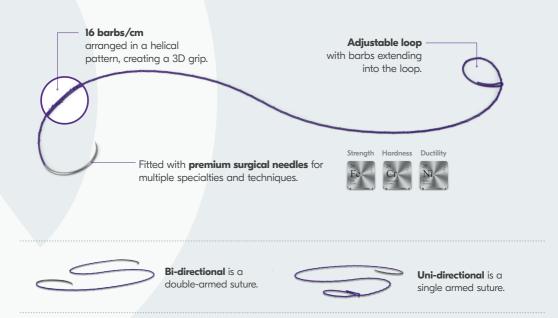


Five case studies detailing the use of Quill[®] barbed suture in the field of **Gynecology & Obstetrics.**



Time-saving tissue closure device.

Quill[®] HD has 16 barbs/cm along its tissue, which collapse during tissue delivery and re-engage for a secure fixation, **minimizing tissue trauma**.

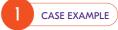


Quill[®] barbed sutures are associated with reduced and/or significantly reduced closure times in some surgical fields. **Mean savings of 5 minutes**¹¹⁻³

Quill[®] bi-directional barbed sutures are reported to be **more efficient in terms** of closure time and lower in direct operative cost^{11,3}



REF. I. Sah A.P. Is There an Advantage to Knotless Barbed Suture in TKA Wound Closure? A Randomized Trial in Simultaneous Bilateral TKAs. Clin Orthop. 2015. 2. Ardovino M. et al. Bidirectional barbed suture in laparoscopic myomectomy: clinical features. J Laparoendosc Adv Surg Tech A. 2013. 3. Gililland JM. Et al. Barbed Versus Standard Sutures for Closure in Total Knee Arthroplasty: A Multicenter Prospective Randomized Trial. J Arthroplasty. 2014. Compared to conventional sutures.

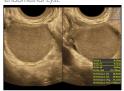


- Patient was diagnosed with N80, deep infiltrating endometriosis.
- Due to strong, sudden pain and signs of internal bleeding the patient was admitted for exploratory laparoscopy.
- Patient admitted to hospital with severe abdominal pain lasting 48h, not associated with indigestion.
- CT scan made on ER showed 500ml of blood in pelvic area and ovarian cyst 6cm in diameter; confirmed in TV USG.
- Upon admission her hemoglobin level was 11.5g/dl and 3h later after admission to gynecology department it dropped to 10.1g/dl.

- Her pain symptoms were not alleviated with iv paracetamol and metamizol, abdomen was hard and painful during palpation.
- Considering diagnosis of ovarian cyst rupture, the decision was made to perform emergency laparoscopy.
- In 30min patient was admitted to the OR.
- Laparoscopic approach is currently golden standard in treatment of endometriosis.
- European Society of Human Reproduction and Embryology recommendations clearly state that we should avoid surgery in young, assymptomatic women. In case of pain symptoms the surgeon must do everything possible not to damage ovarian tissue.



Typical echogenicity of



For better pre-surgical assessment it is wise to rotate US probe 90 degrees to measure all 3 dimensions of the cyst.



1. Cyst dissection.



2. Sealing ovarian cyst bed with uni-directional Quill VLP-2006, #2-0, 20cm in length, 26mm needle.



3. Locking the suture in place by performing 1-2 backstitches.

Patient history:

- 28 year-old woman with post caesarean complications, ovarian endometrioma, intra-abdominal bleeding was admitted for emergency surgery due to ovarian cyst rupture.
- The patient was admitted from the ER with history of l c-section.
- Patient was in good general health, with minor thyroid insufficiency (25mcg of thyroxin daily), with BMI of 24 and regular menstrual bleeding every 28 days, duration 4-6 days, moderate in flow, but painfull (8/10 in visual pain score).

Surgical procedure:

 After installing laparoscope, it was clear that the pelvis was filled with blood and clots.

- After suction, there were multiple endometriosis lesions on the pelvic and abdominal peritoneum to be seen, as well as on intestines and omentum major.
- Some endometriosis implants were visible on the surface of liver.
- Left ovary was normal, while right was filled with endometrial cyst ~7cm in diameter.
- On the left side of pelvic wall there were severe adhesions with sigmoid colon; the adhesions were released to ease dyshesion the patient reported.
- The ovarian cyst was removed carefully to avoid destruction of ovarian tissue.
- To minimize the use of bipolar energy the ovary was sewn with #2-0 Quill[®] (20cm).

Conclusion:

- ✓ Reduction of operation time by approximately 25 minutes.
- \checkmark It was useful to use flexible suture; the ovarian tissue is very sensitive and it is easy to tear it with other barbed sutures.



- ✓ No need for tying a knot is essential in emergency surgery, especially for less experienced surgeons; even for experienced surgeons.
- \checkmark Using Quill® reduces operation time and helps prevent loss of ovarian tissue.

- Patient was diagnosed with D25 myomas and N93 abnormal uterine bleeding.
- There was no increased risk of bleeding.
- · There was an additional risk factor due to obesity.
- · Minimally invasive treatment via laparoscopy was solution of choice.
- Laparoscopic hysterectomy prevents further bleedings, pain syndrome, urgent voiding.
- Today it is possible to remove even very large uterus in laparoscopy, but difficulty of surgery grows with myomas.
- Laparoscopic approach is especially recommended in overweight and obese patients to promote healing and rehabilitation and avoid pain syndrome.



Huge uterine myona, FIGO type 5.



Multiple myomas FIGO type 2, typical cause of abnormal uterine bleeding



1. Incorporating ligaments.



2. Going through the loop using uni-directional Quill, VLP-2051, #0, 15cm in length, 26mm needle.



3. Cuff after hysterectomy.

Patient history:

- 53 year-old female patient with abnormal menstrual bleeding for last 7 months.
- During perimenopause her myomas have grown from 6 to 14cm in diameter.
- Menstual bleedings were worse every month, despite medical therapy.
- · Her BMI was 31 and she was resistant to lose weigh.

Surgical procedure.

• This was a primary, elective surgery.

Steps undertaken during this procedure:

- 1. Separation and ligation of Infundibulopelvic ligament.
- 2. Ligation of round ligament.
- 3. Separation of two layers of broad ligament.
- 4. Separating of peritoneum from utero-vesico pouch.
- 5. Visualisation and ligation of uterine artery and vein.
- 6. Dissection of uterus from the vagina.
- 7. Suturing gap in the vagina.

Conclusion:

- \checkmark Barbs provides strong fixation in the suture, reducing risk of dehiscence.
- ✓ Easy application of Quill[®] barbed suture reduces stress at the end of the surgery and helps to achieve good effect.



✓ Reduction of operation time by approx. 20 minutes.



- Patient had an increased risk of bleeding due to surgery in the muscle (uterus), with an additional risk of hemorrhage due to previous surgery in the same site.
- At risk are especially patients with multiple previous interventions in the uterine muscle, like other deliveries or myomectomies.
- Adhesions can form both in the subcutaneous tissue and inside the peritoneum.
- Improper scar formation and surgical site healing can be specifically expected in patients with obesity, diabetes and gestational diabetes mellitus.
- CTG scan was normal, the patient was admitted in 39th week of pregnancy for elective caesarean section.



CASE EXAMPLE

JS scan of the fetus.



US scan of the fetus.



1. Starting the incision closure with two parallel stitches at in the far corner of the incision.



2.Closing the skin incision with uni-directional Quiil VLP-2033, #2-0, 30cm in length, 26 mm needle.



3. End of surgery and skin incision closure.

Patient history:

- 29 year-old pregnant patient, ICD-O26, gravida 4, para 3.
- Patient had two caesarean sections, last one 2 years earlier.

Surgical procedure:

- · Patient was scheduled for elective surgery.
- · During surgery we discovered hernia in abdominal fascia.
- Adhesions connecting bladder with uterine wall and subcutaneous tissue were released before delivery.
- Healthy boy 3,534g with APGAR score 10, was delivered.

Conclusion:

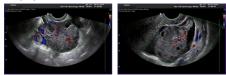


- ✓ Barbed sutures such as Quill[®] offer more confidence in proper distribution of tension in the scar.
- ✓ They offer better quality of muscle closure.
- \checkmark Eliminate the need for single stiches, which are time consuming.
- ✓ With the growing epidemy of c-sections, more and more of patients like this one will be observed.
- ✓ Reduction of operation time by approx. 30-minutes.

- Patient was diagnosed with R10 abdominal pain and D27 – benign ovarian tumor.
- · There was no increased risk of bleeding.
- On ultrasound strong suspicion of ovarian torsion enlarged ovary with sings of oedema and restricted venous blood flow.
- During surgery this diagnosis was confirmed, both ovary and the fallopian tube were turned several times blocking the blood flow and causing massive pain and tissue necrosis.



Ovarian torsion is characterised by swollen ovarian core tissue, with peripheral follicles.



In most cases we can visualise some free fluid in the pelvis, but is not patognomonic sign.



1. Fixing ovarian messentery.



2. Going through the loop using uni-directional Quill, #0. Either VLP-2008 (20cm, 26mm needle) or VLP-2051 (15cm, 26mm needle) can be used.



3. End of surgery.

Patient history:

- 19 year-old female patient admitted during the night with sudden episode of strong, persistent pain in lower abdomen.
- · No previous surgical or medical history.

Surgical procedure:

- · This was a primary, elective surgery.
- Immediate surgery allowed to restore blood flow and avoid ovariectomy in young patient.

Steps undertaken in this procedure:

- 1. Assessment of situation.
- 2. Reversing the torsion.
- 3. Observing return of blood flow.
- 4. Suturing ovarian mesentery to pelvic wall.

Conclusion:

- ✓ Quill[®] barbed sutures allows almost anyone to perform high quality surgery.
- Reversing the torsion the blood flow is quickly restored both in fallopian tube and in the ovary.



 \checkmark Reduction of operation time by approx. 20 minutes.

Use of Quill[®] barbed suture in laparoscopic closing of tumor bed, after **myomectomy**



Preliminary remarks:

- · During observation the tumor has grown to 8cm.
- It lead to improper function of the fallopian tubes due to restriction and local inflammation.
- There was an increased risk of bleeding due to surgery in the muscle.
- Additional risk factors included: risk of hysterectomy in fertility clinic patient and risk of uterine rupture in subsequent pregnancy.



FIGO type 7 (pedunculated) myomas are easy to remove reaardless of size.



Finding the proper plane for tumor enucleation.



1. Preparation of the myoma.



2. Tissue approximation of remaining muscle, using uni-directional Quill VLP-1001, #0, 20cm in length, 36mm needle.



3. The uterus restored its anatomical shape.

Patient history:

- 32 year-old patient with history of fertility treatment for 5 years.
- · The patient was diagnosed with myoma 4 years ago.
- At the time the tumor has 4cm in diameter.
- During treatment she was pregnant 2 times via in vitro fertilization.
- In both pregnancies she had spontaneous abortions at gestational age 8 and 6 weeks, probably due to constriction of the uterine cavity by the myoma.

Surgical procedure:

- · This was a primary, elective surgery.
- Minimal invasive approach is best solution for benign gynecological surgery.
- It leads to less blood loss and pain and allows faster healing.
- In case of myoma surgery it is essential to obtain strong suture line to prevent both bleeding and scar separation.
- In this case it was especially important as patient was undergoing fertility treatment.
- Using Quill[®], #0 30cm allowed to place two layers of stiches to ensure proper scar formation and restoring proper anatomy of the uterus.

Conclusion:



- ✓ Using Quill[®] barbed suture facilitated the surgery.
- Thanks to various lengths and sizes of sutures it is easy to choose one perfect for planned surgery.
- ✓ Reduction of operation time by approx. 30 minutes.
- ✓ Laparoscopic approach shortened hospital stay to 3 days.
- ✓ The patient did not needed any pain medication nor anticoagulant at discharge.
- ✓ Using Quill[®] in myomectomy surgery shortens the operation length and assure tight approximation of tissue.
- \checkmark It allows to perform sophisticated surgery even for intermediate surgeons.

More resources, case studies, videos and information can be found on <u>Corza website</u>, <u>Corza's YouTube</u>, and <u>Vimeo playlist</u> and on <u>Corza's MedTube</u> channel.



To order a Quill[®] sample, arrange a trial, place an order or if you have a Quill[®] related question, contact us: Quill[®]emea@corza.com

All of the five case studies, using Quill® barbed suture, detailed in this brochure, were completed according to information and estimates from Dr. Filip Dąbrowski. Centrum Medyczne Ksztalcenia Podyplomowego · Department of Gynecology and Gynecological Oncology Centre for Post-Graduate Med.Education, Warsow, Poland.

Quill® barbed sutures are indicated for soft tissue approximation. Absorbable barbed sutures shall be used where the use of absorbable suture is appropriate and non-absorbable barbed sutures are excluded from closure of the epidemis. Barbed sutures are not intended to be used by tying surgical knots. Avoid crushing or crimping the suture material with surgical instruments, such as needle holders and forceps. To lock the Quill® device in place, it is recommended to employ a few backstitches and cut the remaining suture flush with the tissue to complete. If approximating the subcuticular layer, exit laterally and cut flush with the skin. To avoid small bowel obstruction, care should be taken to not leave barbed suture ends adjacent to the peritoneum in extra peritoneal tissue closure. As with all surgical sutures, adverse effects may include wound dehiscence, failure to provide adequate wound support, infection, minimal acute inflammatory tissue reaction at the wound site amongst others. The safety and effectiveness of Quill® device has not been established for use in several closures, including fascia, gastrointestinal anastomoses and CV tissue amongst others, therefore this product should not be used for these purposes. For complete indications, contraindications, varning, and adverse reactions, refer to the instructions for use (IFU).



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