# **VNOTES FACT SHEET**

vNOTES (vaginal natural orifice transluminal endoscopic surgery) is an advanced minimally invasive gynecologic procedure using the vagina as a surgical access route. The vNOTES technique is most commonly used for hysterectomy procedures, as well as salpingectomy, oophorectomy and cystectomy procedures.

### • WHAT IS VNOTES?

- o vNOTES is the next advancement in minimally invasive gynecologic surgery.
- o vNOTES is performed by using the vagina as a surgical access route for the procedure, leaving the patient with no visible scarring.

#### PATIENT BENEFITS

vNOTES has been shown to provide the following benefits compared to the laparoscopic approach:

- Shorter hospital stay<sup>1</sup>
- Less postoperative pain<sup>1,2</sup>
- Less pain medication<sup>1,2</sup>
- No visible scars<sup>1,2</sup>

- Faster recovery time<sup>1</sup>
- Fewer postoperative infections<sup>3</sup>

#### vNOTES PROCEDURES

- Hysterectomy
- Salpingectomy
- Oophorectomy
- Salpingo-oophorectomy

- Cystectomy
- Uterosacral ligament suspension

## CONDITIONS TREATED BY VNOTES

- o A vNOTES hysterectomy can treat the following conditions:
  - Abnormal uterine bleeding
  - Chronic pelvic pain

- Fibroids
- Prolapse of the uterus
- vNOTES adnexal surgery can be performed for the following indications:
  - Adnexal mass
  - Sterilization

Prophylactic ovarian cancer prevention

## • vNOTES TECHNIQUE

- o vNOTES combines the benefits of the laparoscopic and vaginal approaches to gynecologic surgery using a vNOTES device known as the <u>GelPOINT<sup>TM</sup> V-Path transvaginal access platform</u>.
- vNOTES is performed by using the vagina as a surgical access route. The vNOTES device is placed through the vagina into the pelvic cavity, giving access to the uterus, fallopian tubes and ovaries.
- The abdomen is inflated with carbon dioxide gas to give the surgeon the space needed to see and operate. vNOTES enables the surgeon to operate at a lower carbon dioxide gas pressure.<sup>4</sup>
  - Research has shown that operating at a lower pressure is associated with reduced postoperative pain.<sup>5</sup>
- A high-definition camera and specialized instruments are inserted through the vNOTES device, allowing surgeons to operate with the utmost precision and visualization. Once the surgery is completed, the vNOTES device is removed and the gas is evacuated.

### SURGICAL SOCIETY RECOMMENDATIONS

 The American College of Obstetricians and Gynecologists (ACOG) and the American Association of Gynecologic Laparoscopists (AAGL) have recommended vaginal hysterectomy, whenever feasible, as the approach of choice.<sup>6,7</sup>

#### RESEARCH FINDINGS

- The HALON study¹ was conducted from December 2015 to June 2017 and was published in January 2019 in *BJOG: An International Journal of Obstetrics and Gynaecology*. The study was a single-center, non-inferiority, randomized, controlled trial comparing vNOTES hysterectomy to laparoscopic hysterectomy as an outpatient procedure at the Department of Obstetrics and Gynecology, Imelda Hospital, in Bonheiden, Belgium. The results of the study demonstrated the following benefits to the vNOTES approach compared to the traditional laparoscopic approach:
  - Reduced operating time
  - Reduced pain
  - Reduced analgesics use

- Reduced hospital stay
- Improved recovery time
- The NOTABLE study<sup>2</sup> was conducted from December 2015 to February 2021 and was published in July 2021 in *BJOG: An International Journal of Obstetrics and Gynaecology*. This study was performed by the same group that carried out the HALON trial. It was conducted as a single-center, non-inferiority, randomized, controlled trial comparing vNOTES adnexectomy to laparoscopic adnexectomy. The results of the study demonstrated the following benefits to the vNOTES approach compared to the traditional laparoscopic approach:
  - Reduced operating time
  - Reduced analgesics use

- Less pelvic pain at 3 months postoperatively
- Many studies have been published since the HALON and NOTABLE trials that reproduce the results
  of these two trials, as well as expand upon their work. To read more, please visit vNOTES.com and
  see the <u>Clinical Evidence</u> page under the Healthcare Professionals section.

## • SURGERY STATISTICS

Hysterectomy

- o In the U.S., about 500,000 hysterectomies are performed each year. 8,9
- The average age a woman receives a hysterectomy is 40–45 years old.

# Adnexal Surgery

- vNOTES provides better access to the fallopian tubes and ovaries compared to vaginal surgery.<sup>10</sup>
  - As recent data points to the fallopian tube as the origin of most high-grade serous ovarian cancers, removal of the fallopian tubes can significantly reduce the risk of ovarian cancer.<sup>11,12</sup>
  - Reports of successful adnexa removal by the traditional vaginal approach vary greatly, with failure rates ranging from 22 to 36%.<sup>13,14</sup>
  - Compared to the traditional vaginal approach, vNOTES may facilitate the successful removal of the fallopian tubes due to the benefits of improved access and visualization.<sup>15</sup>

## Pelvic Organ Prolapse Repair

- While only 3–6% of women in the U.S. report symptoms associated with pelvic organ prolapse, data shows that up to 50% of women present with pelvic organ prolapse on examination.<sup>16</sup> vNOTES offers a minimally invasive way to address pelvic organ prolapse via uterosacral ligament suspension.
  - vNOTES allows the surgeon to visualize the ureter as they place suspensory sutures beneath the uterosacral ligament. This direct visualization can lead to decreased ureteral kinking during USLS when compared to a vaginal approach.<sup>10</sup>

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- <sup>4</sup> Baekelandt, Jan. "vNOTES (vaginal Natural Orifice Transluminal Endoscopic Surgery): is this the future of gynaecological surgery?."
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- <sup>7</sup> AAGL Position Statement: Route of hysterectomy to treat benign uterine Disease. (2011). *Journal of Minimally Invasive Gynecology, 18*(1), 1–3. https://doi.org/10.1016/i.jmig.2010.10.001
- <sup>8</sup> Cohen, S. L., Ajao, M. O., Clark, N. V., Vitonis, A. F., & Einarsson, J. I. (2017). Outpatient hysterectomy volume in the United States. *Obstetrics & Gynecology*, 130(1), 130–137. https://doi.org/10.1097/aog.000000000002103
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