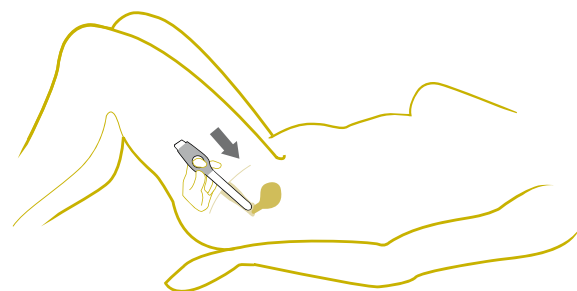
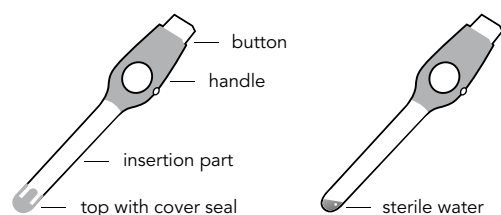


Read these instructions carefully before using the Delphi Screener

The Delphi Screener enables you to collect a fluid sample from your cervix and vagina in a simple and pain free way. The Delphi Screener has been designed to make sure that the top will get close to the cervix with insertion in the vagina.

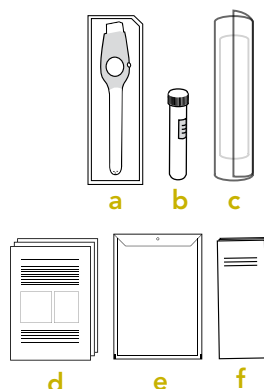
The top contains a small amount (teaspoon) of sterile water. By pressing the button at the back, the sterile water will spread around the cervical area. When the button is released, the water will flow back into the Screener with fluid from the cervix and vagina. After taking out the Screener from the vagina the sample is then transferred into a test-tube. The laboratory will test the sample.

Do not use the Screener when you have your period (i.e. when menstruating). If you have a bleeding that is not associated with menstruation you may use the Screener though. If you use vaginal medication or irrigation, you must stop using this 2 days before using the Screener. You can continue to use a vaginal ring, condoms or water-based lubricants. So far, there has been no experience of use with pregnant women, however due to the soft and rounded shape of the Screener, no health or safety risks are expected.



Preparation

- 1 Check the content of the envelope:
 - a- Delphi Screener
 - b- test-tube
 - c- plastic bag with towel
 - d- study documents
 - e- return envelope
 - f- user instructionsPlease check that your personal identification number is correct on the test-tube and on the questionnaire.



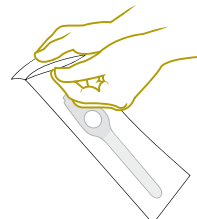
- 2 Wash your hands.



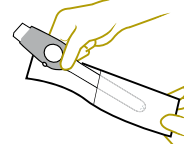
- 3 Take out the test-tube, unscrew the cap and keep both nearby.



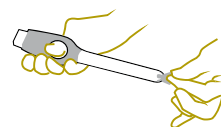
- 4 Open the pouch with the Screener.



- 5 Take the Screener by holding the blue handle.



- 6 Pull the cover seal off the top of the Screener. Some water drops may be visible.



Choose your position

- 7 **a. Lying down**
Lie with your buttocks on a cushion. Cover the cushion with a towel. Pull up your knees and spread your legs.



- b. Sitting down**
Sit with your legs spread on the toilet seat.



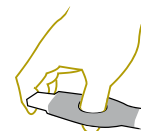
How to do the self collection

You may have some fluid coming out of your vagina after sampling. This is not a problem. Only a small amount of fluid is needed for the test to be done. You may find some blood or mucus on the Screener – this is normal and will not influence the results of your test.

- 8 Hold the Screener by the blue handle as shown in the picture and use your other hand to spread your labia (vaginal lips). Insert the top of the Screener slowly into the vagina, tilting it backwards until you feel resistance.



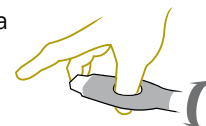
- 9 Hold the Screener whilst pressing the white button fully down.



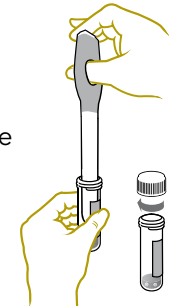
- 10 Count to 3.



- 11 Let go of the button and take the Screener out of your vagina slowly, turning it as you do so. The flushed fluid will then flow back into the screener. Sometimes the white button does not return immediately to its initial position when taking the Screener out.



- 12 Hold the top of the Delphi Screener halfway into the test-tube. Keep the tube and Screener in upright position. Press the button of the Screener fully down. The sample will be released into the tube. The sample is cloudy and may contain mucus; this is normal. Only a small amount of sample fluid in the tube is needed for the test.



- 13 Take the Screener out of the tube. Place the cap on the tube and make sure it is tightly closed by firmly screwing it on the tube.



What to do after taking a sample?

14 The Screener can only be used once.
Throw the Screener away in the garbage.

15 Wash your hands again.

16 Put the test-tube in the plastic bag with towel. Close the bag with the seal strip.

17 Return the bag with test-tube together with the completed questionnaire into the box and close the box. Please check that you remembered to sign the informed consent on the last page of the questionnaire.

18 Put the box in the return envelope. The envelope is pre-address and pre-paid, you can mail it without a stamp. Return within 24 hrs.

RETURN YOUR SAMPLE WITHIN 24HRS AFTER COLLECTION TO GUARANTEE THE QUALITY OF THE SAMPLE!

General information

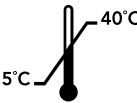
You cannot use the Screener after its best before date. This is indicated on the pouch. (⌚...-....).

If the pouch is damaged or opened, the sterility of the Screener cannot be guaranteed and a new one must be used.

Please visit www.delphiscreener.com for an animation video on the use of the Screener, or for additional information on the Delphi Screener.



STERILE R



Delphi Bioscience B.V.
Glashorst 126
3925 BV Scherpenzeel
The Netherlands



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Disclaimer
Delphi Bioscience cannot accept responsibility in any way for careless or incorrect use of the medical device. If, despite these instructions, there are any questions or doubts about the use of the device, please contact the local helpdesk.

User Instructions Delphi Screener

