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Paragonix Technologies, Inc., Announces an Exclusive Supply Agreement with Sanbor Medical for the Manufacture and Assembly of SherpaPak™ Organ Transport Systems

The SherpaPak™ Organ Transport Systems combine innovative cooling technology with a safe, consistent method for cold ischemic storage and transport of donor kidneys and hearts to recipients for implantation.

January 04, 2017 06:00 AM Eastern Time

BRAINTREE, Mass.--([EON: Enhanced Online News](#))--Paragonix Technologies, Inc. today announced entering into a supply agreement with Sanbor Medical, LLC for the manufacture and assembly of SherpaPak™ Cardiac Transport System^{1,2} and SherpaPak™ Kidney Transport System^{3,4}. Sanbor Medical is a vertically integrated medical device contract manufacturer based in Allentown, PA.

Bill Edelman, Chairman and CEO, for Paragonix commented, "We are excited to partner with Sanbor Medical, a contract manufacturer for medical devices. Sanbor Medical has the expertise, scale and infrastructure for the production of the SherpaPak™ Organ Transport Systems. This supply agreement will accelerate our commercialization strategy for the Paragonix SherpaPak™ product portfolio. This agreement will enable Paragonix to meet growing clinical demand for SherpaPak™."

"Innovative Cold Storage Of Donor Organs Using The Paragonix SherpaPak™ Devices"

Previous Announcements

Paragonix previously announced December 22, 2016 an exclusive distribution agreement with Bio Instruments for Paragonix SherpaPak™ Cardiac and Kidney Transport Systems in the Midwestern United States

Paragonix previously announced November 9, 2016 an exclusive distribution agreement with Pacific West Medical Sales for Paragonix SherpaPak™ Cardiac and Kidney Transport Systems in California

Paragonix previously announced June 29, 2016 a Product Supply Agreement with Waters Medical Systems LLC, for Waters IGL and Celsior® Cold Storage Solutions for Use with the SherpaPak™ Kidney Transport System and SherpaPak™ Cardiac Transport System

Paragonix and Essential Pharmaceuticals LLC previously announced June 28, 2016, a Product Supply Agreement for Custodiol® HTK Organ Preservation Solution for Use with the SherpaPak™ Cardiac Transport System and SherpaPak™ Kidney Transport System

Paragonix previously announced on July 23, 2015, Publication of "Innovative Cold Storage Of Donor Organs Using The Paragonix SherpaPak™ Devices"⁵

Paragonix previously announced on February 9, 2015, Innovative Tracking Technology For Real-Time, National Location Tracking of Donor Organs

Paragonix previously announced on December 2, 2014, clearance of two 510(k) Premarket Notifications by the US Food and Drug Administration, allowing the Paragonix Sherpa Pak Transport Systems to be combined and distributed with any FDA-cleared, commercially-available preservation solution.

Paragonix previously announced on Nov 17, 2014, Receipt of ISO 13485:2003 Certification for the Paragonix Sherpa Organ Storage and Transport Systems

Paragonix previously announced on Nov 3, 2014, filing of two 510(k) FDA Pre-Market Notifications to combine the Paragonix Sherpa Pak Cardiac and Kidney Transport Systems with any effective organ preservation solution currently marketed under 510(k) Pre-market Clearance

Paragonix previously announced on Oct 27, 2014, joining of David D'Alessandro, MD, as Medical Director for Paragonix

About Sanbor Medical

Sanbor Medical, based in Allentown, PA, is a vertically integrated contract manufacturer serving the Medical Device OEM community for more than 15 years with high quality, cost effective manufacturing and contract assembly services of medical devices and sub-assemblies.

About the Paragonix SherpaPak™ and SherpaPerfusion™ Cardiac Transport System

Currently, the availability of cardiac transplantation is governed by the "ischemic time", that being, the elapsed time from heart donation to recipient implantation. According to The International Society Of Heart and Lung Transplantation ("ISHLT") guidelines⁶ for the care of heart transplant recipients, the projected ischemic time should not exceed 4 hours^{7,8}, limiting the distance available to transport a donor heart. Paragonix SherpaPak™ Cardiac Transport System is fully disposable,

eliminating problems associated with maintenance, device transport and contamination. The Paragonix SherpaPerfusion™ Cardiac Transport System combines innovative oxygenated perfusion of organs and safe organ storage with the ultimate goal of extending ischemic time to 12 hours, significantly altering the transportation range of donor hearts.

About the Cardiac Transplantation Market

Cardiac transplantation is considered the gold standard therapy for patients in end-stage heart failure.⁹ With over 5.8 million Americans currently diagnosed with heart failure (HF), growing at an annual rate of 400,000 per year¹⁰, there is a persistent need to provide end-stage heart failure support to this expanding population. Estimates of the prevalence of symptomatic HF in the general European population are similar to those in the United States.¹¹ The annual economic burden of treating heart failure exceeds \$34.4 billion¹², over 50% of which is due to the cost of hospitalization.¹³ The financial demands associated with transplantation are considerable. The estimated first year costs for heart transplant are \$997,700, and subsequent annual costs can easily exceed \$30,000¹⁴. In the United States, around 30,000 people die annually from end-stage heart disease. As of June 1, 2012, 3,203 patients in the United States are on the waiting list for a heart transplant¹⁵. Based on 2011 data, just over 2,300 patients will receive a live-saving transplant each year, which is reflective of the enormous donor heart shortage. These data, however, only seem to represent the tip of the iceberg. Assuming that up to 50,000 people with end-stage heart failure are candidates for transplantation¹⁶, maximization of donor organ utilization has enormous potential in cardiac transplantation.

About Paragonix Technologies, Inc.

Based in Massachusetts and founded in 2010, Paragonix Technologies, Inc., is a privately held medical device company innovating the Paragonix SherpaPak™ and SherpaPerfusion™ Cardiac Transport System, a novel, single-use organ preservation device to improve donor organ quality. Paragonix has established a pipeline of donor organ transport devices that address the current donor organ shortage by maximizing donor organ utilization, improving donor organ quality and extending donor organ transport throughout the entire United States.

¹ The ShepaPak™ Cardiac Transport System is protected by patents, both issued and pending

² The ShepaPak™ Cardiac Transport System has received FDA 510(k) pre-market clearance

³ The ShepaPak™ Kidney Transport System is protected by patents, both issued and pending

⁴ The ShepaPak™ Kidney Transport System has received FDA 510(k) pre-market clearance

⁵ Michel et al. Heart, Lung and Vessels; 2015;7(3):246-55

⁶ ISHLT Guidelines for the Care of Heart Transplant Recipients, Task Force 1: Peri-operative Care of the Heart Transplant Recipient (Aug. 4, 2010)

⁷ J Heart Lung Transplant 2001; 20(2):212.

⁸ J Am Coll Cardiol 2004; 43(9):1553-1561.

⁹ Datamonitor senior cardiovascular analyst Dr. Sergey Ishin. "Cardiac transplantation continues to be the gold standard for the treatment of end-stage heart failure.

However, the number of potential transplants far exceeds the number of donors." <http://about.datamonitor.com/media/archives/314>

¹⁰ Circulation 2010;121:e46-e215

¹¹ <http://about.datamonitor.com/media/archives/314>

¹² Circulation 2011;123(8):933-944

¹³ Circulation 2007;115(5)

¹⁴ <http://www.transplantliving.org>

¹⁵ <http://optn.transplant.hrsa.gov>

¹⁶ <http://www.uptodate.com/contents/heart-transplantation-beyond-the-basics>

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Recent Stories



February 20, 2018

Paragonix Technologies, Inc., Announces European Conformity ("CE") for the SherpaPak™ Cardiac Transport System and SherpaPerfusion™ Cardiac Transport System

BRAINTREE, Mass.--(EON: Enhanced Online News)--Paragonix Technologies, Inc., Announces European Conformity ("CE") for the SherpaPak™ and SherpaPerfusion™ Cardiac Transport System [More »](#)



August 08, 2017

Paragonix Technologies Inc. Announces Extension of Product Portfolio with the Addition of SherpaPak™ Lung Transport System

BRAINTREE, Mass.--(EON: Enhanced Online News)--Paragonix Technologies Inc., Announces Extension of Product Portfolio with the Addition of SherpaPak™ Lung Transport System [More »](#)



April 24, 2017

Paragonix Technologies Inc., Announces Presentation of the SherpaPak™ Organ Transport Systems at the American Transplant Congress (ATC) (Chicago, April 29 - May 3, 2017)

BRAINTREE, Mass.--(EON: Enhanced Online News)--Paragonix Technologies Inc., Announces Presentation of the SherpaPak™ Organ Transport Systems at the American Transplant Congress (ATC) (Chicago, Apr... [More »](#)

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