

## BI Funnel – For Optimal Implant Insertion

The BI Funnel is a medical device which allows surgeons to easily, quickly, and safely put a silicone gel breast implants into the pocket without seriously damaging patients and implants.

Implantation assistant, inserter / Medical device

## Description



The BI Funnel is a sterile, transparent, conical shaped implantation assistant. The BI Funnel is made using a flexible PVC film and lubricious hydrophilic coating on the inner surface. The device is supplied double packed with Tyvek.

## Intended Use

The BI Funnel is intended to deliver silicone gel implants to the surgical pocket by providing little friction during insertion of the implant.

## Manufacturer



MEDISQUARE  
GREENCOSKO

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## PRODUCT ORDERING

Contact your local Sales Representative or the Greencosko.

+82-2-541-2941, [info@medisquare.co.kr](mailto:info@medisquare.co.kr)

## Product Warranty

GREENCOSKO stands behind the BI funnel. If you experience difficulty in its use resulting in the need for a second funnel being used per patient, we will replace it at no charge. If you are not fully satisfied after the use of the BI Funnel, please contact our office.

+82-2-541-2941 / [info@medisquare.co.kr](mailto:info@medisquare.co.kr)

The instructions for use are provided in electronic form on the homepage; [www.greencosko.com](http://www.greencosko.com)

If you want the instructions for use in paper form, please contact our office. It is provided free of charge if requested within 7 days of ordering the product.



Sterilized Using Ethylene Oxide



Catalog Number



Keep Dry



Room Temperature  
(1~30°C)



Do Not Re-use



Do Not Re-sterilize



Use-by Date



Do Not Use  
if package damaged



Authorized Representative  
in the European Community



Batch Code



Manufacturer



Date of Manufacture



Consult Instructions for Use



Caution

## Preparation

Unpack the product in a non-contaminated operating room with talc-free gloves.  
Open the large Tyvek packaging, take out the small Tyvek packaged product.  
Open the small packaging, and remove the inserted paper to open the folded funnel.  
The product is placed in a sterile place.

## General Instructions for Using the BI Funnel

1. Cut the small end of the funnel large enough so that the silicone gel implant can gently pass through the funnel and into the surgical pocket.



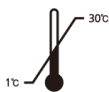
### CAUTION

Implants have different shape, surface, size, and cohesiveness from manufacturer to manufacturer. They may make an impact on proper trim location. It is the user's responsibility to size the small end of the funnel to be suitable for gently implant passage. Breast Implants: The following guideline is printed on the funnel.  
The surface type is according to ISO 14607:2018.

SMOOTH (less than 10µm)		MICROTEXTURED (from 10µm to 50µm)	MACROTEXTURED (over 50µm)
(INTEGRITY, SUBLIMITY) Low: as shown Semi Mod & Mod: +1.0 cm High / Full: +1.5cm	(PURITY) Mod: as shown High: + 0.5cm	(VOLUPTY) Mod: +1.5cm High: +2.0cm	(SENSITY) All types: +2.0cm

2. Hydrate the funnel with saline to make the inner surface wet and slippery. Using an empty syringe, or an empty container, etc., put saline inside the funnel and shake it sufficiently to make the inner surface hydrated as a whole. Pour the remaining saline from the small end of the funnel into a container. Or, fully immerse the funnel in a basin of sterile solution to prepare the inner surface slippery.
3. Remove the packaging of the implant and load the silicone gel implant into the funnel without touching as much as possible. Since the hydrated inner surface is attached, hold each rounded top (Rabbit ears) of the funnel and fully open the mouth. Implant should be placed before the inner surface is dry. To ensure the funnel is fully lubricated, we suggest sliding the implant back and forth within the funnel. If the size of the small end is small, remove the implant and trim appropriately again.
4. Check the pocket and incision to insert the implant. The end of the small end is placed on the incision while supporting the funnel containing the implant with one hand. Squeeze the end of the funnel behind the implant to gently move forward the implant into the surgical pocket.

## Storage / Handling condition



Room temperature (1 ~ 30°C)  
Keep Dry

## Precautions for use



Check for damage to the packaging and product.  
Do not use damaged products and request replacement.  
Check the expiration date of the product. Dispose of products beyond the expiration date.



### Warning



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



The BI funnel is sterilized by Ethylene oxide with sealed, double-pouched.



Do not re-sterilize the BI Funnel.  
Reuse or re-sterilization may not only cause contamination or infection, but also degrade product performance.

This product is intended for use by plastic surgeons only.



### Undesirable side-effects

- Infection  
Acute infection is rare if the usage and instructions have been properly followed. In case of infection, tenderness, redness, swelling, heating sensation caused by sterilization damage or careless use of the product, it requires an adapted antibiotic therapy.
- Contamination  
Bacterial contamination may occur when the healthcare and surgical environment is contaminated. Typically, bacterial contamination increased on ungloved hands. Hygienic preparation should be observed to avoid bacterial contamination.
- Complications due to the surgical procedure  
Postoperative complications, such as pain, bruising, bleeding, fever are problems which arise as a result of you having had surgery, which were not an intentional effect of the surgery. It can result from sterilization damage or unsuitable surgical technique. Some complications are common and occur frequently despite precautions. Some complications are very serious but most people having surgery will not experience them.



### Contraindications

- The use of BI Funnel is subjected to the following contraindications:
- History or suspected autoimmune diseases.
  - Pathologies affecting blood coagulation, immune defenses or any treatment interfering with them.
  - Any ongoing general or local infectious condition
  - History of sensitivity to foreign bodies or serious allergies.
  - Developing pregnancy or even pregnancy envisaged in the short-term or breast-feeding in progress
- The product is used only on the patients who need breast implantations to assist with the implantation of silicone gel breast implant during breast implantation surgery. The recommended minimum age for breast implants surgery is 22 years old for silicone implants.