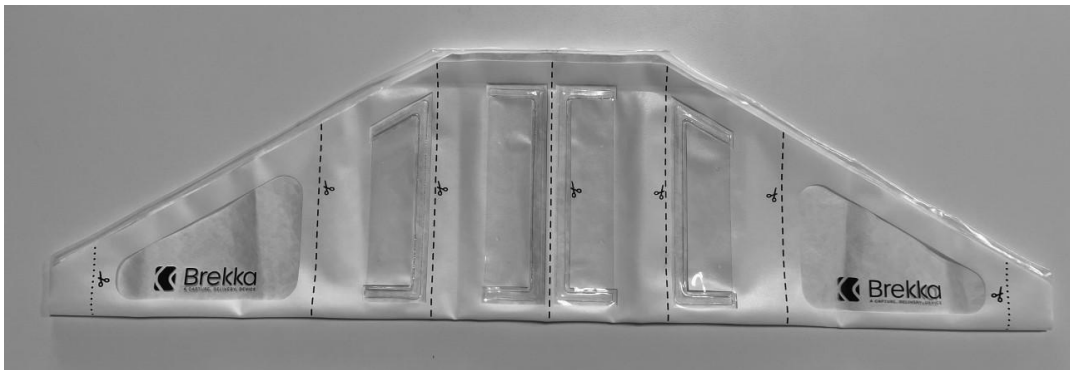
Brekka
Vita Group

510(k) Exempt Notification
Sept 15th 2022



510(k) Exempt Summary
Vita Group
BREKKA
BK100
www.brekkamedical.org
Phone: 651.756.1919

General Information

Applicant:
Vita Group
451 Commerce Drive Suite 400
Woodbury, MN 55125
Phone: 651.756.1919
www.vitagroup.io

Establishment Registration Number:
3022158379

Listing Number:
D481334

Regulatory Consultant:
Adam Johnson

adam.johnson@vitagroup.io

Device Identification

Classification Name: KIT, SURGICAL INSTRUMENT, DISPOSABLE
Product Code: KDD
Regulatory Class: Class 1 510(k) Exempt
Generic/Common Name: Implant Delivery Device
Trade Name: Brekka

9.15.22
Model Name
BK100

Device Name
Brekka - Implant Delivery Device

✔ Facility | Products Listing

Confirmation - Create a New Device Listing

Be sure to print a copy of this page to maintain a record of the details about this new listing.

Note: If this listing is for product(s) that will be exported to the United States from a country/area outside the U.S., be sure to reference the listing number and your registration number on all shipping invoices.

Show 10 per page Filter:

Listing Number	Submission Type	Product Code(s)	Device Name(s)	Proprietary Names	Facility Registration Number - Activities
D481334	510(k) exempt	KDD	Kit, surgical instrument, disposable	View All	Registration Number: 3022158379 [Manufacturer, Complaint File Establishment]

Brekka

A CAPTURE, DELIVERY, DEVICE

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

STERILE EO — Sterilized by Ethylene Oxide	Use by Date	Caution
Date of Manufacture	Manufacturer	Keep Dry
Refer to Instructions for Use	REF — Catalog Number	LOT — Batch Code
Do Not Resterilize	Do Not Reuse	DEHP — Non-Phthalate
10°C 50°F / 21°C 69°F — Temperature Range	90%RH / 10%RH — 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	LATEX — 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.

STERILE EO — STERILE PRODUCT

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

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

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 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.

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.

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
451 Commerce Drive,
Suite #400
Woodbury, MN 55125
Phone: 651-756-1919

REF BK100

MADE IN USA

BRK-052, Rev 3, 9/2022

GENERAL INSTRUCTIONS FOR USING THE BREKKA

1. PREPARE DEVICE

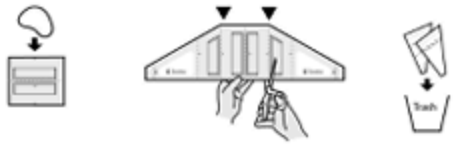
Open inner pouch and retrieve device maintaining sterility.

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.

A.



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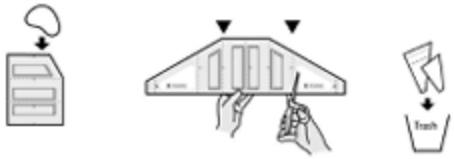

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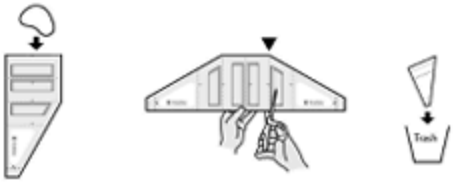
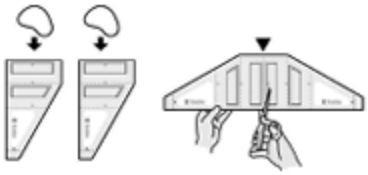


D.



3. REMOVE PAPER LINER

Remove internal paper liner pieces before proceeding.

4. TRIM END OPENING (OPTIONAL)

Trim (If needed, Configurations 'C' or 'D' with Implants over 400cc.)

If using Configurations 'A' or 'B' or Implant volume is 400cc or lower, no trimming is necessary.

4. TRIM END OPENING (CONTINUED)

For Configurations 'C' or 'D':If Implant volume is greater than 400cc:
Cut at Black Dotted Line

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. For purposes of maintaining sterilization, use a concentration of betadine prep solution totaling 90ml per implant, depending on user preference.
2. Add 30cc of betadine prep 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 and pour 30cc of betadine prep over new sterile gloves.

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

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

7a. Load - Option 'A'
Pour implant with its sterile bath into the desired end of the device. 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.