

# The VOICE Study

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# **New HIV Prevention Products Are Needed**

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# HIV/AIDS and Women

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# Women's Vulnerability

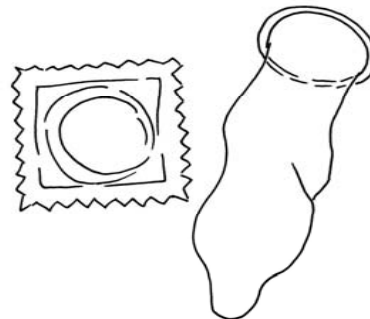
- Women are more vulnerable to HIV infection than men, due to biological, economic, and cultural factors.



Source = GCM presentation module, "AIDS Has a Woman's Face"

# Current HIV Prevention Methods

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# Something New is Needed

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- Researchers are trying to find new products that will work to prevent getting HIV infection.





# Finding New Products That Work



# The VOICE Study

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# Gel and Tablets

## □ Vaginal Gel

- Tenofovir 1% gel
- Placebo gel



## □ Oral Tablets

- Tenofovir tablet
- Tenofovir placebo tablet
- Truvada tablet
- Truvada placebo tablet



# Main Study Questions

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- Are Tenofovir tablets, Truvada tablets, and Tenofovir gel **effective for preventing HIV?**
- Are Tenofovir tablets, Truvada tablets, and Tenofovir gel **safe for women to use?**

# Other Study Questions

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- Do women **take their tablets or use their gel every day**?
- Do women's **behaviors change** while using study products?
- How often does **HIV drug resistance** occur?

# Study Clinics





# Women Who Can Join

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- Able and willing to provide informed consent
- Able and willing to be contacted by the study staff
- Sexually active



# Women Who Can Join

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- ❑ Not pregnant and willing to use family planning
- ❑ Do not have HIV
- ❑ In general good health



# Study Groups

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# Five Study Groups

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- Women in the study will use either gel or tablets.



OR



# Two Gel Groups



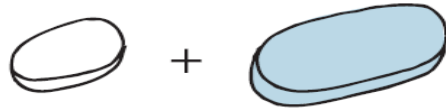
Tenofovir gel



Placebo gel

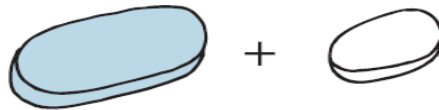


# Three Tablet Groups



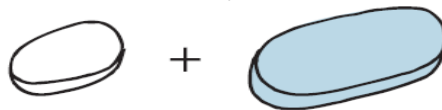
Tenofovir tablet

Truvada placebo



Truvada tablet

Tenofovir placebo



Tenofovir placebo

Truvada placebo



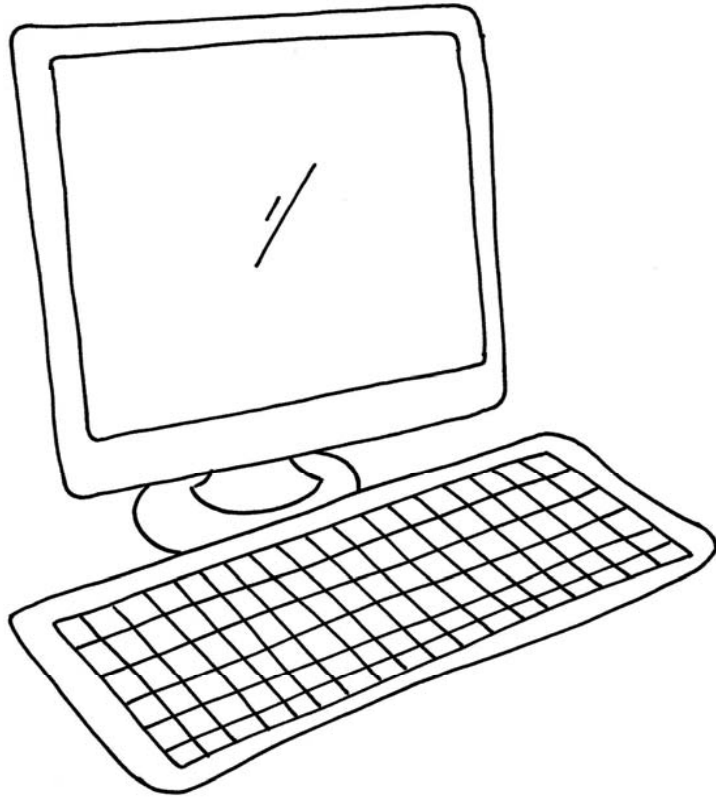
# Study Groups

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Who is receiving...	Will Participants Know?	Will Study Staff Know?
Gel or Tablets	<b>YES</b>	<b>YES</b>
Active or Placebo Gel Active or Placebo Tablets	<b>NO</b>	<b>NO</b>

# Study Group Assignments

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All women have an equal chance of being placed into 1 of the 5 groups.



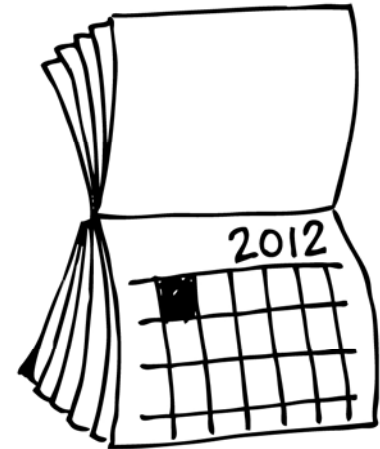
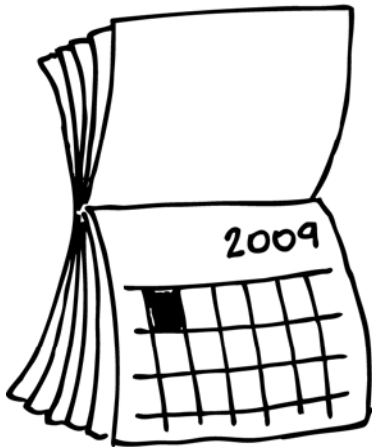
# What Happens in the Study

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# Length of Study

- The study will take about 4 years, from the time the first woman joins to the time the researchers have the study results.

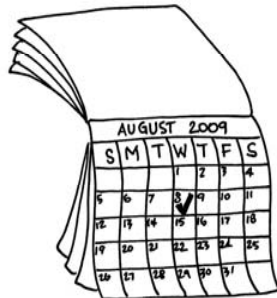
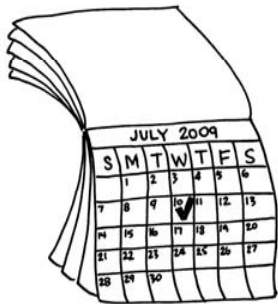
**BEGIN**



**END**

# Study Visits

- Women in the study will visit the study clinic every month.



# Study Visits

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- Women will have examinations of their body and counseling and treatment for STIs if needed.



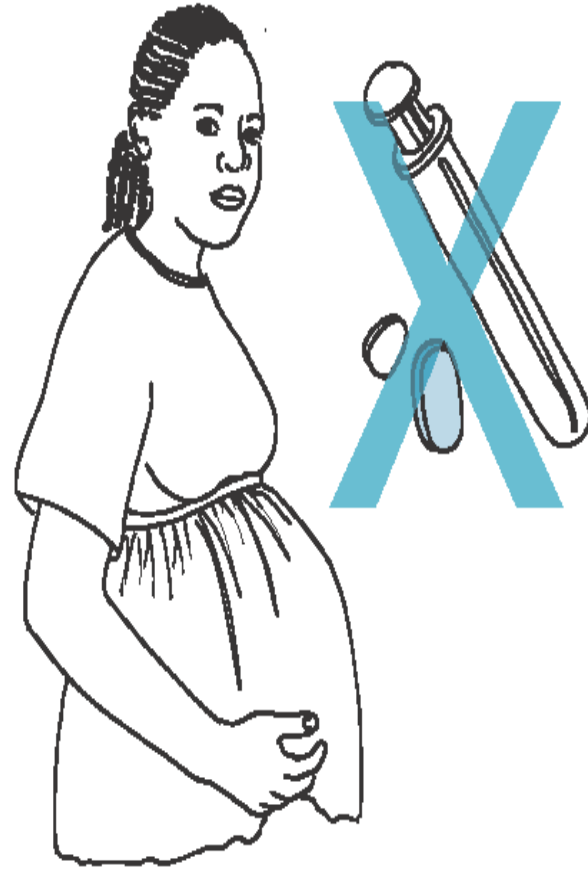
- Partners can come to the clinic for STI testing and treatment.



# Women in the Study

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- Women should not get pregnant while in this study.



# Women in the Study

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- Women must never share or sell their gel or tablets.





# Women in the Study

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- Women cannot take part in other research studies.





# Study Results

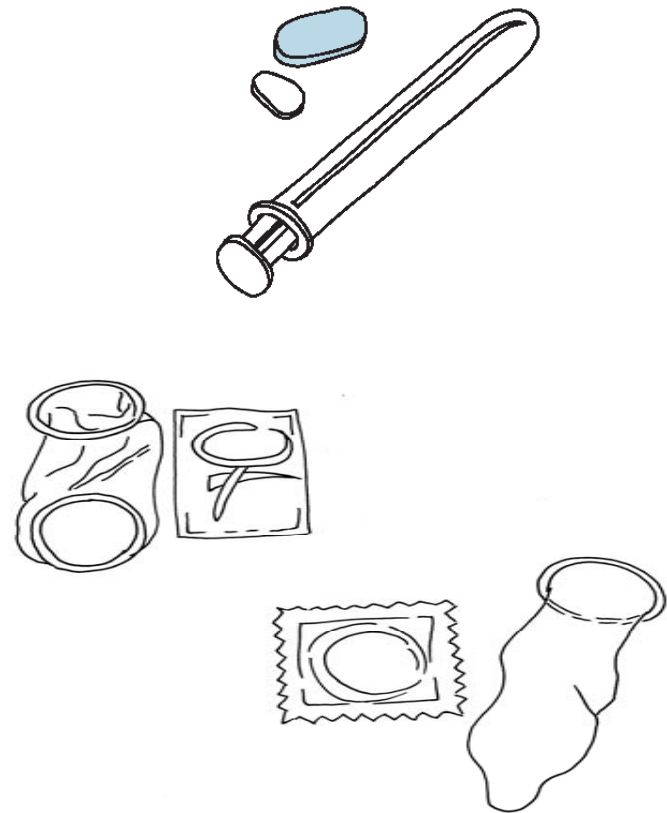
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- Is Tenofovir gel safe? Is it effective for preventing HIV?
- Is Tenofovir tablet safe? Is it effective for preventing HIV?
- Is Truvada tablet safe? Is it effective for preventing HIV?

# The VOICE Study

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- There are things we do not know about the gel and tablets.



# The VOICE Study

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- Women who join this study are volunteers in the fight against HIV/AIDS.





# **Information About HIV Drug Resistance**

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# What is Resistance?

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- To understand HIV drug resistance, we first need to understand some things about the virus itself.





# Why is HIV Drug Resistance a Problem?

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- When resistance happens, an ARV medicine is no longer able to stop HIV from making copies of itself.



# Why is HIV Resistance a Concern in The VOICE Study?

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- If a woman becomes infected with HIV while in the study and keeps using Tenofovir or Truvada, the virus in her body could become resistant to these ARV medicines.



# Preventing HIV Resistance

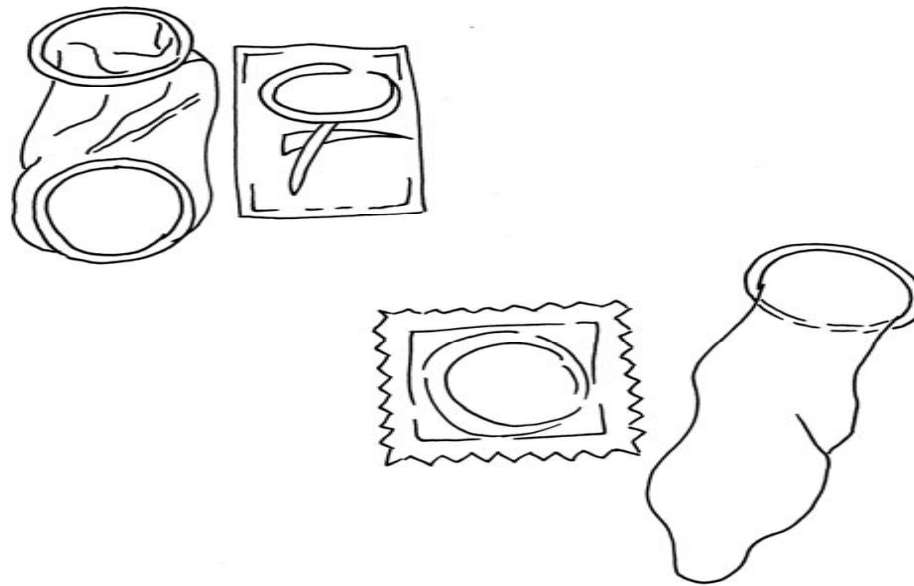
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- There are 3 ways to avoid resistance in the VOICE study...

# Avoid Getting HIV

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- Use a condom correctly with every partner, every time you have sex.



# Attend Study Visits Every Month

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- HIV testing will be done monthly for women in the study.



# Do Not Share Gel or Tablets

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- Sharing gel or tablets with other people, even with a partner, could be harmful.





# Family Planning Methods

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The content of this portion of the presentation was adapted from  
“Family Planning: A Global Handbook for Providers” developed by  
USAID, Johns Hopkins Bloomberg School of Public Health and WHO

# Male Condom

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## What is it?

- A male condom is a thin rubber sock that is placed over the erect penis before sexual intercourse begins.





# Male Condom

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## How is it used?

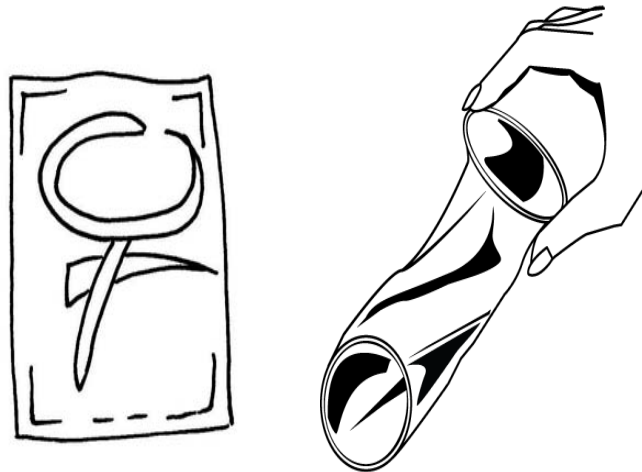
- A couple must use a new condom every time they have sexual intercourse. Before any genital contact, the man unrolls the condom all the way to the base of his erect penis.
- To be effective, a condom must be used correctly every time.

# Female Condom

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## What is it?

- A female condom is a thin plastic pouch that fits loosely inside a woman's vagina.



# Female Condom

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## How is it used?

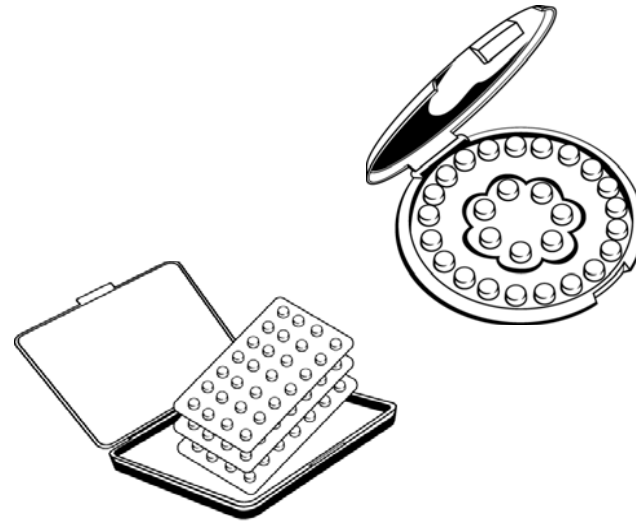
- A couple must use a new female condom every time they have sexual intercourse. Before any genital contact, the female condom is inserted into the vagina.
- To be effective, a female condom must be used correctly every time.

# Oral Contraceptives

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## What is it?

- An oral contraceptive is a pill that contains hormones (estrogen and progestin) that stop the ovaries from releasing eggs.



# Oral Contraceptives

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## How is it used?

- A woman must take one pill every day, even on days when she does not have sexual intercourse.



# Injectable Contraceptives

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## What is it?

- Injectable contraceptives are hormone injections that stop the ovaries from releasing eggs.



# Injectable Contraceptives

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## How is it used?

- A woman receives one injection every 2-3 months from a clinician.



# Implants

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## What is it?

- Implants are small flexible rods or capsules that contain the hormone progestin.





# Implants

## How is it used?

- Implants are placed just under the skin of the upper arm by a clinician.
- They provide long-term pregnancy prevention for 3 to 7 years.

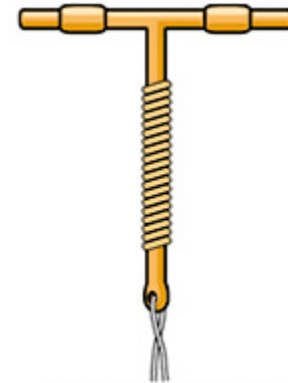


# Intrauterine Contraceptive Device

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## What is it?

- Also known as an IUCD.
- T-shaped device that is placed in the uterus (womb).

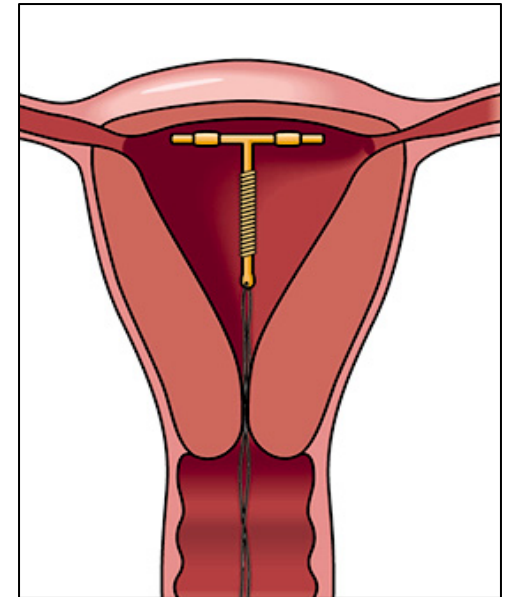


# Intrauterine Contraceptive Device

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## How is it used?

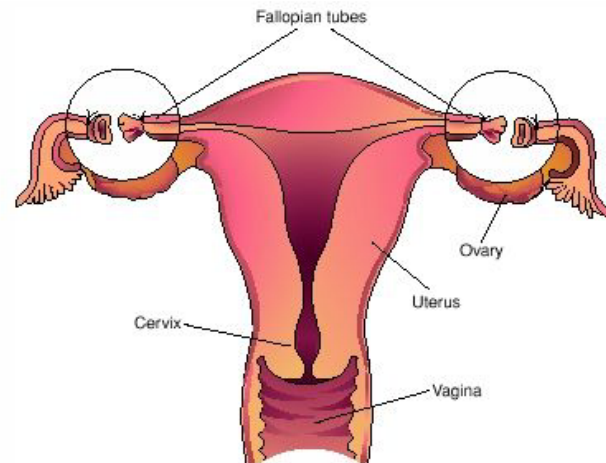
- An IUCD is placed in the uterus by a specially trained clinician.
- It can stay in place and provide pregnancy prevention for 5 to 10 years, depending on the type.



# Female Sterilization

## What is it?

- ❑ Female sterilization is a surgery that permanently prevents pregnancy.
- ❑ In most cases, the tubes that carry eggs from the ovaries to the uterus are cut and/or closed.





# Female Sterilization

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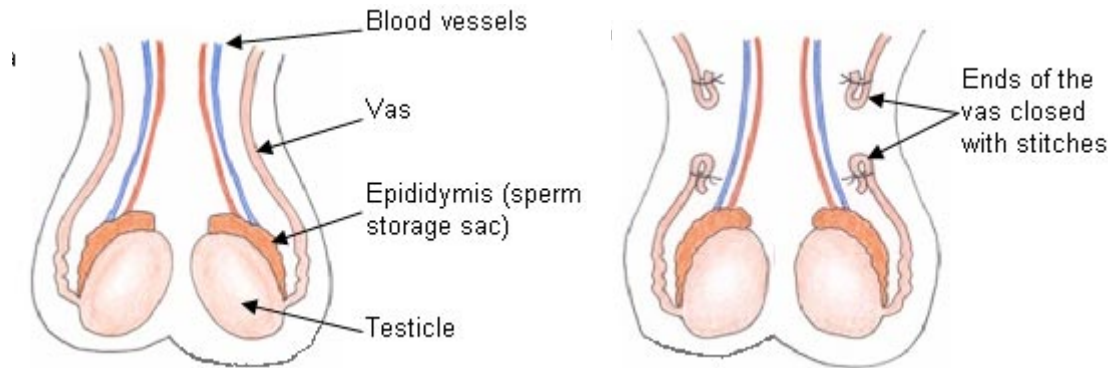
## How is it used?

- Female sterilization is a surgery that a woman has only once.
- It is done by a specially trained clinician and it is permanent.

# Vasectomy

## What is it?

- Vasectomy is a simple and safe surgery where the tubes that carry a man's sperm are cut and closed.





# Vasectomy

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## How is it used?

- A vasectomy is a surgery that a man has only once.
- It is done by a specially trained clinician and it is permanent.



# **Let's Discuss Your Questions**

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# The VOICE Study

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- The United States National Institutes of Health is paying for this research study.