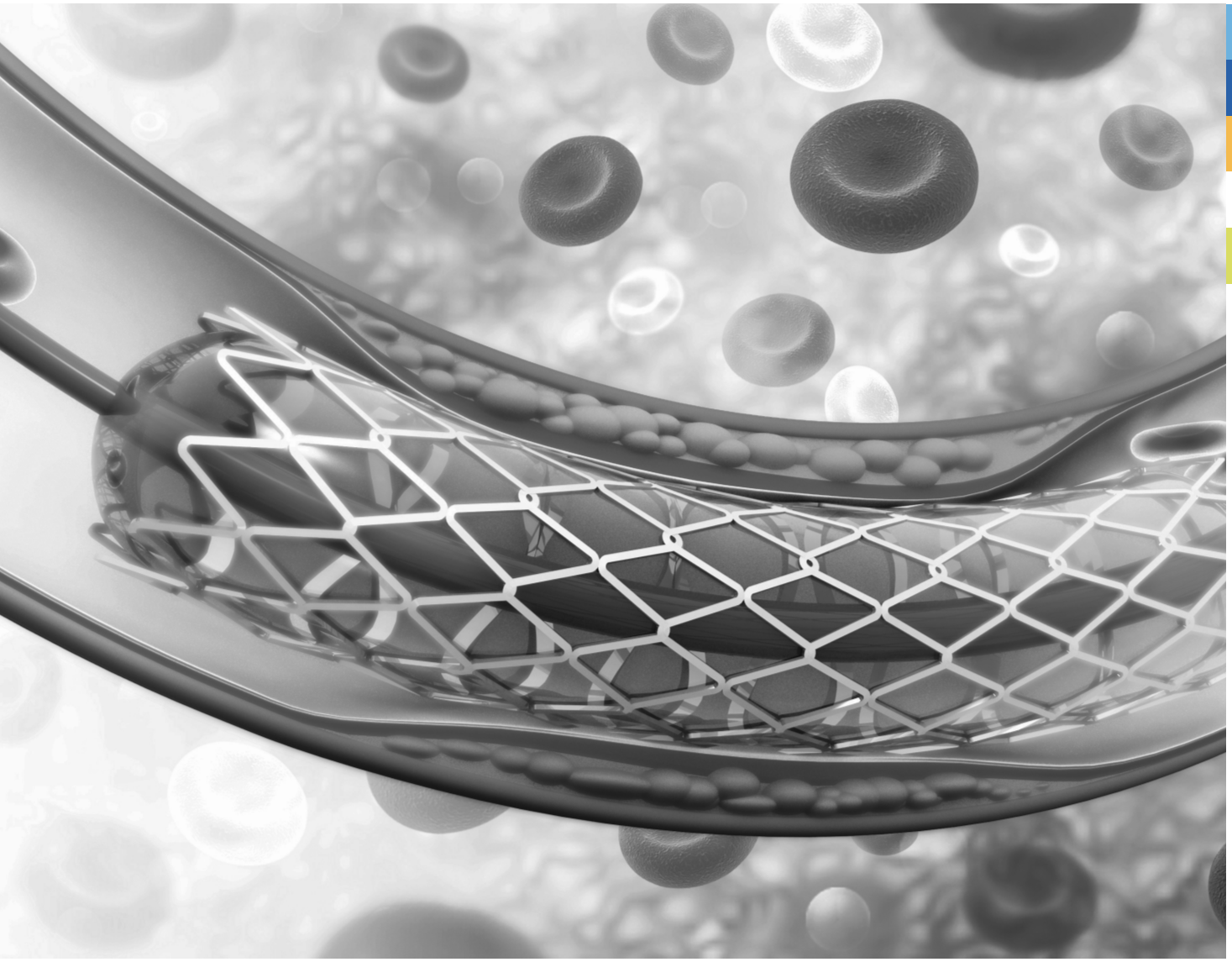


Advances in Peripheral Catheter Production

Eliminating catheter delamination on the production line.

Advances in minimally invasive catheter-based procedures have transformed the management of many peripheral conditions. Catheter technology and production techniques are developing rapidly. However, manufacturing microcatheters can be challenging, particularly when bonding the many specialized layers required. Due to contrasting chemistries, these layers can often separate, known as ‘delamination’. This recurring vulnerability puts patients at risk and poses a serious and costly challenge for manufacturers.

Market: Medical Device

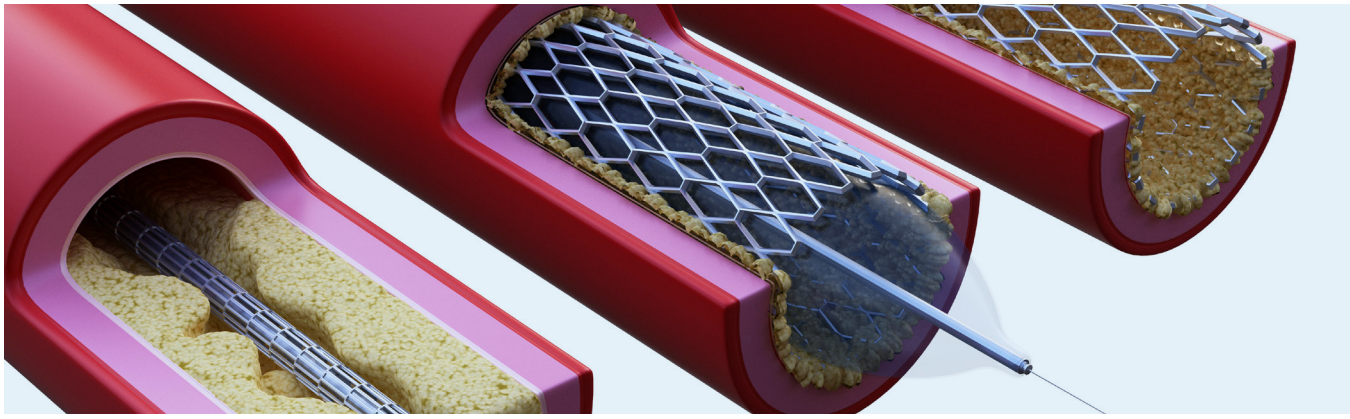
Sub-Market: Peripheral

Process: Catheter Construction

Challenge: Delamination

Category: Catheters

Zeus Product: Tie Layer



The Growth of Peripheral Endovascular Intervention

The management of peripheral diseases have been transformed over time as a result of advances in endovascular intervention. Endovascular treatment has become an excellent lower-risk alternative to open surgery for many patients with peripheral conditions, such as atherosclerosis. Balloon angioplasty and stenting are mainstays of peripheral endovascular therapy, with newer, innovations including drug-eluting stents and drug-coated balloons also growing in popularity.

These advances in endovascular therapy have only become possible thanks to engineering breakthroughs.

One of these breakthroughs is the development of highly innovative catheter devices. Medical device manufacturers, supported by their innovative component suppliers, now have the ability to produce catheters which are small enough, flexible enough, and strong enough to safely access the far reaches of the body.

As a result of these advances, many of the catheter devices produced by OEMs are today being used for peripheral endovascular applications.

50%

Atherosclerosis is the underlying cause of about 50% of all deaths in westernized society.

Source: https://www.ncbi.nlm.nih.gov/books/NBK507799/

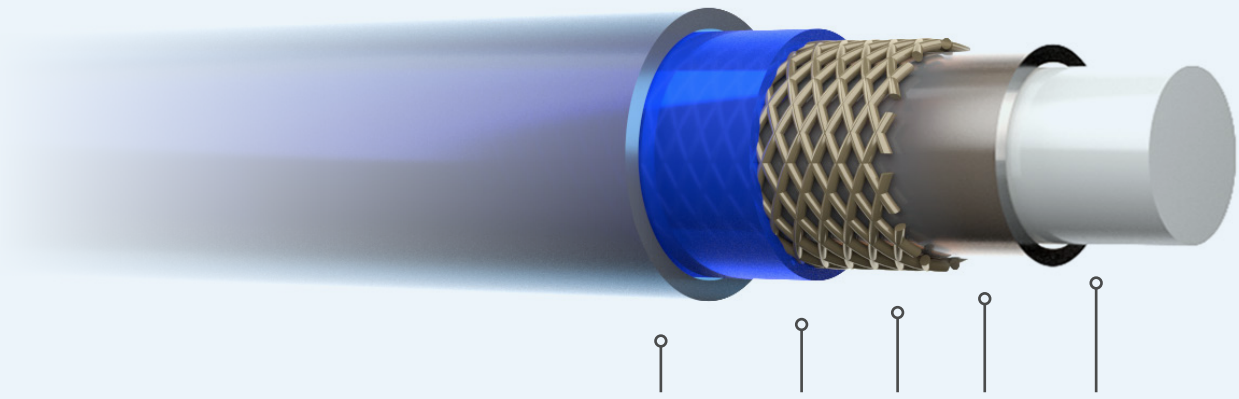
A Layering Approach to Catheter Construction

To access the far reaches of the body, the catheter needs to be stiff at the proximal end, but flexible at the distal end. It also needs to be small enough to pass through tiny and tortuous blood vessels without causing trauma. Proper material selection and catheter construction ensures the catheter will have the desired properties required for use in peripheral applications.

At its simplest form, a catheter is composed of a number of important material layers. Key components typically include a base liner (usually PTFE), braiding or coiling reinforcement, an outer jacket layer, and a reflow aid such as a heat shrink fusing sleeve.
During construction, these materials are layered on top of one another in a specialized order. This layering approach of multiple materials is vital to accomplish important mechanical performance objectives such as strength, pushability, kink-resistance, and lubricity amongst other properties.

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

The material layering approach used in catheter construction:



The Delamination Challenge

For a catheter to perform effectively it is vital that there is strong adhesion between all layers. However, different materials can have contrasting chemistries and as a result they do not form strong bonds with each other during the construction process.

As a result, catheters built with multiple materials can be subject to delamination. The term 'delamination' refers to the separation of material layers within the catheter. Delamination typically remains undetected until final testing and completion of the catheter assembly.

When delamination occurs, the catheter must be scrapped, leading to high scrappage costs for manufacturers and a serious impact on production line yield.

In a small number of cases, delamination is not detected, and the catheter makes it to the field. This is an extremely serious situation as the catheter could potentially fail while in use and compromise patient safety. A lengthy and costly product recall also ensues for the manufacturer.

Despite many advances in catheter construction, delamination still remains a recurring vulnerability and a serious challenge for manufacturers. It's clear that an urgent solution to delamination is required to protect patient safety and reduce manufacturing scrap costs.

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 catheter construction. The coating creates a melt-bondable surface that improves adhesion to the catheter jacket following the reflow process. Testing shows that catheters constructed with Tie Layer can display from 20% to 40% better bond strength than those without.

Better Bond Strength

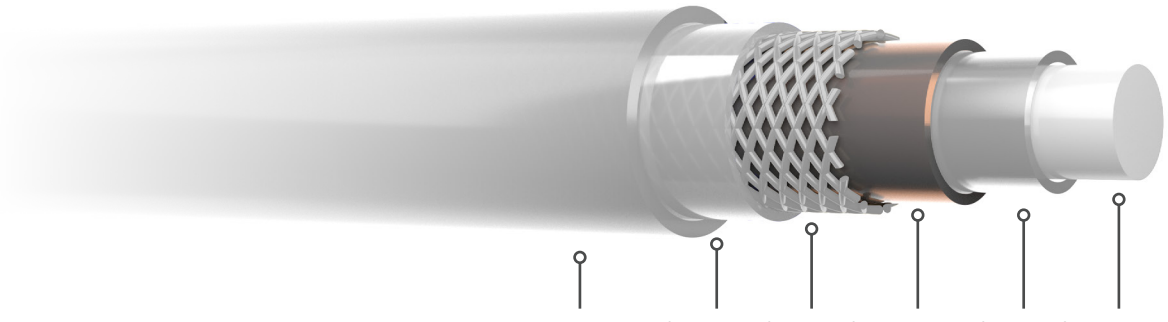
The Tie Layer has been proven to provide enhanced jacket-to-liner bond strength ranging from 20% to 40%.

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

It's vital that catheters used in peripheral applications have the lowest overall profile possible. As coating dimensions are as thin as 0.0025 mm (0.0001"), any impact to the overall catheter profile is minimal.

Heat Weldable

Since Tie Layer coatings easily melt and combine with any jacket reflow process, they form a strong, heat-welded bond during the construction of catheters for peripheral applications.

Legacy and Next Generation Compatible

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

Multiple Durometers

The ultra-thin coating is available in various durometers, allowing design engineers to tailor
the performance of the finished catheter.

More Design Possibilities

Having access to a variety of Tie Layer materials and durometers allows engineers to customize flexibility or stiffness into their next catheter design.

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."

Bob Chaney, General Manager,
Global Sales & Marketing,
Zeus Industrial Products, Inc.

Peripheral Applications

Tie layer can be applied to all catheters developed for use in peripheral applications.

- Guiding Catheters
- Support Catheters
- PTA Catheters
- Microcatheters
- Delivery Catheters
- Aspiration Thrombectomy Catheters
- Atherectomy Catheters
- Diagnostic Catheters
- Imaging Catheters
- Embolization Catheters

Available Sizes

Tie Layer is available for a variety of catheter sizes, depending on the application. For peripheral 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 Line Manager,
Zeus Industrial Products, Inc.

A Critical Development for Catheter Manufacturing

Endovascular therapy is incredibly important for the treatment of peripheral conditions such as atherosclerosis.

Given that atherosclerosis is the underlying cause for around half of deaths in westernized society, catheters have 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, yield or patient safety. Yet delamination has remained a persistent problem.

Tie Layer creates a melt-bondable surface to improve adhesion and enable product designers and engineers to reduce or even eliminate delamination.

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

ZEUS®

zeusinc.com | info@zeusinc.com

Americas: +1 803 268 9500 | Europe: +353 74 9109700 | Asia-Pacific: +(86)20 38254906