iTraumaCare™
INNOVATIVE TRAUMA CARE™

PRESS RELEASE

FOR IMMEDIATE RELEASE
DATE: May 16, 2013
CONTACT: Lisa Owens, lisaowens@regval.com, 210.601.6647

Medical Device Firm iTraumaCare™ Receives FDA 510(k) Clearance for iTClamp™ Hemorrhage Control System

[May 16, 2013 – SAN ANTONIO, TEXAS] iTraumaCare, an early-stage medical device firm focused on developing traumatic injury solutions for first responder and military medicine applications, has achieved its third regulatory milestone from the US Food and Drug Administration (FDA). The company received FDA 510(k) clearance to market its first product, the iTClamp™ Hemorrhage Control System, in the United States. The product, which was licensed for sale in Canada in late 2012 and received its CE Mark for sale in Europe in March 2013, will be available to medical professionals in the US within 30 to 45 days.

The iTClamp™ is designed to control severe bleeding – a leading cause of death in traumatic injury – in seconds. The iTClamp™ seals the edges of a wound closed to create a temporary pool of blood under pressure, which forms a stable clot that mitigates further blood loss until the wound can be surgically repaired.

510(k) clearance by the US FDA indicates that the iTClamp™ meets with the FDA's regulatory standards for patient safety and efficacy. FDA clearance is required for the commercial sale and distribution of Class II medical devices in the US, like the iTClamp™.

iTraumaCare's CEO and founder, Dr. Dennis Filips, said, "With this regulatory milestone achieved, we look forward to putting the iTClamp in the hands of health care professionals in the United States and improving patient care."

Incorporated in 2010 and based in Edmonton, Canada with its global commercialization headquarters in San Antonio, Texas, iTraumaCare is addressing unmet needs in the field of emergency medicine by developing, manufacturing, and commercializing solutions to treat common causes of preventable death in traumatic injury scenarios.

###