

# TRUCLEAR<sup>◊</sup> Procedure Background Information

## What is Hysteroscopy?

- A scope, known as a hysteroscope, is inserted into a patient's uterus through her cervix, allowing the doctor to see the inside of the patient's uterus.
- A lighted camera, saline fluid, and specially designed cutting instruments are all able to be inserted and removed through the scope so there is no need to remove and re-insert instruments.
- Doctors may schedule a hysteroscopy to look inside a patient's uterus to determine causes of abnormal uterine bleeding, intrauterine abnormalities or infertility issues and may perform a visual dilation and curettage (D&C) to take a biopsy.

## About the TRUCLEAR Procedure

- Minimally invasive treatment option removes uterine adhesions, fibroids, polyps, and other abnormal uterine tissues with only a single insertion
- Contraindicated for the following conditions: pregnancy, pelvic infection, cervical malignancy, and previously diagnosed endometrial cancer
- Performed as an outpatient procedure or even in the doctor's office with minimal recovery time; many patients return to normal activities the next day
- Offers a safe and effective way to diagnose and treat retained products, adhesions, fibroids, and polyps
- Can help preserve a patient's uterus by helping to avoid the need for a hysterectomy
- Localized treatment minimizes the risk of damage to the lining of the uterus, which can help preserve future chances of pregnancy
- Small size of hysteroscope often eliminates the need to dilate the cervix, requiring little to no anesthesia
- Capable of helping women who suffer from heavy menstrual bleeding due to fibroids, polyps, or other uterine abnormalities
- Capable of helping women who are hoping to improve their chances of a successful full-term pregnancy by removing abnormal uterine growths which may be contributing to fertility issues
- Removes abnormal uterine tissues through mechanical cutting instruments, eliminating the risk of electrical injury in the uterus
- Provides doctors with the ability to see inside the uterus with a small camera for a truly visual D&C, as opposed to traditional blind D&Cs
- Allows doctors to remove abnormal tissues at the same time the tissues are discovered rather than scheduling a separate procedure at a later date
- First-in-class with more than 8 years of positive market physician and patient feedback

## Abnormal Uterine Bleeding

Menorrhagia is the clinical term for menstrual periods with excessive flow and/or duration. A normal menstrual cycle is 21-35 days in duration, with bleeding lasting an average of 7 days and flow measuring 25-80 ml<sup>1</sup>. Clinically defined as total blood loss exceeding 80 ml per cycle or menses lasting longer than seven days,<sup>2</sup> menorrhagia is a common gynecologic complaint among women. In practice, measuring menstrual blood loss is difficult. Thus, the diagnosis is usually based upon the patient's history.

## Abnormal Intrauterine Tissues and Infertility

Abnormal uterine tissues such as adhesions, fibroids, and polyps can interrupt successful embryo implantation.

- Adhesions can result in either failure to achieve pregnancy or miscarriages<sup>3</sup>:
- Fibroids that grow and bulge toward the inside of the uterus have been associated with negative effects on fertility<sup>4</sup>
- Polyps can prevent sperm from entering either the uterus or the fallopian tubes and keep embryos from implanting in the uterine wall.

## **Facts and Stats**

- 10 million women suffer from abnormal uterine bleeding<sup>5</sup>:
- Each year, over 2 million women consult their physicians about it<sup>5</sup>.
- It is the most common gynecologic complaint and the reason for two-thirds of all hysterectomies.
- Fibroids are a common health issue for women<sup>6</sup>:
  - 80% of women are estimated to be affected by fibroids
  - 20% of childbearing-age women have fibroids
  - 70% - 80% of women may develop fibroids by the age of 50
  - African-American women are more likely than Caucasian women to develop fibroids
  - Over 200,000 women annually receive hysterectomies due to fibroids<sup>7</sup>
- Endometrial polyps:
  - Cause irregular spotting and pre- or postmenstrual staining
  - Incidence of polyps increases with age<sup>7</sup>
  - Cancerous polyps are not common, risk rises with postmenopausal bleeding and increasing age<sup>7</sup>
  - AAGL Practice Report suggests all symptomatic polyps be removed for testing.<sup>7</sup>

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1 Wright RC. Hysterectomy: past, present, and future. *Obstet Gynecol.* Apr 1969;33(4):560-3

2 Lentz GM. Abnormal Uterine Bleeding. In: Katz VL, Lentz GM, Lobo RA, Gershenson DM. *Comprehensive Gynecology*. 5th. Philadelphia, PA: Mosby; 2007:915-932.

3 Intrauterine Adhesions Fact Sheet. The Patient Education Website of the American Society for Reproductive Medicine. <http://www.asrm.org>. 2012.

4 Peter Kovacs, MD, PhD. Effects of Fibroids on Women's Fertility. *Medscape*. Apr 29, 2009.

5 "Introducing Office Hysteroscopy to Your Practice: Roadblocks, Speed bumps, and Driving in the Fast Lane", Linda M. Bradley, MD, Vice Chair OB/GYN, Cleveland Clinic, 2013.

6 "Treatment Options for Uterine Fibroids", David Hickam and Joe V. Selby, Patient-Centered Outcomes Research Institute, March 2013.

7 AAGL Practice Report: Practice Guidelines for the Diagnosis and Management of Endometrial Polyps. *Journal of Minimally Invasive Gynecology* (2012) 19, 3-10