Catheter Bonding Technology Overview

a white paper by:

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Introduction

The global medical device and diagnostics market is poised to reach $362 billion by 2015, according to a report recently released by Global Industry Analysts, Inc. Catheter tube bonding is the backbone of many cutting edge new product developments.

The most precise and demanding applications require use of thermoplastic materials, which may be bonded using one of three processes, depending upon budget and application.

This paper explores the various processes associated with thermoplastic bonding, welding and fusing to assist catheter manufacturing engineers in selecting the optimum process for their individual application.

Catheter Tube Bonding Overview

The medical industry remains strong and growing in spite of a weak economy. Catheter manufacturing is among the most viable sectors of the medical device supply industry. The cutting edge technologies continually being developed by doctors, scientists and biotechnologists require unique and specialized catheters to enable a multitude of new processes. In order to keep up, catheter manufacturing technology is constantly evolving to offer more cost-effective, precise and reliable solutions.

Catheter tube bonding is the backbone of many of these new product developments. Quality catheter tube bonding is the result of proper interfacing of material, tooling and heat delivery. Two materials frequently used in medical catheter manufacturing are thermoplastic tubing and heat shrink tubing. These materials are selected for strength, flexibility and molding properties.

Thermoplastics, the material of choice for many of the most precise and demanding applications, may be fused using one of three processes, depending upon budget and application.

Thermoplastic catheter fusion include three common types: butt joining, the co-joining of two faces of tubing into a bond, lap joints, the overlapping of two materials to create the bond, and balloon bonding, the process of bonding a catheter balloon to a catheter shaft.

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Bond Characteristics

Butt Joints	**Lap Joints**	**Balloon Bonds**
Butt joining used for when material diameter cannot increase. Often requires thick wall tubing. Materials must be similar polymer.	High pull strength / bond strength requirement. Can be similar or dissimilar materials.	Bonding balloon to shaft.
Process Characteristic: Axial compression to facilitate material flow.	Process Characteristic: Radial compression.	Process Characteristic: Needs heat shielding, joint transition.

Butt joining is used when material diameter increase over the largest shaft OD. The materials used must be similar and compatible polymers. This process often requires thick wall tubing to produce a successful weld and requires axial compression to facilitate material flow.

Lap joining is used for to fulfill high pull strength/bond strength requirements. Lap joints can be performed using dissimilar materials, and an increase in OD is not a critical requirement for this process. Lap joining does necessitate both adequate overlap tube lengths and radial compression during processing.

The third common fusion process application is balloon bonding, or fusing a balloon to a shaft. This process requires heat shielding, joint transition and radial compression.

Technology Considerations

Two basic technologies exist to support the catheter fusion process. These are thermal bonding, using air and heated dies, laser or adhesive bonding utilizing cyanoacryate or UV Cure. Each of these process alternatives has distinct advantages and disadvantages to be considered based upon results objectives, time and budget.

Thermal Bonding (Die Head)	• Cost ($9k average) • Cycle time • Precision alignment • Yields all bond types (Butt, Overlap, Balloon) • Efficient use of bench space • Low maintenance / calibration • Simple tool interchange • Creates uniformity • Tight, repeatable bond results

Laser	• Cost ($100k average) • Rotation needed • Elaborate product fixturing • Primarily for Balloon Bonding • Higher maintenance (gas, calibration) • Large footprint • Cumbersome operator interface
Adhesive	• Inconsistent Bond quailty • Operator dependent (even with precise dispenser, there are many uncontrollable factors for the Process Engineer and QA personnel). • Chemical introduction (bio-compatibility issues) • Most thermoplastics are not conducive to adherence to adhesives; • expensive surface treatments such as plasma to facilitate the joint.

Additional process considerations include production cycle times and product handling requirements.

Results Objectives

Typical catheter fusion results objectives are defined as precision, quality and yield. Precision relates to the size of the finished product, quality is here defined as strength, smoothness and flexibility requirements, and yield pertains to throughput expectations, or the number of finished products needed.

Depending upon the materials you select, your process will mandate specific tooling requirements. Catheter fusion may require use of a mandrel, in either metal or Teflon, as well as die heads

In Conclusion

The quality of a catheter tube bond is the result of proper interfacing of material, tooling and heat delivery. In today's competitive marketplace, catheter manufacturing engineers rely upon precision, durability and repeatability to optimize process results. Upon reviewing the alternatives, results show the bonding of thermoplastic materials using air and heated dies consistently offers catheter manufacturers the most reliable, cost-effective, high-quality results currently available.