



HemoLife Medical, Inc.

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LLUMC Leads Way in New Plasma Toxin Removal Study

I.M.P.A.C.T. System™ "wakes up" patient from deep hepatic coma

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Loma Linda University Medical Center (LLUMC) leads the way in developing new methods of care for the more than 30,000 Americans that die each year with liver failure. The Medical Center is the lead test center in a new study of a plasma detoxification system (described by some as a "liver dialysis"). Presently, the first patient has completed the treatment on the new device. The 56-year-old woman has responded well to this new treatment, "waking up" from a deep hepatic coma. She was discharged to home and continues to await liver transplantation through LLUMC.

The device is under an investigational device exemption (IDE) FDA study for use in Acute-on-Chronic Liver Failure designed and developed by HemoLife Medical, Inc., located in San Clemente California. Under the supervision of Donald J. Hillebrand, MD, Associate Professor of Medicine and Medical Director of liver transplantation at LLUMC, this study targets people in the later stages of liver disease. The study is meant to provide the FDA with data to allow clearance of the device for use in this patient population. Other patients with disease such as sepsis and autoimmune disorders will be studied in the future.

Dr. Hillebrand and the LLUMC multi-disciplinary team recently completed the treatments on the first patient within the study. The treatment is derived from a set of protocols developed by Dr. Hillebrand, the LLUMC team, and the study sponsor through experience with liver support and critically ill patients with liver failure.

"This device is designed to help, not replace the liver," says Dr. Hillebrand.

The study sponsor is providing the financial backing for the study. The goal is to investigate this novel potential treatment for hepatic coma, which is the impaired consciousness, drowsiness, confusion and/or stupor related to liver failure that may develop in the estimated 4 million people suffering from hepatitis and alcohol-induced cirrhosis.

This new system is a compact, mobile device designed to be wheeled to a patient's bedside. The treatment is comparable to kidney dialysis (hemodialysis). Treatment involves a patient being hooked up to the machine with a catheter in a vein in either the leg or the neck. Blood is pumped into the unit where the plasma is temporarily separated to interact with materials that bind toxins. The clean plasma then rejoins the blood cells and flows back into the body. Separating the plasma (liquid portion) of the

blood from the blood cells (red blood cells, white blood cells, and platelets) is designed to enhance the treatment's safety. The device does not contain any living liver cells thus avoiding major cost, infection, and compatibility issues. One treatment lasts four hours. Treatment may be continued daily for up to five days or until the patient's hepatic coma recovers. The total amount of the blood outside the body at any time is less than the amount taken when blood is donated.

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