

New Data for the CerviLenz® Device Presented at the 10th World Congress of Maternal and Neonatal Health

Cleveland, Ohio and Rome, Italy – December 20, 2011

Two new studies demonstrating the clinical utility of the CerviLenz® device were presented today at the 10th World Congress of Maternal and Neonatal Health in Rome, Italy. The CerviLenz device is simple to use and disposable, allowing cervical length measurement in any health care setting and providing an immediate quantitative result.

The Congress sponsors include the World Health Organization, the European Association of Perinatal Medicine, the World Association of Perinatal Medicine, and the March of Dimes. Cervical length during pregnancy is the best predictor of preterm birth risk. At the Congress, experts from around the world came together in a scientific session, "Prevention of Prematurity and Care of the Premature," to address this global public health epidemic affecting 13 millions babies every year. The President of the Congress, Gian Carlo Di Renzo, MD, PhD, addressed risk factors and interventions for preterm delivery and introduced the CerviLenz device as a cost-effective innovation with potential to improve maternity care worldwide.

Dr. Di Renzo said, "CerviLenz is a simple device with great promise to identify patients at risk for preterm delivery as well as those in real preterm labor."

Dr. Di Renzo shared data from his recent evaluation of the CerviLenz device in 50 patients at the Santa Maria della Misericordia University Hospital in Perugia, Italy. At each patient's mid-gestation prenatal visit, cervical length was measured by transvaginal ultrasound (TVU) and CerviLenz by two different examiners blinded to the other result.

"Our data show 100% agreement," reported Dr. Di Renzo. "Both TVU and CerviLenz measurements identified all of the patients with a cervical length less than 30 mm, and the correlation coefficient was excellent. I am very pleased with the performance of this new device to identify high risk patients so they can be treated appropriately with progesterone therapy to prevent preterm delivery."

Justin Lavin, MD, the Professor Emeritus, Department of Obstetrics and Gynecology at Northeast Ohio Medical University also shared new data with the Congress today. In this study, conducted at the Akron General Medical Center in Akron Ohio, 144 pregnant women presenting with regular contractions between 22 and 34 weeks of gestation had cervical length measurements completed by a physician utilizing the CerviLenz procedure. A CerviLenz measurement of 25 mm or more ruled out delivery within 7 days with 100% accuracy, and delivery before 34 weeks with 97% accuracy.

“These data show similar results to published data with transvaginal ultrasound assessment of cervical length to rule out suspected premature labor. The CerviLenz device holds great promise as a tool to help physicians make decisions in this challenging clinical situation,” said Dr. Lavin.

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About CerviLenz Inc.

CerviLenz Inc. manufactures and markets the CerviLenz® device– an innovative medical device that measures vaginal cervical length to help identify and manage pregnant women at high risk for premature birth. Dedicated to making a difference in the world of prematurity, CerviLenz Inc. donates a portion of revenue to charitable organizations that advance maternal and fetal health globally. Founded in 2008, the company headquarters is in Chagrin Falls, a suburb of Cleveland, Ohio. The CerviLenz device was designed and is manufactured in Ohio by Interplex Medical, LLC. The device is single-use and made of recyclable plastic. The CerviLenz device is cleared for sale in the U.S. and has its CE Mark and ISO 13485 Certification. For more information, visit www.cervilenz.com or contact Melanie Sweeney, Vice President of Marketing (440.337.4253 or melanie@cervilenz.com).