



TRUCLEAR[®]
System

A potential
treatment for your
abnormal
uterine bleeding





Do You Suffer from Abnormal Uterine Bleeding?

What is a Hysteroscopy?

What is the **TRUCLEAR^o Procedure?**

What Happens **Before** Your TRUCLEAR Procedure?

What Happens **During** Your TRUCLEAR Procedure?

What Happens **After** Your TRUCLEAR Procedure?



With the TRUCLEAR^o Procedure, your options have never looked better.

The Smith & Nephew TRUCLEAR Procedure makes it possible for your doctor to remove abnormal uterine tissue without making incisions or using electricity (which can burn normal tissue) inside your uterus. That means less risk of damaging your uterine lining and more hope of preserving your chances for future fertility.

Whether your doctor is removing polyps or fibroids to treat abnormal uterine bleeding, removing adhesions to help improve your chances of getting pregnant, or simply removing a tissue sample for a biopsy, the TRUCLEAR Procedure provides you with a safe, minimally invasive treatment option that is performed as an outpatient procedure.

Be sure to discuss your symptoms and your treatment expectations with your doctor. As with any procedure, you will need to talk to your doctor for more information about the potential risks of this procedure and whether it is right for you.

Do You Suffer from Abnormal Uterine Bleeding?

If you are one of the over 10 million women suffering from abnormal uterine bleeding¹, perhaps polyps or fibroids are to blame. Abnormal uterine bleeding can include prolonged bleeding, irregular bleeding or even post-menopausal bleeding. This can be caused by many different reasons including polyps and fibroids. Polyps and fibroids both grow inside the uterine cavity; polyps typically cause bleeding in between periods



while fibroids are more likely to cause heavy bleeding and prolonged periods. Previously, treatment may have been a hysterectomy, which required the removal of the uterus. Another procedure used was an electrical instrument, which

could burn normal tissue as the polyp or fibroid was removed. With the TRUCLEAR[®] Procedure, your doctor can remove polyps or fibroids while keeping your uterus intact – something important to all women.

Endometrial polyps grow from the lining of the uterus, known as the endometrium. These polyps cause irregular spotting and pre- or postmenstrual staining. The incidence of polyps increases with age and typically peaks between ages 40 and 50, but can be seen earlier. Although cancerous polyps are not common, the risk does rise with postmenopausal bleeding and increasing age. Therefore, it is suggested that these symptomatic polyps be removed for testing.² Polyps can also lead to fertility concerns.

1 "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.

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

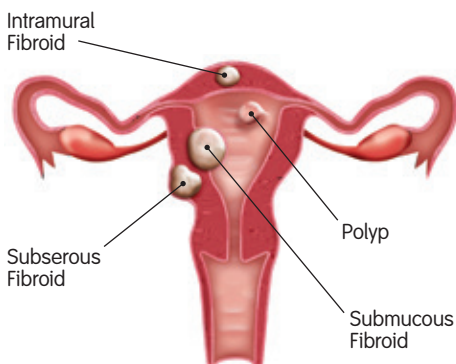
Uterine fibroids can cause back pain, pelvic pain, and heavy/prolonged/frequent bleeding. Fibroids are not typically associated with an increased risk of uterine cancer and they rarely develop into cancer. However, fibroids are a common health issue³:



- **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

Submucosal fibroids, which grow and bulge toward the inside of the uterus, have been associated with negative effects on fertility⁴:

- **64%** reduction in pregnancy rates
- **69%** reduction in live birth rates
- **67%** increase in miscarriage rates



The **TRUCLEAR[®] Procedure** allows for safe removal of both endometrial polyps and submucosal fibroids to treat abnormal uterine bleeding while minimizing risks to your health and helping to preserve your chance of future pregnancy. Unlike a hysterectomy, TRUCLEAR is an outpatient procedure with minimal recovery time.

³ "Treatment Options for Uterine Fibroids", David Hickam and Joe V. Selby, Patient-Centered Outcomes Research Institute, March 2013.

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



What is a Hysteroscopy?

Your doctor may have suggested a hysteroscopy to get a better look at what's happening in your uterus. With a hysteroscopy, your doctor can see inside your uterus using a scope (also known as a hysteroscope) and take any necessary tissue samples for testing. Unlike the traditional "blind D&C", (Dilation and Curettage) where a small spoon-like instrument was inserted into the uterus, this procedure allows your doctor to use a camera to see the inside of your uterus to determine which tissue to remove for testing.

If your doctor finds abnormal tissue such as polyps or fibroids when viewing your uterus, this tissue can be removed at the same time rather than scheduling a return visit.

Are Adhesions Affecting Your Fertility?

Your fertility can be compromised by uterine abnormalities known as adhesions, scar tissue inside the uterus that is typically caused by a previous uterine surgery. With the TRUCLEAR[®] Procedure, your doctor can remove the adhesions

What is the TRUCLEAR[◇] Procedure?

The Smith & Nephew TRUCLEAR Procedure provides a safe, minimally invasive treatment option for women suffering from abnormal uterine bleeding due to abnormalities such as polyps and fibroids.

TRUCLEAR is an incisionless procedure performed in an outpatient setting. A scope will be inserted through your cervix, allowing your doctor to see inside your uterus. Your doctor inserts a small instrument through the scope that rapidly removes the uterine tissue. The special design of the TRUCLEAR instrumentation also helps minimize damage to the lining of the uterus, which may help preserve the possibility of pregnancy at a future date.

Unlike many other treatments, the TRUCLEAR Procedure does not use electricity in the uterus. That means the risk of electrical burn injury to the uterus lining is eliminated. Plus, this process is typically faster than the electrical option which means less exposure to anesthesia.

Read on for more information about what to expect before, during, and after your TRUCLEAR Procedure.



with instruments that allow visualization inside the uterus and are designed to reduce potential damage to the surrounding healthy tissue. Removing these adhesions may help improve the likelihood of embryo implantation.

What Happens Before Your TRUCLEAR[◇] Procedure

Preparing for Your Procedure

Your doctor will provide you with instructions on how to prepare for your procedure. Common practices you can expect include:

1. Your doctor may conduct a thorough review of your health history including conditions such as diabetes and heart disease.
2. Your doctor may require blood work to be done including tests for pregnancy and infection.



3. You should avoid sexual intercourse, vaginal creams, medications and douching for a few days prior to your procedure.
4. Your doctor may suggest that you take an over-the-counter pain reliever an hour before the procedure to help relieve any possible post-operative cramping.
5. Your doctor may prepare the uterus with medication beforehand to make the procedure easier to perform. This is determined by your doctor and varies by patient.
6. If anesthesia is utilized, you may be told not to eat or drink anything after midnight on the night before your procedure, as preparation for anesthesia.

On the Day of Your Procedure

The TRUCLEAR[®] Procedure may take place in the outpatient surgery center or the hospital. Depending on the location, these activities may occur on the day of your procedure:

1. Your doctor will discuss the TRUCLEAR Procedure with you and confirm any diagnostic reports.
2. Your vital signs, such as blood pressure and temperature, may be measured.
3. You may be given an IV for fluids and medication during and after your procedure.
4. If anesthesia is necessary, the anesthesiologist or anesthesiologist, will discuss the type of anesthesia you will receive.

What Happens During Your TRUCLEAR Procedure



1. Your doctor inserts the hysteroscope into the vagina, through the cervix, and into the cavity of the uterus. The hysteroscope contains a light and camera that allows your doctor to see inside your uterus.



2. Saline fluid flows through a small channel in the hysteroscope, opening your uterine cavity so your doctor can better see and access the tissue that will be removed.



3. A specially designed instrument is inserted into the hysteroscope to remove the unwanted tissue.



4. After removing the tissue, your doctor will remove the instruments, completing the procedure. While recovery times vary by case, most patients are able to go home within a couple of hours and return to normal activities the next day.

What Happens After Your TRUCLEAR[◇] Procedure

Your doctor will give you specific details about your postoperative care, but these are a few things that may occur after your treatment:

1. You could have bleeding and menstrual-like cramps after your treatment. If so, your doctor may instruct you to use pads instead of tampons.
2. You will not be able to douche or use vaginal medications for a period of time after the treatment. Your doctor will define this period for you.
3. You will not be able to engage in sexual intercourse for a period of time after the treatment. Your doctor will define this period for you.
4. Your doctor will probably schedule a follow-up appointment after your treatment to discuss your results with you.
5. While unlikely, you may need further treatment depending on the initial treatment results. Your doctor will discuss this with you.





The TRUCLEAR[◊] Advantage

- Minimally invasive option to treat uterine cavity abnormalities
- Incision-less
- Possible with minimal anesthesia
- No electricity inside the uterus
- Minimal recovery time
- Helps to preserve the uterus and uterine lining, which can help preserve the chance of future pregnancy

Important Notes:

The TRUCLEAR Procedure is intended to remove intrauterine tissue; this tissue may be causing abnormal uterine bleeding or infertility. As with any procedure, there are potential risks with this procedure such as fluid overload and uterine perforation. Women who are pregnant, have a pelvic infection, or previously diagnosed endometrial cancer should not have this procedure. Be sure to talk to your doctor to determine if the TRUCLEAR procedure is right for you.

The information listed on this brochure is common guidance and is not meant as medical advice. Every patient's case is unique and each patient should follow her doctor's specific instructions. Please discuss medication and treatment options with your doctor to make sure you are getting the proper care for your particular situation.

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