



PRODUCT LITERATURE | BARTHOLIN CATHETERS

Word Bartholin Catheter - Instructions for Use

Official Manufacturer IFU | English

The following pages reproduce the manufacturer's official document without alteration. For availability, quotations and support in Canada, please contact Beauray Inc.

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Word Bartholin Catheter



Endotoxin : <20 EU /device

Not made with natural rubber latex

Description:

The silicone balloon catheter used to treat cysts of the Bartholin gland.

The catheter includes a silicone balloon that is inserted into the cyst and then inflated to hold the catheter in place and allow the cyst to heal without closing again.

Production No.: WC-400

INDICATIONS:

Word Bartholin Catheter is used for the treatment of abscesses and cysts of the Bartholin gland.

CAUTION:

1. Sterile product unless package is opened or damaged.
2. Do not reuse for avoiding user may be infected by the microorganism.
3. This device is sold by or on the order of a physician.
4. If the sterile package is damaged or unintentionally opened before use, do not use.

CONTRAINDICATIONS:

Any condition that would preclude normal incision and drainage of the vulvar cyst or abscess.

DIRECTIONS FOR USE:

1. Make an incision in the outer wall of the cyst to drain the abscess.
2. After draining the abscess, insert the deflated silicone catheter through the incision and into the abscess.

3. Using the 3cc syringe, filled with saline solution, carefully inflate the silicone catheter within the cyst cavity by injecting the saline into the catheter.
4. Do not exceed maximum inflation volume (3 ml) (Figure1.). Once inflated, remove the syringe and needle leaving the self-sealing saline inflated Word/Bartholin catheter within the abscess.
5. Tuck free end of the catheter up into the vagina.
6. After the epithelization of a new orifice is accomplished, the saline solution and catheter are removed from the cyst.
7. Remove the catheter, the abscess will generally shrink and completely heal leaving the Bartholin gland to function normally.

WARNINGS:

1. Always inflate the balloon with a sterile saline. Never inflate with air, carbon dioxide or any other gas.
2. Do not use petroleum based ointments or lubricants since they may damage silicone and burst balloon.
3. Do not exceed the maximum 3 ml inflation volume. Using excessive pressure to inflate the balloon on this device may cause the balloon to rupture.
4. Consider underlying malignancy in women over age 40 who present with Bartholin Gland cysts or abscesses.
5. Epithelization time may vary depending on each patient. The inflated catheter is not intended to be left indwelling for periods of time greater than 28 days.
6. Dispose of medical waste properly in accordance with regulations after using.



Figure 1. Do not exceed maximum inflation volume (3 ml).

	Warehouse temperature 10~40°C		Warehouse humidity 30~80%RH.
	Sterile EO		Not Made With Natural Rubber Latex
	Batch code		Manufacturer
	Expiry date		Biological risks
	Do not reuse		Consult instructions for use
	Caution		