

- PN-ADB-159 -

# Testing Carraguard™

What you need  
to know



 Population Council

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**This booklet is about a study to test a  
new vaginal gel called**

# **Carraguard**

**This booklet contains lots of information, to help you  
understand:**

**What Carraguard is**

**Why Carraguard is being developed**

**How Carraguard is being tested**

**What it means to take part in this study**

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# Finding out about Carraguard™



## Why is Carraguard being developed?

At the moment, the only ways to prevent sexual transmission of HIV/AIDS and other STDs are:

Abstinence – which means not having sex

Mutual monogamy – you and your partner only having sex with each other

Using condoms every time you and your partner have sex.

But these are not possible for many women. So, scientists are working to develop “vaginal microbicides.” These are products that women could put into their vaginas before sex to protect themselves from getting HIV or other STDs.



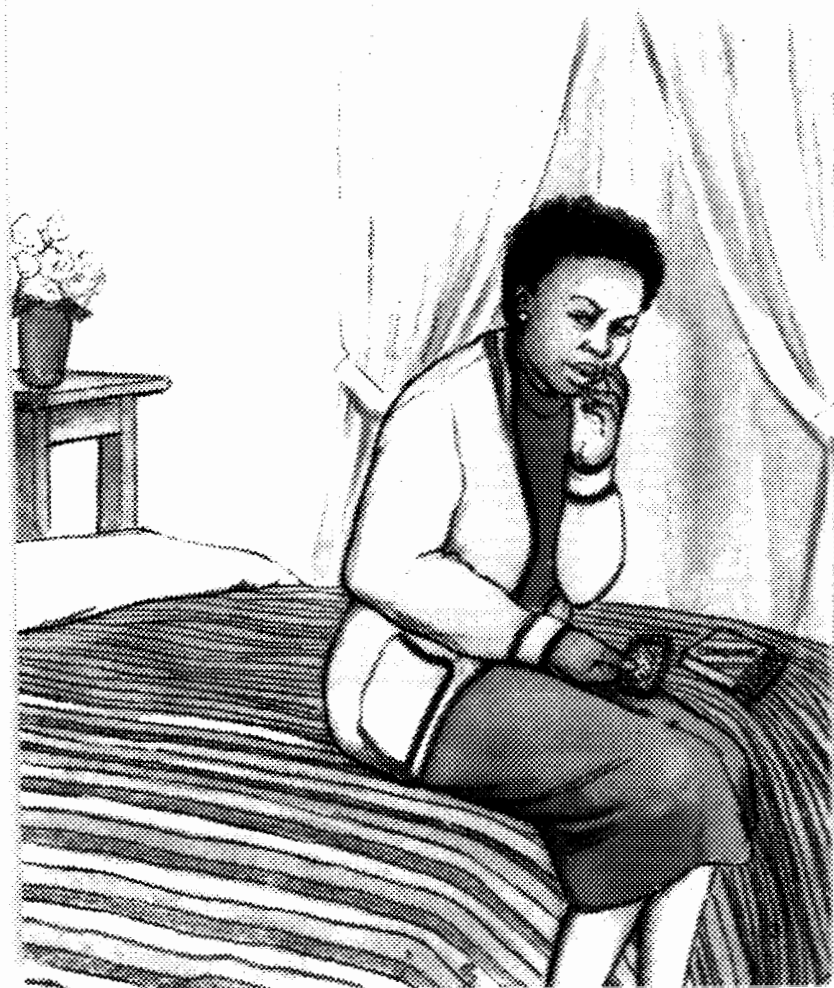
As of now, no microbicides to prevent HIV exist, but there are many products being tested to see if they **might** work.

Carraguard is one of the products that scientists are testing.

This study is to see if Carraguard will work to protect women from getting HIV through sex. If Carraguard does this, it will be a microbicide.

We do not yet know if Carraguard works to prevent HIV.

*Women can find it difficult to persuade their partners to use condoms. We need to find other ways for women to protect themselves against HIV/AIDS.*



## What is Carraguard?

Carraguard is a gel made for vaginal use. Carraguard will not prevent pregnancy.

Carraguard has:

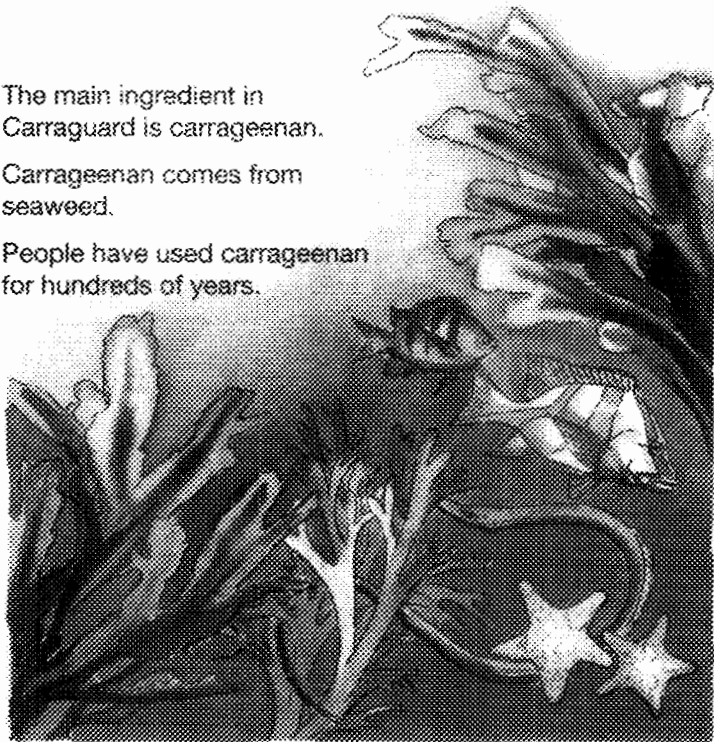
- NO colour (it is clear)
- NO smell
- NO taste.



The main ingredient in Carraguard is carrageenan.

Carrageenan comes from seaweed.

People have used carrageenan for hundreds of years.



Carrageenan is already used in cosmetics, like skin lotions and creams.

Carrageenan is also an ingredient in things like:

- Soups
- Baby formula
- Toothpaste.

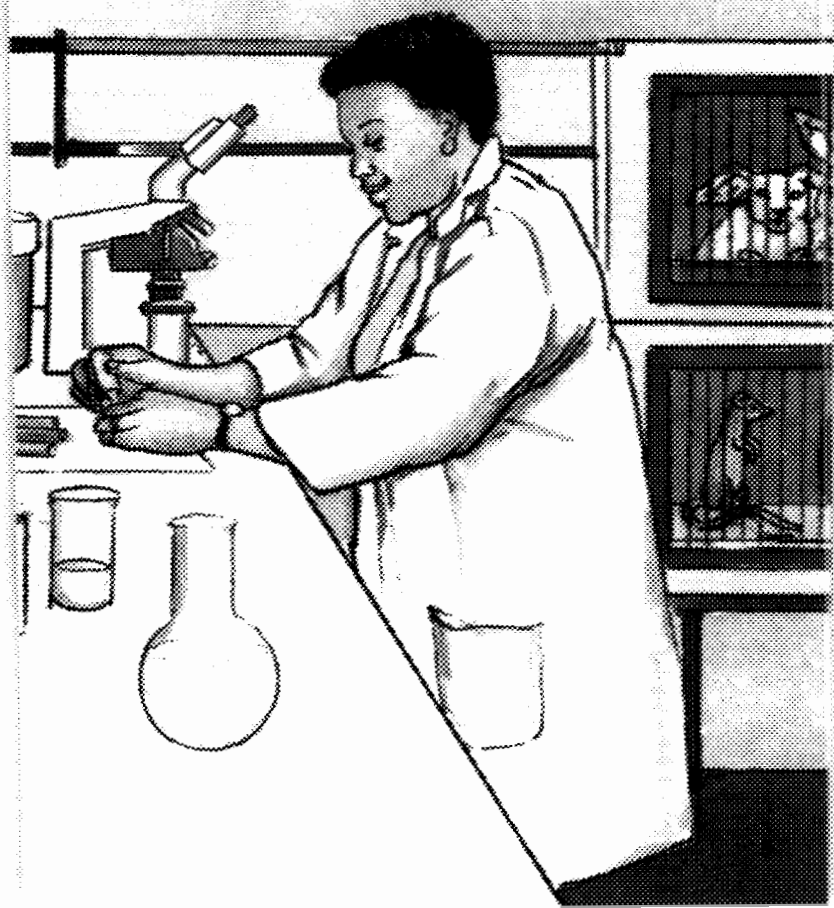




## What do we know about Carraguard?

### *Testing Carraguard in the laboratory*

Research in the laboratory has shown that Carraguard may prevent HIV, but scientists do not know if Carraguard works in people. Before scientists can test a product in people, it must be tested in animals. Carraguard was tested in animals and it did not cause them any harm.



## **Testing Carraguard in people**

Once scientists knew that Carraguard was safe in animals, it was then tested in several studies to make sure it was safe for people. By safe, we mean that the gel doesn't cause any problems, like itching, burning or pain in the vagina or to the penis.

1. First, 2 small studies were done with 60 women from the United States, Thailand, Australia, Finland, Chile and the Dominican Republic. Women used gels very similar to Carraguard **once a day for a week** without sex. In those studies, the gels were found to be safe.



2. Next, Carraguard was tested in 2 bigger studies with 565 women in South Africa and Thailand. These women used Carraguard or a comparison gel several times a week, including during sex, for 6 to 12 months. In these studies, Carraguard was found to be safe.



3. Carraguard was also tested in a study with 55 couples in Thailand. In that study, Carraguard was found to be safe for men, too.



Now we want to find out if Carraguard works to prevent HIV and make sure it can be used for up to 2 years without causing problems.

## **What do we want to find out in this study?**

Now we are doing a study to see if Carraguard works as a microbicide to prevent HIV/AIDS. In this study we are testing to:

1. Find out if Carraguard protects women from getting HIV through sex.
2. Make sure Carraguard does not cause any problems in the vagina, like burning, itching or pain when used for up to 2 years.

Scientists call this a Phase 3 efficacy trial.

### **The kind of study is called a clinical trial**

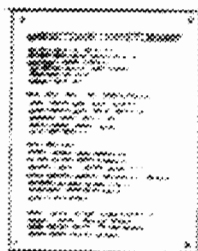
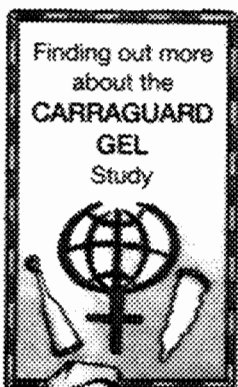
#### **What is a clinical trial?**

A clinical trial is a scientific process that tests medicines and other health products. The general public cannot use health products unless they have been tested. This is to make sure the products do not harm anyone, and that they work properly.

In South Africa, the Medicines Control Council (MCC), a special government agency that makes sure medicines are safe, must approve clinical trials. This must happen before a product can be tested and used.

Researchers, including doctors and nurses, run clinical trials.

# Finding out if Carraguard works as a microbicide



## **Who is conducting this Phase 3 trial?**

The Population Council, the organisation that developed Carraguard, is conducting this study together with several research institutions in South Africa.

All of these institutions are non-profit organisations or universities. At each organisation, the study has been reviewed and approved by an ethics committee that makes sure people are treated fairly and properly in research.

Each study site also has a Community Advisory Group (CAG) that has been consulted.

## **Volunteering for this study**

We need thousands of volunteers to do this Phase 3 trial.

A total of about 6,270 women from South Africa will take part in this study.

Each woman will be in the study for up to 2 years.

The whole study will last about 3 years.

Taking part in the study is completely voluntary.

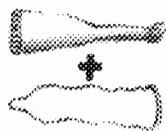
It is up to you to decide whether or not you want to take part, but if you are under 18, you may also need permission from a parent or guardian.

If you choose to enrol in the study, you are free to withdraw at any time.

It is your free choice!

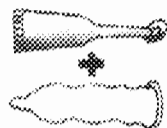
## Study groups

If you join the study, you will be put into 1 of 2 study groups, by chance. One group will use Carraguard gel + condoms every time they have sex. The other group will use a comparison gel + condoms every time they have sex.



### Group 1

= Carraguard Gel  
+ Condoms



### Group 2

= Comparison Gel  
+ Condoms



## What is the comparison gel?

The comparison gel looks and feels like Carraguard but **does not have carrageenan** in it. The comparison gel is made from methyl cellulose which is used in many products such as eye drops, skin lotions and other vaginal products.

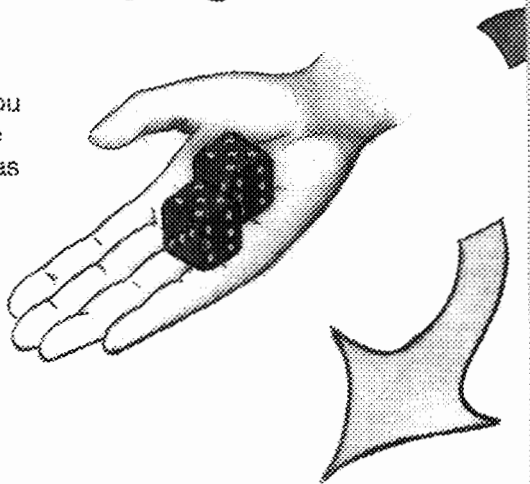
Scientists have tested the comparison gel in the laboratory and found that **it does not prevent HIV**. It also will not prevent pregnancy. In earlier studies, the comparison gel **caused no harm when used in the vagina**.

## How will I be put into a study group?

Each woman who joins the study will have an equal chance of being in either of the two groups. In the same way that numbers come out of the lotto machine by chance, or the roll of a dice is by chance, a computer will decide by chance what group each woman is put into.



Once you enrol, you will be in the same group for as long as you are in the study.



## Why do we need two groups?

Everyone in both groups follows all of the same steps. The only difference between the groups is that one group uses Carraguard and the other uses the comparison gel.



At the end of the study, scientists will compare the number of women who became HIV-positive in each group. If fewer women became infected in the Carraguard group than in the comparison gel group, it means Carraguard worked to help prevent HIV infection.

But remember, we do not yet know if Carraguard works to prevent HIV.

You and your partner should also use condoms every time you have sex. This is because condoms are currently the best-known method to prevent HIV.

**BOTH** groups are equally important to finding out if Carraguard works.



## **How will we know if Carraguard works if everyone uses condoms?**

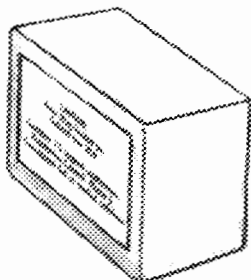
Even though we are encouraging everyone to use condoms, some people may not be able to use a condom every time they have sex. So, if at the end of the study, the group that used Carraguard got fewer infections than the group using the comparison gel, it means that Carraguard worked to protect women against HIV when they were not using condoms.

But remember, we do not know if Carraguard works, so it is very important to always try to use condoms.

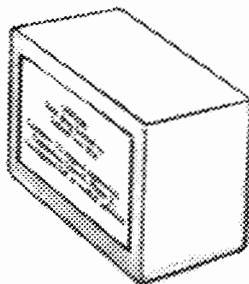
## Will I know which gel I am using?

Neither you nor the study staff will know if you are getting Carraguard or the comparison gel. The reason for this is that if women know which gel they are using, it may affect what they think and say about it. If the study staff know who is using which gel, it may affect how they interpret what they see and hear in the exams and interviews.

Only after the study is over will the researchers be able to find out who had which gel, and whether the study results show a difference between the 2 groups. If you want to know which gel you were using, you will be able to find out when the whole study has finished.



Group 1



Group 2

**Neither the study staff nor the women in the study will know which boxes contain which gel.**

Both gels are packed in white boxes. The boxes look exactly the same. Each box contains 15 applicators. All the applicators look exactly the same.

## Who is eligible to be in the study?

You can take part in the study if:

- \* You are a woman and you are 16 or older.\*
- \* You have been living in the study site area for at least 1 year and plan to continue living there for at least 2 years.
- \* You are sexually active – this means you had sex at least once in the last 3 months.
- \* You can understand the study purposes and steps.
- \* You are HIV-negative when you join the study.
- \* You are willing to be tested for HIV and told the results before joining the study and during the study.
- \* You are willing to be in either of the 2 study groups: Carraguard + condoms or comparison gel + condoms (see pages 12-15 for explanation of study groups).
- \* You are willing to come for clinic visits every 3 months (see pages 36-39 for details).
- \* You can give informed consent.  
(This means that you understand the contents of this booklet and agree to what we are asking of you.)

*\* 16 and 17-year old girls may also need permission from a parent or guardian.*

## Who is not eligible?

Some women may not be eligible to join the study. You cannot join this study if:

You are pregnant or planning to fall pregnant in the next two years.

You had a baby, a miscarriage, or a termination of pregnancy (TOP) in the last 4 weeks.

You have cervical cancer.

You are HIV-positive.

You are in any other HIV prevention study or clinical trial.

*You have a completely free choice as to whether or not you want to take part in this study.*



## Telling your partner

If you are eligible, it is up to you to decide whether or not to join the study. If you join the study, it is your choice who you tell that you are in the study. However, since this study involves sex, it may be helpful to let your partner know you are taking part.

If you have difficulty talking to your partner about the study, the counsellor may be able to help you sort out the problem. You can also bring your partner with you to learn about the study and ask the study staff questions.

*Many women from earlier studies said they liked having their partners' support.*





If you want to take part  
in the study, what do  
you need to do?

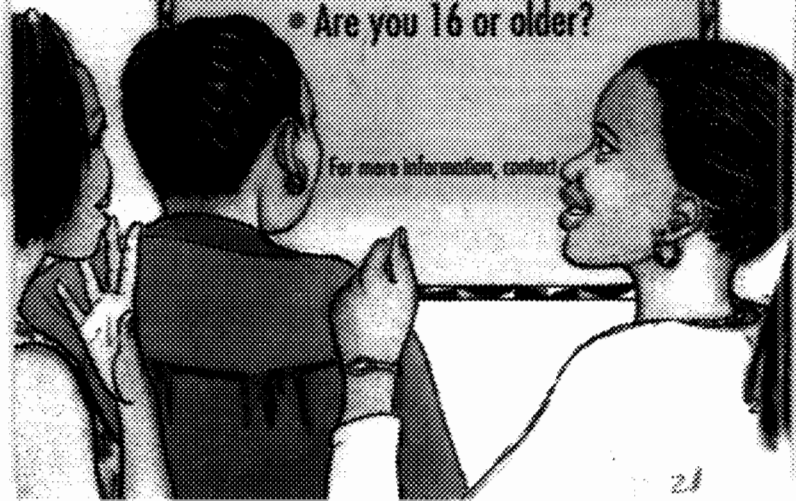
The screening process

DO YOU WANT TO TAKE PART IN THE  
**CARRAGUARD** STUDY?



- Are you sexually active?
- Are you 16 or older?

For more information, contact



# 1. The screening process

If you are interested in being in the study, you will need to go through a process to see if you are eligible. Here is what will happen:

First, you will be screened.

Then, you will get your screening results.

If your results show you are eligible, you can then enrol in the study.

There are 6 steps in the screening process:

First, you need to agree to take part in the study – this is called **informed consent**.



- ② You will need to answer some personal questions about yourself in an **interview**.



- ③ You will have a urine **pregnancy test**.



You will receive **counselling**.



- ⑤ You will have an **HIV rapid test**.



- ⑥ You will have a **vaginal exam** with STD testing.



You will find more details about each of these steps in this section of the booklet.

## Informed consent

The researchers doing this study want to make sure that everybody who takes part in the study understands what the study is all about and that they take part voluntarily.

So, the first step is to explain to you in detail what it means to be in the study. A staff member will read through this study booklet and the Informed Consent Form with you. You will also be shown a video. You will also have the chance to ask questions about anything you are not sure about.

If you feel ready to take part, you and the staff member will sign the form together.

Remember, even if you sign the Informed Consent Form, you can still decide not to be in the study. It is also important to remember that even if you sign the form, you may not be eligible to join the study.

*If you think you may not be able to understand the form you may bring a friend or relative who reads well with you to help you. She will also need to sign the form as a witness.*



## Eligibility checklist and interview

After you have signed the Informed Consent Form, a member of the study staff will ask you some basic questions to make sure you are eligible to be screened for the study (see pages 18 and 19).

You will also be asked some questions about your background and sexual practices. This information is very important for the researchers to be able to interpret the results at the end of the study.



*All interviews will happen in private  
and the information will be kept  
confidential.*

## Pregnancy test

You will have a urine pregnancy test. Remember, you cannot be in the study if you are pregnant.



### If you are **pregnant**:

You cannot join the study now.

You can be screened again for the study 4 weeks after the end of your pregnancy.

## Counselling

This is a private meeting with a trained counsellor.

She will give you counselling before and after your HIV test.

She will talk to you about HIV/AIDS and other STDs. She will talk about how you get these diseases and how you can protect yourself. She will also show you how to use condoms.

This is the opportunity for you to discuss the study, to discuss safer sex, and to get advice on how to talk about these things with your partner.

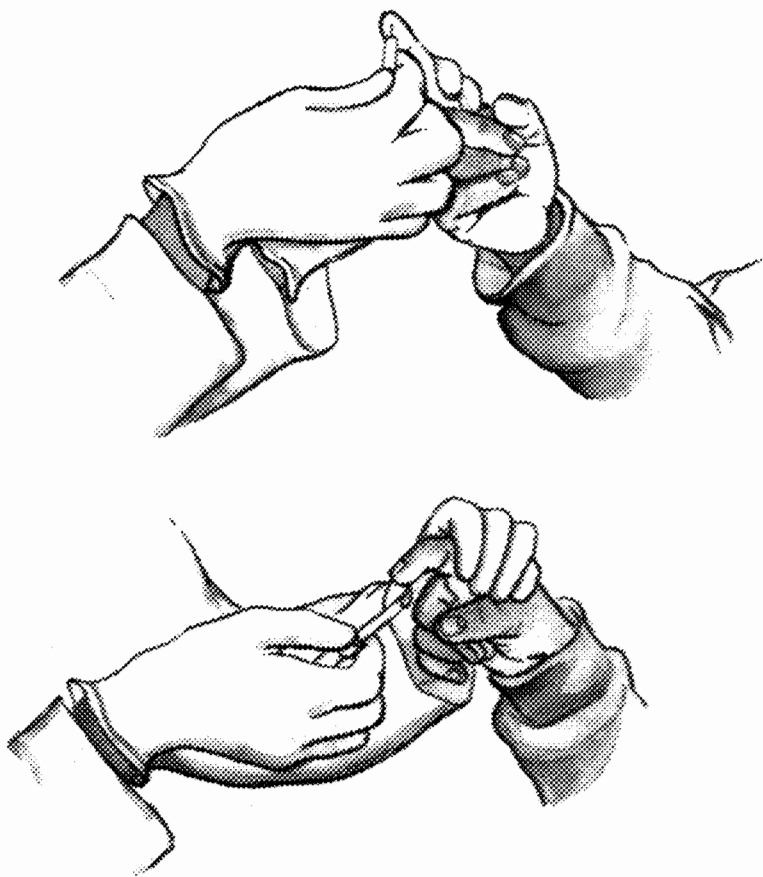
*This is your opportunity to discuss any concerns you have about the study.*



## HIV test

The nurse or doctor will prick your fingertip to collect a small amount of blood for two rapid HIV tests.

Usually, you will get your HIV test results in about 20 minutes. If your rapid test results show that you have HIV, you will not be eligible to join the study. The study staff will help you find care and support services for people living with HIV in your community.

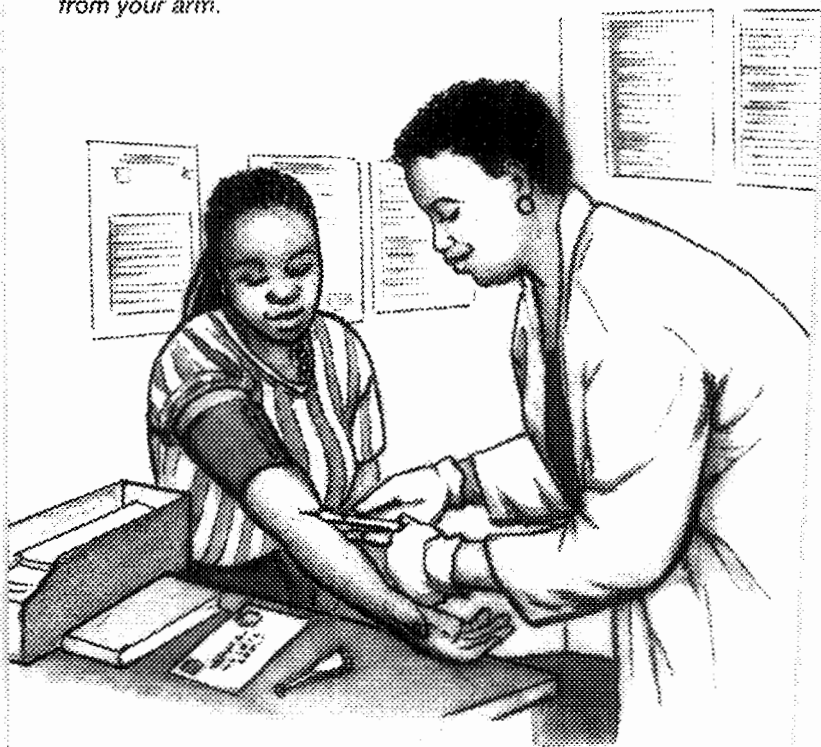


## Blood test

You will also have a blood test. The nurse or doctor will use a needle to collect a small amount of blood from your arm. This blood sample will be sent to a laboratory to check for syphilis. You will get your test results about two weeks later at your next study visit. If your results show that you have syphilis, you will be treated and can enrol in the study.

If your HIV rapid test results were uncertain, we may need to take another blood sample for an HIV confirmation test.

*The nurse or doctor will use a needle to collect a small amount of blood from your arm.*





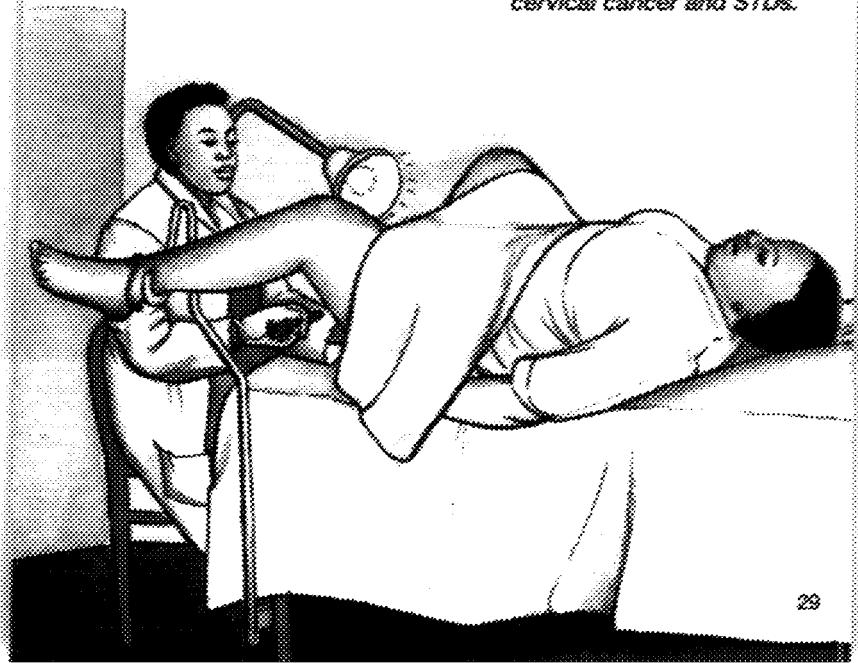
## Vaginal exam with lab testing

You will have a physical exam where the nurse or doctor will take your blood pressure and check your general health. This will also include a breast exam and a vaginal exam, with a speculum. A speculum is an instrument to help see inside the vagina.

During the vaginal exam, the nurse or doctor will use swabs to take samples from your vagina and cervix to test for infections, including STDs, and a Pap smear to test for cervical cancer. If the nurse or doctor sees signs of a curable infection, you will get treatment at this visit or at your next study visit, about 2 weeks later.

You must not be menstruating when you come for screening because the study staff will not be able to do a vaginal exam. So, make an appointment to come for screening when you are not menstruating.

*A vaginal examination can be a little uncomfortable and embarrassing but it will help you by testing for diseases like cervical cancer and STDs.*



## 2. Results

You will return to the clinic about two weeks after your screening visit, once the results of the Pap smear and the other STD tests have come back from the laboratory.

**If your test results are normal and you still want to enrol in the study, you will have another pregnancy test. If you are not pregnant, you will be able to enrol at this visit.**

**If you have a curable vaginal infection or STD...**

You will receive treatment, unless you were already treated at your screening visit. You will receive a partner referral so that your partner can also be treated.

**If you have an abnormal Pap smear...**

You may need to be referred to a specialist before you can enrol.

**If you have cervical cancer...**

You will not be able to join the study.

You will be referred to a specialist for treatment.

Your first referral visit will be paid for by the study.

### 3. Enrolment

After you go through the screening process, if you are eligible and you would still like to join the study, you will be enrolled. At your enrolment visit you will have a vaginal exam, a blood test, meet with a counsellor, and have an interview, just like at screening.

At this visit, a study staff member will open a sealed envelope with a code that shows which boxes of gel to give you. But remember, neither you nor the study staff will know which gel you are getting because the boxes look identical.

You will use the same gel for as long as you are in the study. You will be shown how to use the gel.

*At your enrolment visit you will be given condoms and boxes of gel.*



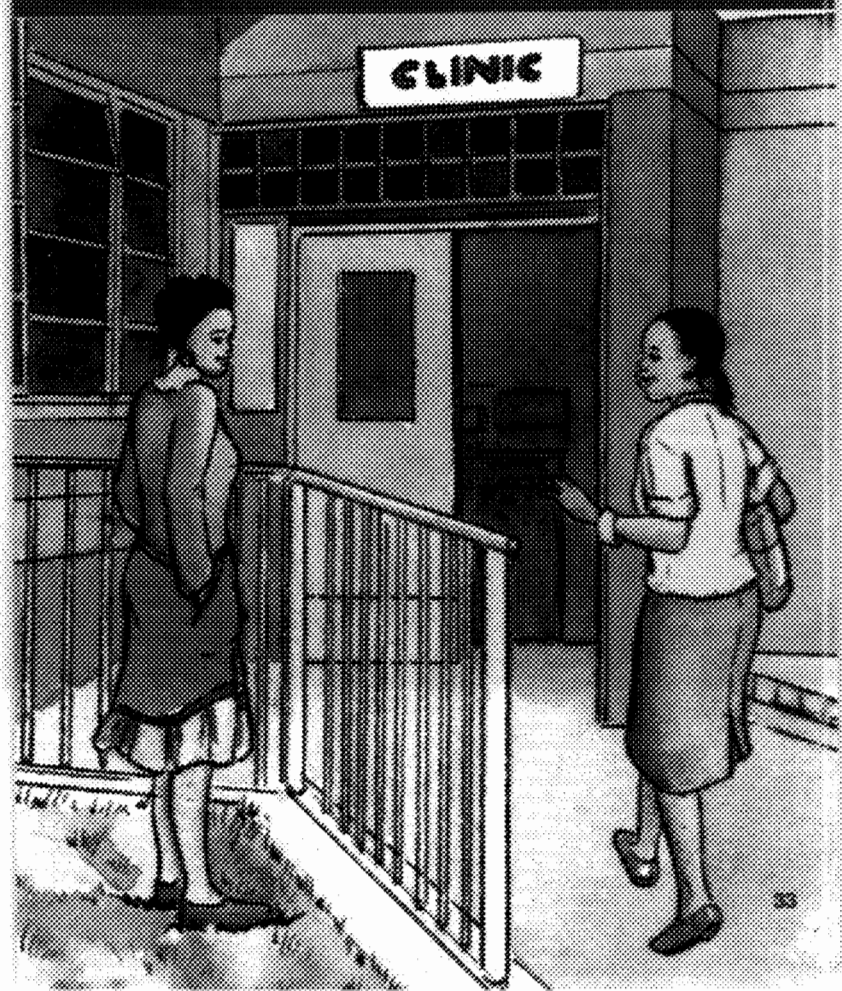
## **Family planning during the study**

Because neither Carraguard nor the comparison gel will prevent you from falling pregnant, you should use a family planning method while you are in the study.

- If you don't have a family planning method, the study staff can give you a method or refer you to a local family planning clinic.
- You may also use condoms for family planning.

If you fall pregnant while you are in the study, you must stop using the gel because we do not know what effects the gel might have on an unborn baby. You will no longer be in the study. However, the study staff will follow up with you and your doctor about your pregnancy and the health of your baby.

# Being part of the study



## Using the gel

Once you have joined the study the main responsibility you have is to use the gel every time you have sex.

### **REMEMBER:**

Put one applicator of gel into your vagina each time you have sex.

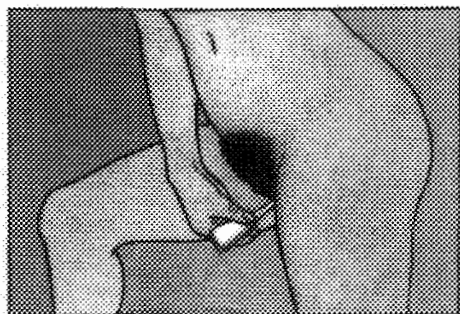
You can have sex immediately after you put the gel in, or you can have sex anytime up to one hour after putting it in.

If you have more than one round of sex, insert a new applicator before every round.

Only use the gel in your vagina; do not use it in your mouth or anus.

If you run out of gel before your next clinic visit, you can come to the clinic to fetch more gel.

It is important that you use only the study gel that you have been given by the study staff.



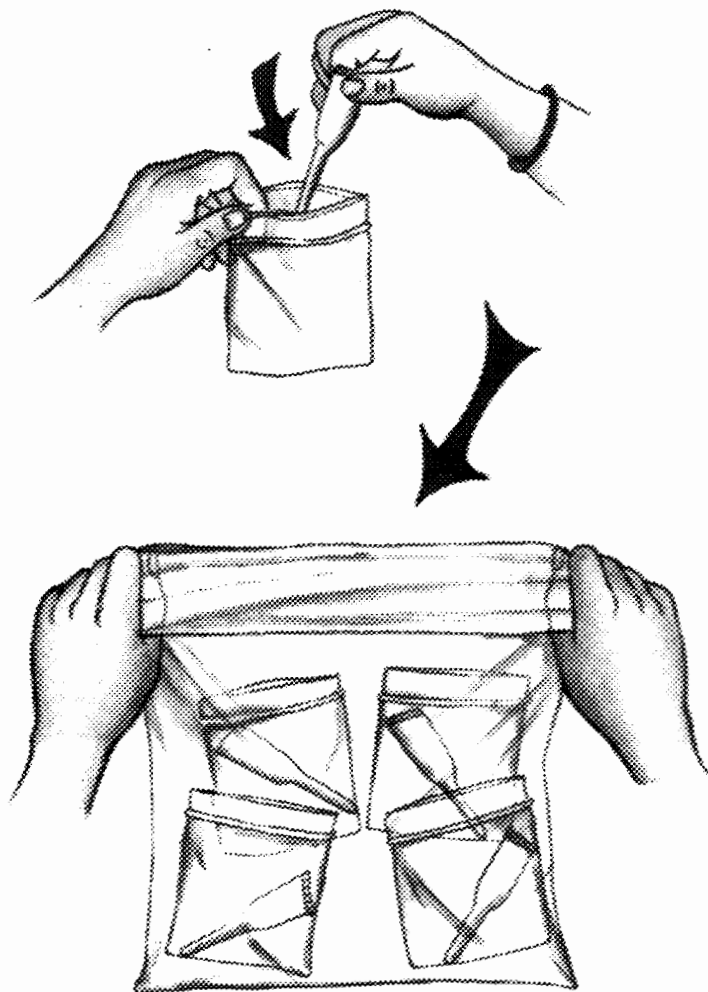
You and your partner should also use condoms every time you have sex, because we do not yet know if Carraguard works to prevent HIV and because you may be getting the comparison gel.

## What to do with used and unused applicators

It is very important that the researchers get all applicators back to be able to account for each one given out.

Put each **used** applicator into a separate small plastic bag after you use it. Put each small plastic bag with an applicator in it, into the bigger plastic bag. Bring the big plastic bag with all the smaller bags in it to the clinic when you come for your study visit.

Remember to bring the **unused** applicators, too.





## Study visits

Once you enrol, you will also need to come to the clinic regularly for study visits. After your enrolment visit, you will need to come in 1 month, then 2 months later, and then every 3 months (about 10 times) for up to 2 years. Each visit will last a few hours.

At each study visit, you will have a vaginal exam, counselling, a rapid HIV test and a pregnancy test, just like at screening.

At months 3, 6, 12, 18 and 24, you will also:

- be tested for STDs; and
- have a blood test for syphilis.

At months 12 and 24 you will also have a physical exam, breast exam and a Pap smear.

If you have signs or symptoms of an STD or any other vaginal infection at any other visit, the nurse or doctor may also do tests at those visits.



## **Interview**

At each study visit you will be asked questions about sexual activity, gel use, condom use, and any problems such as itching and burning from gel use. So it's important that you remember these details between each study visit. Your answers are very important to help the researchers find out if Carraguard works and to make sure it is safe to use for 2 years.

## **Compensation**

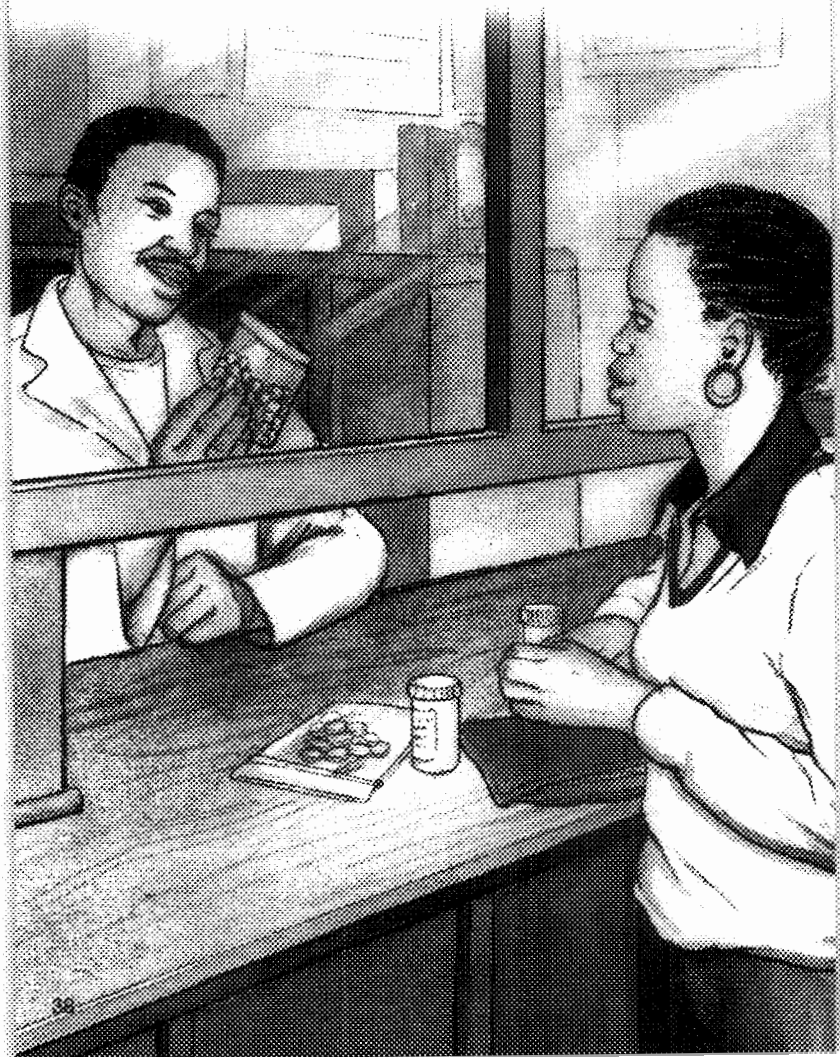
You will be compensated for each scheduled clinic visit. This is to help cover some of the costs associated with being in the study.

## Treatment and care

You will get treatment for all curable STDs and vaginal infections. If your lab results show that you have an infection that was not already treated, you will be contacted to come to the clinic for treatment. You will also receive a referral letter for your partner to be treated.

You will be referred to a specialist for any abnormalities on your cervix.

*You will get treatment for any curable infections.*



If the nurse or doctor thinks the study gel may be causing you problems, you may be asked to stop using the gel for a short time or permanently. Even if you stop using the gel, you should continue using condoms.

If you test positive for HIV during the study, you will no longer be in the study. You will be referred to care and support services in your community.

Even if you stop using the gel you should continue using condoms.

## Risks and burdens

Possible risks and burdens of taking part in the study include:

- You might have some discomfort and/or bleeding during or after the vaginal exam.
- You might have soreness or bruising on your finger or arm after blood has been taken.
- You may be embarrassed by some of the questions you are asked.
- You may feel worried, anxious or upset if you find you have an STD or HIV, or by learning more about your risks for these conditions.
- If you find you have HIV or an STD it could cause problems in your relationships with your partner or family.
- Using either Carraguard or the comparison gel could cause itching, burning or pain. Based on what we know from earlier studies, this is **not** very likely to happen.
- Having to use the gel each time you have sex could cause problems in your relationship with your partner.
- If you have not used condoms before, starting to use them during the study might cause problems in your relationship with your partner.
- There is also a very small chance that either Carraguard or the comparison gel could increase the risk of getting certain STDs. Based on what we know, this is also not likely.

## Benefits

Benefits from taking part in the study include:

- Free testing for STDs and HIV/AIDS, which may find infections with no symptoms;
- Free treatment for all curable STDs;
- Referral letter(s) for your partner(s) to be treated for STDs;
- Regular vaginal exams;
- Free Pap smears and referral for abnormal results; the study will pay for your first referral visit;
- Referral for your partner for HIV testing and counselling if he wishes;
- Safer sex counselling at each study visit, and the option of bringing your partner with you;
- Free condoms; and
- If you test positive for HIV during the study, referral to services available in your community.
- By taking part in the study, you will also help researchers find out if Carraguard works to prevent HIV/AIDS.

## Privacy and confidentiality

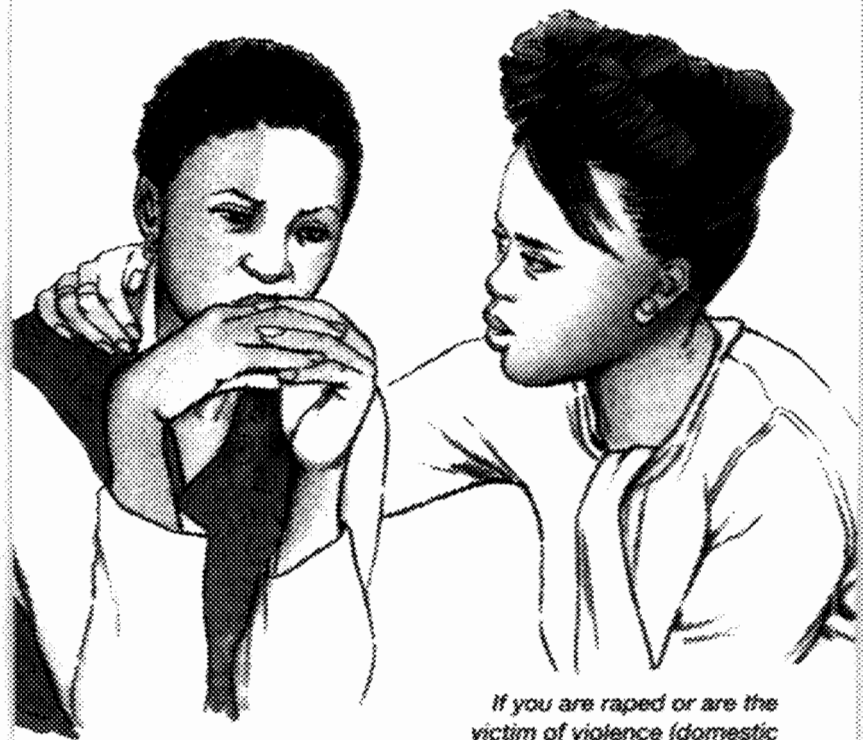
All of your interviews, vaginal exams and counselling sessions will happen in private so that you can feel comfortable.

Your answers to the interview questions, the results of your exams, and lab tests will be written on forms that have a study identification number and not your name. This information will be locked in the study office. Only a few people from the study staff will be able to link your study ID number with your name.

Monitors from the Population Council, the organisation making the gel, will look at your records to make sure the study is being done right. People from the United States Food and Drug Administration (FDA) and the South African Medicines Control Council (MCC) may also want to look at your records. None of these people will be able to link your study information with your name. This way, everything about you and other women in the study stays confidential.

At the end of the study, the report that is published will not have your name or names of any other participants in it.

If a member of the study staff thinks you may harm yourself or another person, she has to follow legal and professional rules. These rules say she must to try to prevent that harm – even if it means sharing confidential information about you.



*If you are raped or are the victim of violence (domestic or other), the study staff will help you to report your case to the police, welfare and support services.*

You may want the study staff to discuss your sexual health, HIV status or anything else related to the trial with your partner, family member or anyone else. This includes people at referral agencies, like professional services, clinics, government or community bodies. In this case, you would need to sign a separate written consent form that lists exactly what information you would like to be shared, and with whom.

## Understanding HIV/AIDS

Many people in South Africa have already become sick with HIV or died of AIDS. This is a condition that affects everyone. So it is important to understand what it is, and how we can all take a stand against it.

The virus called HIV causes AIDS. HIV weakens the immune system, which means the body cannot fight against sicknesses and disease. Eventually the person with HIV can't fight against sickness any more and he or she dies.

The main way HIV is spread is through unprotected sex (anal, vaginal or oral intercourse) without condoms. It can also be spread in these ways:

- through blood transfusions;
- from mothers to their babies during childbirth or through breastfeeding; and
- when people share needles when they inject themselves with drugs.

AIDS is not spread through:



*kissing, touching  
or hugging*



*sneezing*



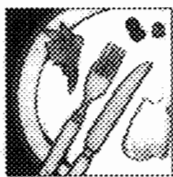
*coughing*



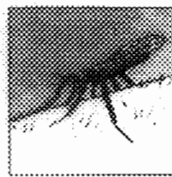
*holding hands*



*using the  
same toilet*



*sharing food,  
utensils, cups  
or plates*



*mosquitoes*



## What is safer sex?

At present there is still no cure for AIDS. But we can stop HIV from being passed from one person to another by practising safer sex.

Safer sex means:

- Having only one sexual partner, if possible. If not, limiting the number of sexual partners you have.
- Avoiding anal sex.
- Using a condom every time you have sex.
- Using a new condom every time.
- Having sex that does not involve penetration, like kissing, hugging, mutual masturbation.
- Talking to your partner about sex. Discuss condoms and why they are important to use.

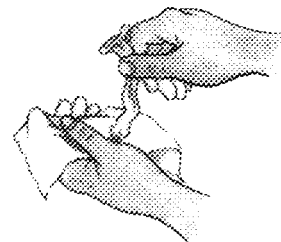
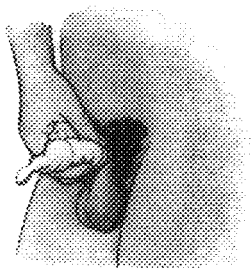
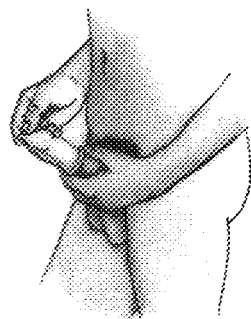
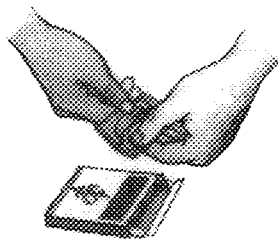
The most important point to remember: always use a condom!

## How to use a condom

To protect yourself against getting HIV/AIDS and other STDs, you should use a condom every time you have sex.

Here are some simple guidelines for using a condom:

- Use a new condom each time you have sex. Check the expiry date.
- Carefully unwrap the condom. Be careful not to tear or break it.
- Start to put the condom onto the erect penis. Press the tip of the condom to push any air out.
- Now roll the condom down over the whole penis.
- After sex, carefully take the condom off. Be careful not to let any semen leak out of the condom.
- Dispose of the condom safely by flushing it down the toilet or wrapping it in paper and putting it into the rubbish bin.



# Testing Carraguard™

## What you need to know

### Contacts

#### Gugulethu and Cape Town

Empiliswani Centre for Wellness Studies	(021) 633-6599 tel (021) 673-7389 fax
UCT Study Office	(021) 406-6481 tel (021) 406-6308 fax
FAMSA	
Cape Town	(021) 447-7951
Gugulethu	(021) 673-6706
NICRO	(021) 422-1225
Lifeline	(021) 461-1111
Western Cape Network on Violence Against Women	(021) 633-5287
Trauma Centre	(021) 465-7373
AIDS Helpline	0800 012 322

#### UCT

School of Public Health and Family Medicine  
Infectious Diseases Epidemiology Research Unit  
Level 3 Falmouth Building, Anzio Road, Observatory 7925,  
Cape Town, South Africa  
Tel: (021) 406-6481  
Fax: (021) 406-6308

#### Soshanguve and Medunsa

Setshaba Research Centre, Soshanguve	(012) 799-2422
Medunsa Study Office	(012) 521-5644
AIDS Training and Information Centre (ATTIC)	(012) 308-8743
Lifeline	(012) 342-9000
Trauma Counselling	(012) 662-1795
People Against Women Abuse (POWA)	(011) 642-4345
Agisanang Domestic Abuse Prevention & Training (ADAPT)	(011) 786-6608
ADAPT Counsellors	(011) 440-4047

#### MEDUNSA

Department of Medical Microbiology,  
Room N315, 3rd Floor, Clinical Pathology Building,  
Medunsa  
PO Box 211, Ga-Rankuwa 0204, South Africa  
Tel: (012) 521-4010  
Fax: (012) 521-5727

#### Registrar of Medicine, Medicines Control Council, South Africa

Department of Health, Private Bag X828, Pretoria 0001  
Tel: (012) 312-0000