



## 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](http://www.csafe.us/medreviews2012.pdf) and soon to be available on the MedReviews publisher's website: [www.medreviews.com/issues.cfm?journal=5](http://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](http://www.csafe.us).

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