



IFU CLAIM STATES:

"When incorporated into a suitable garment and worn in accordance to instruction, the HART CC (commotio cordis) Pad device has been shown to reduce the mechanical impact received by the chest that may facilitate the reduction in risk of commotio cordis."



Development of a Chest Wall Protector Effective in Preventing Sudden Death by Chest Wall Impact (Commotio Cordis)

PEER-REVIEWED, PUBLISHED STUDY, CLINICAL JOURNAL OF SPORT MEDICINE, MARCH 2016

Lead PI, Dr. Mark Link, Cardiologist, Tufts Medical Center, world leading expert on Commotio Cordis

STUDY HIGHLIGHTS

Objective:

"Commotio cordis, sudden death with chest impact, occurs clinically despite chest wall protectors worn in sports. In an experimental model of commotio cordis, commercial available chest wall protectors failed to prevent ventricular fibrillation (VF). The goal of this investigation was to develop a chest wall protector effective in prevention of commotio cordis."

Results:

"..Of 12 chest protectors assessed, only 3 significantly lowered the risk of VF compared with impacts without chest protectors. These 3 heart protectors were combinations of [Unequal's] Accelleron,® Airilon,® TriDur® and ImpacShield® of different thicknesses."

Clinical Relevance:

"Chest protector designs incorporating these novel materials [Unequal] will likely be effective in the prevention of commotio cordis on the playing field."



BACKGROUND

Commotio cordis, #2 killer in sports, #1 killer in baseball, is sudden death caused by a random, non-penetrating blow to the chest usually from a ball, bat, stick or hand. Most victims are not resuscitated. Unequal's HART® products offer the world's first heart protection technology shown to credibly safeguard at-risk athletes from sudden death.

After the peer-reviewed, published study from Tufts proving Unequal effectiveness, the FDA granted an IFU claim for Unequal HART device, an historic accomplishment for commotio cordis protection. The patented HART is one of the most important breakthroughs for commotio cordis protection that can safeguard the almost 40 million at-risk kids (ages 6 - 18) that play sports. As Tom Adams, the father of a 16-year old Commotio victim, sadly stated, "No one should die playing sports."

MILESTONES

- 2013 Unequal begins prototyping commotio cordis protection
- 2014 Landmark study begins
- 2016 Peer-reviewed study publishes, establishing Unequal HART as first effective protection. FDA application submitted with claim Unequal reduces risk of commotio cordis
- 2017 FDA indication-for-use (IFU) claim granted