



Brolex C SAFE cesarean section safety device receives top scores, rated a MUST HAVE medical device for performing c/sections.

IRVINE, Calif., Dec. 12, 2012 /PRNewswire/ -- Brolex LLC announced today that the C SAFE cesarean section safety device was evaluated in "*Reviews in Obstetrics & Gynecology*." In this unsolicited review by James A. Greenberg, MD, Assistant Professor of Obstetrics, Gynecology, and Reproductive Biology at Harvard Medical School, Vice Chairman of Obstetrics and Gynecology at Brigham and Women's Hospital, and Chief of Gynecology at Faulkner Hospital, C SAFE received the highest number of perfect "5" scores in the history of "*MedReviews – OB Product Reviews*." This device review article is a testimony to the need, benefit, and value for hospitals to incorporate the C SAFE medical device for use in cesarean sections within their institutions. In the review article Dr. Greenberg comments "*I think it is time we made newborn lacerations a "never" event and C SAFE is one tool to get us there.*"

The full review is available at www.csafe.us/medreviews2012.pdf and soon to be available on the MedReviews publisher's website: www.medreviews.com/issues.cfm?journal=5

The review article discusses the value of C SAFE, giving it a perfect score of 5, and goes on to state "*when the costs of a laceration to a baby (including actual medical costs, malpractice costs, and the cost of the ill will generated) are added up, this device looks like one of the best bargains in health care.*"

Scott Berlin, MD, CEO and Founder of Brolex LLC commented, "*The time is approaching that hospitals may need to explain why they didn't have C SAFE available for safer cesarean sections.*" In the most recent UpToDate® Official Topic on Cesarean Delivery: Technique, Vincenzo Berghella, MD, Jefferson Medical College, lists the C SAFE device as one option for entering the uterus, as a device designed to reduce the risk of lacerating the fetus.

Mario Guralnik, PhD, COO and President of Brolex LLC explained that C SAFE is being well received by hospital risk management offices, primarily due to the medicolegal implications for a device that is designed as a SAFETY device for performing SAFER c/sections. In quoting Dr. Greenberg, "*With all the wasted money we throw at the sacred altar of Patient Safety, this product actually makes sense and is worth the marginal cost.*" The key message is really that as c/section rates are rising around the globe, and that elective c/sections are increasingly part of the landscape, we should be acting to minimize those risks involved.

Brolex LLC is the owner and manufacturer of the C SAFE medical device. C SAFE is a novel medical device clinically tested and designed specifically for **performing safer cesarean sections by preventing lacerations to newborns**. Published literature documents there is a 1.5 - 3.0% risk of lacerations or nicks in c/sections. There is strong evidence to suggest that this rate is actually higher than reported or documented. At a documented risk of 1.5 - 3.0%,

this translates to 45,000 newborns annually that experience some level of laceration injury related to c/section. For nonvertex c/sections, reports of a 6.0% risk for lacerations nearly double the number of injuries to newborns.

The **C SAFE medical device reduces or eliminates laceration injury risks**. Benefits of using C SAFE, as well as implementing a Risk Management and Patient Safety Initiative Program using the C SAFE device include:

- Clinical outcomes improvement for newborns
 - Eliminate minor lacerations to acute injuries
 - Avoid short term to long term complications
- Minimize / eliminate medical intervention costs on laceration injuries
- Proactively address medicolegal implications
 - Lacerations do occur,
 - and have negative medical and economic consequences
 - Implications of "Best Medical Practices"
 - What happens when an available safety device is NOT used
- Risk mitigation programs
 - Clinical Risk Mitigation
 - Legal Risk Mitigation
 - Economic Risk Mitigation

For more information, visit www.csafe.us.

CONTACT: Mario Guralnik, PhD, +1-714-660-6066

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