

AN INCISIONLESS
TREATMENT
FOR ABNORMAL
UTERINE BLEEDING
ASSOCIATED
WITH POLYPS AND
FIBROIDS

Learn more about
the TruClear™ system



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FIND ANSWERS TO YOUR QUESTIONS

- What is abnormal uterine bleeding?
- What is a hysteroscopy?
- What is the TruClear™ system procedure?
- What happens **before** your TruClear™ system procedure?
- What happens **during** your TruClear™ system procedure?
- What happens **after** your TruClear™ system procedure?

With the TruClear™ system procedure, your options have never looked better.

The TruClear™ system procedure makes it possible for your clinician to remove abnormal uterine tissue without making incisions or using electricity inside your uterus. That means less risk of scarring your uterine lining and more hope of preserving your uterus for the future.

Clinicians use the TruClear™ system for a number of procedures, including the removal of:

- Polyps or fibroids that may cause abnormal uterine bleeding
- Tissue samples for biopsy

The TruClear™ system is a minimally-invasive treatment option that's performed as an outpatient procedure — and in many cases, right in your clinician's office.

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





What is abnormal uterine bleeding?

Abnormal uterine bleeding can include prolonged, irregular, or even postmenopausal bleeding. If you're one of the 10 million women who suffers from abnormal uterine bleeding,¹ polyps or fibroids might be to blame.

What are polyps and fibroids?

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, but they can appear earlier and sometimes interfere with fertility. Cancerous polyps aren't common, but the risk rises with increasing age and postmenopausal bleeding. That's why clinicians suggest removing these symptomatic polyps for testing.²

Uterine fibroids aren't typically associated with an increased risk of uterine cancer—and they rarely develop into cancer. Still, they can cause back and pelvic pain, as well as heavy, prolonged, and/or frequent bleeding.³ Fibroids are a common health issue that affect⁴:

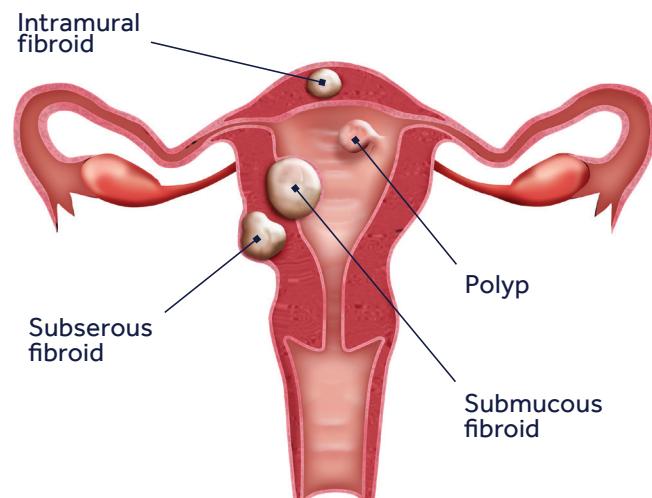
- 20% of childbearing-age women
- 70%–80% of women younger than 50

Submucosal fibroids grow and bulge toward the inside of the uterus. They are usually removed because they have been associated with these increased negative effects on fertility⁵:

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

Treatment options

Treatments for abnormal uterine bleeding range from hormone therapy to complete removal of the uterus (hysterectomy). The TruClear™ system procedure is a gentle option for the safe removal of endometrial polyps and submucosal fibroids.





What is a hysteroscopy?

A hysteroscopy is when your clinician uses a scope with a camera — known as a hysteroscope — to examine your uterus. If polyps or fibroids are found, they can be removed at the same time.

What is the TruClear™ system procedure?

The TruClear™ system procedure provides a minimally invasive treatment option for women suffering from uterine bleeding due to abnormalities such as polyps and fibroids.

The TruClear™ system gives clinicians the ability to remove abnormal uterine tissue without making incisions. The procedure is usually performed in an outpatient setting or your clinician's office. A scope will be inserted through your cervix, allowing your clinician to see inside your uterus. Once the abnormality has been identified, your clinician will insert a small instrument through the scope and quickly remove the uterine tissue. The special design of the TruClear™ system instrumentation also helps minimize damage to the lining of the uterus and with uterine preservation.

Unlike many other treatments, the TruClear™ system 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.⁶

Read on for more information about what to expect before, during, and after your TruClear™ system procedure.





What happens before your TruClear™ system procedure?

Your clinician will provide you with instructions on how to prepare for your procedure. While every patient experience is unique, these are some common practices you might expect:

- Your clinician may conduct a thorough review of your health history. You may be asked if you have pre-existing conditions such as diabetes and heart disease.
- Your clinician may require blood work to be done to test for things such as pregnancy and infection.
- You should avoid sexual intercourse, vaginal creams, medications, and douching for a few days before your procedure.
- Your clinician may suggest that you take an over-the-counter pain reliever an hour before the procedure to help relieve any possible postoperative cramping.
- Your clinician may prepare the uterus with medication beforehand to make the procedure easier to perform. This is determined by your clinician and varies by patient.
- If anesthesia is used, you may be told not to eat or drink anything after midnight on the night before your procedure.

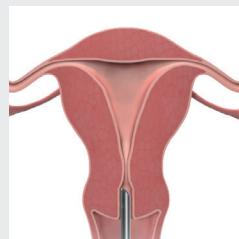
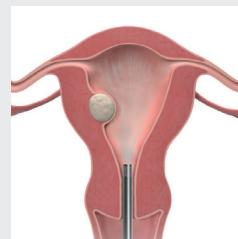
On the day of your procedure

The TruClear™ system procedure may take place in your clinician's office, outpatient surgery center, or the hospital. Depending on the location, these activities may occur on the day of your procedure:

- Your clinician will discuss the TruClear™ system procedure with you and confirm any diagnostic reports.
- Your vital signs, such as blood pressure and temperature, may be measured.
- You may be given an IV for fluids and medication during and after your procedure.
- If anesthesia is necessary, the anesthesiologist or anesthetist, will discuss the type of anesthesia you will receive.

What happens during your TruClear™ system procedure?

1. Your clinician 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 clinician to see inside your uterus.
2. Saline fluid flows through a small channel in the hysteroscope, opening your uterine cavity so your clinician 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 via a rotating blade.
4. After removing the tissue, your clinician 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.



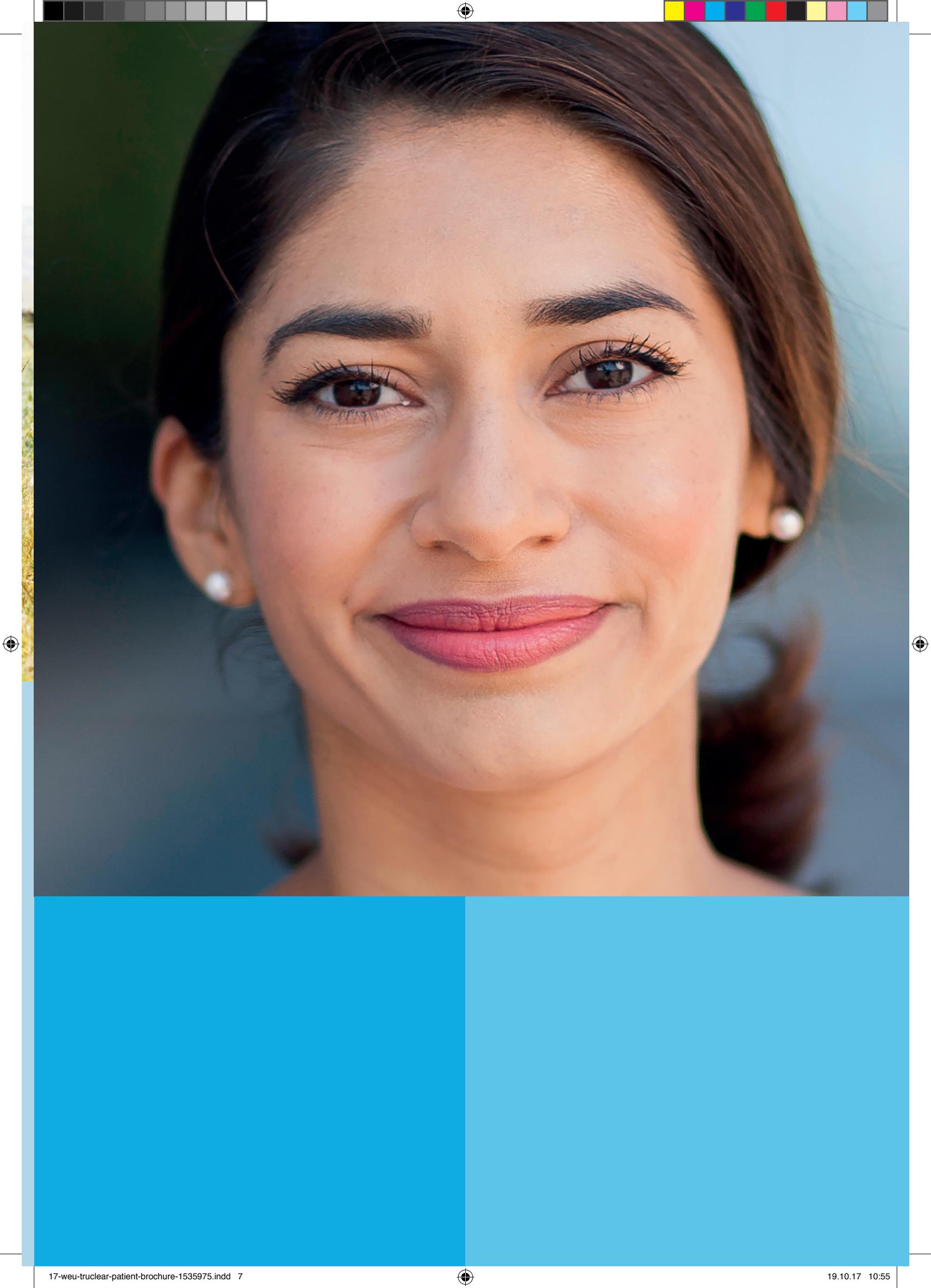


What happens after your TruClear™ system procedure?

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

- You could have bleeding and menstrual-like cramps after your treatment. If so, your clinician may instruct you to use pads instead of tampons.
- You will not be able to douche or use vaginal medications for a period of time after the treatment. Your clinician will define this period for you.

- You will not be able to engage in sexual intercourse for a period of time after the treatment. Your clinician will define this period for you.
- Your clinician will probably schedule a follow-up appointment a few days after your treatment to discuss your results with you.
- While unlikely, you may need further treatment depending on the initial treatment results. Your clinician will discuss this with you.



THE TRUCLEAR™ SYSTEM ADVANTAGE

The TruClear™ system provides a minimally invasive option to treat uterine cavity abnormalities. Its advantages include:

- An incisionless procedure
- No electricity inside the uterus
- Minimal recovery time⁷
- Minimized risk to the uterus and uterine lining preserved

Important Notes

The TruClear™ system 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 are known to have endometrial cancer should not have this procedure. Be sure to talk to your clinician to determine if the TruClear™ system 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 clinician's specific instructions. Please discuss medication and treatment options with your clinician to make sure you are getting the proper care for your particular situation.

References

1. Curtis, M, Linares, S, Antoniewicz, L. *Glass' Office Gynecology*. 7th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2014:176.
2. American Association of Gynecologic Laparoscopists (AAGL). AAGL practice report: practice guidelines for the diagnosis and management of endometrial polyps. *J Minim Invasive Gynecol*. 2012;19(1):3-10.
3. Uterine fibroids. Office of Women's Health Website. <https://www.womenshealth.gov/a-z-topics/uterine-fibroids>. Updated Feb. 6, 2017. Accessed July 25, 2017.
4. Hickman D, Selby JV. Treatment options for uterine fibroids. Patient-Centered Outcomes Research Institute. March 2013.
5. Kovacs P, M.D., Ph.D. Effects of fibroids on women's fertility. Medscape website. <http://www.medscape.com/viewarticle/701937>. Published April 29, 2009. Accessed on Jan. 31, 2017.
6. Emanuel M, Wamsteker K. The Intra Uterine Morcellator: A New Hysteroscopic Operating Technique to Remove Intrauterine Polyps and Myomas. *J Minim Invasive Gynecol*. 2005; 12(1), 62-66.
7. Emanuel M. New Developments in Hysteroscopy. *Best Pract Res Clin Obstet Gynaecol*. 2013; 27, 421-429.

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IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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