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Fall/Winter 2012 Product Reviews

A member of the *Reviews in Obstetrics & Gynecology* editorial board reviewed the following devices. The views of the author are personal opinions and do not necessarily represent the views of *Reviews in Obstetrics & Gynecology* or MedReviews®, LLC.

Product: C SAFE®
Company: Brolex, LLC
Retail Price: \$280 per box of 10

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Design/Functionality Scale

- 1 = Poor design; Many deficits
- 2 = Solid design; Many deficits
- 3 = Good design; Few flaws
- 4 = Excellent design; Few flaws
- 5 = Excellent design; Flaws not apparent

Innovation Scale

- 1 = Nothing new
- 2 = Small twist on standard technology
- 3 = Major twist on standard technology
- 4 = Significant new technology
- 5 = Game changer

Value Scale

- 1 = Added cost with limited benefit
- 2 = Added cost with some benefit
- 3 = Added cost but significant benefit
- 4 = Marginal added cost but significant benefit
- 5 = Significant cost savings

Overall Scale

- 1 = Don't bother
- 2 = Niche product
- 3 = Worth a try
- 4 = Must try
- 5 = Must have



Design/Functionality: 5

Innovation: 2

Value: 5

Overall Score: 5

Background

In the previous century, when I was an intern, I nicked a baby's eyebrow while making the hysterotomy during a cesarean delivery. The laceration was tiny and the baby was fine, but I was freaked out for a long time thinking how close I came to the baby's eye.

In their product literature, the makers of C SAFE® (Brolex, LLC, Bay Shore, NY) report the incidence of fetal lacerations during cesarean deliveries to be 1.5% to 3.0%,¹ although other studies put this rate much lower, at 0.7%.² Nonetheless, even at the lowest published rate, with about 1.5 million cesarean deliveries per year in the United States, this amounts to approximately 10,500 unnecessary injuries annually.

Design/Functionality

C SAFE has straightforward design that offers a stainless steel surgical blade encased in a plastic handle that extends past the blade and forms into a pointed tip. The idea is to use the plastic tip to enter the uterus and then extend the hysterotomy by pushing the tissue through the blade.

Guess what? In trial use during a cesarean delivery, C SAFE worked exactly as expected. Push the blunted plastic tip through the uterus, bend your hand, push the device, and *voilà*—a hysterotomy with almost no laceration risk to the baby.

Design/Functionality Score: 5

Innovation

C SAFE is another example of a truly simple device that someone should have thought of sooner but didn't. It is pretty much a box cutter with a protected plastic tip. It isn't an iPhone (Apple, Cupertino, CA), but it doesn't have to be.

Innovation Score: 2

Value

Measuring the value of this device is difficult. C SAFE is not expensive (\$28 per piece retail). However, it is seeking to replace a #10 surgical steel blade that is as cheap as medical products get. Regardless, 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.

Value Score: 5

Summary

Initially, I was turned off by the company's brochures featuring picture after picture of mangled babies. Too histrionic. Too much fear mongering. Nonetheless, I tried the product and reflected on my own experience. In the end, C SAFE won me over. 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. I think it is time we made newborn lacerations a "never" event and C SAFE is one tool to get us there.

Overall Score: 5

References

1. Smith JF, Hernandez C, Wax JR. Fetal laceration injury at cesarean delivery. *Obstet Gynecol.* 1997;90:344-346.
2. Alexander JM, Leveno KJ, Hauth J, et al; National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Fetal injury associated with cesarean delivery. *Obstet Gynecol.* 2006;108:885-890.



C SAFE®. Image courtesy of Brolex, LLC (Bay Shore, NY).