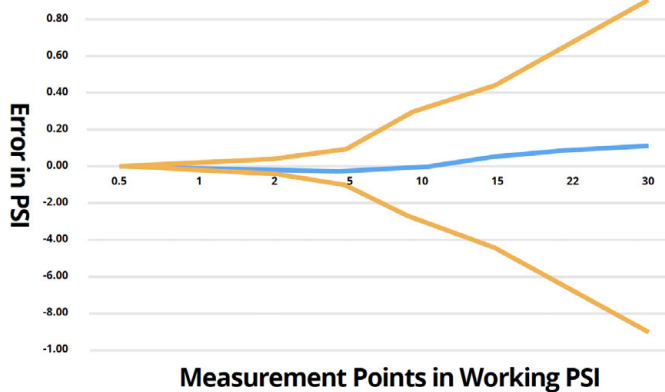
- Sterilizable by Gamma, Autoclave, EtO and compatible with typical sanitization chemicals to support a variety of process integration strategies.
- 2-year post-irradiation shelf life supports use in sterile assemblies.

aSURE™ Instrument Tees are available integrated into SaniSure® custom assemblies and as stand-alone components sold directly and through distribution partners.

Closed System Processing:

- Welded isolator membrane reduces the risk of process contamination.
- 100% leak tested during manufacturing ensures leak-free performance.
- ISO 7 manufacturing environment ensures clean components.

Superior Accuracy



Applications:

Pressure sensing for monitoring and control of single-use processes

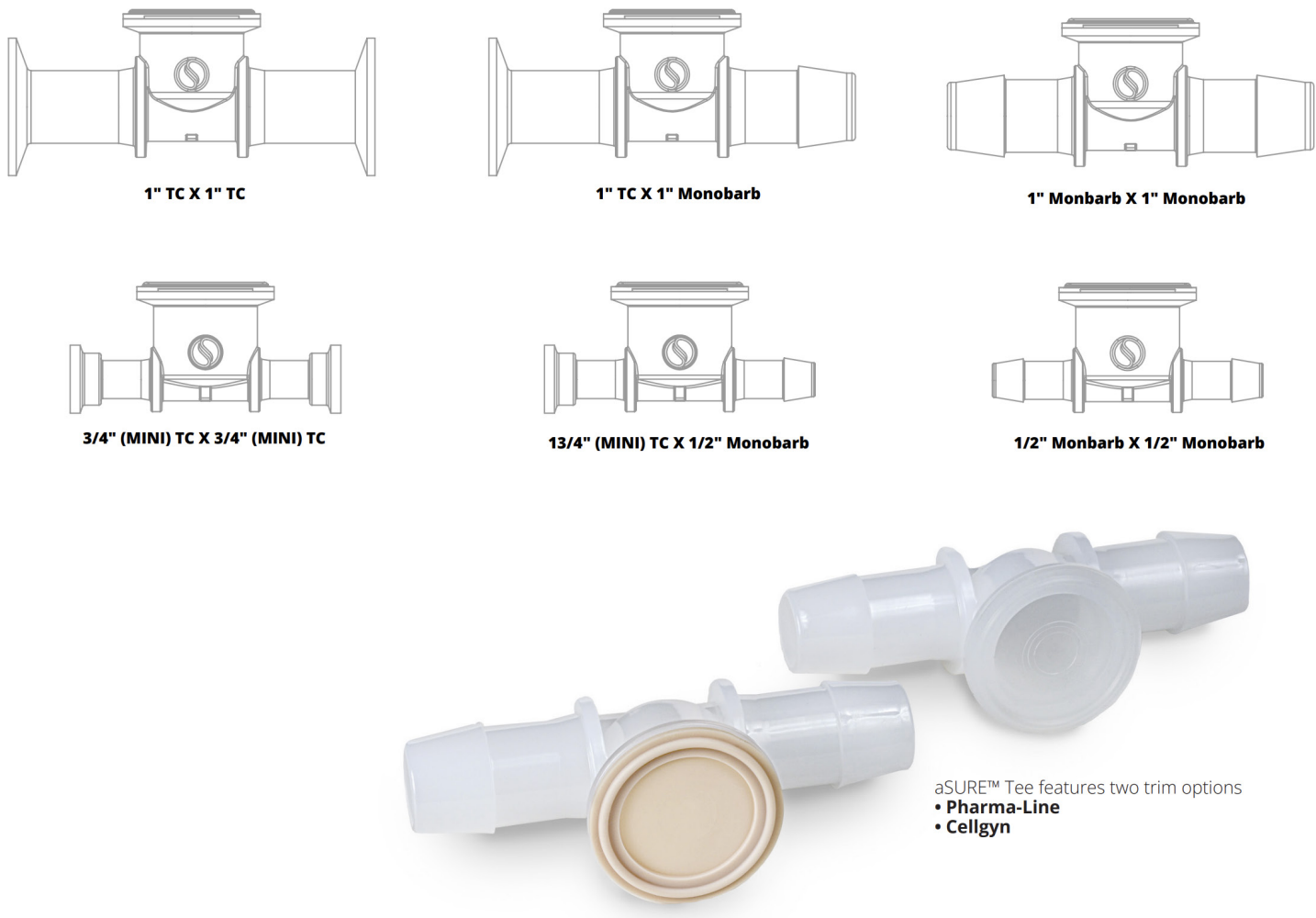
- Perfusion
- Clarification
- Chromatography
- Bioburden reduction filtration
- Tangential flow filtration
- Virus filtration
- Bioburden reduction filtration
- Sterile filtration

Qualification:

- Accuracy
- Biocompatibility
- Shelf life
- Sterilization compatibility
- Leak testing
- Pressure rating



A Broad Range of Configurations



aSURE™ Tee features two trim options

- Pharma-Line
- Cellgyn

Figure 1: This is a snip from the existing aSURE™ Brochure

Materials of Construction

aSURE™ Instrument Tee with Cellgyn® Diaphragm		aSURE™ Instrument Tee with Pharmaline™ 1 Diaphragm	
Body	Diaphragm	Body	Diaphragm
Polypropylene: Invista P5M6K	SaniSure® Cellgyn® TPE	Polypropylene: Invista P5M6K	Sanisure® Pharmaline 1TPV



Substances of Concern

Based upon our manufacturing processes and information provided by our resin suppliers, aSURE™ Instrument Tees do not intentionally contain any of the following substances:

- Bisphenol A (BPA)
- Nitroamines
- Latex
- PFAs
- Melamine
- Phthalates – Trace residual Phthalates may be present in Pharmaline 1 diaphragms
- ICH Q3C Residual Solvents
- Slip Agents
- Gluten
- Lactose

BSE / TSE Risk & Animal Derived Components

The resins used to manufacture aSURE™ are animal derived component free (ADCF) or undergo process conditions compliant with EMA/410/01 rev. 3.

In addition, no additives or manufacturing aids are introduced during the manufacture of the aSURE™ Instrument Tees.

Biocompatibility

The resins used in the manufacture of aSURE™ have been tested for biocompatibility according to USP and ISO testing requirements:

Body: Invista P5M6K PolyPropylene: USP <88> Class VI, ISO 10993-5

Diaphragm: SaniSure® Cellgyn® TPE or Pharmaline TPV: USP <87>, <88>/ Class VI, ISO 10993-5, 6, 10 & 11

Manufacturing Environment

Instrument tee injection molding, diaphragm molding, diaphragm fusion, and primary and secondary packaging are performed in ISO 7 conditions. The final pack out into lined cardboard cartons is performed in a controlled, non-classified space.

Quality Management System

aSURE™ Instrument Tees are manufactured in a facility with an ISO 9001-2015 certified quality management system.

Sterilization / Sanitization

aSURE™ Instrument Tees may be sterilized via gamma or X-ray irradiation with a maximum dose of 45 kGy, and via autoclave with a maximum temperature of 135°C. The materials used to manufacture aSURE™ Instrument Tees are compatible with ethylene oxide gas sterilization and typical high pH sanitization solutions.

Shelf Life and Storage Conditions

The shelf life of non-sterile aSURE™ Instrument Tees is 5 years from the date of manufacture. The shelf life of aSURE™ Instrument Tees sterilized by gamma irradiation is 2 years from the date of sterilization or 5 years from the original manufacturing date, whichever is shorter.



Ordering Information:

aSURE™ Instrument Tee/ Cellgyn® Diaphragm		aSURE™ Instrument Tee/ Pharma-Line™ Diaphragm	
Description	Part Number	Description	Part Number
aSURE Instrument Tee polypropylene W/ Cellgyn Diaphragm 1/2" Monobarb each end	IT24-CGN-08M08M	aSURE Instrument Tee polypropylene W/ PHI Diaphragm 1/2" Monobarb each end	IT24-PHI-08M08M
aSURE Instrument Tee polypropylene W/ Cellgyn Diaphragm 1/2" Monobarb X mini TC	IT24-CGN-08M08T	aSURE Instrument Tee polypropylene W/ PHI Diaphragm 1/2" Monobarb X mini TC	IT24-PHI-08M08T
aSURE Instrument Tee polypropylene W/ Cellgyn Diaphragm 1/2" Monobarb X mini TC each end	IT24-CGN-08T08T	aSURE Instrument Tee polypropylene W/ PHI Diaphragm 1/2" mini TC each end	IT24-PHI-08T08T
aSURE Instrument Tee polypropylene W/ Cellgyn Diaphragm 1" Monobarb each end	IT24-CGN-16M16M	aSURE Instrument Tee polypropylene W/ PHI Diaphragm 1" Monobarb each end	IT24-PHI-16M16M
aSURE Instrument Tee polypropylene W/ Cellgyn Diaphragm 1" Monobarb X 1" TC	IT24-CGN-16M16T	aSURE Instrument Tee polypropylene W/ PHI Diaphragm Monobarb X 1" TC	IT24-PHI-16M16T
aSURE Instrument Tee polypropylene W/ Cellgyn Diaphragm 1" TC each end	IT24-CGN-16T16T	aSURE Instrument Tee polypropylene W/ PHI Diaphragm 1" TC each end	IT24-PHI-16T16T

SaniSure® is known for developing custom solutions by listening closely to our customers' unique needs. If you don't find the exact connection you're looking for, contact us —we'll work with you to develop it.

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