

2-in-1 Implant Delivery Device



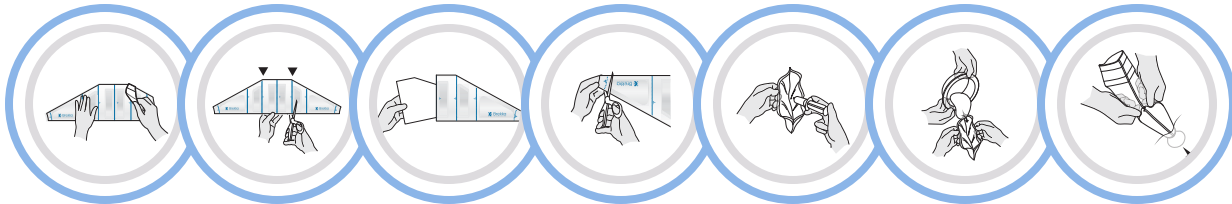
DESCRIPTION

The Brekka is a sterile, configurable device used to assist in surgeries involving the placement of a variety of implants at a variety of implant insertion locations.

INTENDED USE

The Brekka device is intended to facilitate the delivery of silicone gel implants by providing a shell-tissue interface with less friction during insertion of the implant. Optionally, depending upon the implant type and user preferences, the Brekka device may facilitate implementation of a contact-free implant insertion.

How to use (To view the full instructions, follow the IFU QR code show below.)



CONFIGURE

Depending on the implant type and user preferences, cut the device to the desired configuration using the blue dashed lines as a guide. Review IFU configurations A, B, C or D.

TRIM DISTAL END

The recommended trim line is a suggested dimension only. Follow the implant manufacturers' guidelines for determining and making the optimum cutting positions based on the specific implant being used.

HYDRATE

Use approximately 60cc of saline or povidone-iodine prep solution per implant. Add 30cc of solution into the implant tray around the implant and 30cc into the device. Spread fluid as desired.

LOAD & DELIVER

Pour implant with its sterile bath into the device and agitate to ensure implant & distal end is saturated. Deliver the implant by applying pressure behind the implant, pushing it towards the desired opening.



"It worked flawlessly. You have handles to be able to open it up and drop the implant in."

DANIEL C. MILLS, MD, FACS



"I'm really loving it. It seems to perform just as well as the others that we've had and you get two for one!"

ASHLEY GORDON, MD, FACS

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