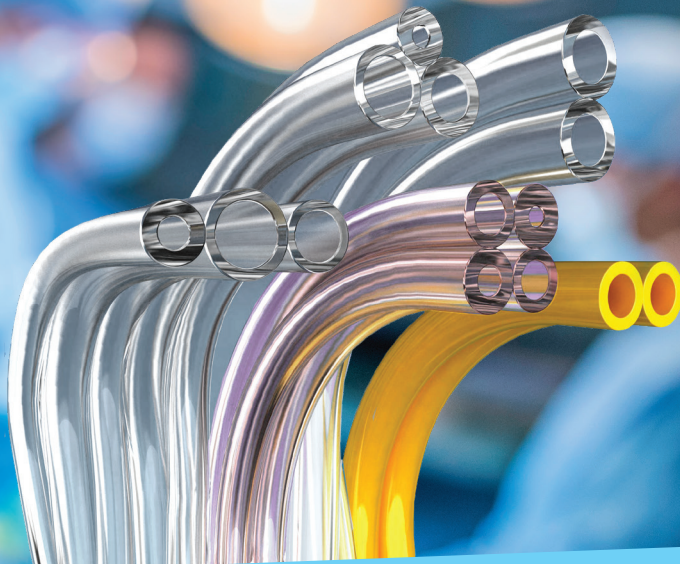




## Consistent quality through advanced materials science

How TekniPlex Healthcare stepped in to create superior tubing components for a life-saving medical device that improved patient outcomes



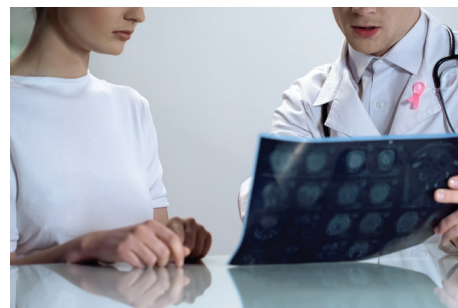
## A DANGEROUS DISCONNECT

A leading manufacturer of breast biopsy devices was experiencing quality control issues with its paratubing supplier, leading to a variety of mission-critical concerns. On the manufacturing side, the company was suffering costly production slowdowns. More troubling, on its end-customer side, the challenging tubing component was causing the safety of the overall device to be called into question. These issues prompted unacceptable levels of product rejects from surgeons and other medical personnel utilizing the devices on the front lines.

For this breast biopsy device, the paratubing – also known as peel-apart or bonded tubing – was a four-tube configuration, with individual tube lines employed for suction, site irrigation, medicinal delivery, and light source access. The paratubing difficulties fell into two distinctly detrimental categories: (1) inconsistent inter-tube bond strength, and (2) inconsistent dimensional tolerances.

The former, inconsistent bond strength between tubes, was trickling down into several sub-issues. When the inter-tube bond was too high, tubes were frequently being damaged during the separation process. While most of the resulting flaws were caught during end-of-line inspection, the resulting materials waste from rejects had a negative impact on cost, production speed, and order fulfillment – adversely impacting both the company and its customers.

On the other hand, tubes bonded at too low a strength level are far more likely to disconnect prior to use, leading clinicians or surgeons to summarily – and embarrassingly – reject them.





Worse still, often the more subtle tube damage – such as so-called “chatter marks” on tube walls – were exceedingly difficult to inspect and reject. Those units that found their way into the device posed the risk of fluid leaks or suction loss during the biopsy procedure, as the connectors could not be sufficiently solvent-bonded. For patients, tube failure could lead to an unnecessarily lengthy time under anesthesia, as a new tubing set would need to be set up. Tube failure during the procedure itself could also lead to elevated post-operative discomfort or pain.

As if that wasn't worrisome enough, the second scenario – inconsistent inner and outer diameter tolerancing and concentricity – had an even poorer outcome. Issues with incompatible inner (ID) and outer (OD) diameters can lead to connector fit issues that pose serious risks for fluid leaks or suction loss during the procedure.

The status quo simply could not stand. Components for any medical device must be precisely manufactured to ensure reliable functionality and premium performance. This vital breast biopsy device, screening for the most common form of cancer in the world, certainly was no exception to that rule.

## A DELICATE BALANCE FOR A CRITICAL PURPOSE

Several methods exist for bonding tube lines together to create paratubes, which can be manufactured in a wide variety of configurations. Some processes, while comparably inexpensive, are more prone to consistency issues in the final product.

As in other manufacturing processes, there is a tight and strict process window. For paratubing

applications to perform reliably, the inter-tube bonds must not dip below 0.22 pounds of pull force, nor must they exceed 1.5 pounds. Tubes falling short of the lower threshold are apt to fall apart under little or even no tension, while those subjected to excessive pull force are likely to incur damage during separation.

Unfortunately, the existing paratubing supplier was utilizing a subpar, less-costly manufacturing process in which controlling the bond force between tubes was overly challenging, and the undesirable consequences were all too evident. It was one thing to cut costs – but quite another to do so at the expense of quality.

Not only was the manufacturing work itself inadequate, but the documentation of that work was lacking as well. In addition to an inferior production process, the existing supplier did not perform internal validation exercises to ensure its paratubing products could consistently maintain the required end-customer specifications. This resulted not only in poor product quality, but a lag or even total failure in properly identifying these inherent flaws.

## SAVING LIVES – AND REPUTATIONS

The manufacturer of the breast biopsy device turned to the team at TekniPlex Healthcare to upgrade both the process and, through it, the product. The first hurdle was reining in the errant tube bonding.

TekniPlex Healthcare quickly developed a paratubing solution with a consistent bond between 0.22 and 1.5 pounds of pull force. Further, since TekniPlex Healthcare is a vertically integrated supplier of both compounds and tubing, the team was able to recommend a far more suitable PVC compound for the device. Product formulation specialists proposed a compound that optimized the extrusion process for a consistent quality paratubing solution that would:

- **Reduce pre-operative device rejects**
- **Improve patient safety**
- **Lower overall manufacturing costs**

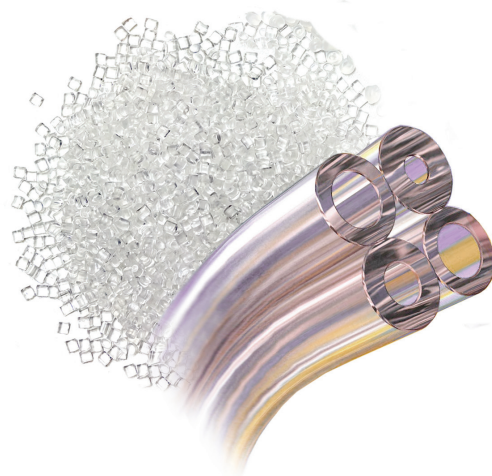




TekniPlex Healthcare also provided full validation of inter-tube bond strength, as well as proof of inner and outer dimension (ID & OD) consistency. This quality control protocol ensured that the performance of the paratubing product tested during design stages of the medical device would be repeatable when full-scale manufacturing began.

The paratubing solution designed by TekniPlex Healthcare allowed the breast biopsy device manufacturer to offer a safer product... one designed to restore confidence among healthcare personnel while decreasing patient risk. Manufacturing costs also were reduced – primarily through less wasted and/or rejected product, and partly through the elimination of an additional inspection step put in place to address the initial supplier's persistent paratubing problems.

In short order, surgeons and clinicians utilizing the device noticed far less tubing-centric issues, leading to a much-needed image boost in a sector where quality is paramount and reputation is invaluable. The device manufacturer has since broadened its overall market share in the life-saving niche of breast cancer screening and diagnosis.



## ABOUT TEKNIPLIX HEALTHCARE

TekniPlex Healthcare deploys world-class material science expertise to deliver value in creating products for medical devices, diagnostics, and drug delivery. With a deep understanding of the needs of end-users, our offerings ensure we provide innovative solutions at the point of patient care. For more information about TekniPlex Healthcare and our solutions, visit [www.Tekni-Plex.com/healthcare](http://www.Tekni-Plex.com/healthcare).