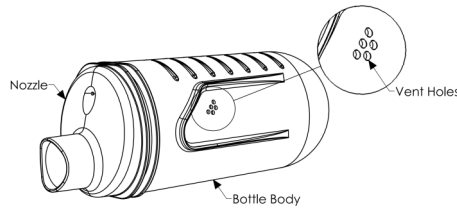
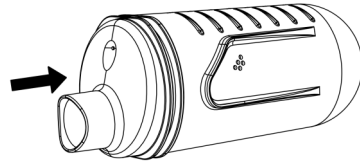


CAUTION: Before using the BIRD, manually free the implant shell from any attachment to the surrounding implant capsule.

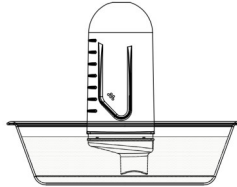
1. Remove bottle from all packaging. Inspect device for any cracks or damage prior to use.



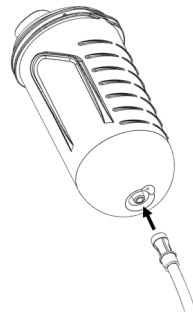
2. Firmly press the nozzle and the bottle body together before connecting to vacuum source to ensure a tight seal. It is possible for the two components to loosen during shipping.



3. Briefly dip the nozzle portion of the device in a basin of sterile solution. The inner nozzle surface should be wet for best results.



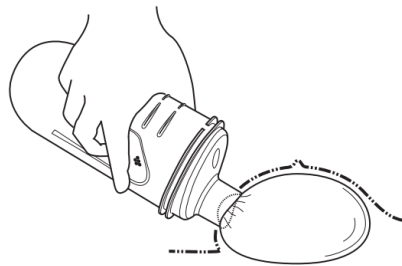
4. Connect vacuum tubing (not included) to vacuum port on bottle. Be sure tubing fits snugly.



CAUTION: The recommended suction pressure range for larger implants is 300 to 500 mmHg. Smaller implants may require less suction pressure.

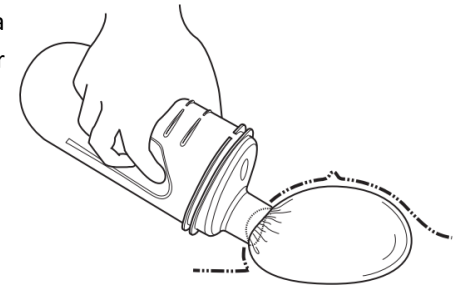
NOTE: Only connect to a regulated vacuum supply and use the minimum required vacuum.

5. Leaving the side vent holes open (no suction pressure), insert the nozzle through the surgical incision to fully engage nozzle tip with the implant. The nozzle of the bottle must make a seal with the implant.



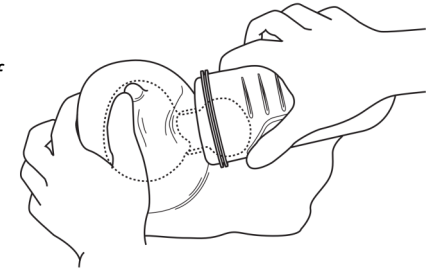
NOTE: It is recommended the device only be used with inframammary incisions of at least 60 mm in length.

6. With the nozzle in contact and making a seal with the implant, slide a finger over the side vent holes to apply suction pressure at the nozzle tip and begin aspiration. If there is initially no movement of material into the bottle, gently manipulate the nozzle tip to fully engage the implant.



CAUTION: Only apply suction to implant shell and silicone gel material. Avoid application of suction to surrounding tissue.

NOTE: If unable to make a seal with the implant, or to do so without applying suction to surrounding tissue, use manual implant extraction technique.



NOTE: To stop suction pressure for any reason, uncover the vent holes.

NOTE: Rate and extent of implant aspiration will vary with vacuum level and implant characteristics including size, shape, texture, and silicone type. Higher suction pressure, within Step 4 limits, may improve results. Range of implants tested successfully:

Size	Shape	Texture	Silicone	Size	Shape	Texture	Silicone
100	Round	Textured	Cohesive I	415	Round	Textured	High Cohesivity
100	Round	Smooth	Cohesive I	775	Shaped	Textured	High Cohesivity
130	Round	Textured	Cohesive II	775	Shaped	Textured	Cohesive III
285	Round	Textured	Cohesive	775	Shaped	Textured	High Cohesivity
350	Round	Smooth	Cohesive I	800	Round	Smooth	Cohesive I
400	Round	Smooth	Cohesive I	800	Round	Smooth	Cohesive

NOTE: If implant aspiration stalls after initial movement into the bottle, and manipulation of the nozzle is unsuccessful in re-starting the aspiration process, remove fingers from the vent holes to stop the suction pressure and manually remediate any implant adherence before re-suming suction.

7. Remove suction pressure as soon as implant is extracted by removing fingers from vent holes.
8. After removing the bulk of the implant as described above, any residual leaked silicone material should be removed by conventional techniques like manual removal/extraction.

Disposal:

1. Turn off vacuum source and disconnect vacuum tubing.
2. Hold bottle firmly to transport to disposal area. **DO NOT** hold bottle by nozzle. The weight of the contents may cause the nozzle to separate from the bottle.
3. Dispose of used product according to hospital policy.

CAUTION:

- Device is **NOT** intended to remove residual silicone in the breast pocket after implant extraction. Use conventional techniques like manual removal/extraction.
- The nozzle tip is **NOT** intended to be applied to surrounding tissue when suction pressure is on (vent holes covered). If suction pressure is inadvertently applied to tissue, immediately uncover vent holes to discontinue suction and reposition nozzle tip to ensure it is only in contact with implant.
- Single Use Only. Do not attempt to clean, sterilize or reuse device. Possible consequences of reuse include: 1) implosion, 2) content leakage, and 3) exposure to bloodborne pathogens.
- Do not exceed suction pressure of 500 mmHg.
- Use extra care when tissue is sensitive or friable.
- Not intended as a measuring device - only for general reference.
- Canister contents are considered potentially hazardous. Use appropriate PPE and handle accordingly.
- Check expiration date on product for use-by date.
- Do not use any cleaning solvents on device.
- Device is provided sterile.
- Store in a cool dark place. Long term exposure to light and heat may compromise product performance and result in breakage during use.
- Prior to any subsequent procedure requiring vacuum, check suction tubing for any obstruction from residual implant contents (e.g., silicone), and replace tubing, as necessary.



Consult Instructions for Use



Do not Reuse



Catalog Number



Date of Manufacture



Batch Code



Manufacturer



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



Use by Date



Sterilized using Irradiation



INDICATION FOR USE: The BIRD is a single-patient, single-use suction device used to assist in the removal of one intracapsular ruptured silicone breast implant.

Not intended for en bloc removals. Not intended to remove residual silicone or be applied directly to tissue.

CONTRAINDICATIONS: Do not use on patients who have undergone prior breast reconstruction.

Do not use on patients who show tissue characteristics that are clinically incompatible with device use, including previous mastectomy, radiation, including compromised vascularity or ulceration.

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