

Keller Medical, Inc.

KellerFunnel™ Addresses Capsular Contracture and Implant Rupture Complications

Capsular Contracture

Clinical papers suggest that while the causes of capsular contracture are multi-factorial, exposure to biofilms and bacterial contamination almost certainly have a relationship.¹ Limiting handling of the implants and limiting skin contact prior to the insertion are also suggested.² Research shows that higher capsular contracture rates exist for procedures using periareolar incisions than for inframammary incisions, most likely due to an increase in contamination of the breast pocket with intraductal material colonized by bacteria.³ Advocates of the “no-touch” technique claim eliminating implant skin contact will mitigate transfer of biofilms to the implant and should therefore reduce Bakers Grade III/IV capsular contracture, the most commonly occurring complication of breast augmentation.

FACT: The Keller Funnel™ allows a surgeon to insert prefilled breast implants into a surgical pocket using a “no-touch” technique that eliminates direct contact of the implants with the patient’s skin.

Implant Ruptures

The FDA suggests that one of the mechanisms for rupture is damage during implantation.⁴ The traditional insertion method whereby the implant is forced through an incision with the tip of the surgeon’s finger causes significantly higher local stress than is caused with KellerFunnel™ usage. The KellerFunnel™ minimizes stress on the implant by dispersing a much smaller force over a much larger surface area.⁵ By decreasing stress on the implant, long term intracapsular rupture rates may be reduced along with costly reoperations to replace failed implants. As an example, an independent engineering study showed that by using the KellerFunnel™ the measured force on a 300 cc smooth round implant inserted through a 3.5 cm incision was reduced from a mean of 8700 grams (19.2 lbs) to a mean of only 273 grams (0.60 lbs).⁵

Summary

There is international consensus that complications and reoperations related to surgeries with breast implants or tissue expanders add significant long term cost to patients and health care providers. Usage of the KellerFunnel™ positions surgeons to be on the forefront of medical innovation and be proactive in working towards the goal of reducing complication rates for capsular contracture and intracapsular implant ruptures.

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