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# OmniCure® Assembly Solutions

*Bonding of Balloon Catheters*

**APPLICATION NOTE**
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## The Challenge

Repeatable, uniform curing of balloon catheters.

## The Solution

The OmniCure® S2000 UV Spot Curing system with Closed-Loop Feedback technology and a four-leg High Power Fiber Light Guide or Cure Ring optical accessory.

## The Benefit

Strong and repeatable bonding of plastic parts.

## INTRODUCTION

Catheters are plastic tubes, sometimes coated, that are inserted into vessels or cavities in the body to facilitate a variety of functions. Catheters make it possible to drain or inject fluids, maintain open passageways or to access areas of the body with surgical instruments. Key applications for catheters include cardiovascular, urological and intravenous. Urological catheters are the top selling applications based on unit sales; however, cardiovascular catheters have the largest share of revenue.

UV spot curing is used extensively in the manufacturing of cardiovascular catheters since there are a number of bonding applications, such as balloon bonding, hub bonding and marker bonding; each requiring a strong and repeatable bond of different materials. The critical nature of cardiovascular catheters makes this an ideal application for UV spot curing systems with the highest level of control. This application note will show how using an OmniCure® S2000, an OmniCure R2000 Radiometer, and a High Power Fiber Light Guide or Cure Ring will allow for the repeatable assembly of balloon catheters for cardiovascular applications.

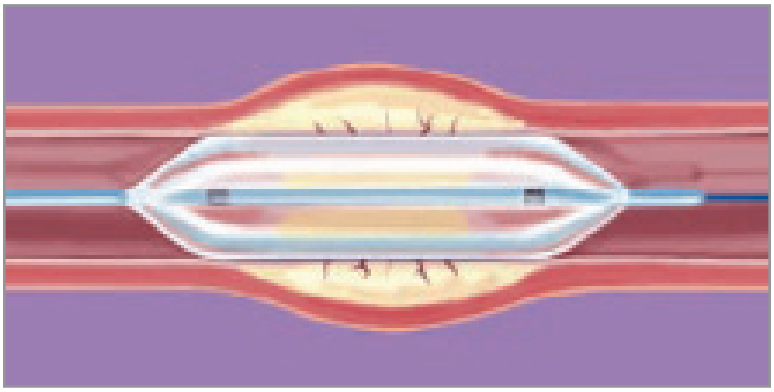
## Catheter Market

The global catheter market was estimated at over $14.5B for 2008 and forecasted to have a compound annual growth rate of 8.3% until 2012, reaching about $22B.[1] Cardiovascular catheters are the strongest segment of the catheter market, expected to reach nearly $15B in revenues by 2012.[2] The market for cardiovascularcatheters is significant and continues to grow because of the extent of heart and cardiovascular disease. Cardiovascular disease is the number one cause of death globally and is projected to remain the leading cause of death, accounting for 30% of disease worldwide.[3]

Atherosclerosis, the progressive narrowing of blood vessels due to a buildup of fatty plaque along the vessel walls, is the main disorder underlying most cardiovascular diseases. Percutaneous transluminal coronary angioplasty (PTCA) is a less-invasive procedure where a balloon catheter is used to open damaged or obstructed coronary arteries. The market for PTCA catheters will experience a strong compounded annual growth rate of 17.1% from 2007 to 2012, reaching nearly $4B in revenue as the number of procedures involving the use of PTCA catheters increases.[4] This increase results from both an aging population and improvements in the catheter technology that now allow the procedure to be performed on patients who, only a few years ago, would not have been candidates due to their more advanced conditions.

1 The Global Catheters Market, BCC Research, August 2007
2 The Worldwide Market for Catheters, Kalorama Information, February 2008
3 3. Source: World Health Organization, www.who.int
4 4. The Worldwide Market for Catheters, Kalorama Information, February 2008

## Curing Process



The assembly process for any medical device must be controlled and repeatable to ensure the highest quality of the finished product. This is especially important for devices used in cardiovascular procedures. The OmniCure S2000 system includes Closed-Loop Feedback technology to automatically maintain a repeatable dose of UV energy to each balloon catheter assembly. UV curing systems without this feature require additional user intervention to maintain a constant dose or risk changes in their process, which could result in inconsistency in the finished parts. The OmniCure R2000 Radiometer can be used to calibrate and set the output on all of your OmniCure S2000 systems, to ensure an exact process across all assembly lines. The OmniCure R2000 calibration is traceable to NIST.

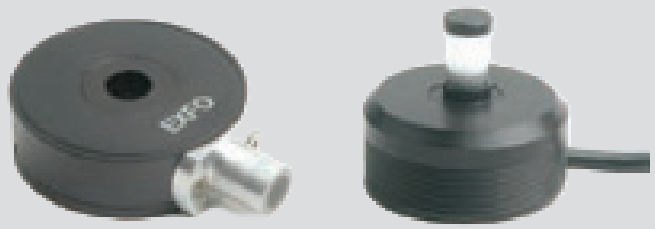
Alternatively, a balloon catheter can be cured using a multi-legged High Power Fiber Light Guide consisting of 3 or 4 legs, arranged radially around the catheter to provide uniform 360° curing. Using a 3-4 multi-legged Light Guide will generally make it easier to bring the catheter in and out of the curing area. With no losses from an optical accessory, it will also require less energy to cure the adhesive. Lowering the irradiance level set on the system will result in increased lamp life, reducing the cost of operation for the curing process. Proprietary technology within the High Power Fiber Light Guide ensures that equal energy is outputted from each leg, which is essential for curing evenly along the bond line of the balloon.

The OmniCure S2000 UV Spot Curing System is ideally suited for today's growing medical device market. It is simple to use and provides the highest levels of control and repeatability. Accessories such as the OmniCure R2000 Radiometer, High Power Fiber Light Guides and Cure Rings allow users to customize their UV spot curing process to optimize the assembly of balloon catheters.

## CATHETER BALLOON BONDING

Balloon bonding of a catheter requires uniform 360° illumination to properly irradiate the assembly. Curing both ends of the balloon catheter interface simultaneously is also advantageous. Specially designed light delivery accessories like the Cure Ring can be coupled to standard Light Guides to provide 360° of uniform curing power. The Cure Ring is available in solid or slotted versions, which can make for easier insertion of the catheter.

Any time there is a connection in the optical path of the system, there will be losses in the light energy through the path. Therefore, when using an optical accessory such as the Cure Ring, it is important to remember that the output irradiance from the Cure Ring will be lower than the output as measured from the tip of the Light Guide. For this reason, a special Cure Ring detector accessory is available for the OmniCure R2000 Radiometer, which allows the output from a Cure Ring to be measured directly.



## OMNICURE UV CURING TECHNOLOGY – PRECISE AND REPEATABLE

- The Closed-Loop Feedback technology found in the OmniCure S2000 system ensures constant irradiance levels, for a repeatable curing process with consistently strong bonds.
- The OmniCure R2000 Radiometer can be used to calibrate and set the output on all of your OmniCure S2000 systems.
- A Cure Ring coupled to standard Light Guides will provide 360° of uniform curing power.
- Proprietary technology within the High Power Fiber Light Guide ensures that equal energy is outputted from each leg.