ZEUS

Neurovascular Microcatheter Production

Eliminating damage to microcatheters on the production line.

Thanks to advances in minimally invasive catheter-based procedures, endovascular therapy has become a mainstay in the treatment of many neurovascular disorders. Microcatheter technology and production techniques are advancing rapidly. However, manufacturing these microcatheters is not without its challenges, particularly when it comes to the final step in production, the removal of heat shrink from the device. Heat shrink is typically removed using a skiving tool or razor blade, which often leads to damage of these small and delicate devices. The result? A severe impact on production line yield.

Market: Medical Device

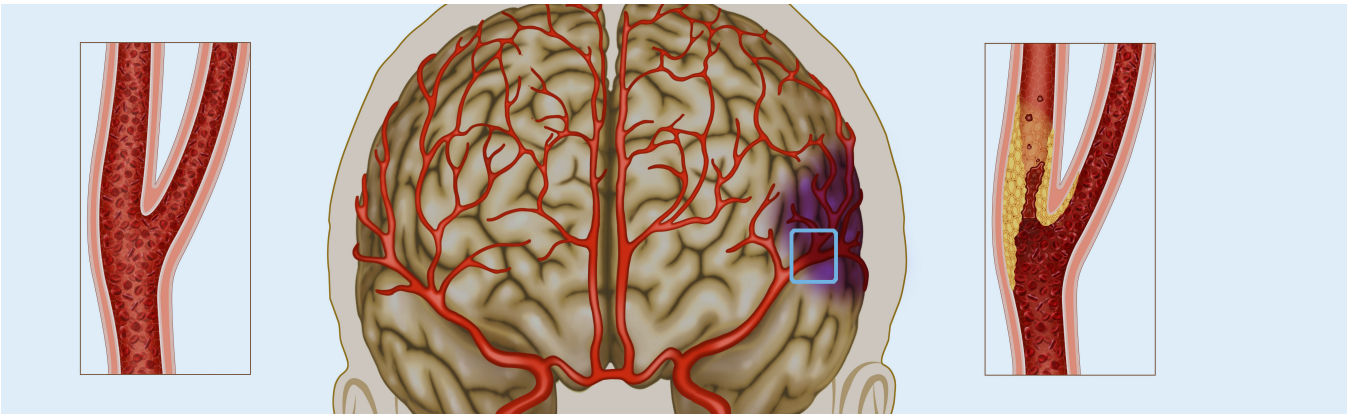
Sub-Market: Neurovascular

Process: Heat Shrink Removal

Challenge: Microcatheter Damage During Production

Category: Microcatheters

Zeus Product: FluoroPEELZ™



The Growth of Endovascular Neurosurgery

Neurological conditions such as stroke, carotid artery disease, and intracranial atherosclerotic disease are widely recognised as serious causes of disability and morbidity globally.

The typical treatment method is endovascular surgery. This method of intervention is now more common than open neurovascular surgery, thanks to the safety, efficacy, and excellent patient outcomes associated with endovascular techniques.

Neuroendovascular treatment is set to become one of the most important treatment modalities within the neurovascular field as a result of both ever increasing patient demand, and an increasing scope of neurovascular disorders that can be treated this way.

Like many in the field, medical device manufacturers are diverting more and more resources into the design and production of microcatheters that are suitable for neurovascular applications.

2nd

Stroke is the 2nd leading cause of death worldwide*

*https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(19)30030-4/fulltext

Bonding Material Layers with Heat Shrink

Heat shrink is a vital component used during the construction of neurovascular microcatheters.

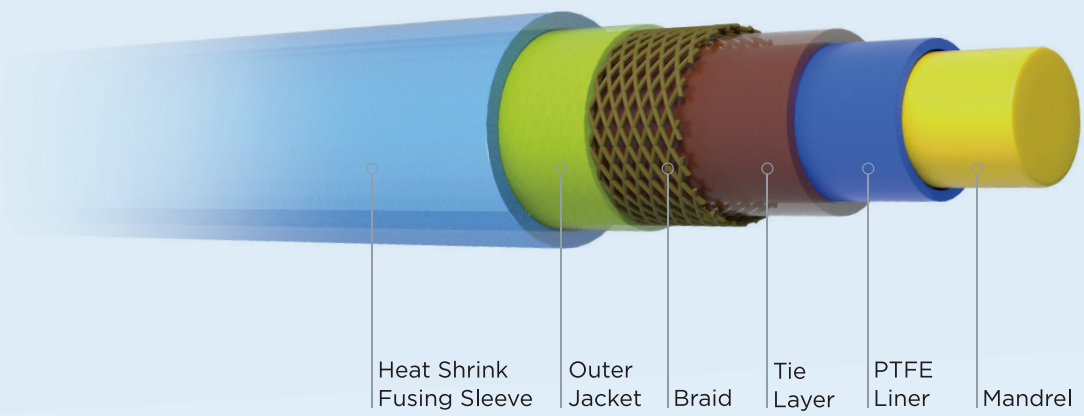
Used over nylon or Pebax®, heat shrink encapsulates the underlying jacketing while heat is applied to the outer layer. This heats the underlying jacketing material, allowing the jacket to reflow through the braiding and bond to the liner.

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

A skiving tool with a razor blade is typically used to do this. The operator must manually apply the blade to shave off all the heat shrink layer before disposing of it. Only then is the microcatheter ready for sterilization and packaging.

The removal of heat shrink is typically seen as a time-intensive and troublesome procedure for the operator.

The material layering approach used in catheter construction:



Skiving Tools & Razor Blades

Using a skiving tool with a razor blade to shave off the heat shrink from the microcatheter can pose many risks and challenges.

By their very nature, neurovascular microcatheters are extremely small and delicate, and damage to microcatheters at this stage of the construction process is extremely common.

When an operator uses a blade to skive the heat shrink away, it's easy to cut too deep, damaging the critical layers of the microcatheter below.

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

When damage occurs, the nearly finished microcatheter must be scrapped, leading to increasing production costs and a serious impact on yield.

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 neurovascular microcatheter innovation has advanced, OEMs are still using outdated methods of removing heat shrink during their production. It's clear that an effective alternative to skiving tools with razor blades is critical.

IT'S FINALLY HERE
FLUOROPEELZ™ PEELABLE HEAT SHRINK

A *peelable* heat shrink that removes skiving tools from the production line, *eliminating damage* to microcatheters and *increasing yield*.

FluoroPEELZ™ heat shrink allows operators to easily peel, instead of skiving, heat shrink from the microcatheter shaft after the reflow heating process.

Simply use the FluoroPEELZ™ slit fixture to slit the end of the heat shrink, peel it back from the microcatheter surface, and discard.

Higher Yields

Manufacturers scrap fewer damaged microcatheters and see a significant increase in yield. Using FluoroPEELZ™, customers are anecdotally reporting manufacturing cost savings of 10 - 15%.

Faster Production

Manufacturers dramatically reduce the time it takes to construct a microcatheter because the heat shrink can be safely removed in seconds.

Improved Safety

Manufacturers can completely remove skiving tools from the production line, meaning operators work in a safer environment.

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. Operators can then quickly and easily peel away the heat shrink from the microcatheter.

High Optical Clarity

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

"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

FEATURES

FluoroPEELZ™ Peelable Heat Shrink

High 2:1 Shrink Ratios

Higher shrink ratios are particularly useful for neurovascular microcatheters production due to their smaller sizes. This gives engineers more flexibility to work and can also eliminate the need for multiple heat shrinks to accommodate the catheter transitions.

Suitable for Long Catheters

Microcatheters used in neurovascular applications are typically long, as they need to reach the brain. 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.

"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

NEUROVASCULAR APPLICATIONS

FluoroPEELZ™ Peelable Heat Shrink

GUIDING CATHETERS

CEREBRAL EMBOLIZATION AND ANEURYSM COILING DEVICES

- Embolic Coils
- Flow Diversion Devices
- Liquid Embolic Agents

CEREBRAL ANGIOPLASTY AND STENTING SYSTEMS

- Carotid Artery Stents
- Embolic Protection Systems

NEUROTHROMBECTOMY DEVICES

- Clot Retrieval Devices
- Suction Devices
- Vascular Snares

SUPPORT DEVICES

- Microcatheters

AVAILABLE SIZES

FluoroPEELZ™ Peelable Heat Shrink

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

FLUOROPEELZ™ TYPICAL SIZE RANGES				
SHRINK RATIO	EXPANDED ID	RECOVERED ID	WALL THICKNESS	WALL THICKNESS TOLERANCE
1.3:1	0.015″ – 0.500″ (0.381 mm – 12.7 mm)	0.012″ – 0.385″ (0.305 mm – 9.779 mm)	0.008″ – 0.013″ (0.203 mm – 0.330 mm)	± 0.002″ (± 0.051 mm)
1.4:1	0.015″ – 0.500″ (0.381 mm – 12.7 mm)	0.011″ – 0.358″ (0.279 mm – 9.093 mm)	0.009″ – 0.013″ (0.229 mm – 0.330 mm)	± 0.002″ (± 0.051 mm)
1.5:1	0.015″ – 0.500″ (0.381 mm – 12.7 mm)	0.010″ – 0.334″ (0.254 mm – 8.484 mm)	0.010″ – 0.014″ (0.254 mm – 0.356 mm)	± 0.002″ (± 0.051 mm)
1.6:1	0.016″ – 0.500″ (0.406 mm – 12.7 mm)	0.010″ – 0.313″ (0.254 mm – 7.950 mm)	0.010″ – 0.018″ (0.254 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
1.7:1	0.017″ – 0.500″ (0.432 mm – 12.7 mm)	0.010″ – 0.295″ (0.254 mm – 7.493 mm)	0.010″ – 0.018″ (0.254 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
1.8:1	0.030″ – 0.500″ (0.762 mm – 12.7 mm)	0.017″ – 0.278″ (0.432 mm – 7.061 mm)	0.013″ – 0.018″ (0.254 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
1.9:1	0.032″ – 0.500″ (0.813 mm – 12.7 mm)	0.017″ – 0.264″ (0.432 mm – 6.706 mm)	0.013″ – 0.018″ (0.330 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)
2.0:1	0.034″ – 0.500″ (0.864 mm – 12.7 mm)	0.017″ – 0.250″ (0.432 mm – 6.35 mm)	0.013″ – 0.018″ (0.330 mm – 0.457 mm)	± 0.002″ (± 0.051 mm)

HEAT SHRINK PROPERTIES				
WORKING TEMP.	SHRINK RATIOS	RECOVERY TEMP.*	SPECIAL FEATURES	APPLICATIONS
200 °C / 392 °F	Up to 2:1	215 °C / 420 °F ± 10 C° / 18 F°	• Peelable • Clear • Class VI approved resins available	• Catheter manufacturing • Packaging • Manufacturing aids

**We recommend beginning the recovery process at 215 °C (420 °F). Anticipate adjusting this temperature in 10 C° (18 F°) increments, upward or downward, until desired recovery characteristics are achieved.*

A Critical Development for Microcatheter Manufacturing

Endovascular intervention is incredibly important for the treatment of neurovascular conditions such as stroke, dramatically reducing surgery rates and accelerating patient recovery time.

Given that serious neurovascular conditions such as stroke are on the rise globally, microcatheters have an increasingly critical role to play as the future of medicine unfolds.

Microcatheter production methods must keep pace with innovation in endovascular techniques. No part of the production process should hinder productivity or yield. Yet the remove of heat shrink, a critical step in production, can lead to damaged devices and high levels of scrap.

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 microcatheters when treating neurovascular disorders.

ZEUS®

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