Characterization
The biocompatibility of Sani-Tech platinum-cured silicone tubing manufactured with Sani-Tech silicone has been tested and validated for the following:

- USP Class VI (88) biological reactivity, in vivo
  - Intracutaneous test
  - Systemic injection test
  - Implantation test
- USP 87 biological reactivity, in vitro
  - L929 MEM elution
  - AGAR diffusion
- USP 381 elastomeric closure for injection
- USP 661 containers
- USP 151 pyrogen test
- European Pharmacopoeia 3.1.9
- USP limits for total organic carbons
- Gamma irradiation
- Infrared analysis
- Heavy metals
- ISO 10993

Sani-Tech TA Tubing Assemblies

Sani-Tech® TA Tubing Assemblies offer a comprehensive array of sizes and lengths to suit a variety of connectivity needs. Utilizing Saint-Gobain’s Smooth Inner Bore (SIB®) technology, Sani-Tech TA eliminates entrapment areas and the need for tube clamps or tie wraps while providing leak-free connection points.

Characteristics
End users can specify from a standard product offering of Sani-Tech TA Tubing Assemblies, ranging from 1/8” to 1” ID. Sani-Tech TA Tubing Assemblies are available in either Sani-Tech STHT®-C non-reinforced silicone tubing or Sani-Tech STHT®-R braid-reinforced silicone hose for elevated pressure applications.

Biocompatibility
Sani-Tech TA Tubing Assemblies are manufactured from the finest grade of platinum-cured silicone materials and are fully validated and tested to a variety of specifications including USP Class VI criteria, ISO 10993 and European Pharmacopoeia 3.1.9. For additional compliance data, please review characterization information on the back page.

Sterilization Methods
- Autoclavable
- Radiation — up to 5.0 Mrad (50 Kilogram)
- Gas — ethylene oxide

NOTE: Sani-Tech silicone tubing will not deteriorate with repeated autoclaving. This method of sterilization is strongly recommended. Sani-Tech silicones should not be considered for consistent steam applications.
Features/Benefits

- Ultra-pure, biopharmaceutical grade silicone materials
- Unsurpassed surface smoothness
- Eliminates entrapment, leak points and pulsation, assembly time and fitting connections
- Ready-to-install system in sizes from \( \frac{1}{8} \)" to 1" in standard lengths from 6" to 120"
- 3/4" mini or 1 1/2" large sanitary ends
- Polysulfone or stainless steel back-up cups
- Choose from either STHT-C non-reinforced silicone tubing or STHT-R braid-reinforced silicone hose for elevated pressures
- Manufactured in an ISO Class 7 certified clean room

Typical Applications

- Closed single-use systems
- Sterile filling
- Peristaltic pumps
- Filtration and fermentation
- Sampling
- Drug delivery and discovery

Customization available; contact your District Sales Manager or Customer Service.

Sani-Tech® PRODUCTS ARE NOT INTENDED FOR USE AS AN IMPLANT MATERIAL

IMPORTANT: It is the user’s responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

For a period of 12 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized. Saint-Gobain Performance Plastics Corporation assumes no obligations or liability for any advice furnished by it, or for results obtained with respect to those products. All such advice is given and accepted at the buyer’s risk.