

Step 5

- Within two days of taking the sample, place the sample in the plastic bag with the absorbant material (do not remove) and use the pre-addressed mailing container to return the sealed sample container to the lab. Package should be mailed priority 2-day.
- Put your name and Customer ID number on the vile and fill out the Patient Information form and complete the Customer Feedback Survey on the top of the ID Card, tear off the bottom of the ID Card and keep it for your records and return both items with the collected sample. The purpose of the Customer ID number is to link the following: Sale of the kit for TGA purposes; duty of care from patient to the laboratory; Customer Feedback form; Patient Information form; results to the patient from your doctor.
- Dispose of all remaining kit components.

IMPORTANT: Your results are reported directly back to your medical practitioner or healthcare professional. Please identify your doctor's name (or if you wish to use a GP2U doctor) on the Patient Information form. **If you have any questions and or concerns, please call 1800 633 797.** Our web address is www.solopap.com.au.

Thank you for choosing SoloPap.

Dispose of all remaining kit components properly.



Single-use Only

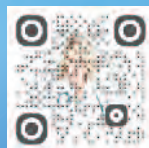


Manufactured by:

R & G Medical and Development Corporation
5101 Deer Run Drive • Ft. Pierce, FL 34951

Distributed by:

Medical Systems International Pty Ltd Australia
24 Alexander Street, COLLAROY, NSW 2097
1800 MEDSYS (1800 633 797)



US Patents

(#5,787,891 - #6,302,853 - #7,087,028) & Patent Pending
AU Patent (2001247207)

SoloPap™

Early detection is the solution

Cervical Cell Collection System Instruction Booklet

NOTE: If you have a major medical concern or emergency of any kind, consult with your healthcare professional before using this product.

Do not use this product if you are pregnant or suspect you may be pregnant.

SoloPap Use and Application Guide

IMPORTANT: Read all instructions first. Fill out the patient form and the Customer ID Card and return them with the sample in the pre-addressed mailing container. Dispose of all remaining kit components after use.

Use of vaginal products

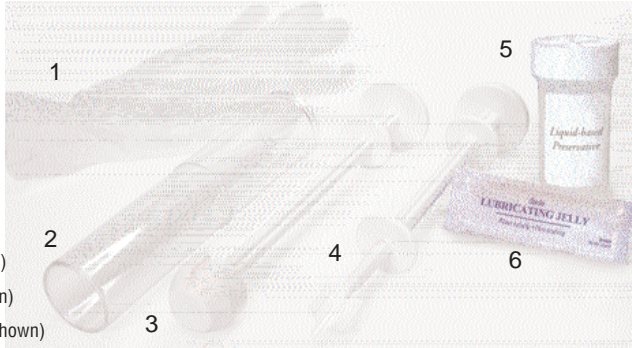
The most common cause of false negative Pap smears is sample failure, which means that no abnormal cells are present in the slide or sample given. To minimise the chance of sample failure, avoid intercourse or the use of douches, vaginal medicines, spermicidal foams, creams or jellies for two days prior to performing the Pap test. These products may wash away or obscure abnormal cells.

Timing of Pap test

The best time to have a Pap test is between 10 and 20 days after the first day of your menstrual cycle. You can take the test at any time if you are menopausal.

The SoloPap Test Kit consists of the following components:

1. Disposable gloves
2. Tube speculum
3. Introducer
4. Brush sampling unit
5. Sample container
6. Lubricant
7. Plastic bag (not shown)
8. Mailing container (not shown)
9. Customer ID Card (not shown)
10. Patient consent form (not shown)



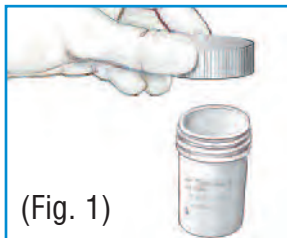
IMPORTANT - Before proceeding, find a private, comfortable place where you can undress, lay down and still have access to the kit materials. You will need about 5 minutes to complete the sample collection steps. Wash your hands with warm water and soap and dry them before proceeding. Gloves are provided for your protection. It is optional but not required.

OBTAINING THE PAP SMEAR

Step 1

- Put on the gloves
- Make sure the brush is fully seated to the brush holder.
- Remove sample container lid (Fig. 1).
- Slightly cover the rounded sides of the introducer (try avoiding the tip) with a thin layer of lubricant. (Fig. 2) Lubricant may also be placed at the opening of the vagina for added ease of insertion.

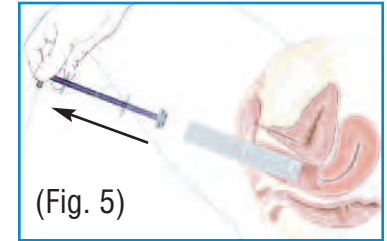
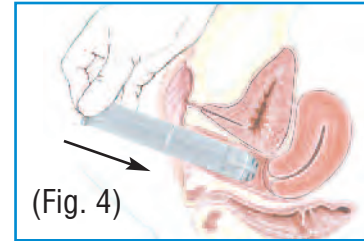
NOTE: Your kit comes with the tube and introducer preassembled and ready for **Step 1**.



Step 2

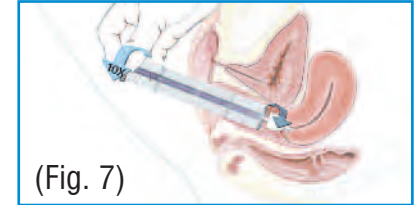
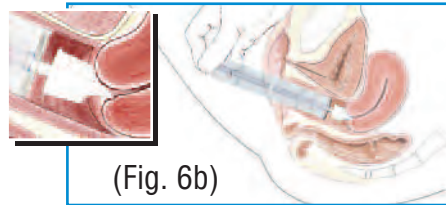
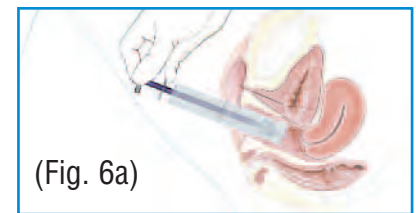
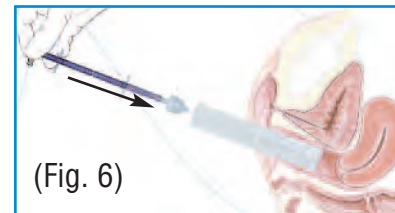
- Lie on your back with your knees bent and spread.
- With your thumb and index finger, gently and slowly insert the tube speculum into your vagina.

- **Insert to about half the tube's length.** (As the device enters the upper portion of the vagina, it will be easier to move. **Insert until the center ridge on the tube speculum is at the vaginal entrance.** This will let you know that it is in the proper position.) (Fig. 4)
- Leave the tube speculum in place and remove the introducer. (Fig. 5)



Step 3

- Insert the brush handle assembly into the tube speculum. Be careful not to disturb the position of the tube speculum as you do this. The brush sampling unit does need to be inserted all the way, or only until you feel resistance. (Fig. 6)
- Rotate the brush clockwise 5 turns, using the wheel end. You may feel some cramping; this is normal. (Fig. 7)



Step 4

- Remove the brush handle assembly, then the tube speculum. The brush may be slightly bloody. This is normal and nothing to worry about.
- Use your thumb and forefinger to pop/push off the brush into the sample container (Fig. 8), and replace the cap onto the sample container tight and securely.
- **Shake lightly.** (Fig. 9)

