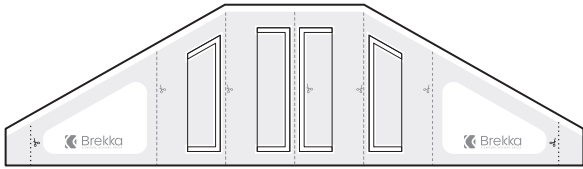


Instructions for Use



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.

SYMBOLS



Sterilized by Ethylene Oxide



Use by Date



Caution



Date of Manufacture



Manufacturer



Keep Dry



Refer to Instructions for Use



Catalog Number



Batch Code



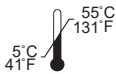
Do Not Resterilize



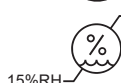
Do Not Reuse



Non-Phthalate



Temperature Range



Humidity Range

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a physician.



Do not use device if the package has been opened or damaged



Not made with natural rubber latex

WARNINGS



SINGLE USE. The product is intended for single patient use only. Depending upon implant type and insertion location, the device can be configured to be used for two insertions on the same patient in a single procedure.



DO NOT USE DEVICE AFTER ITS "USE BY" DATE.



STERILE PRODUCT



Always configure and trim the device according to the implant type and insertion location prior to loading the implant to avoid damaging the implant.



DO NOT USE IF PACKAGE HAS BEEN OPENED OR DAMAGED. The device is sterilized using Ethylene Oxide in sealed, double pouch packaging. Sterility is only maintained if the package seals are intact.



Do not use excessive force when delivering the implant. Stop if the implant does not advance using moderate pressure. Confirm that the incision and the surgical pocket are clear of obstructions and are appropriately sized for the implant. Check that the device isn't twisted or creased in a manner that could obstruct the implant.



DO NOT RE-STERILIZE THE DEVICE. Re-use or re-sterilization shall not be performed under any conditions as contamination or infection may occur.

TROUBLESHOOTING

Problem: The device split during implant delivery.
Solution: Check sizing for implant volume.

Problem: The implant won't move without excessive force. **Solution:** Check sizing for implant volume and also ensure implant and distal end are saturated with solution.

Problem: The implant is damaged.
Solution: Check sizing for implant volume. Replace implant.



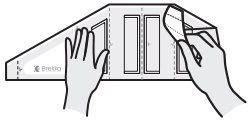
Tested for use with silicone gel implants including, but not limited to, Sientra HSC 10621-700, Mentor SHPX-790, up to 790 cc.



Brekka Medical LLC
390 Commerce Drive,
Woodbury, MN 55125
Phone: 612-500-7433

GENERAL INSTRUCTIONS FOR USING THE BREKKA

1. PREPARE DEVICE

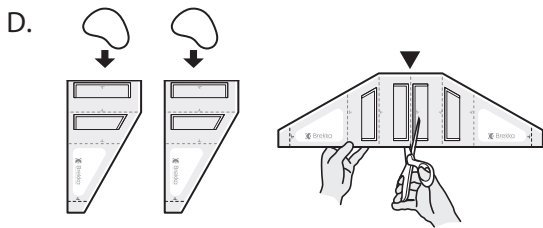
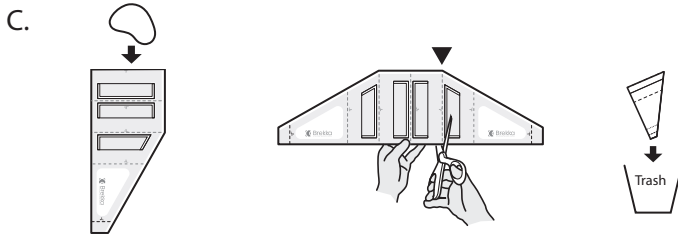
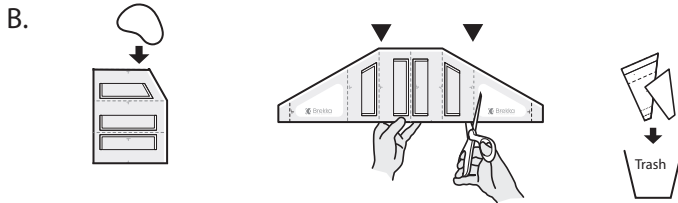
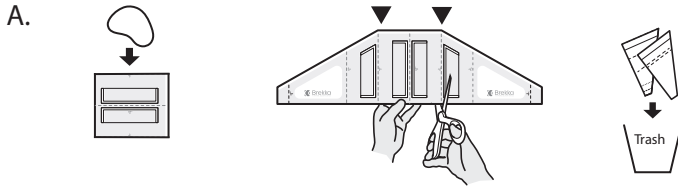


Open inner pouch and retrieve device maintaining sterility.

Unfold the BREKKA, and lay device flat on a sterile surface.

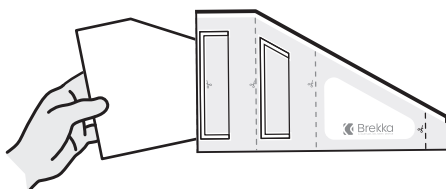
2. CONFIGURATIONS

Depending on the implant type and user preferences, cut device to desired configuration (A, B, C or D) using the Blue dashed lines as a guide.

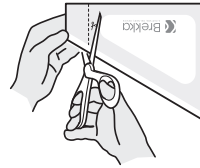


3. REMOVE PAPER LINER

Remove internal paper liner pieces before proceeding.



4. TRIM END OPENING



Trim (Configurations 'C' or 'D' to black dotted line for all implant sizes or based on physician preference).



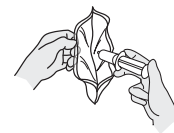
Markings – The recommended trim line is a suggested dimension only. Follow the implant manufacturers' guidelines for determining and making the optimum cutting positions based on the specific implant being used. It is the responsibility of the user to assure that the openings are adequate to assure implant passage without damage to the implant.

5. LOAD IMPLANT

1. Use approximately 60cc of saline or povidone-iodine prep solution per implant, depending on user preference.
2. Add 30cc of solution into the implant tray around the implant in the manner preferred.
3. Agitate the implant in the container.
4. Replace sterile gloves with a new pair.



5. Open
Open the device at the desired end using the supplied handles.



6. Add fluid
Inject 30cc of fluid (from a 60cc or similar syringe) into the device. Spread fluid as desired by pressing and wiping the device from the outside and ensure full solution coverage.



- 7a. Load - Option 'A'
Pour implant with its sterile bath into the desired end of the device and agitate back and forth a few times to ensure implant & distal end is saturated with solution. Note orientation of the implant.



- 7b. Load - Option 'B'
Depending on user preference, use your hands to adjust implant position.

6. DELIVER IMPLANT



Propel - Manipulate and deliver the implant by applying pressure behind the implant, pushing it towards the desired opening. Depending upon implant type and orientation, the user may opt to directly manipulate the implant by hand during delivery.