

Prytime Medical Devices Announces FDA 510(K) Clearance for Expanded Indication for the ER-REBOA™ Catheter

San Antonio, TX – April 4, 2017 – Prytime Medical Devices, Inc. (*The REBOA Company™*), today announced FDA 510(k) clearance for expanded labeling changes to the ER-REBOA™ Catheter.

The labeling changes include:

- Specifically including emergency control of hemorrhage as an indication
- Reducing the mandatory use of fluoroscopy during placement to recommending use of X-ray or fluoroscopy
- Allowing placement and use without imaging when none is available
- Including a summary of real world post market clinical data supporting these changes
- Increase shelf life from one to three years

“The military in particular has been interested in the potential clinical benefit of early placement and use of the ER-REBOA™ catheter to save combat wounded,” stated Dr. John Holcomb, Prytime’s Chief Medical Officer. “The FDA has a long tradition of support for military issues, which I applaud. This expanded indication will directly support the military’s interest in safely treating patients closer to the time of injury.”

Hemorrhage due to trauma is the leading preventable cause of death in the military and civilian setting, accounting for up to 90% of potentially preventable deaths. A significant majority of civilian and combat-related mortality caused by traumatic truncal hemorrhage occurs before reaching definitive care. Therefore, early hemorrhage control as a bridge to definitive surgical care may yield a large survival advantage.

The ER-REBOA™ Catheter is the first catheter designed specifically for rapid, temporary occlusion of large vessels in the emergency and critical care environment. Key design benefits include a patented atraumatic P-Tip® , guidewire free placement, external insertion length markers, small sub 7Fr size and built-in blood pressure monitoring.

About REBOA

REBOA (Resuscitative Endovascular Occlusion of the Aorta) is a minimally invasive technique to temporarily occlude large vessels by using a balloon catheter. Leading trauma centers across the US are adopting REBOA as a vital temporizing adjunct to control hemorrhage, which has been identified as the number one cause of potentially survivable death in the surgical, emergency, and critical care environment.

About Prytime Medical Devices (The REBOA Company™)

Prytime Medical is an innovative medical device company that designs, develops and commercializes minimally invasive solutions for trauma. The company’s flagship product is the

ER-REBOA™ Catheter, a patented 7 Fr compatible balloon catheter for temporary occlusion of large vessels and pressure monitoring including patients requiring emergency control of hemorrhage. The company is developing multiple next generation REBOA catheters and other minimally invasive solutions of interest. More information can be found at www.prytimemedical.com or by calling (210) 340-0116. Media inquiries to Ms. Fafa Madanipour at fmadanipour@prytimemedical.com.

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