

STERILEEO

Sterilized by Ethylene Oxide



Date Manufactured



Consult Instructions for Use

EC **REP**

European Authorized Representative



Do Not Re-sterilize



Room Temperature (22°C)



DO NOT use the product if the package has been opened or damaged.

Rx Only

U.S. Federal Law restricts this device to sale by or on the order of a licensed physician.



Use by Date



Manufacturer

REF

Catalog Number

LOT

Batch Code



Do Not Reuse



Caution



Keep Dry



Not made with natural rubber latex

DESCRIPTION

The Keller Funnel™2 is a sterile, transparent, cone-shaped sleeve constructed of a flexible, polymeric film and has a lubricious hydrophilic coating on the inside surface.

INTENDED USE

The Keller Funnel™2 is intended to assist with the delivery of silicone gel implants by providing a shell-tissue interface with less friction during insertion of the implant.

**SINGLE USE**

This product is intended for single use, one patient only.

STERILEEO**STERILE PRODUCT**

Each Keller Funnel™2 is sterilized by ethylene oxide in a sealed, double-pouched configuration. Sterility is maintained only if the package seals are intact.



Do not re-sterilize the funnel.

Re-use or re-sterilization should not be performed under any conditions as contamination or infection may occur. Attempts to re-use or re-sterilize may cause diminished product performance, including loss of lubricity, potentially causing implant damage, including rupture.



Do not use the product if the package has been opened or damaged.



Not made with natural rubber latex.

PRODUCT ORDERING

To order directly in the U.S.A. or for product information, visit us online at: www.kellerfunnel.com

Contact your local Keller Medical Sales Representative or the Keller Medical Customer Service Department at +001-772-219-9993.

PRODUCT WARRANTY

Keller Medical stands behind the Keller Funnel™2. If for any reason you experience difficulty resulting in the use of more than one funnel per patient, we will replace it. If after using your first full box of HA-005 you are not completely satisfied with your purchase, please call our Customer Service Department to receive a full refund.

Keller Medical, Inc.

Instructions for Use Keller Funnel™2

REF HA-005

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For patent marking information:
www.kellerfunnel.com/patents

IFU.101, Rev. D

General Technique for Using the Keller Funnel™2

Trim the small “distal” end of the funnel to an opening large enough so that when the inner surface of the funnel is hydrated, the implant can be gently manipulated to pass through the funnel and into the surgical pocket. Immerse the funnel in a basin of sterile saline to render the inner surface slippery. Load the implant into the large “proximal” end of the funnel. With the tissue retracted, insert the distal end of the funnel into the tissue pocket. Squeeze the proximal end of the funnel behind the implant to gently guide the implant into the pocket. Once the implant is inserted, gently remove the funnel.



1. TRIM: It is recommended to use sterile straight blade scissors to trim the distal end. The funnel opening should be sized large enough to allow the implant to gently pass through the funnel without being too large thus inadvertently enabling the implant to pass through.

Note: The length of the distal end of the funnel after being trimmed does not dictate the incision length. Follow the implant manufacturers’ guidelines for determining and making the optimum incision based on the specific implant being used.



CAUTION!

There are many different manufacturers and types of implants, each with multiple variations of geometries, volumes, sizes, shapes, surface textures, cohesiveness, etc., as well as routine introductions of new models. The trim guidelines are only suggested trim locations. It is the responsibility of the user to assure the length of the distal funnel opening is adequate to assure implant passage without damage to the implant.

Breast Implants: For various styles of breast implants based on their volume (cc’s), the following trim guidelines are printed on the funnel:

- Smooth Round
- Moderate & Moderate Plus – as shown
- High Profile + 0.5 cm larger
- Ultra High Profile + 1 cm larger
- Textured Round
- Moderate & Moderate Plus + 1.5 cm larger
- High Profile + 2 cm larger
- Ultra High Profile + 2 cm larger
- Anatomical / Shaped Implant + 2 cm larger



2. HYDRATE: Fully immerse the funnel in a basin of sterile solution to render the inner surface slippery. When not in use, the Keller Funnel™2 should be laid flat on the back table so that the inner surface remains moist. The inside surface should be fully hydrated before each use.

Note: The funnel should not be allowed to soak for longer than necessary in the basin of sterile solution, but should be kept moist to prevent the coating on the inner surface from drying completely. Lubricity of the hydrophilic coating is diminished when allowed to completely dry.




3. LOAD / Confirm Sizing: Insert the implant into the large proximal end of the hydrated funnel. Use one hand to support the distal end and the other hand to manipulate the funnel behind the implant moving the implant forward through the tapered funnel and ejecting the implant onto a sterile field. If the implant does not exit the small end of the funnel using gentle force, then remove the implant, re-trim the distal end, and repeat the test gradually trimming larger opening sizes until the desired result is achieved. Load implant for delivery into tissue pocket. Using one hand, apply slight pressure behind the implant to remove any slack, verify positioning of the implant orientation within the funnel and advance the implant to approximately 1cm from the distal end.



4. PROPEL: With the incision opening retracted, continue applying slight pressure behind the implant. Insert the distal end of the funnel approximately 1 cm through the incision. Use one hand to support the funnel and use the opposite hand to employ a pushing/squeezing technique behind the implant to gently propel the implant forward into the center of the surgical pocket.

HOW TO OPEN STERILE PACKAGE

Remove the Keller Funnel™2 from its package in an aseptic environment using talc-free gloved hands.

 **DO NOT** expose the Keller Funnel™2 to lint, talc, sponges, towels, or other surface contaminants.

1. Peel open outer package.
2. Invert package over sterile field, allowing inner pouch to gently fall into sterile field, or by presenting the inner peel pouch to the gowned and gloved scrubbed person using sterile technique.
3. Using sterile gloves, open inner pouch and remove Keller Funnel™2 placing it into sterile field.
4. Unfold Funnel, then remove and discard the packaging insert from inside of the funnel.

CAUTION!

Using excessive force may damage the implant.

*If the implant does not gently advance through the funnel into the surgical pocket, similar to the amount of force required during the sizing confirmation step, **STOP!** Ensure the distal end is not folded, pinched, wrinkled or overly constricted. Verify that both the **incision** and **surgical pocket** are large enough to accommodate the implant. Verify the end of the funnel is not inserted more than 1 cm, is directed toward the center of the surgical pocket, and the pathway is not obstructed by muscle tissue, or surgical instruments.*

TROUBLE SHOOTING GUIDE

Issue: The funnel tore during the sizing step or during implant delivery.

Question: Was the end trimmed appropriately for the implant volume?

1. Open and trim a new funnel according to instructions in #1.
2. Sizing the funnel for textured shaped or high-profile implants may require larger trim size.
3. Confirm funnel is trimmed correctly and the implant moves easily through the funnel before proceeding

Issue: Funnel is sized properly, but the implant does not move easily through the funnel.

Question: Is the inner surface of the Keller Funnel™2 slippery or lubricious?

Considerations:

1. Ensure the inner surface is hydrated as instructed in #2.
2. Deliver the implants into the surgical pocket as soon as possible after hydration.

Issue: Surgeon delivers the implant on one side of the patient easier than the other.

Question: Is the surgeon right or left hand dominant?

Considerations:

1. For a Transaxillary Approach such as for Breast or Pectoral Implant Procedures
 - a. Right Hand Dominant surgeons can stand above the arm-board when delivering the right implant and below the arm-board when delivering the left implant.
 - b. Left Hand Dominant surgeons can stand below the arm-board when delivering the right implant and above the arm-board when delivering the left implant.
2. For most general Bilateral Procedures
 - a. Right Hand Dominant surgeons can stand on patient’s right side when delivering both left and right implants.
 - b. Left Hand Dominant surgeons can stand on patient’s left side when delivering both left and right implants.