



Contact: George Wallace, CEO  
EMBA Medical™ Limited  
+1 954 604-6236  
[www.EMBAmedical.com](http://www.EMBAmedical.com)  
[info@EMBAmedical.com](mailto:info@EMBAmedical.com)

**FOR IMMEDIATE RELEASE**

**EMBA MEDICAL™ LIMITED CLEARED TO MARKET  
HOURGLASS™ PERIPHERAL EMBOLIZATION PLUG IN NEW ZEALAND**

**Clinical Study Results for First Over-the-Wire Embolic Device Also Released**

**DUBLIN, IRELAND** –EMBA Medical™ Limited announced today that the company may now market its revolutionary peripheral embolization device in New Zealand due to the successful completion of the WAND (Web Assisted Notification of Devices) notification. In addition, the company announced completion of enrollment and release of 30-day follow-up data for the 10 patient EMBA Peripheral Embolization Device (EPED) Study conducted at Auckland Hospital.

EMBA Medical™ Limited completed the notification for the device, known as the Hourglass™ Peripheral Embolization Plug, through the New Zealand WAND database in conjunction with in-country sponsor Emergo on September 21, 2015.

George Wallace, CEO of EMBA Medical™ Limited, said, “This is the first integrated, over-the-wire device designed for peripheral embolization procedures. We believe that the Hourglass™ device will provide a new level of confidence, precision, and control for physicians performing peripheral embolization procedures.”

Interventional Radiologist Andrew Cragg, MD, co-inventor of the Hourglass™ device, commented, “The goal with over-the-wire design is to provide physicians with accurate, stent-like delivery of the device in the vessel. The device’s unique design was created to take advantage of natural hemodynamic forces to provide immediate, focal, stable occlusions.”

Patient interim results from the EPED Study demonstrated the benefits of both the hourglass design and over-the-wire delivery including:

- 90 to 100% occlusion at 1 minute post-implant placement
- Trackability rated as “easy” in 10 out of 10 procedures
- PED occlusion at completion rated as “complete” in 100% of cases
- Value of over-the-wire device placement rated as “very useful”

Dr. Andrew Holden, Director of Interventional Radiology at Auckland Hospital and Associate Professor of Radiology at Auckland University School of Medicine, is the primary investigator in the EPED clinical study. Following the first 10 cases with the 5F Hourglass™ Peripheral Embolization Plug, he commented, “We implanted the EMBA Hourglass™ in a variety of clinical embolization procedures. We found that the device was superior to coil embolization in many aspects including



the ability to accurately deploy over a wire and obtain immediate occlusion with a single device in a wide range of vessel sizes.”

The Hourglass™ Peripheral Embolization Plug is a Class IIb medical device and is manufactured in the EMBA Medical™ Limited ISO-certified manufacturing facility in Miramar, Florida, USA. The device was awarded a CE certificate on July 10, 2015, enabling the company to pursue commercial activities in EU nations. The device has been submitted to the FDA and is currently under review.

**About EMBA Medical™ Limited**

EMBA Medical™ Limited is a Dublin, Ireland, domiciled medical device company that designs and develops innovative peripheral embolization technologies focused on improving safety, control, and outcomes. Malin Corporation plc, the Irish-based global life sciences company, is the lead investor in EMBA Medical™. Intersect Partners, a medical device incubator with extensive experience in vascular interventions, is the developer of the technology. EMBA Medical™ Limited is located at Block 2 Harbour Square, Crofton Road, Dun Laoghaire, Dublin, Ireland. EMBA Medical and Hourglass are trademarks of EMBA Medical, Inc.

The company can be contacted at [info@EMBAmedical.com](mailto:info@EMBAmedical.com).

###