	Affix Patient Label
	Patient Name: _____ Date of Birth: _____

**Informed Consent
For Excisional Biopsy and / or Laser Ablation of Condyloma**

This information is given to you so that you can make an informed decision about having an **Excisional Biopsy and / or Laser Ablation of Condyloma**

Reason and Purpose of the Procedure:

Condyloma accuminata are also called genital warts. They are caused by the human papilloma virus (HPV). They are usually transmitted by sexual contact. Treatment involves destroying the individual lesions or warts. The treatment does not destroy the virus, so it is possible the warts will come back.

Local anesthetic will be injected at the condyloma site. You will also be given some intravenous relaxing medication and pain medicine during the procedure. For most patients, the procedure is well tolerated. Some patients will have moderate discomfort which is well controlled with the intravenous sedation and pain medication. If general anesthesia or stronger sedation is needed, your doctor will discuss that with you.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- The lesions will be removed.

Risks of Procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

Risks of this procedure:


- **Recurrence:** Condyloma can return. It is very possible this will happen.
- **Infection:** Infection is possible. . You may need antibiotics.
- **Scarring:** Scarring can occur where the lesion was removed.
- **Chronic Pain:** You may develop chronic pain in the area that has undergone the procedure..
- **Hematoma:** This is when a blood vessel continues to ooze or bleed. This is rare if an excisional biopsy was performed. If it is unusually large or does not improve a further procedure may be needed.
- **Urethral Stricture:** This complication may be seen following procedures treating intraurethral condyloma. It is possible to develop a scar anywhere in the urethra. If it is significant and interferes with normal urination, a repeat scope procedure may be necessary to open the scar.

Information on Moderate Sedation:

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called “moderate sedation”. You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level. If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing. Even if you have a NO CODE status:

- you may need intubation to support your breathing.
- you may need medications to support your blood pressure.

We will re-evaluate your medical treatment plan and your NO CODE status when sedation has cleared your **body**.

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General Risks of Procedure:

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotic and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke may occur.
- Bleeding may occur. If there is too much bleeding, you may need a transfusion.
- Reaction to the anesthetic may occur. The most common reactions are nausea and vomiting. In rare cases, death may occur. The Anesthesiologist will discuss this with you.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

Alternative Treatments:

Other choices:


- Do nothing. You can decide not to have the procedure
- Topical Therapy: Medicines applied only to the lesions that destroy tissue on contact.
- Antiviral Topical Therapy: Medicines applied to the entire general area that attacks the virus following penetration into the skin or lesion.
- Cryotherapy: Application of liquid nitrogen to freeze and destroy lesion.
- Cauterization: Application of an electrical heat current to destroy lesion.
- Laser Ablation: Use of specific types of laser to destroy lesion.

If You Choose Not to Have this Treatment:

- Lesions may grow in size and spread to other areas.

General Information:

- During this procedure, the doctor may need to perform more or different procedures than I agreed to.
- During the procedure the doctor may need to do more tests or treatment.
- Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.
- Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.
- Pictures and videos may be done during the procedure. These may be added to my medical record. These may

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be published for teaching purposes. My identity will be protected.

By signing this form I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Excisional Biopsy and / or Laser Ablation of Condyloma**

- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents, or other staff may help with surgery. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to surgery. IF so, please obtain consent for blood/product.

Patient Signature _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Interpreter: _____ Date _____ Time _____
Interpreter (if applicable)

For Provider Use ONLY:
I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back

Patient shows understanding by stating in his or her own words:

____ Reason(s) for the treatment/procedure: _____

____ Area(s) of the body that will be affected: _____

____ Benefit(s) of the procedure: _____

____ Risk(s) of the procedure: _____

____ Alternative(s) to the procedure: _____

Or

____ Patient elects not to proceed: _____ (patient signature)

Validated/Witness: _____ Date: _____ Time: _____