

March 30, 2017



RenovoRx Announces FDA Clearance for Expanded Labeling

LOS ALTOS, Calif., March 30, 2017 /PRNewswire/ -- RenovoRx, manufacturer of the RenovoCath adjustable dual-balloon infusion catheter, today, announced it has received FDA 510(k) clearance to expand its indications for use to include the 'delivery of chemotherapeutics'. The RenovoCath device isolates segments of the peripheral vasculature, allowing physicians to deliver therapeutic agents in a more targeted fashion.

The new clearance expands the catheter's marketability for use with chemotherapeutics and potentially increases the number of diseases the RenovoCath may be used to treat. "This additional FDA indication marks yet another milestone for RenovoRx as we continue to work towards making our technology available to physicians to treat difficult diseases," says Shaun Bagai, RenovoRx's CEO.

Studies show that the targeted delivery of chemotherapy may allow for higher concentrations of chemotherapy to reach the desired target, while potentially reducing overall side-effects typically associated with systemically delivered chemotherapy. The RenovoCath's dual balloons can be inflated independently and, unlike other catheters, the distance between the two balloons can be adjusted to isolate the desired treatment target. This adjustable length may allow for truly targeted therapy, while reducing washout of the therapy and potential systemic side effects. At his presentation at the November 2016 AIM/VEITH Symposium in New York, David Madoff, M.D., Professor of Radiology and Chief of Interventional Radiology at New York Presbyterian/Weill Cornell Medical Center and RenovoRx Advisory Board Member, described the versatility of the technology: "This catheter technology is different in that there's two balloons within a single catheter that can be inflated separately and has distinct lumens. You can adjust the length between the balloons to actually isolate and customize the area that you want to treat."

Dr. Madoff, who has used the catheter in several procedures has said that targeted delivery of drugs, like chemotherapy, has the potential to manage diseases that are otherwise difficult to treat and described the RenovoCath as the "ideal catheter for targeted delivery."

The RenovoCath is indicated for the isolation of blood flow and delivery of fluids, including diagnostic, chemotherapeutic and/or other therapeutic agents, to selected sites in the peripheral vasculature system.

About RenovoRx

RenovoRx (www.renovorx.com) is developing innovative solutions for targeted therapies. The ability to deliver therapeutic and/or chemotherapeutic materials at high concentration to specific vasculature, safely and without perfusion overlap to other regions, is a central paradigm of the company's technology. RenovoRx is based in Silicon Valley, California, and its top financial backers include Astia Angels, Golden Seeds, The Angels' Forum, The Halo Fund III, L.P., Plug and Play, and Rising Tide Fund/Portfolia.

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