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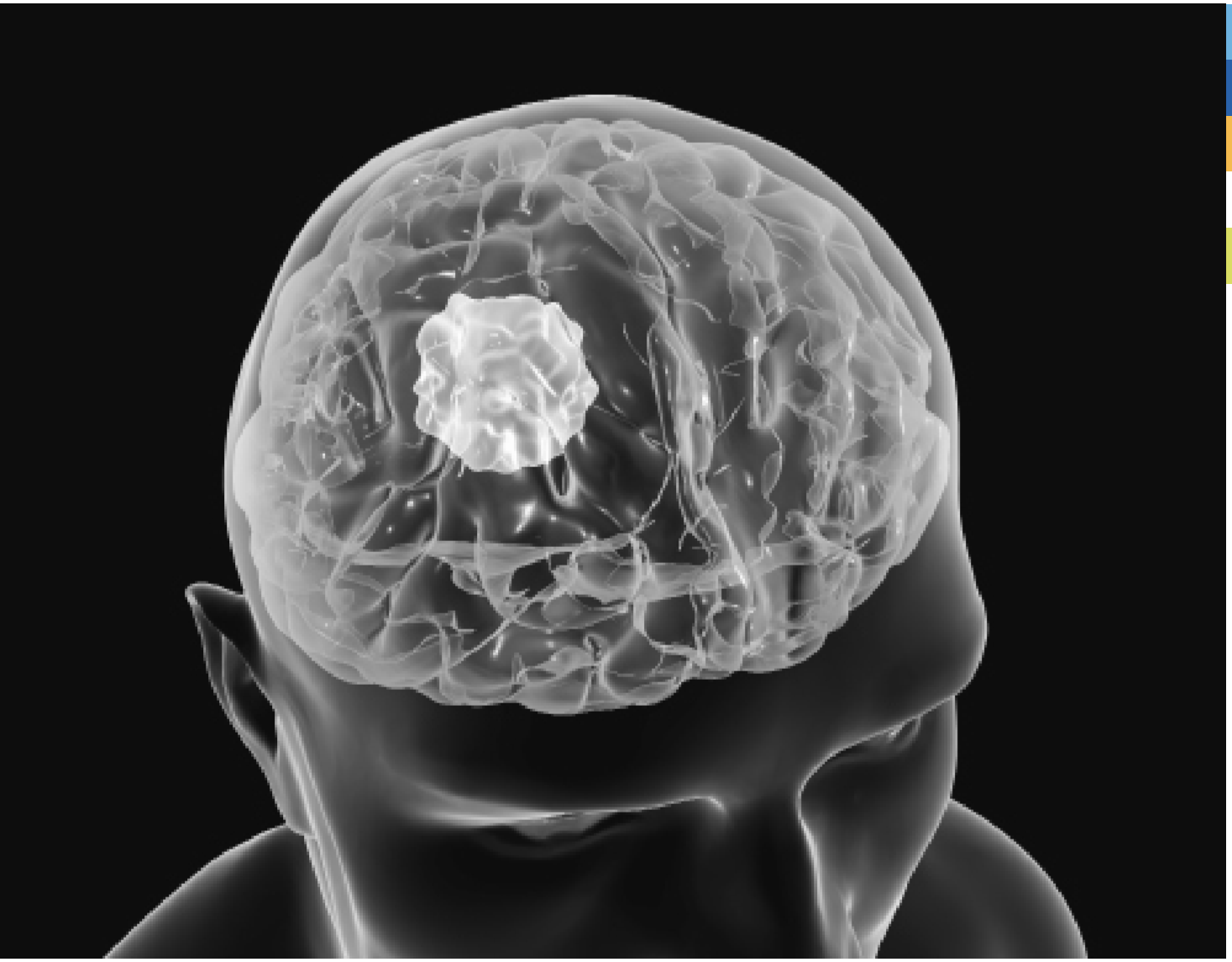


Transforming Neurovascular Microcatheter Production

Eliminating the production challenge of microcatheter delamination.

Innovative microcatheter technology and production techniques have enabled sophisticated treatments for patients with neurovascular conditions such as ischemic stroke and cerebral aneurysms. However, microcatheter manufacturers still face obstacles, including the bonding of the many specialized layers of the microcatheter together. One of the critical challenges, 'delamination', occurs when specialized catheter layers separate due to contrasting chemistries. Manufacturers must overcome this recurring vulnerability to improve patient safety and reduce scrap levels during production.

Market: Medical Device

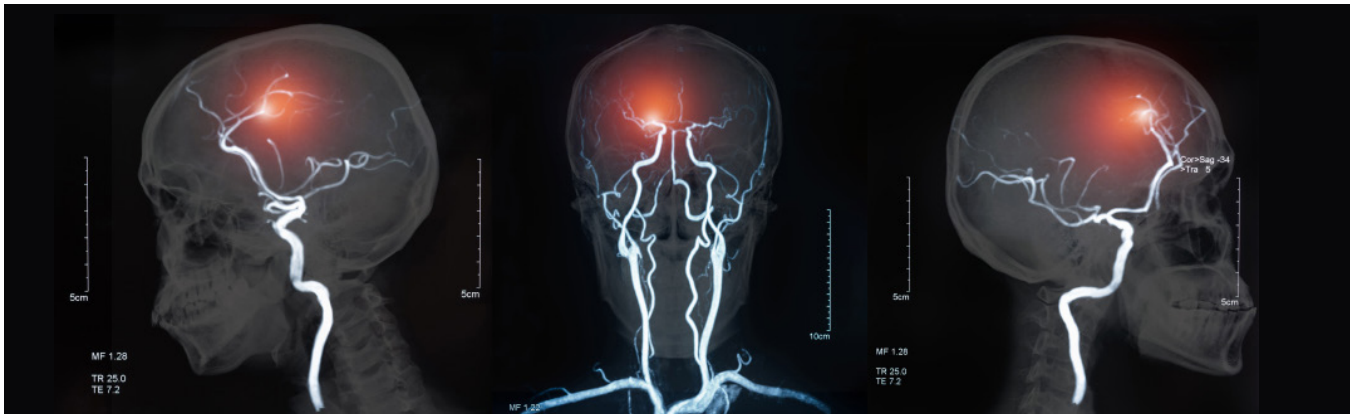
Sub-Market: Neurovascular

Process: Microcatheter Construction

Challenge: Delamination

Category: Microcatheters

Zeus Product: Tie Layer



Endovascular Management of Neurovascular Diseases

Neurovascular diseases encompass any abnormalities of the blood vessels either within, or supplying blood to, the brain and spine. These abnormalities could be responsible for a reduction in blood flow to the brain, which increases the risk of stroke, brain aneurysms, and intracranial bleeding; conditions that come with a huge health and economic toll.

Significant resources have been directed to the diagnosis, treatment, and management of these conditions because of their devastating effect on patients. This has led to an explosion of innovation in areas such as patient diagnosis, medical therapies, and medical devices. Today, there are a broad range of treatment options available for neurovascular patients, with endovascular therapies in particular paving the way for improved patient outcomes and reduced treatment costs.

Neurovascular diseases and events commonly treated through endovascular intervention include cerebral aneurysms (a weak or thin spot on an artery in the brain that balloons or bulges out and fills with blood) and other serious neurovascular occurrences such as ischemic stroke. Cerebral aneurysms can be treated using occlusion balloon catheters and embolization techniques. Ischemic stroke can be treated via thrombectomy and retrievable stents, aspiration devices, or a combination of both.

As a result of the growth of these minimally invasive treatment options, there has been much focus from medical device OEMs on the research and production of neurovascular devices, including specialized microcatheters.

13.7 million

Globally, there are approximately 13.7 million new strokes each year.

Source: https://www.world-stroke.org/assets/downloads/WSO_Global_Stroke_Fact_Sheet.pdf

Material Layering During Microcatheter Construction

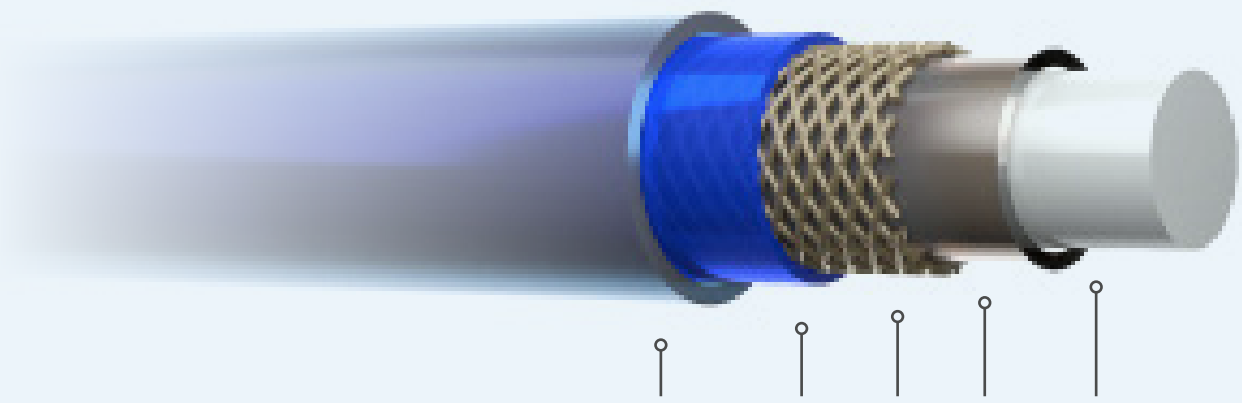
Neurovascular microcatheters are composed of a number of different layers of materials including a base liner, braiding or coil reinforcement, and an outer layer known as a jacket.

Heat shrink is then used to melt the underlying jacketing material, allowing the jacket to reflow into the microcatheter braiding. This bonds the microcatheter base liner, braiding, and jacketing together.

Layering these materials upon each other in a specialized order is key to ensuring that the microcatheter will have the desired properties for successful neurovascular intervention.

Size, strength, and flexibility are all typical properties that are required in a neurovascular setting. The device must be small enough to pass through the brain's tiny blood vessels without causing trauma and must also be both strong and flexible to reach the brain through often tortuous blood vessels.

The material layering approach used in catheter construction:



The Impact of Microcatheter Delamination

There must be a strong bond between the microcatheter's material layers to ensure it can perform effectively. This can be difficult, as each of the materials will have their unique chemistries – and as a result, do not automatically form strong bonds with each other during the layering process.

This can lead to delamination, which is the separation of the material layers that make up the microcatheter. When this occurs during production, the microcatheter must be scrapped as it will not be fit for purpose.

Unfortunately, delamination is not easy to detect until final testing of the device - which happens after final assembly of the microcatheter. Microcatheters must then be scrapped, which naturally has a serious impact on production yield.

More seriously, albeit in a small number of cases, delamination is not detected and the compromised microcatheter makes its way to the field. This can have grave consequences for patient safety and can lead to a costly and reputation-damaging product re-call for the manufacturer.

Despite many advances in neuroendovascular surgery, delamination remains a common challenge for manufacturers of neurovascular devices. To protect patient safety and improve manufacturing yields, it's clear a better solution is needed to overcome the delamination challenge.

IT'S FINALLY HERE
TIE LAYER

An ultra-thin thermoplastic coating between the inner PTFE liner and the outer jacket of the catheter which delivers the *crucial adhesion* required to *prevent delamination*.

Tie Layer is a very thin thermoplastic coating that is placed over a PTFE liner during microcatheter construction to improve adhesion to the catheter jacket following the reflow process.

Testing shows that microcatheters built with Tie Layer display up to 20% to 40% better bond strength than those without. With coating dimensions as thin as 0.0025 mm (0.0001"), impact to overall microcatheter profile is minimal.

Better Bond Strength

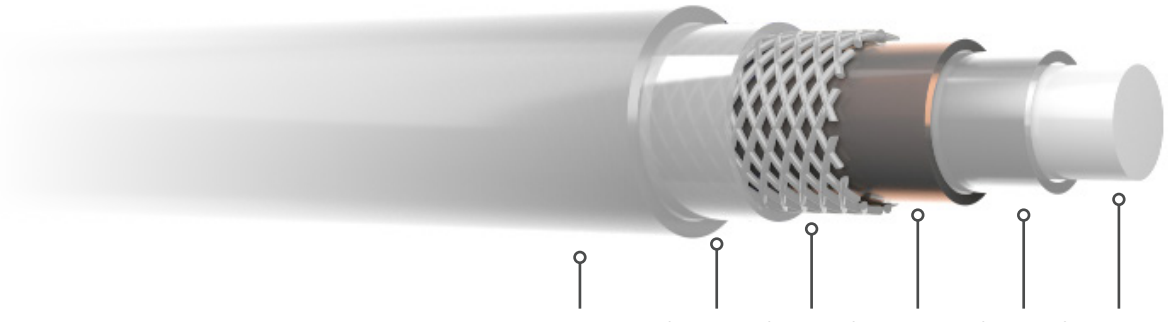
The Tie Layer has been proven to provide enhanced jacket-to-liner bond strength ranging from 20% to 40%.

Improved Patient Safety

Delamination can cause microcatheters to fail in the field with very serious consequences for patient safety. Tie Layer significantly reduces this risk.

Reduced Scrap Costs

Manufacturers can reduce scrap rates and inspection costs, with anecdotal reports of 2-5% scrap reduction, and an increase in yield.



Fusing Sleeve | Jacket | Braid | Tie Layer | Liner | Mandrel

FEATURES

Tie Layer

Ultra-thin Coating

Due to the small nature of the brain's blood vessels, it's critical that microcatheters used in neurovascular applications have a very low profile. Tie Layer coatings are ultra-thin, so the impact on the overall profile is extremely minimal.

Heat Weldable

Tie Layer coatings form a strong, heat-welded bond during the construction of neurovascular microcatheters, as the coating easily melts and combines with any jacket reflow process.

Legacy and Next Generation Compatible

Tie Layer can be applied to legacy designs as well as next-generation neurovascular catheter designs.

Multiple Durometers

Design engineers can tailor the finished microcatheter's performance as a result of the ultra-thin coating being available in various durometers.

More Design Possibilities

With access to multiple Tie Layer materials and durometers, engineers can customize flexibility or stiffness into their next microcatheter design as required.

Bio-compatible

Only USP Class VI approved thermoplastic materials are used for Tie Layer coatings.

"The Tie Layer coated liner addresses the market's need for reducing or even eliminating delamination. Our new Tie Layer solution provides product designers and engineers with an excellent option for addressing these challenges."

Peter Theirl, Vice President, Global Sales & Marketing, Zeus Industrial Products, Inc.

Neurovascular Tie Layer Applications

Tie Layer can be applied to all microcatheters developed for use in neurovascular applications.

- Guide Catheters
  - *Balloon guide catheter*
  - *Non-balloon guide catheter*
- Delivery Catheters
  - *Embolic Coils*
  - *Flow Diversion Devices*
  - *Liquid Embolic Agents*
  - *Stents*
- Cerebral Angioplasty and Stenting Systems
  - *Carotid Artery Stents*
  - *Embolic Protection Systems*
- Neurothrombectomy Devices
  - *Mechanical thrombectomy*
  - *Aspiration thrombectomy*
- Occlusion Balloon Catheter
- Intermediate Catheter
- Microcatheters

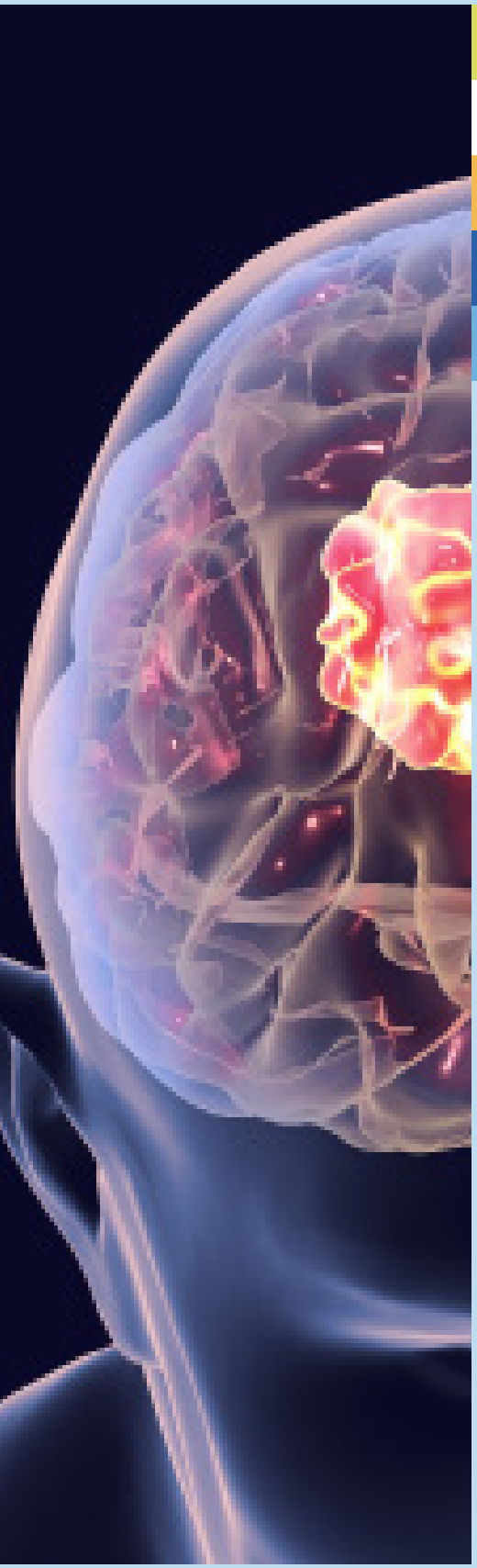
Available Sizes

Tie Layer is available for a variety of catheter sizes, depending on the application. For neurovascular manufacturing, OD offerings are 0.381 mm to 6.350 mm (**0.015"** to **0.250"**).

Larger sizes available upon request.

"Improving patient safety and reducing manufacturing costs represent top priorities for the medical device industry. For over 50 years, Zeus has developed and delivered polymer solutions that help address these concerns. Our latest Tie Layer innovation creates a melt-bondable surface to improve adhesion and allows our customers to elevate the performance of their devices."

Matt Allen,
Senior Product Liner Manager,
Zeus Industrial Products, Inc.



Overcoming the Delamination Challenge

Endovascular therapy is a vital tool in the treatment of neurovascular conditions such as cerebral aneurysms and ischemic stroke.

Given that stroke alone is the second leading cause of death worldwide*, endovascular therapy and specialized microcatheters will prove instrumental in delivering improved patient outcomes.

Catheter production methods must evolve to enable new treatments and refine existing techniques. Anything that threatens patient safety, productivity, or yield cannot be tolerated. Delamination is a prime target.

Tie Layer is an urgently needed addition to the production process. The melt-bondable surface improves adhesion and enables product designers and engineers to reduce or even eliminate delamination.

OEMs can incorporate Tie Layer into their production line to meet the increasing demand for safer, more reliable micro-catheters in neurovascular interventions.

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

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