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Ultrasound Technique Breaks Down Blood Clots

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Global Innovations: Speedy 3D X-Rays in the Operating Room

MackMedical manages suppliers for over 30 components for the disposable patient circuit for Vapotherm's Precision Flow® device. This device was designed to help chronic obstructive pulmonary disease patients avoid more invasive therapies like intubation.

From the Publishers of TECH BRIEFS

Device Helps Patients Avoid Intubation, Improve Outcomes, Reduce Cost

COPD (chronic obstructive pulmonary disease) is a lung disease associated with airflow obstruction. A chronic, debilitating, and sometimes fatal condition, COPD is one of the most common lung diseases, predicted to be the fifth leading cause of disease burden by the year 2020, according to the World Health Organization. Unlike heart disease and cancer, it is the only major disease seeing an increased death rate each year among both men and women.

That said, the disease can be controlled and slowed down with early detection, proper care, and treatment. A critical component of the treatment for COPD and a broad range of other lung diseases and airway inflammations is high flow oxygen therapy. Before the last decade, high flow treatments required some version of mask therapy or intubation and a ventilator. These conventional methods are fraught with issues, both for the patient and health care in general.

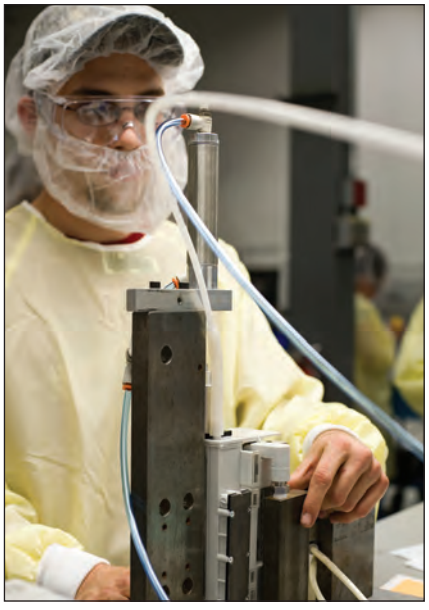

Fig. 1 – MackMedical conducts functional testing at several points throughout the manufacturing process, as well as an operational test in the end-use device.

With mask therapy, many patients are not compliant. They feel claustrophobic and uncomfortable with a mask, and have to take it off frequently to eat, drink and talk. The more they take it off, the less therapy they receive and the sicker they get, often leading to ventilation.

"Helping patients avoid or reduce the duration of mechanical ventilation is one of our primary goals," said Chairman William Niland, founder and chief business development officer, Vapotherm, Inc. (Stevensville, MD). "While it can certainly be necessary and lifesaving, intubation and mechanical ventilation is highly invasive and has known negative side effects, including the effects of pressure on the lungs and the risks associated with infection. It can also be very difficult to wean a patient from a ventilator, and the overall financial costs for our healthcare system are extremely high. Our technology is all about reducing these risks with a noninvasive, patient- and clinician-friendly approach."

Solution: Patented Membrane Technology

Before Vapotherm delivered its first respiratory therapy device in 2001, the industry standard for the flow of breathing gases through a narrow tube, like a nasal cannula, was six liters per minute (lpm). Providing the higher flows needed for the treatment of COPD and other lung diseases through a nasal cannula was limited because of the discomfort and irritation caused by delivering cold, dry breathing gases to the nasal passages.

Using patented membrane technology to warm and saturate the gas stream, however, Vapotherm overcame this limitation, now allowing a flow range up to 40 lpm via nasal cannula with minimal condensation or dilution with room air. "Studies have shown that patients are much more compliant on a high flow nasal cannula than they are on any type of mask therapy, which leads to more consistent usage and better outcomes," said Niland. "Patients are more compliant because they're more comfortable. They can eat, drink, and talk with their doctor and family without interrupting therapy. And for neonatal patients, parents can hold their babies, which they couldn't do with the masks and other types of nasal interfaces used previously."

Beyond improved comfort, compliance, and outcomes, Precision Flow® is helping patients avoid more invasive therapies, which is not only good for the patient but for the health system itself. "Any time a hospital has to put a patient on a ventilator or into an Intensive Care Unit, their costs rise by as much as 50 percent," said Niland.

In spite of the impressive list of benefits, changing the way people do things has been the biggest challenge in getting the product to the patient, according to Niland. "Respiratory therapists are used to putting masks on patients. Changing the normal way people do things is still our biggest obstacle today."

Vapotherm addresses that reluctance through education and a staff of clinical product specialists who are certified respiratory therapists. The company provides onsite clinical product support, including in-servicing, technical support and continuing education. "Once physicians and hospital staff see how much better their patients fare when using Precision Flow® therapy, they're sold," said Niland.

Key Components

The critical component of the FDA-approved Precision Flow® device is the disposable patient circuit, which includes a disposable water path (DWP) with water spike, the patient delivery tube, and a vapor transfer cartridge (VTC).

Manufactured by MackMedical/Mack Molding (Arlington, VT), the patient circuit is detachable and disposable. The

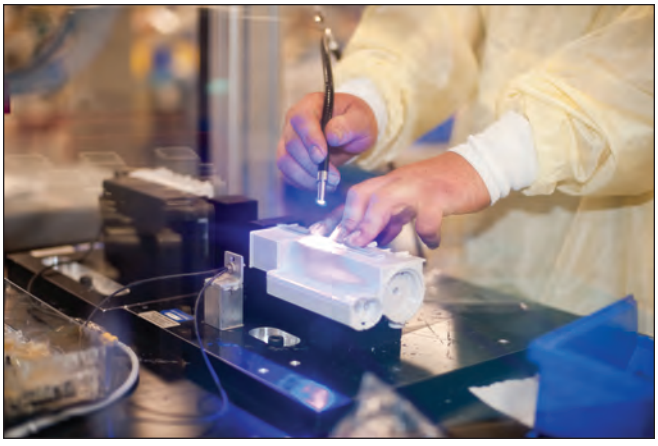

Fig. 2 – Mack installs functional lenses in the disposable patient circuit via an ultraviolet gluing process.

patient delivery tube features a patented triple lumen design, with air surrounded by two water-filled channels. The VTC is the core humidification technology, which allows molecular water vapor to pass into the gas stream, but prevents actual contact between the water source and breathing gas.

Mack worked closely with Vapotherm early on to ensure moldability of the part's design. Many specific details must be held to tight tolerances for precise fit and function. Mack molds five parts from ABS resin for the disposable patient circuit. The assembly included six critical ultrasonic welds, including one that attaches the membrane technology to the unit. Mack employs a robotic ultraviolet gluing process to install clear lenses for viewing the water level and to expose reflectors that signal the device when the patient circuit is in place and functional.

Mack manages suppliers for over 30 components for the project, and completely assembles the disposable unit. The contract manufacturer also conducts functional testing at various points throughout the build process, as well as an operational test in the end-use device.

Future Products

Vapotherm has just expanded its product line to include a high-flow therapy device for home care called Flowrest®, which has received both FDA 510(k) clearance and CE marking. The company has about 10 other products in various phases of development, all revolving around its current hospital and home care platforms. Additionally, Vapotherm has 15 more patent applications in the works.

This article was written by Bryan Campbell, Headquarters Plant Manager for MackMedical/Mack Molding, Arlington, VT. For more information about MackMedical/Mack Molding, visit ***http://info.hotims.com/40431-163****, and for more information about Vapotherm, visit* ***http://info.hotims.com/40431-164****.*

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