OmniCure® UV Curing • In Control

Assembly of Blood Oxygenators

The Challenge

Bonding and sealing of transparent polycarbonate housing in blood oxygenators.

The Solution

The OmniCure[®] S2000 UV Spot Curing System with Closed-Loop Feedback technology and a Liquid Light Guide along with a light-curable adhesive.

The Benefit

A controlled and repeatable curing process for the assembly of specialized medical devices.

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UV spot curing provides a reliable and repeatable assembly process; important in any manufacturing process, but essential in medical device manufacturing. This application note provides a brief overview of the important role of UV spot curing in the assembly of blood oxygenators used in open heart surgery. Manufacturers can benefit from using a UV curable adhesive along with the OmniCure[®] S2000 UV Spot Curing System to optimize the assembly of the oxygenator housing.

Application Overview

For most cardiac operations, the cardiopulmonary bypass is performed using a heart-lung machine (or cardiopulmonary bypass machine). The machine replaces both the heart's pumping action and the lungs' gas exchange function during the open bypass surgery. Since the heart is stopped during the operation, this permits the surgeon to operate on a bloodless, stationary heart.

One component of the heart-lung machine is the oxygenator. The oxygenator component serves as the lung, and is designed to expose the blood to oxygen and remove carbon dioxide. It is disposable and contains a membrane permeable to gas but impermeable to blood, in the form of hollow fibers. Blood flows on the outside of the hollow fibers, while oxygen flows in the opposite direction on the inside of the fibers.



Figure 1: Cardiopulmonary Bypass Machine.

After the blood has flowed around the fibers of the membrane oxygenator, it must be collected and routed outside the blood oxygenator through an outlet manifold. The housing is often made using two molded polycarbonate components which are assembled and permanently affixed to each other with a medically approved ultraviolet (UV) curable adhesive. The clear plastic allows the physician to visually confirm that the oxygenator is filled with blood.



Figure 2: Oxygenator.





Over 900,000 open heart procedures are performed each year in the United States alone¹, including nearly 2000 heart transplants². At least 48 percent of U.S. adults have some form of cardiovascular disease based on the latest statistics provided by the American Heart Association.³

Assembly Process

The oxygenator assembly can be an automated process where a glue dispenser arm is used to apply a bead of a suitable light curable adhesive along the seal ledge in preparation for assembly. The two halves are then placed together and a curing arm is used to bring a Liquid Light Guide along the full length of the adhesive joint. A Liquid Light Guide is ideal for this application as it is flexible and easily attached to the automated arm, leaving the actual curing system remote to the cure site. The adhesive is fully cured along its length to form a strong, tight seal between the polycarbonate pieces.

Automated assembly provides a number of key advantages for medical devices of this type, foremost being that assembly is extremely accurate and repeatable. The OmniCure S2000 UV/ Visible Spot Curing System includes PC control, multi-function I/O ports and a new high speed shutter, making it ideal for automated assembly processes.

Whenever a polycarbonate-to-polycarbonate joint is being formed, special precautions must be taken to avoid inducing stress cracking in the plastic during the curing process. Special adhesives are used which cure rapidly to form flexible, load bearing bonds. It is important to provide a controlled and repeatable dose of UV energy during the curing process. Curing the adhesive too rapidly or using too high of an irradiance level may cause stress cracking in the polycarbonate joint.

Some thermoplastics, including many grades of polycarbonate, contain additives that block UV radiation and therefore cannot be used with UV-cure adhesives.

For these materials, a special visible light-cure adhesive can be used to solve this problem. However the UV spot curing system must be able to filter out the UV light before it reaches the polycarbonate. The UV energy would be absorbed by the material, heating the plastic and causing stress cracking in the joint. The OmniCure S2000 UV/Visible Spot Curing System has five different filter options including a 400-500 nm filter for blocking the UV light which would be absorbed by the polycarbonate. This allows for a controlled cure without heating of the plastic.

Manufacturing of blood oxygenators requires that the UV adhesive be cured evenly, without inducing stress cracking in the polycarbonate material. Lumen Dynamics' OmniCure technology offers unique benefits over and above standard UV curing, ensuring controlled, even and repeatable curing of the oxygenator for optimal assembly of specialized disposable medical devices. The OmniCure S2000 is the leading UV spot curing system for medical device assembly where lives depend on a repeatable curing process.



The OmniCure S2000 UV/Visible Spot Curing System provides adjustment of the UV irradiance in 1% increments allowing for the precise selection of the irradiance level required for curing the adhesive. Once the optimum irradiance level is selected, the proprietary Closed-Loop Feedback control maintains that level for every cure, ensuring a repeatable curing process. If for any reason the unit is unable to maintain the required irradiance level, an alarm will sound to alert the operator that an error has occurred

Figure 3: Excelitas Closed-Loop Feedback Technology.

^{1.} https://idataresearch.com/over-900000-cardiac-surgeries-performed-every-year-in-the-united-states/

^{2.} https://pubmed.ncbi.nlm.nih.gov

 $[\]label{eq:2.1} 3. \ https://www.cardiosmart.org/news/2019/2/latest-statistics-say-nearly-half-of-americans-have-some-form-of-heart-disease$



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 S2000 cures UV adhesives in seconds and can easily be integrated into fully automated production processes.
- The OmniCure S2000 has a choice of five different filter options to provide low heat curing for materials that absorb UV energy.



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