PROCEDURE EDUCATION LITERATURE AND CONSENT FORM

We recommend that you read this handout carefully in order to prepare yourself or family members for the proposed procedure. In doing so, you will benefit both the outcome and safety of the procedure. *If you still have any questions or concerns, we strongly encourage you to contact our office prior to your procedure so that we may clarify any pertinent issues. “An educated patient is the best patient.”*

CERVICAL CONIZATION (CONE BIOPSY)

**Definition**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Cervical</td>
<td>Pertaining to the neck (cervix) of the womb (uterus) that extends into the birth canal (vagina)</td>
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<td>Conization</td>
<td>Surgical removal of a cone of tissue</td>
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<td>Biopsy</td>
<td>Removal of tissue from a living patient for diagnostic evaluation so that the nature of a disease may be determined following examination of that tissue</td>
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Cervical conization, also known as cold knife cone or cone biopsy, is both a diagnostic and treatment tool used to detect and treat abnormalities of the cervix.

The cervix, just like your skin and many other surfaces, is covered with tissue that is continuously being replaced. As the cells on the top become “old” and are shed, cells from below move to the surface and replace them. The Papanicolaou smear, commonly referred to as a “Pap smear,” is a test that collects the cells of the cervix that are to be shed and examines them with a microscope. When normal cells are replaced with abnormal cells, a condition known as dysplasia has developed. Areas of dysplasia on the cervix are considered premalignant (pre-cancerous). Dysplasia can go away on its own, remain unchanged, or become more concerning and may lead to cancer.

Risk factors for abnormal findings on Pap smear and cervical biopsy are thought to include any one or a combination of:

- Vaginal infection, with bacteria, yeast and/or other non-sexually transmitted or sexually transmitted organisms
- Cervicitis, inflammation of the cervix caused by such factors as chemical exposure (such as soaps, douches, deodorized tampons, and spermicides), exposure to a foreign body (such as a diaphragm, cervical cap, or pessary) or vaginal infection
- Viral infection, including a variety of Human Papilloma Virus (HPV) strains, and in particular high-risk (ability to cause abnormal cellular growth) HPV strains
- Compromised immune states, such as pregnancy, chronic steroid use, immunosuppression following organ transplant, and HIV/AIDS
- In utero exposure (exposure in mothers' womb) to the medication diethylstilbestrol (DES)

Cervical conization is an outpatient procedure that is usually performed after a precancerous condition is found on cervical biopsy. Cervical conization also may be performed if there is an abnormality detected on your Pap test or if the result of your cervical biopsy and colposcopy (examination of the cervix with magnification) do not adequately explain the result of your abnormal Pap test.

Treatment of cervical dysplasia can be divided into ablative (destructive) and excisional (cutting out) techniques. Ablative procedures (cryotherapy and laser therapy) are often used for smaller abnormalities that can be seen in their entirety. Larger more advanced abnormalities often require excisional procedures, such as LEEP or cervical conization. Your doctor will make recommendations for treatment based on your history, Pap smear, colposcopy, and biopsy.
Preparation
Cervical conization is considered an ambulatory (same day) surgical procedure, for which hospitalization is not necessary. As with all procedures performed under general anesthesia, you must not eat or drink anything for six to eight hours before surgery. You may brush your teeth in the morning but should not swallow the water. If you are on medications that must be taken, you will have discussed this with us and/or the anesthesiologist and instructions will have been given to you. The procedure may not be performed if you are currently taking, or have recently taken any medication that may interfere with your ability to clot your blood (“blood thinners, aspirin, anti-inflammatory medicines, etc…”). The most common of these medications are aspirin and all related pain relievers or anti-inflammatory compounds (whether prescription or over-the-counter). Please refer to the attached list and tell us if you took any of these within the past 10 days. If your new medication is not on the list, alert us immediately so that we may ensure optimal procedure safety. We will have reviewed all of your current medications with you during the pre-operative/pre-procedure consultation. You are obligated to inform us if anything has changed (medication or otherwise) since your previous visit.

Procedure
General anesthesia is administered, and you will “go to sleep” for the duration of the surgery. You will be lying on your back with your knees bent and heels in stirrups as you would for a pelvic examination. The procedure usually takes less than 30 minutes. The vagina is held open with an instrument called a speculum and, using a scalpel (a “cold knife”) or a laser, your doctor removes a cone-shaped piece of the cervix, ideally containing the entire area of abnormal cells. The canal of the cervix (endocervical canal) is then gently scraped (curettage) to collect tissue beyond reach of the cone, in order to be sure all the abnormality is contained within the cone specimen. The resulting hollow bed is repaired by stitching the along the edges of the wound. Alternatively, the wound may be left open, and electrical heat used to stop bleeding. Your doctor may then apply a solid (silver nitrate), liquid or paste-like (Monsel’s) solution to the cone bed to stop the remaining bleeding.

The “cone” of tissue is then sent to the laboratory for examination by a pathologist for signs of cancer and other conditions that may cause abnormalities in the cervix. If cancer is present, extensive examination of the cone specimen is performed. Recommendations for treatment will be made based on the specific results of your testing. Often, cervical conization is the only surgery necessary and your Pap test can be followed closely for future changes. However, sometimes more surgery is recommended, most often in the form of a hysterectomy (surgical removal of the cervix and uterus).

Post Procedure
You will be in the recovery room for a short time before returning home. You may experience some vaginal discomfort and uterine cramping for the next five to seven days. You will have some bloody vaginal discharge for several weeks following the procedure. If your doctor used silver nitrate of Monsel’s solution, you can anticipate a dark, flaky, coffee ground-like discharge.

Please refrain from sexual intercourse (sex), tampon use, and douching for four weeks.

It is normal to have some bloody discharge from the vagina for several days. If you have significant bleeding or are soaking menstrual pads, please contact the office immediately. You may shower after surgery, but no bathing or swimming (unless otherwise instructed). We ask that you refrain from any strenuous activity or heavy lifting for one week.

We strongly encourage you to take one or two days off from work and perhaps more if your occupation requires strenuous activity or heavy lifting. Some patients have almost no discomfort while others are somewhat uncomfortable for a few days to weeks. Severe pain is unlikely but possible. We may provide you with a prescription for pain medication to alleviate most of the discomfort. Take this medication as prescribed and as needed. If any side effects occur, contact our office immediately.

*You must refrain from any strenuous activity or heavy lifting until we tell you otherwise. Sexual activity of any sort is absolutely prohibited (usually four to six weeks) until we tell you that you may resume.
Expected Outcomes of Outcome
The objective of cervical conization is the diagnosis of the type and extent of cervical disease. A fortunate secondary result of the procedure is often complete removal of the area of active disease. When this is the case, continued long-term follow-up is recommended. In those cases where a clear “disease-free” margin around the cone specimen is not seen, further treatment is necessary. Treatment options might include repeat conization, hysterectomy, or for some patients, continued careful follow-up. You and your doctor will discuss your options for treatment, based on the specific results of your testing, your motivation for follow-up, and if you have a desire for continued childbearing.

Possible Complications of the Procedure
All surgical procedures, regardless of complexity or time, can be associated with unforeseen problems. They may be immediate or even quite delayed in presentation. We would like you to have a list so that you may ask questions if you are still concerned. Aside from anesthesia complications, it is important that every patient be made aware of all possible outcomes, which may include, but are not limited to:

- **Wound Infection:** The incision sites can become infected. Infection may lead to the development of a foul-smelling vaginal discharge, fever, chills, or low abdominal tenderness.
- **Blood Loss / Transfusion:** The cervix is quite vascular. Usually blood loss in this procedure is minimal to moderate. About one of every ten women who have a conization will have sudden and heavy bleeding several days to two weeks following surgery. When this occurs, it can be difficult to control and significant enough to necessitate transfusion.
- **Treatment Failure:** If the surgical specimen has edges that are “positive” for disease, further treatment will be recommended due to the risk of return of cervical disease. Surgical specimens with “disease-free” edges have a lower risk for return of cervical disease, but must be followed closely so that early detection can be made.
- **Cervical Stenosis:** The opening of the cervical canal, which leads to the uterine cavity, will sometimes become narrowed or blocked by scar tissue. Cervical stenosis can lead to painful menstrual periods, make future Pap testing difficult, and make achieving pregnancy more difficult.
- **Cervical Incompetence:** Excisional procedures can leave the cervix without sufficient strength and size to resist opening from the pressure of the pregnancy, which can lead to higher chances of pregnancy loss and preterm labor. The risk of cervical incompetence appears to be related to the amount and depth of tissue removed.
- **Deep Vein Thrombosis (DVT)/Pulmonary Embolus (PE):** In any operation (especially longer operations), you can develop a clot in a vein of your leg (DVT). Typically, this presents two to seven days (or longer) after the procedure as pain, swelling, and tenderness to touch in the lower leg (calf). Your ankle and foot can become swollen. If you notice these signs, you should go directly to an emergency room and also call our office. Although less likely, this blood clot can move through the veins and block off part of the lung (PE). This would present as shortness of breath and possibly chest pain. We may sometimes ask the medical doctors to be involved with the management of either of these problems.
- **Lower Extremity Weakness/Numbness:** This, too, is a rare event that may arise due to your position on the operating table. It is possible in procedures in which you are in the lithotomy (legs up in the air) for a long period. The problem is usually self-limited, with a return to baseline expected.
- **Perforation of the Uterus:** Rarely, a deep cone biopsy may go entirely through the wall of the uterus. Although rare, this complication could lead to injury of other structures and organs within the abdomen and may need another operation for repair.
- **Risks of anesthesia:** There are risks to the anesthesia such as an allergic reaction, seizures or death. These risks are small.
Consent for Cervical Conization (Cone Biopsy)

I understand that during the course of the procedure unforeseen conditions might arise or be revealed that could require an extension of the procedure or performance of other operations, procedures or treatments. I therefore authorize and request the below-named individual or their designees to perform such operations, procedures or treatments that are or might become necessary in the exercise of their professional judgment.

I acknowledge that ________________ has explained the proposed procedure to me and has answered any questions that I have to my satisfaction.

I hereby consent to the above procedure. In addition, I accept all of the risks inherent to that procedure and request that it be performed.

________________________________________  ____________________________  __________________________
Patient Signature  Patient Name (Printed)  Patient ID  Date

________________________________________  ____________________________  __________________________
Physician Signature  Physician Name (Printed)  Date

________________________________________  ____________________________  __________________________
Witness  Witness Name (Printed)  Date

*The information contained in this Medical Informed Consent Form ("Consent Form") is intended to solely inform and educate and should not be used as a substitute for medical evaluation, advice, diagnosis or treatment by a physician or other healthcare professional.*

*Please call your doctor if you have any questions.*