ICU
MANAGEMENT & PRACTICE

Medical Device Firm iTraumaCare™ Receives CE Marking for iTClamp™ Hemorrhage Control System

iTraumaCare, an early-stage medical device firm focused on developing traumatic injury solutions for first responder and military medicine applications, has achieved its second regulatory milestone. The company received CE Mark approval to market its first product, the iTClamp™ Hemorrhage Control System, in participating European Union countries. The product, which was licensed for sale in Canada in late 2012, will be available to medical professionals in participating European Union countries within 30 to 45 days.

The iTClamp is designed to address massive hemorrhage – a leading cause of death in traumatic injury – by controlling critical bleeding 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.

CE Mark approval is a key indicator of a product's compliance with EU legislation and enables the free movement of products within the European market. This CE Mark approval applies to the use of the iTClamp Hemorrhage Control System in participating European Union countries only and does not apply in the US. The company expects US clearance of the iTClamp from the FDA in 2013.

iTraumaCare's CEO and founder, Dr. Dennis Filips, said, "We are delighted with the rapid acceptance of the iTClamp and look forward to launching in Europe soon."

Incorporated in 2010 and based in Edmonton, Canada with a 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.

Source: iTraumaCare

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