

Bioartificial Liver Systems

*Committed to
Saving Lives...*

Worldwide.

The Bioartificial Liver System developed by Excorp Medical is an extracorporeal (outside the body) process to metabolize toxins from the blood of a patient in acute liver failure. The patient's blood circulates continuously through a proprietary bioreactor - a cartridge filled with pig liver cells.

Metabolic action by the liver cells is the only way to effectively remove these toxins; otherwise the consequences for patients are prolonged and expensive hospitalizations or death. The therapeutic goal is to provide this metabolic support until a patient's native liver recovers through regeneration or a suitable transplant can be performed.

The liver is the largest organ in the body and performs more than 500 vital biochemical tasks that impact all body systems. Not surprisingly then, compromised liver function has widespread effects on virtually all other organs. The liver is the only solid organ that can regenerate after major injury, with most of the regeneration occurring in the first few days or weeks.

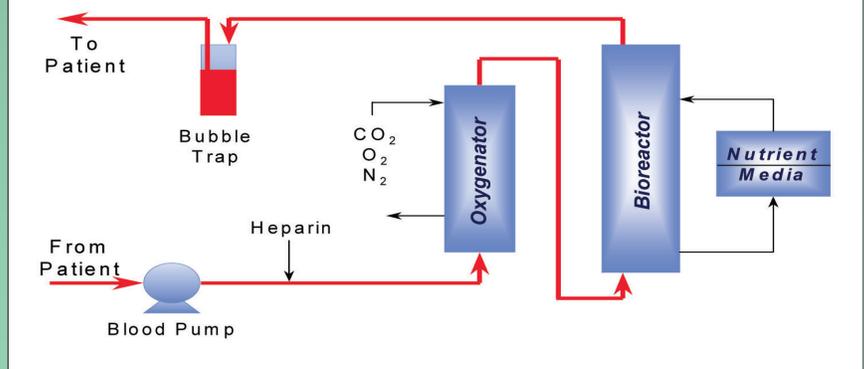
Over 46,000 deaths occur annually in the U.S. from progressive liver failure, but only around 6000 transplants are performed, primarily due to the shortage of donor organs.

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Technical Solution:



The Bioreactor:

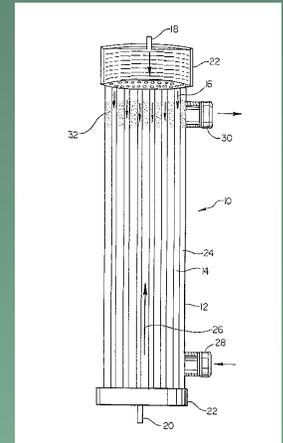
The Bioreactor and associated components comprise a single-use, disposable system. Liver support treatments last 12 hours and may be repeated as necessary. A catheter connects the patient's venous blood to the system which operates outside the body. The system detoxifies blood passing through the Bioreactor which is filled with a suspension containing billions of pig liver cells.

A hollow-fiber membrane provides a barrier to direct contact between the patient's blood and the pig cells. This prevents the patient's immune proteins from attacking the pig cells and unwanted components from the pig cells getting into the patient's blood. However, toxins in the patient's blood, such as ammonia, lactic acid and bilirubin, readily diffuse through the membrane to reach the pig liver cells where they are metabolized into natural by-products that diffuse back into the patient's blood for normal elimination.

Patented Technology:

The Company's patent on this technology was issued in 1999 with international patents pending. It covers non-human cells from any source, packed into the bioreactor at high density. This density is comparable to the cell density in living organisms and substantially greater than the level achieved by standard tissue culture techniques. This higher density allows the liver cells to organize in a manner very similar to normal tissue for greater effectiveness in the removal of toxins from the patient's blood.

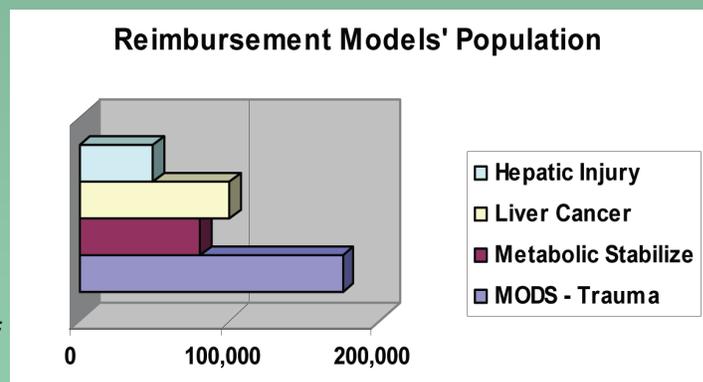
The first indication for use, Hepatic Injury, is further protected in the U.S. by an Orphan Drug Designation, providing a seven-year market exclusivity.



The Marketplace:

The Excorp Medical Bioartificial Liver System will be utilized by hospitals, almost exclusively in the Intensive Care Unit. The Bioartificial Liver System is a life-saving, cost-reducing technology, with virtually no alternative medical therapy. The total population to be served is 350,000 patients per year in the U.S. The indications for use of the Bioartificial Liver System are divided into four reimbursement models.

1. Hepatic Injury: Patients in liver failure who progress to coma despite all available medical care have a very poor prognosis with a mortality rate approaching 90%. There are over 65,000 patients per year in the U.S. with this indication; **2. Liver Cancer:** Patients with primary or secondary liver tumors are frequently treated by surgical excision or by ablation (destroying the tumor, usually with chemicals or temperature). There is a population of approximately 100,000 primary and secondary liver cancer patients per year in the U.S.; **3. Metabolic Stabilization:** Patients with chronic liver disease and cirrhosis are frequently poor candidates for surgery because of metabolic instability due to their damaged livers. There is a population of approximately 80,000 patients per year in the U.S.; **4. MODS - Trauma:** **M**ultiple **O**rgan **D**ysfunction **S**yndrom, a condition arising from septic shock representing a systemic reaction to infection or trauma, such as an automobile accident, battlefield injury or severe burn, may cause liver failure. MODS - Trauma represents a population of at least 175,000 patients per year in the U.S.



This technology is in clinical trials and has not been approved for sale in the U.S.

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