



OmniCure® Assembly Solutions

Ablation Catheters

The Challenge

Repeatable assembly of electrodes within ablation catheters.

The Solution

- OmniCure® S2000 UV Spot Curing System with Closed-Loop Feedback technology
- Multi-leg High Power Fiber Light Guide

The Benefit

Strong and repeatable bonding of metal to high-temperature thermoplastics.



APPLICATION NOTE

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INTRODUCTION

Normally, electricity flows throughout the heart in a regular measured pattern providing the basis for heart muscle contractions. Sometimes, the electrical flow gets blocked or travels the same pathways repeatedly creating a “short circuit” resulting in a cardiac arrhythmia. There are several types of treatment options for arrhythmias, ranging from medication to the implantation of a pacemaker. Another widespread medical treatment option for arrhythmias is catheter-based ablation.

Catheter Ablation

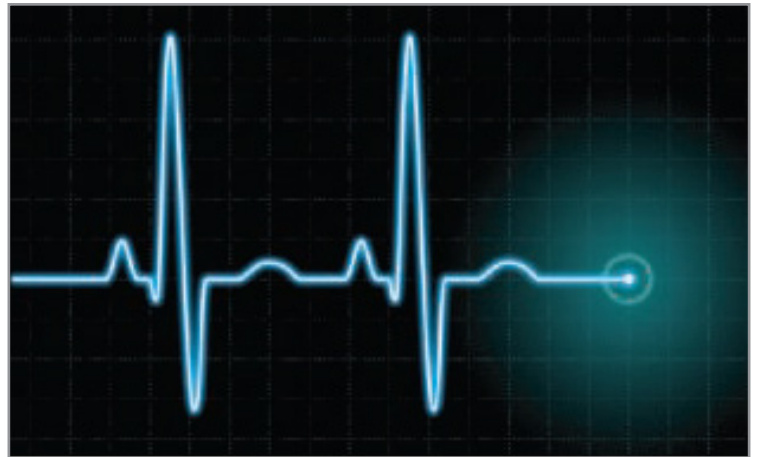
Cardiac ablation is a procedure in which special catheters are inserted into the large veins of the leg and guided up to the heart. Electrophysiology catheters have electrodes at the distal tip to gather data and pinpoint the location of the faulty electrical site.

Ablation catheters are used to destroy small amounts of the tissue causing the electrical disturbance, restoring a healthy heart rhythm.

Catheter-based ablation techniques generally fall into two categories:

- a. RF ablation catheters, the most common form, use radiofrequency (RF) energy to heat the tip of the catheter which is then used to destroy the specific problem areas without harming the rest of the heart.
- b. Cryoablation is a technique where the catheter tip is cooled to subzero temperatures and used to freeze (or cryoablate) the tissue, so it no longer conducts electrical impulses.

UV spot curing is widely used in the manufacturing of cardiovascular catheters because these devices often require numerous bonding steps—such as hub bonding and marker bonding—each of which requires a strong, consistent, and repeatable bond, often between different material types. The critical nature of cardiovascular catheters demands a UV spot curing system with the highest level of control. This application note will show how using an OmniCure® S2000 Elite fitted with a High Power Fiber Light Guide, and an OmniCure R2000 series Radiometer allows for the repeatable assembly of the distal tip of RF ablation catheters for cardiovascular applications.



Ablation Catheter Market

The cardiovascular catheter market, estimated at over \$6B in 2026, is expected to reach nearly \$12.1B in revenues by 2030. Cardiovascular disease, the number one cause of death globally, continues to drive this market. New innovations and better atrial mapping have increased the application of less-invasive procedures such as ablation. For many types of arrhythmias, catheter ablation is successful in eliminating the need for open-heart surgeries or long-term drug therapies.

The market for cardiac catheter ablation may experience a big boost as catheter ablation systems are poised to be indicated for the treatment of atrial fibrillation (AFib). About 5 million Americans are living with atrial fibrillation—the leading cause of hospitalization for arrhythmia in the US. An increase in the number of catheter ablation procedures for treating AFib will fuel a compound annual growth rate of almost 15% in the ablation catheter market over the next five years.

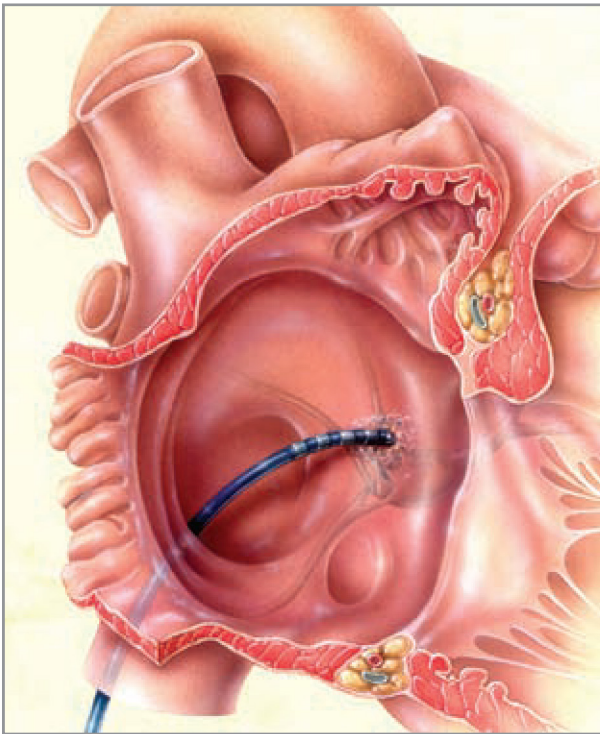


Figure 1: Ablation catheter

Ablation Catheter Assembly Process

The electrophysiology RF ablation catheter includes several distally mounted electrodes, including a tissue ablation electrode along with mapping electrodes. The electrodes are composed of a solid,

electrically conductive material, such as platinum, gold, or stainless steel. The ablation electrode is electrically coupled to the RF generator while the mapping electrodes are electrically coupled to the mapping processor. Using the electrical signals from the mapping electrodes, a physician can identify the specific target tissue sites within the heart and ensure that the arrhythmia-causing substrates have been electrically isolated by the ablative treatment.

Ablation catheters are assembled with the mapping electrodes secured together with the tissue ablation electrode, located as distally as possible on the ablation electrode. However, it is important that the mapping electrodes are electrically insulated from the ablation electrode to provide independent mapping channels. The mapping electrodes are also thermally insulated from the ablation electrode to prevent interference from the heat generated during a radio frequency (RF) ablation procedure. This allows the localized electrical activity of the heart to be measured in real time at the point of energy delivery from the ablation electrode.

To this end, bands of a suitable electrically and thermally insulative material, such as a high-temperature thermoset plastic, are interposed between the ablation electrode and the mapping electrodes. The insulative bands and mapping electrodes are mounted in place using a suitable electrically and thermally insulative, ultra-violet (UV)-curable epoxy to:

- Ensure electrical and thermal insulation between the mapping electrodes and ablation electrode.
- Secure the microelectrodes to the ablation electrode.
- Prevent cross-talk between the otherwise electrically insulated microelectrodes.

UV-curable epoxies are well suited for this application because of their cure-on-demand nature. Once the desired arrangement of the mapping electrodes has been achieved, they can be set almost instantly with a UV-curable epoxy and the appropriate dosage of ultraviolet (UV) energy. Using a standard non UV curable epoxy requires fixturing the electrodes in place over a number of hours while the epoxy cures. In this process, high precision alignment can be difficult to achieve, especially when assembling multiple mapping electrodes onto a single ablation electrode.

The S2000 Elite with closed loop feedback technology ensures optimum consistency of UV output over time. For an added level of accuracy and repeatability, the OmniCure R2000 series Radiometer can be used



to calibrate and set the absolute irradiance output on multiple S2000 Elite systems to ensure an exact process across all assembly lines. The OmniCure R2000 series radiometer calibration is traceable to NIST to provide ultimate accuracy.

A multi-leg High Power Fiber Light Guide is ideal for the application to allow for the simultaneous curing of multiple cure sites. Proprietary technology within the High Power Fiber Light Guide ensures that equal energy is emitted from each leg which is essential for even curing at each of the bond sites, maintaining proper alignment of the electrodes forming the distal tip.

The assembly process for any medical device must be tightly controlled and consistently repeatable to meet stringent regulatory requirements and ensure the highest quality of the final product. This is especially critical in catheter ablation systems, where tiny regions of the heart must be precisely mapped and targeted to correct arrhythmia.

The OmniCure S2000 Elite UV Spot Curing System is simple to use, and provides the highest levels of control and repeatability, making it ideally suited for today's growing medical device market.



Figure 2: OmniCure R2000 Radiometer

OMNICURE UV CURING TECHNOLOGY – PRECISE AND REPEATABLE

- Innovative Closed-Loop Feedback technology ensures constant irradiance levels for a repeatable curing process with consistently strong bonds.
- OmniCure R2000 Series Radiometer can be used to calibrate and set S2000 Elite UV light output to ensure consistency and repeatability across all production lines.
- OmniCure Cure Ring accessory coupled to a standard light guide provides 360 degrees of uniform curing power.
- Proprietary High Power Fiber Light Guide technology ensures that equal energy is emitted from each leg.

