

chf solutions

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FOR IMMEDIATE RELEASE

NEWARK BETH ISRAEL MEDICAL CENTER IS FIRST IN NATION TO ADOPT CHF SOLUTIONS SYSTEM 100 FLUID REMOVAL SYSTEM

Unique Ultrafiltration System Offers Safe, Efficient Therapy for Patients Suffering From Fluid Overload

BROOKLYN PARK, Minn., Sept. 3 – Newark Beth Israel Hospital, Newark, N.J., an affiliate of Saint Barnabas Health Care System, is the first hospital in the nation to adopt and begin treating patients with the System 100 Fluid Removal System, designed by CHF Solutions, Inc. The System 100 is a mechanical pump and ultrafiltration system that safely and efficiently removes excess fluid from patients suffering from fluid overload. Fluid overload can cause severe fatigue, shortness of breath and subsequent hospitalizations.

"Fluid overload is a serious and growing problem and can be caused by many things, including renal failure, post-surgical fluid overload, metabolic disease and congestive heart failure," said John L. Erb, chief executive officer, CHF Solutions, Brooklyn Park, Minn. "We are very pleased that Newark Beth Israel Medical Center is the first facility in the nation to use our System 100 Fluid Removal System. Our mission is to provide physicians with innovative and proprietary medical solutions that enable the treatment of patients with unmet clinical needs. The System 100 is unique in its ability to remove fluid safely and at a controlled rate. Ultrafiltration is an excellent alternative to less predictable intravenous diuretic drug therapies that can incur significant health risks and extended hospitalizations."

In early June 2002, CHF Solutions received marketing clearance for the System 100 from the U.S. Food and Drug Administration. Initially, CHF Solutions is placing the System 100 at a limited number of medical centers and is planning a national introduction late in the third quarter.

According to Mark J. Zucker, MD, JD, FACC, FACP, director of cardiothoracic transplantation at Newark Beth Israel Medical Center, "We have been impressed with the ease-of-use features and clinical benefits of the System 100 in treating fluid overload. We believe many of our patients may be eligible for this treatment alternative. In addition, it does not require extensive training and can be operated by a physician or nurse."

The System 100 Fluid Removal System can reduce the frequency and length of hospital stays, lower related health care costs and improve the quality of life for fluid-overloaded patients. While many health conditions can cause fluid overload, including renal

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failure, post-surgical fluid overload and metabolic disease, congestive heart failure is the leading cause. An estimated five million Americans suffering from congestive heart failure alone. Excess fluid, which often collects in the lungs and lower limbs, causes symptoms such as edema (swelling), fatigue and shortness of breath.

There is significant interest in the cost effectiveness of the System 100. As an example, Medicare reimbursement only covers about half of the approximate \$10,000 cost of hospitalization for fluid overload associated with congestive heart failure. The cost of the System 100 therapy is less than \$1,000 and will be reimbursed under current DRG codes. In the United States each year, congestive heart failure leads to 2.2 million hospital admissions at an estimated cost of \$23 billion annually.

How the System 100 Works

The System 100 allows a clinician to extract a targeted volume of fluid from the blood at a precisely controlled rate using a technique called "ultrafiltration," which removes isotonic fluid from the blood. Using a proprietary disposable blood circuit/filter and a reusable console to perform ultrafiltration, the System 100 connects to the bloodstream through small catheters inserted into peripheral veins, typically in the arms. The system's ability to predictably remove excess fluid reduces the risk of removing too much fluid too quickly, which can result in low blood pressure and vital organ damage.

The System 100 offers a rapid, precise and safe approach to treating fluid overload, removing two to four liters of fluid in a four-to eight-hour period. In contrast, standard intravenous diuretic drugs are used cautiously (due to their increased risk) and may take as many as four days in the hospital to achieve similar results. In addition, the System 100 has been shown to have no impact on blood chemistry, blood pressure or heart rate of clinical significance.

CHF Solutions completed the Simple Access Fluid Extraction (SAFE) clinical trial and submitted the data to the FDA. The SAFE trial showed that the System 100 Fluid Removal System can be used safely and effectively for temporary (less than eight hours) ultrafiltration of patients with fluid overload.

About CHF Solutions

CHF Solutions Inc., based in Brooklyn Park, Minn., designs and manufactures mechanical pump/filter systems to remove excess fluid in fluid-overloaded patients and improve their quality of life. The company's mission is to provide cardiologists with innovative tools to better manage fluid-overloaded patients and to significantly reduce health care costs. For additional information, visit the company's Web site at www.chfsolutions.com.

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