Instructions for Use
Word Bartholin Catheter Set MD

Description

The Word Bartholin Catheter is an invasive, sterile, and single-use device intended for the surgical treatment of abscesses and cysts of the Bartholin gland. It is used following incision and drainage to provide symptom relief and to establish a continuous drainage pathway, thereby reducing the likelihood of recurrence associated with glandular duct obstruction.

Product Model **Basic-UDI : 4719894430501A6**

WC-400 MM REF is provide as a procedure package including:

- **1 sterile silicone Word Bartholin Catheter** with 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.
- **1 sterile scalpel** for incision.
- **1 sterile 3 mL syringe** for balloon inflation.

Clinical Benefits

- Facilitates drainage of Bartholin cysts and abscesses after incision and drainage procedures.
- Supports the formation of an epithelialised tract by maintaining the drainage opening.
- Promotes healing with a patent tract, supporting long term gland drainage and reducing abscess recurrence rate.

Indications for Use

The Word Bartholin Catheter is indicated for the management of symptomatic Bartholin's gland cysts or abscesses. It is intended to provide continuous drainage and to promote the epithelialization of a tract, thereby reducing the risk of recurrence. The device serves as a minimally invasive and conservative treatment option, offering an alternative to surgical excision. The device is intended for use by trained gynecologists in clinical environments such as hospitals or outpatient clinics.

Intended purpose

The Word Bartholin Catheter is an invasive, sterile, single-use medical device intended for the minimally invasive surgical treatment of Bartholin's gland abscesses and cysts. It is used following incision and drainage to provide symptom relief and to establish a continuous drainage pathway, thereby reducing the likelihood of recurrence associated with glandular duct obstruction.

Intended patient population

The Word Bartholin Catheter is used in the field of Bartholin gland treatments for the surgical treatment of abscesses and cysts in female adult patients.

Intended users

The device is intended for use by trained gynaecologists in medical examination environments such as diagnostic or operating rooms in hospitals or clinics.

Potential Side Effects

- Pain or discomfort during insertion or while indwelling.
- Pain, bleeding, tissue trauma or discomfort during removal
- Redness, swelling, or tenderness at the incision site.
- Infection at the treatment site.
- Balloon deflation or leakage, resulting in ineffective treatment.
- Premature dislodgement.
- Allergic reaction to device materials (e.g.silicone).
- Recurrence of cyst after catheter removal.

In case of side effects, discontinue the procedure, provide appropriate medical intervention, and report to the manufacturer and competent authority per MDR requirements.

Contraindications

Catheter treatment is not advised for treatment of deep cysts and abscesses.
Do not use the Word Bartholin Catheter in patients with:

- Acute genital tract or pelvic infections
- Severe vaginal atrophy
- Unexplained vaginal bleeding
- Known allergy to device materials (silicone)

Warnings & Precautions

1. Catheter is intended for **single use only. DO NOT RE-USE.**
   Re-use may introduce risks, including, but not limited to:
   Inflammation, Tissue damage, Allergic reaction, Infection, Abnormal discharge
2. Always inflate the balloon with a sterile saline. Never inflate with air, carbon dioxide or any other gas.
3. Do not use petroleum-based ointments or lubricants since they may damage silicone and burst balloon.
4. 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.
5. Always ensure the balloon is fully deflated before attempting catheter removal. Attempted removal without deflation may cause pain, tissue injury, or device damage.
6. In rare cases, catheter removal may not be possible using standard technique. If removal cannot be achieved safely, surgical intervention may be required.
7. Consider underlying malignancy in women over age 40 who present with Bartholin Gland cysts or abscesses.
8. 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.

Inspection of Device and Preparation

1. Check the package labeling and expiry date prior to use.
2. Visually inspect the device to verify there is no damage prior to use.
3. Visually inspect and verify integrity of the sterile barrier has not been compromised in any way.
4. Do not use it if the sterile package is damaged or open.
5. Check that all components of the kits are supplied. Ensure availability of supplied Scalpel and 3mL syringe.
6. When ready for use, aseptically peel open the pouch and present the device to the sterile field.

Instructions for Use

See Figure 1 for Procedural steps

1. Clean the area around the Bartholin gland with an antiseptic solution.
2. Using a scalpel make a small incision in the outer wall of the cyst to drain the abscess and break up any loculi by making an incision in the outer wall of the cyst, preferably inside the hymenal ring see **Fig.1A**.
3. Ensure the incision size is sufficient to accommodate catheter placement
4. After draining the abscess, insert the deflated silicone catheter through the incision and into the abscess see **Fig.1B**.
5. **Ensure correct depth**: The Word catheter balloon to be placed inside the cyst or abscess cavity only see **Fig.1B**.
6. Attach a 3mL syringe to the catheter valve.
7. Using the 3mL syringe, filled with saline solution, carefully inflate the silicone catheter within the cyst cavity by injecting the saline into the catheter until the balloon is sufficiently anchored into the cyst see **Fig. 1C**.
   Caution: *Do not exceed maximum inflation volume (3 ml).*
8. Once inflated, remove the syringe and needle leaving the self-sealing saline inflated Word/Bartholin catheter within the abscess.
9. Tuck the free end of the catheter into the vagina, **Fig.1D**.
10. Confirm that the catheter is stable and positioned securely.

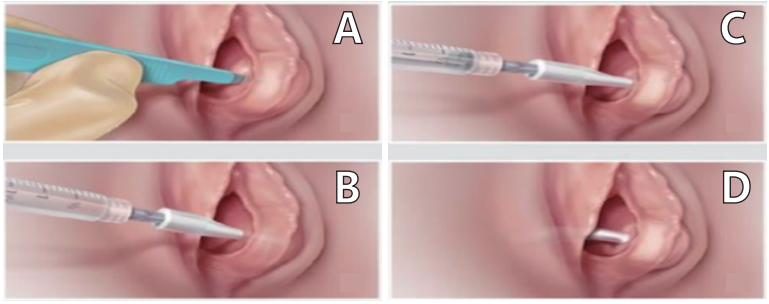

Figure 1. Procedural steps – Word Bartholin Catheter

Instructions for Use
Word Bartholin Catheter Set MD

Indwell Period and Monitoring

1. Leave the catheter in place for up to 28 days or until epithelization is achieved
2. A follow-up evaluation should be scheduled approximately 2 weeks after placement to assess healing progress and verify catheter function.
3. During follow-up and throughout the indwell period, monitor the patient for early signs of complication, including persistent infection, pain, balloon deflation, or premature dislodgement.

Patient Counseling

(Communicated by Healthcare Professionals)

1. Inform patients that mild discomfort may occur; report sever pain or fever.
2. Maintain daily hygiene to reduce risk of infection. Sitz baths may be recommended to aid the healing process.
3. Avoid sexual intercourse until cleared by the clinician.
4. Report if the catheter dislodges, balloon deflates, unexplained bleeding, or if severe pain or fever develops.
5. Patients should be informed of the importance of attending the scheduled 2-week follow-up appointment.

Removal

1. After epithelialization of a new orifice is accomplished, the saline solution and catheter are removed from the cyst.
2. Attach a sterile syringe and withdraw saline to deflate the balloon completely.
3. Remove the catheter gently, the abscess will generally shrink and completely heal leaving the Bartholin gland to function normally.
4. Confirm complete removal of the catheter.

Disposal Instructions

- Dispose of the used device in an approved biohazard container.
- Dispose of the catheter, scalpel, and syringe as single-use medical device in accordance with local regulations for biohazardous or medical waste.
- Do not attempt to clean, reuse, or recycle the device.

Storage & Transportation Conditions

- The shelf life of this device is 3 years from the date of manufacture.
- Store in a clean, dry environment with a temperature between 10–40°C and relative humidity between 30–80% RH.
- The device contains no sensitive materials, liquids, or gases, and is not considered precision machinery.
- It should be transported under normal atmospheric conditions in accordance with the manufacturer's recommendations to prevent damage.
- The transportation methods for export include truck, ship, and airplane, while inland transportation is primarily conducted by truck.

Glossary of Symbols

LOT	Batch code
	Manufacturer
UDI	Unique Device Identifier
	Temperature limit 10-40°C
	Humidity limitation 30-80%RH
	Do not re-use
	Consult instructions for use
	Expiry Date (YYYY/MM/DD)
	Caution
	Do not use if package is damaged and consult instructions for use
STERILIZED	Single sterile barrier system and using ethylene oxide
REF	Catalogue number
MD	Medical device

Reporting of Serious Incidents

If a serious incident related to the device occurs, immediately report the incident to Bioteque Taiwan Ltd. and to the applicable competent authority having jurisdiction in their locale.

Bioteque Taiwan Ltd.
7 F., No. 431, 433, Baozhang Rd., Xizhi Dist., New Taipei City 221036, Taiwan.
Info@bioteque.com

For further assistance, please contact Bioteque Taiwan Ltd.