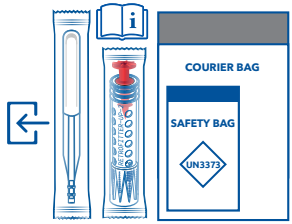
V-Veil UP2™

KIT 4.3

V-Veil UP2™ & UP2 Retrofitter™ tube

Please read and keep this leaflet



WHAT IS AND WHEN CAN THE V-Veil UP2™ KIT 4.3 BE USED?

V-Veil UP2™ KIT 4.3 is a self-sampling procedure pack used to collect secretions, various fluids and substances, which are in the vaginal cavity and cervix for the diagnosis by laboratory tests.

ATTENTION! This KIT can be used during bleeding, pregnancy or following toxic shock syndrome only on the recommendation of a medical professional.

CONTENT:
- 1 **V-Veil UP2™** Vaginal Collector Veil, which is a UVC disinfected, non-sterile, Class I medical device
- 1 Instructions for use
- 1 UP2 Retrofitter Tube
- 1 safety bag UN3373
- 1 courier bag

A stopwatch is required and is not included in the kit.

RECOMMENDATIONS AND ADVICE:
- Wash your hands before using this KIT.
- Do not use if you have had sexual activity in the last 2 days.
- Do not use if you have washed the vaginal cavity more recently than 48 hours.
- Other intravaginal treatments (ovules, gels, creams, contraceptives, disinfectants, lubricants) or other intravaginal procedures (swab, intravaginal tampons, intravaginal wipes, vaginal examination) should be avoided 48 hours prior to self-sampling.
- If you are pregnant or have blood in the vaginal cavity, use this medical device only on the advice of your doctor.
- The veil should not remain in the vagina for more than 30 minutes, but if you forget to remove it, remove it as soon as you remember.
- Use only one veil at a time.
- The veil should not be reused, even when not impregnated.
- For more recommendations, talk to your doctor, gynaecologist or pharmacist.

WHO IS PROHIBITED FROM USING THIS PRODUCT?

Women who:
- have a fever or flu-like symptoms, even mild ones.
- have already suffered a toxic shock syndrome and do not have the recommendation from a medical specialist for taking the test.
- are allergic to plastics and their derivatives.
- are under 18 years of age, without parental and/or medical consent.
- deliberately did not read the instruction sheet.
- have bleeding and do not have a recommendation from a medical specialist for taking the test.
- are pregnant and do not have a recommendation from a medical specialist for taking the test.

IMPORTANT INFORMATION ON TOXIC SHOCK SYNDROME: Toxic Shock Syndrome (TSS) is a rare infection that can affect children, men and women (whether they are menstruating or not). It is caused by a toxin produced by a bacterium (staphylococcus) that commonly exists in the body. Half of the cases of TSS recorded to date have occurred in adolescents and women during menstruation. The syndrome has been associated with the use of tampons, but it can also occur when other means of protection are used (pads, liners...). TSS is a potentially fatal infection and for this reason must be detected very early and treated immediately. Symptoms of TSS may appear suddenly, during menstruation, or shortly afterwards. They may not all be present and may not occur at the same time: sudden fever (>39C), vomiting, diarrhoea, sore throat, dizziness, fainting, muscle aches, sunburn-like rash (skin may peel a few days later). If you experience these symptoms, you should immediately remove the veil and consult your personal physician or nearest doctor. TSS can occur with or without the use of V-Veil UP2™ . If you have already developed a TSS, talk to your doctor before using V-Veil UP2™ . By using V-Veil UP2™ correctly and following the recommendations, you will reduce the risk of developing toxic shock syndrome.

STORAGE:

Store in a clean, dry place away from heat sources.

INCIDENT REPORTING

ATTENTION! Only the instructions for use may be used as a reference for legal information, indications and restrictions. Do not use the product if the packaging is damaged and if the expiry date has passed. If, despite the measures we take in the manufacturing process, you believe you have received a defective product, please do not use it and contact the manufacturer or distributor, clearly indicating the problem and the lot number specified on the packaging. Incidents related to the device can be reported to the manufacturer at client@vvup.org and to the competent authority of the Member State where you are located. The **V-Veil UP2™** KIT is produced in accordance with the applicable provisions and requirements of the European Union.

MD	Medical Device
CE	European Conformity
NON STERILE	Non sterile
	Do not use if package is damaged
	Keep dry
	Keep away from direct sunlight
	Do not reuse
	Attention
	Read the notice
IVD	In-Vitro Diagnostic
	Throw out the garbage into a trash can
	Do not throw in the toilet

FR RO DE ES IT PT AR BG HR CS DA NL ET FI HU GA LV LT MT PL SK SL SV EL TR

Authorized distributor: see packaging information.

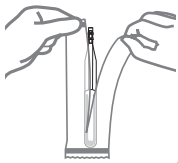
Patents pending - Vaginal Veil Collector **V-Veil UP2™**

V-VEIL-UP PRODUCTION SRL
Ciocanesti 280B Calinesti
117197 Arges ROMANIA
client@vvup.org
TEL : 0040 348 420 620

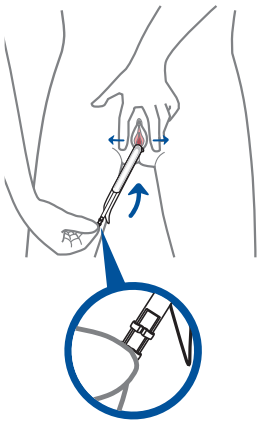
INSTRUCTIONS FOR USE STEP 1

1 Wash your hands and wipe them with a clean towel.

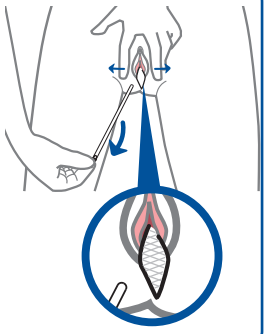
2 Open the box and remove the **V-Veil UP2™** from its packaging, by opening it at the dedicated side. Keep the box and dispose of the opened packaging with your normal household waste.



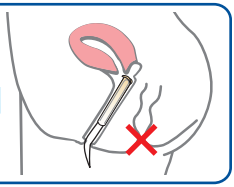
3 Grasp the applicator by the end (in the grip area) with your fingers. Relax and choose the position that feels most comfortable to you: sitting with your legs apart, standing with one leg up or standing with your legs slightly bent.
Remove the outer labia and bring the upper part of the **V-Veil UP2™** close to the vagina. Gently insert the veil with the applicator.
Continue to gently push the veil with the applicator until the clamping area remains outside the vagina. The V-shaped end should hang loosely outside the vagina.

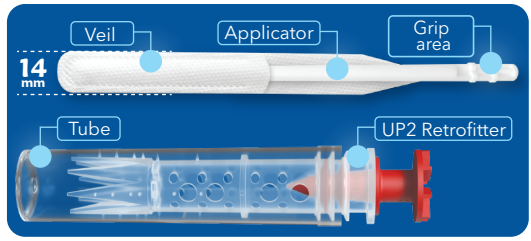


4 To remove the applicator, gently pull it out, making sure not to pull the veil. Dispose of the applicator with normal household waste.
ATTENTION! Depending on the size of your vagina and how you inserted the intravaginal veil, it is mandatory that the V-shaped end remains visible so that it can be removed after use.



5 Wait with the veil inserted into the vaginal cavity for 2 minutes.

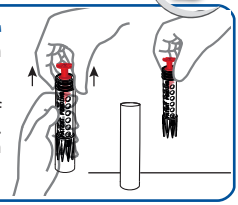




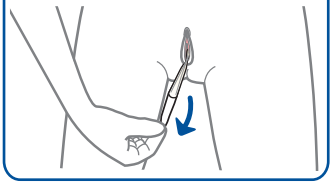
INSTRUCTIONS FOR USE STEP 2

6 To remove **V-Veil UP2™** wash your hands and wipe them with a clean towel.

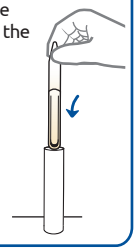
Open the **UP2 Retrofitter™** of the tube and hold it in your hand. Place the tube on a flat, clean surface.



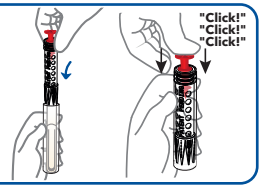
7 Relax and choose the position you find most comfortable from those presented above. The veil can be easily removed, by pulling on the V-shaped end.



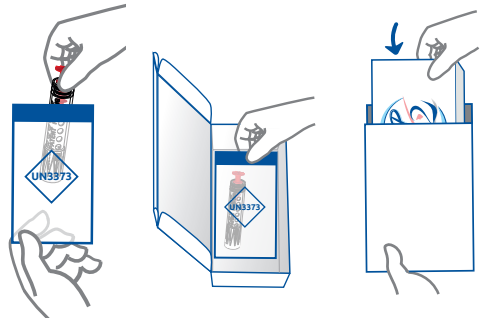
8 Place the sample inside the tube.



9 Press to close the **UP2 Retrofitter™** cap until you hear a "click" 3 times, keeping the sample between the walls of the Retrofitter and the tube.



10 Place the container with the collected sample in the safety bag. Seal the bag and place it in the KIT box. Place the KIT box in the courier bag.
Hand the package to the courier as soon as possible (max. 48h).



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