



StingRay™

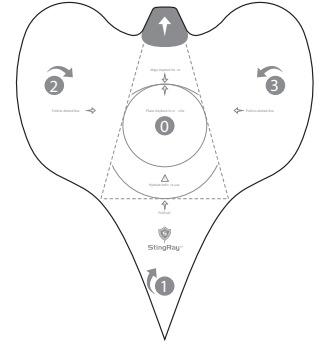
Implant Delivery system
Instructions for Use

DESCRIPTION

The Stingray™ is a sterile flexible sheet used to assist in surgeries involving the placement of implants.

INTENDED USE

Stingray™ is intended to facilitate implementation of a contact-free implant insertion. Stingray™ is intended to facilitate the delivery of silicone gel implants by providing a shell-tissue interface with less friction during insertion of the implant.



SYMBOLS

Sterilized by Ethylene Oxide

Date of Manufacture

Refer to Instructions for Use

Do Not Resterilize

Temperature Range
55°C / 131°F
5°C / 41°F

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

Use by Date

Manufacturer

Catalog Number

DO NOT Reuse

Humidity Limitation
90% RH
15% RH

Not made with natural rubber latex

Caution

Keep Dry

Batch Code

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.

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 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.



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

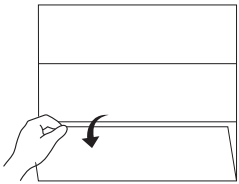


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GENERAL INSTRUCTIONS FOR USING THE STINGRAY™

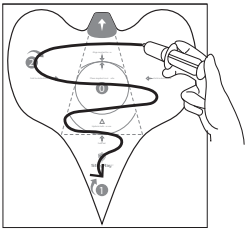
1. SET-UP

- A. Use approximately 60cc of saline solution or povidone-iodine prep solution for each implant and surgery site, depending on user preference.
- B. Add approximately 30cc of the solution into the implant tray around the implant in the manner preferred.
- C. AGITATE THE IMPLANT IN THE CONTAINER.



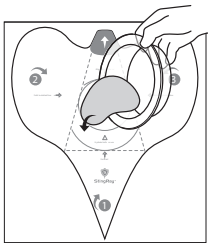
- D. Unfold
Unfold the Stingray™. Remove and discard the top paper liner.
REPLACE STERILE GLOVES WITH A NEW PAIR.

AVOID TOUCHING THE INSIDE SURFACE OF THE DEVICE.

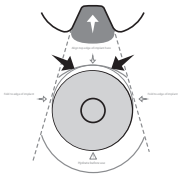


- E. Hydrate
Using a sterile syringe or similar device, evenly distribute approximately 30cc of solution to wet the entire surface.

2. PLACE IMPLANT



- A. Place Implant ("0")
Gently place implant on target spot labeled "0".

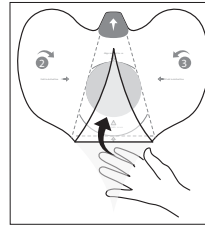


- B. Align Implant
Align top of implant with guidelines as indicated, keeping implant centered between the diagonal dotted fold lines.
NOTE ORIENTATION OF IMPLANT - FACE UP OR FACE DOWN

TROUBLESHOOTING

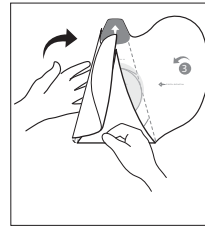
Problem: The sheet opened up during implant delivery.
Solution: Re-wrap the sheet by following instructions and ensure that a firm grip is maintained through implantation.

3. POSITION IMPLANT

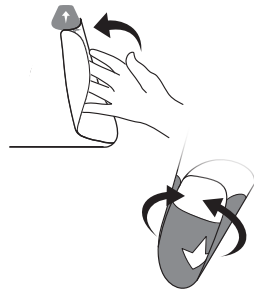


- A. Wrap tail ("1")
Reach under tail and flip up tail flap labeled "1". Fold to top edge of implant.

AVOID TOUCHING THE INSIDE SURFACE OF THE STINGRAY DEVICE.



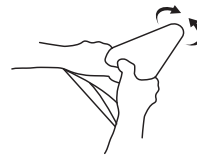
- B. Wrap first side ("2")
Fold over side flap. Fold to edge of implant.



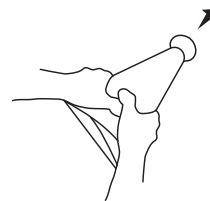
- C. Wrap second side ("3")
Fold over other side flap. Fold to edge of implant.

THE TONGUE SHOULD FORM A ROUNDED CHANNEL AS SHOWN.

4. DELIVER IMPLANT



- A. 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. Insert tongue into incision.

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

Problem: The implant will not move without excessive force.
Solution: Make sure the entire surface of the Stingray™ is completely saturated with solution especially the wings, tail, and distal end.