



Touchless Breast Implant Insertion Device

# Instructions For Use

## DESCRIPTION

The StingRay® device is a sterile flexible sheet used to assist in surgeries involving the placement of silicone gel breast implants.

## INTENDED USE

The StingRay® device is intended to facilitate contact-free breast implant insertion through a unique design that eliminates the need for surgical gloves to ever touch the implant. The StingRay® device's low-friction shell-tissue interface provides safer, faster, easier insertion of the implant.

## SYMBOLS

**STERILE EO** Sterilized by Ethylene Oxide



Date of Manufacture



Refer to Instructions for Use



Do Not Resterilize



Temperature Range



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



Use by Date



Manufacturer



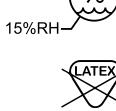
Catalog Number



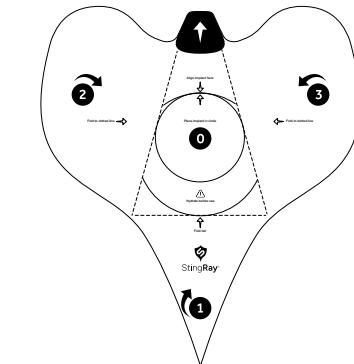
DO NOT Reuse



Humidity Range



15%RH      90%RH  
Not made with natural rubber latex



Caution



Keep Dry



Batch Code



DEHP Non-Phthalate

**Rx Only**

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

## 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



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.



Always configure 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 is not twisted or creased in a manner that could obstruct the implant.



Patented.

For more information:  
[stingraymedtech.com/ifu](http://stingraymedtech.com/ifu)

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



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# General Instructions for Using the StingRay® Device

The StingRay® device was uniquely designed to eliminate all touching of the breast implant with surgical gloves, assuring safe, contact-free insertion.

## 1. TOUCHLESS LUBRICATION

### A. Open

Open the outer pouch and place the inner pouch into sterile field. Open inner pouch and retrieve the device.

### B. Use of Solution

Use approximately 30cc of saline solution or povidone-iodine prep solution for each implant, depending on user preference.

### C. Add Solution

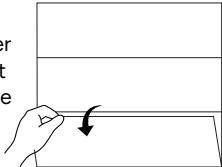
Add approximately 15cc of the solution into the implant tray around the implant in the manner preferred.

### D. Agitate

Agitate the implant in the container

### E. Unfold

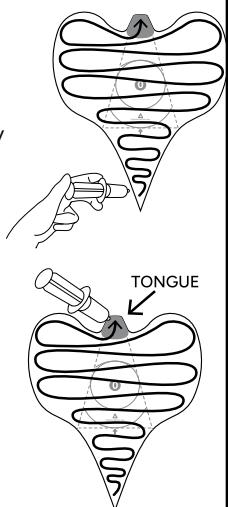
Remove the top paper liner. (Liner will be put back in place once the device is hydrated).



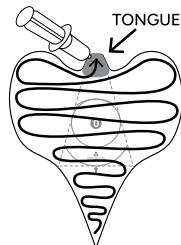
**AVOID GLOVES TOUCHING THE INSIDE SURFACE OF THE STINGRAY® DEVICE.**

### F. Hydrate

Using a sterile syringe or similar device, evenly distribute approximately 15cc of solution to wet the entire surface.



Make sure to include wetting the tongue, which will form the delivery spout when the device is folded.



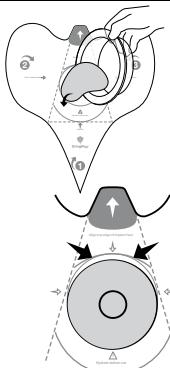
### G. Cover the device again

Re-cover the StingRay® device with the paper liner while the first implant pocket is being dissected.

## 2. TOUCHLESS CENTER & FOLD

### A. Place Implant ("0")

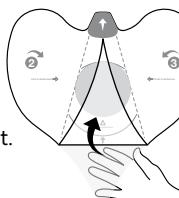
Gently place implant on target spot labeled "0".



### B. Align Implant

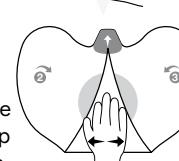
Align top of implant with guidelines as indicated, keeping implant centered between the diagonal dotted fold lines.

**NOTE ORIENTATION OF IMPLANT - FACE UP OR FACE DOWN**



### C. Wrap Tail ("1")

Reach under tail and flip up tail flap labeled "1". Fold to top edge of implant.



### D. Rub Tail

With the tail of the StingRay® device folded over the implant, *without touching the implant* rub the tail to assure neither the top or bottom of the implant is sticking to the StingRay® device.



**AVOID GLOVES TOUCHING THE IMPLANT OR THE INSIDE SURFACE OF THE STINGRAY® DEVICE.**

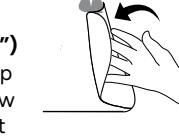
### E. Wrap First Side ("2")

Fold over side flap in the direction of the arrow towards your opposite wrist (not straight across). Fold slightly past edge of the implant.



### F. Wrap Second Side ("3")

Fold over opposite side flap in the direction of the arrow toward your opposite wrist (not straight across). Fold slightly past edge of the implant.



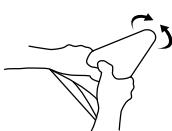
**THE TONGUE SHOULD FORM A ROUNDED SPOUT AS SHOWN.**



## 3. TOUCHLESS INSERTION

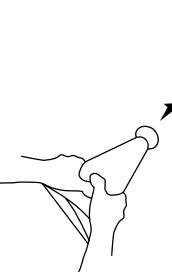
### A. Rotate

Rotate device as needed to orient implant correctly and agitate back and forth a few times to ensure implant & distal end is saturated with solution.



### B. Insertion

Insert spout into incision.



### C. Deliver

Manipulate and deliver the implant by applying pressure behind the implant and pushing it forward.

## SECOND IMPLANT DELIVERY

After the first implant is delivered, unfurl the previously used StingRay® device on the back table.

**AVOID GLOVES TOUCHING THE INSIDE SURFACE OF THE DEVICE.**

Instead, use two syringes or instruments to re-flatten the device.

Then cover the implant with paper again.

Repeat instructions **1B - 3C** when ready to deliver the second implant. (The device should already be unfolded)



Scan for instructional videos.  
stingraymedtech.com/ifu

## TROUBLESHOOTING

**Problem:** The sheet opened up during implant delivery.

**Solution:** Re-wrap the sheet by following instructions and ensure that a firm grip is maintained through implantation.

**Problem:** The implant will not move without excessive force.

**Solution:** Make sure the entire surface of the StingRay® device is completely saturated with solution, especially the wings, tail, and distal end.