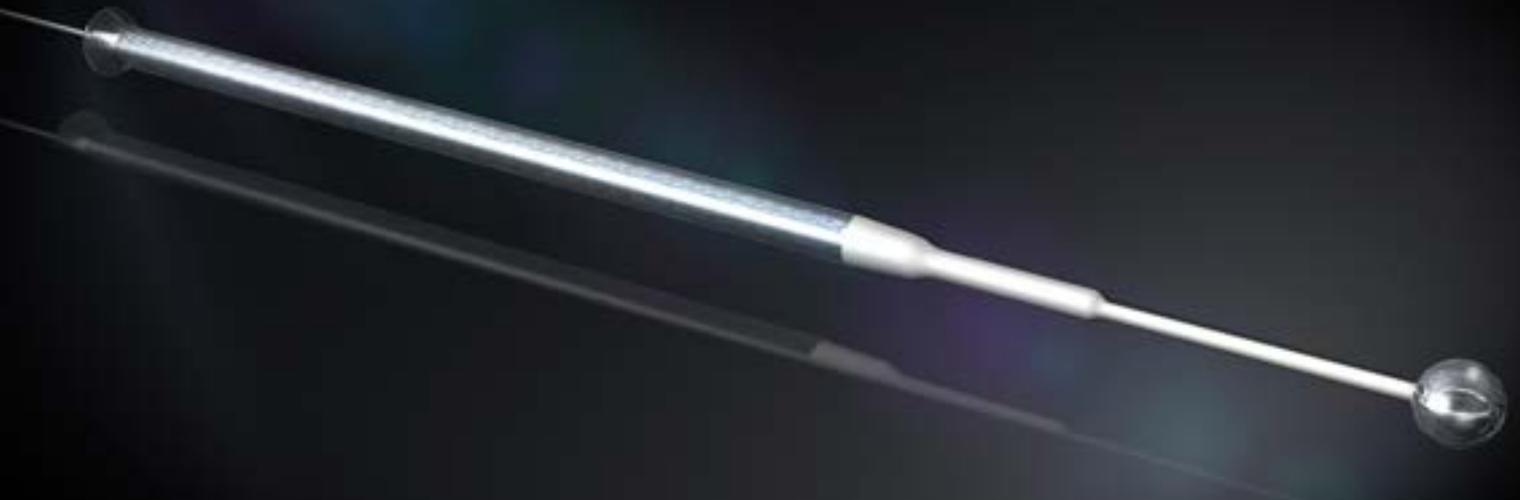


Complete Protection for Stent & Balloon Delivery Systems



Overview

Centurion™ comprises of a number of features to provide a high quality protection solution for a high value device at a fraction of the cost. Stent & Balloon protection is one area that Advant Medical identified in the Medical device market that required development, while OEM companies are rightly focused on the manufacture of superior devices, it was apparent that the current stent & balloon protections available for their device were not performing to the standards required.

Industry Problems

A high rejection rate of the device in the Market due to the inferiority of the protection used on their stent.

Complaints:

1. When the device was removed from the dispenser package the protection used on the stent was remaining in the hoop due to high co-efficient of Friction between the Product, the protector and the hoop.
 - i. Coated stent was coming into contact with the hoop during removal
 - ii. The end user was damaging the stent with their hand as they presumed when handling it that the protector was present.

2. Distal Tip Damage:
As the stylet of the mandrel was not fully encased, the catheter tip was being exposed to the stylet when pushed in too far, in turn the catheter tip was being damaged. This problem occurred during the final assembly & packaging of the product and was not noticed until the device was selected for a procedure.

3. As stent and balloon sizes vary from lot to lot, many companies were purchasing a wide range of protectors to allow for the variation in stent sizes. Some companies were holding an additional 30% inventory per product line.

Challenges Faced

1. Develop a product that protects the Bare metal stent, Drug Eluting Stents and Ceramic coatings and coated balloons.
2. Develop a repeatable process to fully encase the mandrel stylet which also secured the tube to the mandrel. This process also had to accommodate three materials MDPE, HDPE & PTFE
3. Develop a versatile process which could incorporate both standard & custom design options
4. Develop a product that had a reduced Co efficient of friction between the product and the protector
5. Develop a multi functional protector to reduce the requirement of various protectors per lot and reduce the requirement to hold excess inventories.
6. Provide an optimum protector for the market at a competitive cost.



An example of a stent damaged during transportation

Advant Solution

1. The development of key manufacturing Processes and the investment in technology enabled a versatile manufacturing process to allow for various materials and customisation of design without having an impact on cost to the customer.
2. Market Research into the problem areas for the Device manufacturer and End user.
3. Involvement in device technical reviews with customers allowed Advant Medical to design in manufacturability while incorporating key functions into the design in order to provide an optimum solution specific to the various catheter tips.

Hence Centurion™ was born providing an optimum solution for medical device manufacturers.

