

INSIGHTS FROM MOLEX

**The Advantages of  
Pure Fused Silica Capillary Tubing  
in Medical Applications**

**BY: JOE MACOMBER AND KEVIN O'CONNOR**

# The Advantages of Pure Fused Silica Capillary Tubing in Medical Applications

## INTRODUCTION

A wide range of medical devices incorporate tubing for the controlled delivery of therapeutic agents. Other devices employ capillary for mass flow control of ancillary fluids and gases where the rate of delivery is of critical importance to the particular medical procedure. Table 1 provides an abbreviated list of tubing applications in the medical arena. Selection of the most appropriate tubing substrate is a fundamental medical device design concern. Key attributes to consider often include items such as material composition and characteristics, surface inertness, biocompatibility, dimensional repeatability, flexibility and cost contribution per device. Of equal importance is the need to have a tubing material which allows efficient, timely prototyping with minimal capital investment, production scalability, long term sourcing stability and efficient product evolution. Pure fused silica capillary tubing realizes these, and numerous other advantages, making it ideal for a wide range of medical applications.

Fluid Delivery & Aspiration Systems	Infusion Pumps
Drug Delivery and Control	Blood Sampling and Testing
Catheters	Dialysis
Oxygen/Anesthetic Gas Delivery	BBB Specific Systems

Table 1: Tubing in Medical Applications

## What is Fused Silica?

Pure fused silica capillary is manufactured by drawing high purity, preform substrates into linear capillary tubing (1). The preform substrates are synthesized from high purity Silicon tetrachloride by the reaction shown in Equation 1 below, yielding pure silicon dioxide ( $\text{SiO}_2$ ) glass:



Silicon dioxide is the purest of all glass materials, with metal ion content in the sub-ppm level. This results in a non-catalytic, low corrosion surface when compared to metallic tubing materials. As shown in Figure 1, an outer protective, abrasion resistant coating is normally employed, with the coating selected based on application requirements.

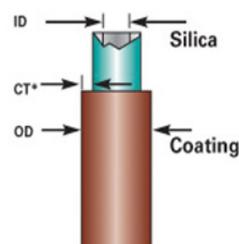


Figure 1: Schematic of Fused Silica Capillary Tubing

Polyimide is often the coating of choice as it offers excellent abrasion resistance even when applied in thin layers. ISO-10993 biocompatibility for polyimide over fused silica is available, with NAMSA employed for all testing. Unique coating properties can be achieved by mixing additives to the coating resin prior to curing, with radio opacity being a leading example. For the purposes of this discussion, polyimide coated fused silica capillary tubing will be considered.

Capillary is very strong and flexible

- tensile strength: ~700 kpsi

Mirror smooth interior surfaces

- rms: < 7 nm

Inert surfaces and high purity

- metal ion content: < 0.2 ppm

Wide range of internal diameters

- standard items down to 2  $\mu\text{m}$

A range of end face finishes

- perpendicularity: < 3°

Table 2: Key Mechanical Attributes

## What makes Fused Silica Capillary Unique?

Mechanically, pure fused silica offers several unique attributes, the highlights of which are outlined in Table 2. In addition to the above attributes, fused silica tubing has an excellent combination of flexibility and memory. As with most materials, flexibility is size dependent. Tolerance control is unmatched when compared to other commonly employed medical tubing options. For example, 50  $\mu\text{m}$  i.d. capillary can be produced to a tolerance of  $\pm 1 \mu\text{m}$ . The combination of tight tolerances and mirror-like surfaces makes capillary tubing ideal for precision flow control in medical devices. The surface inertness maximizes viral and protein activity retention during delivery of such therapeutics. The strength and flexibility make fused silica capillary ideal when routing through catheters or for compact designs in wearable medical drug delivery devices. Laser machined end faces have proven performance in reducing nucleation of dissolved gases. When less demanding end face prep is required, fused silica can be easily cleaved or cut to length. The automation of the cutting processes is well understood and can be appropriately implemented as production volumes scale up.

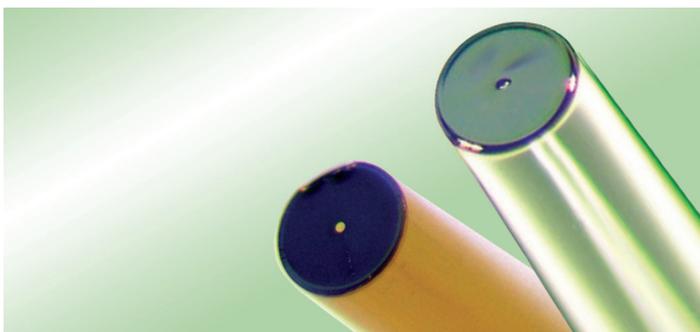


Figure 2: 20 $\mu\text{m}$  i.d. Fused Silica Capillary

## Fused Silica Design Advantages

Design advantages of fused silica capillary tubing are numerous. Among the more important advantages are the availability of off-the-shelf products for early stage prototyping, flexibility for specification changes during the design cycle, efficient scalability into full scale production, and proven performance in the application space.

Pure fused silica has a long history in the analytical and clinical sciences across a broad range of applications. As a result a wide variety of standard products are available, including over 70 stock items ranging in internal diameters from 2  $\mu\text{m}$  up to 750  $\mu\text{m}$ . With two primary outer diameter series (i.e., 150  $\mu\text{m}$  and 363  $\mu\text{m}$ ), rapid prototyping and testing are quick and cost effective. For example, fused silica tubing with a polyimide outer diameter of 363 $\mu\text{m}$  is available with 15 different internal diameters. This offers significant advantages in prototyping and system optimization. For a fixed set of experimental conditions and using capillary tubing of the same length and outer diameter, the flow rate can be varied over 6 orders of magnitude by simply employing different i.d. of stock capillary.

For those instances when a standard i.d. and tolerance do not meet the exact design needs, rapid prototyping of custom sizes and tolerances can be performed. In most cases the same raw materials are employed, so no delays from materials sourcing are incurred. As the manufacturing process allows for easy adjustment of the dimensional parameters, lead times are typically short and nonrecurring engineering charges are rarely required. In those instances where i.d. tolerances are minimized to reduce flow resistance variance, more frequent verification of dimensional parameters is required. Production of custom, unique cross sectional geometries (i.e. square or rectangular) is not uncommon. This is facilitated with an on-site glass fabrication laboratory.

Scalability is always of interest as products transfer to full production during market launch. In drawn fused silica products, prototype tooling used at the design

stage is directly convertible to high volume production; no additional tooling or capital is need in most cases. The same systems are used whether drawing a 100m prototype quantity or manufacturing kilometer volumes. Obsolescence of parts over the lifetime of the medical application is rare at best. For all practical purposes the unique tooling for dimensional control when drawing fused silica capillary would be considered non-perishable. Added value operations such as cutting, cleaving and packaging can be automated as required on a case- by- case basis.

Evidentiary data on the use of fused silica capillary in medical applications can be found in the literature. The leading application is flow rate management in therapeutic delivery devices. Of keen interest are those applications which require precision flow control, ultra-low flow rates, and those requiring low memory, highly flexible capillary tubing. Small diameter, precision controlled tubing is extremely well suited for such applications, with recent efforts on blood brain barrier systems being an area of burgeoning interest (2,3). Wearable drug delivery systems often incorporate one or more pieces of fused silica capillary as a component for delivery control.

### Fused Silica versus Metal and PEEK Tubing

In an effort to better understand some of the key attributes of fused silica capillary, a series of comparisons is offered. Materials of similar dimensions were considered. These included 304 stainless steel hypodermic tubing 33Ga (i.e. HTX-33R) with 107 $\mu$ m i.d., extruded PEEK capillary (i.e. IDEX 1571) with 100 $\mu$ m (i.d.), and polyimide coated fused silica (i.e. Polymicro TSP100375) with 100 $\mu$ m i.d. Figure 3 summarizes the comparative tensile strengths of these materials. Fused silica capillary exhibits outstanding tensile strength due to its high purity, with this strength maintained by an abrasion resistant coating and proper handling techniques. Figure 4 below offers a comparison of both i.d. tolerances in micrometers, as well as material surface finish expressed as average roughness in nanometers. The tolerance values are from published capabilities information on standard product offerings.

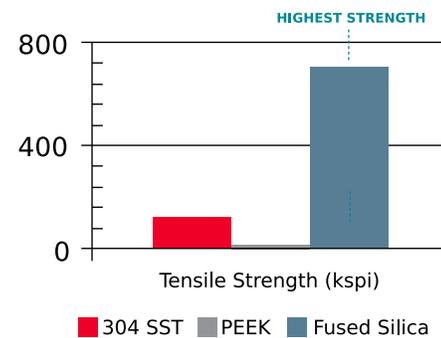


Figure 3: Comparison of Tensile Strength

From a flow rate control perspective, the i.d. tolerance differences are strikingly in favor of employing fused silica capillary. This is a critical factor to consider when attempting to design and implement flow rate control systems for drug delivery. Based on i.d. tolerances of comparatively sized tubing, fused silica capillary can offer flow rate variances that are easily an order of magnitude less than either PEEK or stainless. Further to this is the contribution of surface finish on the flow rate, wherein the most repeatable, predictable flow rates will be found when surface finish contributions are minimized. On a related surface finish topic, surface reactivity influences and apparent inertness is typically related to overall surface area. The smoother a surface is the lower the surface area and, therefore, the lower the net reactivity of the material. The combination of high strength, exacting i.d. tolerances, and unmatched surface finish separate fused silica from other commonly employed tubing materials, especially in the area of flow rate control systems.

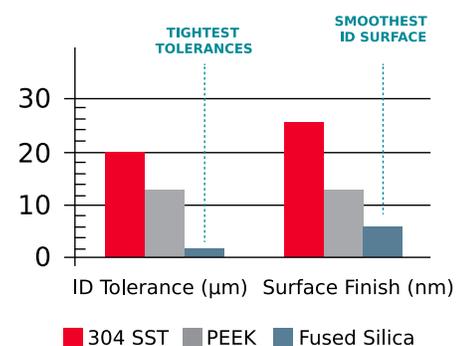


Figure 4: i.d. Tolerances and Surface Finishes

Other related concerns when selecting a material type include corrosion, UV resistance, moisture impact and shelf life. Stainless steel, by its nature, has a reactive surface and when exposed to moisture, corrosion is always a concern. Shelf life can certainly be impacted by this issue, so extra care must be taken to keep materials dry during storage. PEEK is excellent with respect to corrosion, and although it can absorb moisture, it is considered to have limited reactivity issues. PEEK, being a polymeric material suffers from memory. It is often supplied in coils and for many applications it must be physically straightened prior to use to avoid obvious splay issues in manufactured devices. As with most polymers, UV degradation is of concern. Fused silica avoids many of these issues. It has excellent memory, low reactivity surfaces. Although the glass surface can absorb water, it is of little consequence as most medical devices are used to transport aqueous based therapeutics. Fused silica has demonstrated excellent shelf life, with tensile strength dropping only marginally after 20 years under typical storage conditions.

## Conclusion

Capillary tubing is an ideal substrate for many medical applications due to its flexibility, high strength, surface inertness and mirror-like interior surface. Rapid prototyping and ease of scalability to volume production without incurring significant capital investment makes it an attractive, cost effective materials solution. As it can be drawn to exacting tolerances and in internal diameters well below anything currently achievable with other tubing materials, fused silica capillary offers unsurpassed design advantages.



(1) "Drawn Glass and Glass Tubing", *The Book on the Technologies of Polymicro*, Polymicro Technologies Publication, p 1-3, (2011).

(2) M.T. Krauze, J. Forsayeth, J.W. Park, & S. Bankiewicz, *Pharmaceutical Research*, Vol. 23, No. 11 Nov 2006 pp 2493-2504

(3) A.S. Beutler, *Molecular Therapy* vol. 18 No.4 April 2010 pp 670-67