

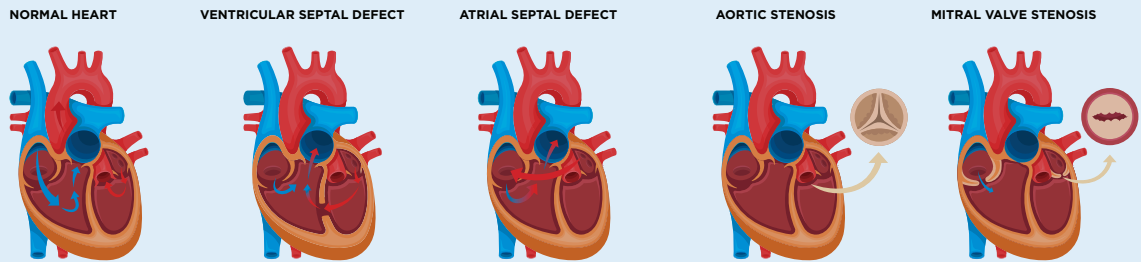
Structural Heart Catheter Construction

Increasing yields and improving safety on the production line.

Thanks to advances in minimally invasive catheter-based procedures, structural heart diseases are now often treated through endovascular therapy. However, manufacturing structural heart catheters is not without its challenges, particularly when it comes to the final stage in production, the removal of heat shrink. The typical method of using a skiving tool or razor blade can be dangerous for operators and cause critical damage to nearly complete catheter devices on the production line.



Market:	Medical Device
Sub-Market:	Structural Heart
Process:	Heat Shrink Removal
Challenge:	Razor Blades on the Production Line
Category:	Catheters
Zeus Product:	FluoroPEELZ™



Treating Structural Heart Diseases

Structural heart diseases involve abnormalities to the heart's anatomy, including the heart chambers, valves, and pockets. These abnormalities can lead to sudden cardiac arrest, stroke or heart failure.

Structural heart disease can be present at birth, but it can also develop later in life. As the patient ages, symptoms often get worse, and complications become more likely.

Open heart surgery was once the only treatment option available to structural heart patients. But today, endovascular treatment has evolved sufficiently to treat structural heart disease using minimally invasive catheter-based procedures.

At least one in eight people over the age of 75 have moderate to severe structural heart disease*. It's therefore a key focus for medical device OEMs globally to produce the catheters relied upon in many structural heart procedures.

1 in 8

More than one in eight individuals 75 years or older have a moderate to severe structural disease.

*Source: ncbi.nlm.nih.gov/pmc/articles/PMC5351823/

Bonding Material Layers with Heat Shrink

Heat shrink is a vital component used during the structural heart catheter construction process.

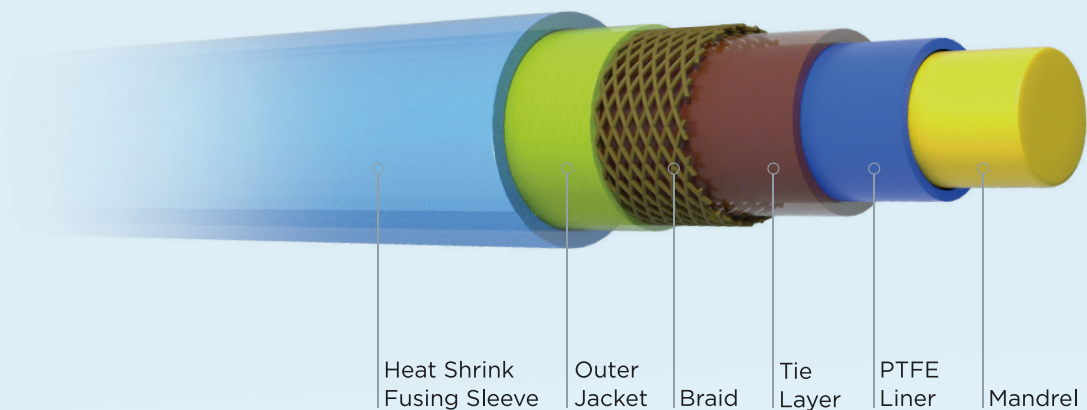
Used over nylon or Pebax®, heat shrink encapsulates the underlying jacketing while heat is applied to the outer layer. This heats the underlying jacketing material, allowing the jacket to reflow through the braiding and bond to the liner. The catheter base liner, braiding, and jacketing are now securely bonded together.

The final step is to remove the heat shrink from the outer shaft of the almost finished catheter.

A skiving tool containing a razor blade is typically used to remove the heat shrink. This is a time-intensive process where the operator manually applies the blade to the catheter to shave off the heat shrink layer before disposing of it. Only then is the catheter ready for sterilization and packaging.

This is a critical manufacturing step, but it is a laborious and troublesome procedure for production line operators.

The material layering approach used in catheter construction:



Skiving Tools Lead to Catheter Damage

Using a skiving tool and razor blade to shave the heat shrink away from the catheter poses many process and safety challenges.

Critical damage to the catheter is incredibly common.

When an operator uses a skiving tool to shave the heat shrink away, it's easy to accidentally cut too deep. This can perforate the catheter layers below and cause critical damage, rendering it useless. The catheter must be scrapped.

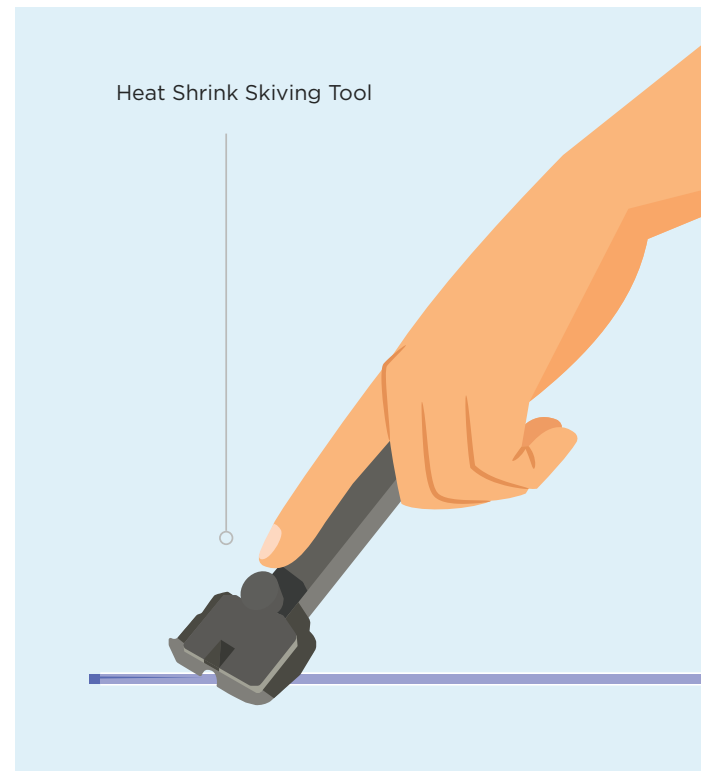
Not cutting deep enough into the heat shrink is also fraught with problems. Without a clean removal, the catheter and heat shrink must be forced apart. Excessive handling can easily lead to catheter damage such as snapping, damage to the surface, or delamination. Again, the catheter must be written off.

Disposing of almost complete catheters is expensive. At this point, the device has gone through many costly manufacturing steps, which must be re-started. Productivity takes a nose-dive and customers could face delayed delivery (or worse still, defection to a competitor).

Manual processes are also time-consuming. Simply put, the use of a skiving tool and blade takes time, which increases the cost of production, regardless of the damage risk.

And finally, using razor blades on the production line presents a serious safety risk. Even a trained operator can easily injure themselves, especially when trying to work at speed.

Whilst catheter technology has advanced, the removal of heat shrink in many production settings has not. It's clear that an effective, safer alternative to skiving with a razor blade is required.



IT'S FINALLY HERE

FLUOROPEELZ™ PEELABLE HEAT SHRINK

A peelable heat shrink that speeds up production, increases yield, and improves safety – removing skiving tools and blades from catheter manufacturing for good.

Instead of painstakingly skiving heat shrink away with a blade, simply peel off FluoroPEELZ™ heat shrink from the catheter shaft in seconds.

Using the FluoroPEELZ™ slit fixture on the end of the heat shrink, just peel it back and fully remove it from the catheter in one quick motion.

Higher Yields

OEMs are anecdotally reporting manufacturing cost savings of 10 - 15% when using FluoroPEELZ™. Fewer damaged catheters are scrapped, resulting in increased yields.

Faster Production

Heat shrink can be removed in a matter of seconds, dramatically reducing the overall time it takes to produce a catheter.

Improved Safety

Operators work in a safer environment with no risk of injury. Skiving tools can be completely removed from the production line.

FEATURES

FluoroPEELZ™ Peelable Heat Shrink

Fully Encapsulated Blade

With its fully encapsulated blade, the FluoroPEELZ™ slit fixture allows operators to safely create a precise linear tear, where they can then quickly and easily peel away the heat shrink from the structural heart catheter.

High Optical Clarity

Because the heat shrink material is clear, it's much easier to spot defects to the catheter during production. Operators can visually inspect the products and clearly see beneath the heat shrink. No more guesswork.

High 2:1 Shrink Ratios

Structural heart delivery systems are often larger in size, due to the nature of the bigger veins and arteries within the heart. A 2:1 shrink ratio allows heat shrink to successfully recover over both the larger and smaller sections of the shaft in a tapered catheter.

Class VI approval

FluoroPEELZ™ is Class VI medical grade approved, offering peace of mind for device manufacturers when it comes to biocompatibility.

Suitable for Long Catheters

Many catheters used in structural heart applications are long. The longer the catheter, the greater the risk that damage will occur. FluoroPEELZ™ allows for long, continuous lengths of the heat shrink and an easier subsequent removal after the reflow is complete.

STRUCTURAL HEART APPLICATIONS

- Guiding catheters
- Delivery systems
- Steerable sheaths

What people are saying:

“FluoroPEELZ™ for quick turn prototyping is a must. Time to market is critical and the removal of this peelable heat shrink is incredibly simple and easy allowing my team more time to evaluate, modify and innovate during the design process.

Medical Device OEM

“Yields have increased tremendously for our customers as they do not have to scrap the entire catheter shaft because of cut or nick from skiving off traditional FEP Heat Shrink.

Dr. Irina Roof, Staff Applications Scientist, Zeus

“Transferring processes to operators is fast and effective. Training operators to learn the nuances of FEP removal is time consuming. Using FluoroPEELZ™ allows our employees to work confidently and efficiently.

Medical Device OEM

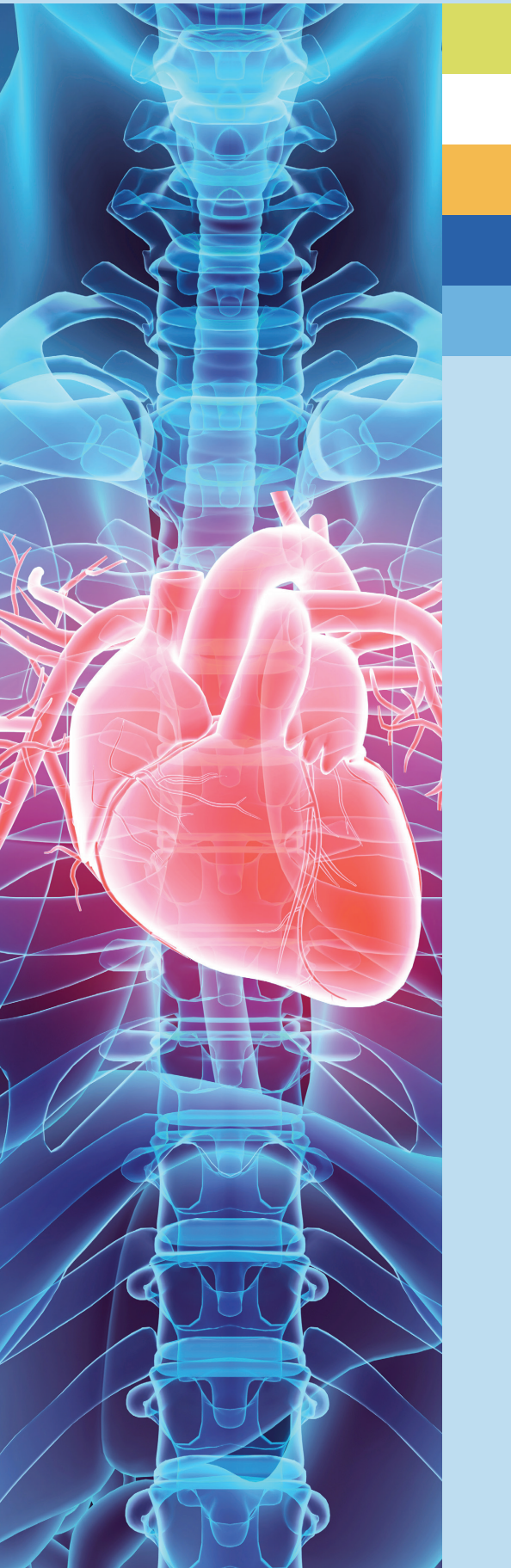


AVAILABLE SIZES

FluoroPEELZ™ Peelable Heat Shrink

FluoroPEELZ™ is available in wide variety of sizes, depending on the application.

For Structural Heart manufacturing, Zeus can supply FluoroPEELZ™ with high ratio capabilities and expanded ID up to .385" (9.779mm).



A Critical Development for Catheter Manufacturing

Endovascular treatment is incredibly important for structural heart disease, dramatically reducing open-heart surgery rates and accelerating patient recovery time. Given that 1 in 8 people over the age of 75 suffer with structural heart disease, catheter-based intervention has an increasingly critical role to play as the future of medicine unfolds.

Catheter production methods must keep pace with innovation in endovascular techniques. No part of the production process should hinder productivity or yield. Yet the removal of heat shrink, a critical step in production, has hampered productivity for far too long. Such a manual and imprecise process risks huge levels of waste, high costs of production, and operator safety.

FluoroPEELZ™ peelable heat shrink completely eradicates this costly production challenge for medical device OEMs.

By embracing new product developments such as this, OEMs can significantly improve their production processes and their ability to support the demand for the widening use of catheters when treating structural heart disease.



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