

Machinery device 42 Medical scraper
General medical device Medical scraper for gynecology (JMDN code 70955000)

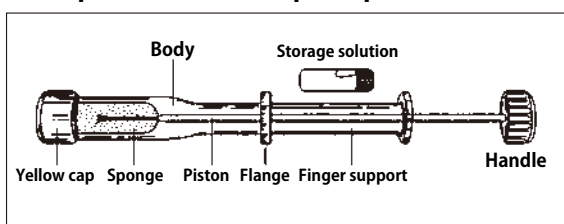
One time use

Kato-type self-scraping device

[Contraindications and prohibitions]

One time use

[Shape, structure and principles, etc.]



1) Composition

Sponge: Formed Polyester urethane

Piston/Cap: Styrene Elastomer

Body/Handle: Denka ABS GR500

Storage solution: 50% ethanol

2) Body dimensions (where it enters the vagina)

Length: 75mm Diameter: 14mm

The tip is capped and inserted into the vagina until the swab reaches the vulva, and the piston is pushed to expose the sponge. Under this condition, the piston is wrapped 5-6 times, and the cells are scraped at the sponge site.

After collection, the piston is pulled as before, removed from the vagina, and the preservative solution is poured, and the cap is attached.

[Intended use, indications]

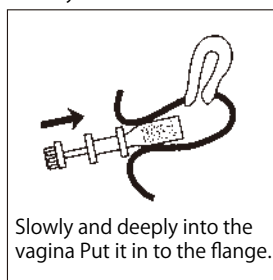
An instrument used to remove mucosal cell tissue from the uterus for cytologic diagnosis. This instrument was designed to facilitate the early detection and treatment of cervical cancer by making it easier for women to undergo cancer testing at home.

[Item specifications]

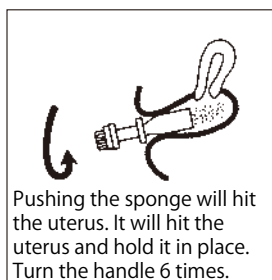
Sterilization assurance level (SAL): 10^{-6}

[Methods of operation or use, etc.]

Carefully read the instruction manual before use.



Slowly and deeply into the vagina Put it in to the flange.



Pushing the sponge will hit the uterus. It will hit the uterus and hold it in place. Turn the handle 6 times.

●The cap of the main body is removed and slowly placed deep into the vagina.

●If the handle is pressed, the sponge is brought into the uterus. Five to six rounds of the handle and the sponge is used to collect cells from the cervix.

[PRECAUTIONS]

※If you have a contraceptive device in utero, consult with your doctor.

※Use this medicine after the menstruation is completed because there are individual differences.

※Collect on the day of submission or the day before.

※Clean your hands before use.

※Do not use this device during pregnancy.

※Avoid sexual intercourse and intravaginal irrigation before use.

※Avoid bathing before use.

※Do not use for purposes other than the intended use.

※Handle your equipment carefully. Slowly insert the tube into the vagina and slowly put out.

※Consult with your doctor if you experience any changes in your physical condition after using this medicine.

[Storage and storage methods

and duration of use, etc.]

Storage conditions

Avoid locations where the product is exposed to high temperature and humidity or direct sunlight.

Keep out of the reach of children.

expiration date: 3 years after sterilization

[Packaging]

1 set/bag

[Primary literature and literature claims].

●Shintakiji et al.: in the screening for uterine cancer Investigation of Kato-type self-scraping device The World of Obstetrics and Gynecology, Volume 29 No. 8: 947 1977.

◆Noda, Kato-sai : Consider of the Kato-style self-sampling method in mass screening for cervical cancer 2004 "Reference Request"

TAISEI MEDICAL CO.,LTD.

2-11-6 Fujinosato Ibarakicity Osaka

tel: 072-640-2125

[Name of the MAH and the manufacturer

Name and address, etc.]

Marketing or Manufacturing Business Liceso Holder

TAISEI MEDICAL CO.,LTD.






〒567-0054

2-11-6 Fujinosato Ibarakicity Osaka

tel: 072-648-3601

Be sure to refer to the instruction manual (on the back of this manual).

Please read the instructions for use of the instrument well.

 <p>If you have a contraceptive device in utero, consult with your doctor.</p>	 <p>Clean your hands, and after the end of the physiological life.</p>	 <p>In pregnant women Without use Please.</p>	 <p>Sexual intercourse before use, Or vaginal lavage Please avoid it.</p>	 <p>Before use In the bath Please avoid it.</p>
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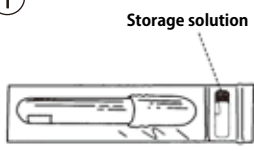
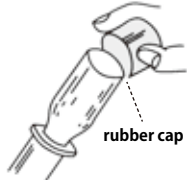

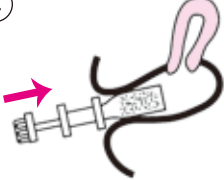
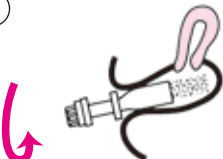
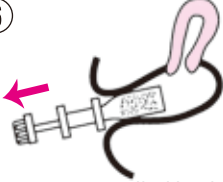

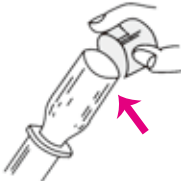
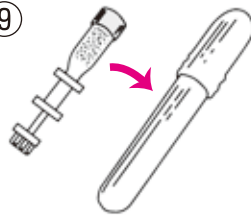

How to use instruments

※ After reading this package insert, collect cervical cells correctly in the order shown below.

If there are any abnormalities in the equipment, packaging, etc., contact us without discarding them.



Remove the yellow rubber cap before use.

<p>①</p>  <p>Remove the equipment and the preservation solution from the case.</p>	<p>②</p>  <p>Strictly remove the yellow cap.</p>	<p>③</p>  <p>In a squatting position, as in Fig...</p>	<p>④</p>  <p>Slowly put into the vagina deep into it.</p>
<p>⑤</p>  <p>Push the sponge into the uterus, so rotate the handle 6 times as needed.</p>	<p>⑥</p>  <p>The piston is pulled back to its original position and the instrument is removed from the vagina.</p>	<p>⑦</p>  <p>Pour all of the reserve liquid into the sponge part of the tip.</p>	<p>⑧</p>  <p>Wipe around this area and firmly apply the cap to the original state.</p>
<p>⑨</p>  <p>The instruments are placed in the original case.</p>	<p>⑩</p>  <p>The instrument used (specimen) should be mailed or submitted to a defined location.</p>	<p>※ Rarely, some bleeding is seen, but there is no concern. For inquiries about product, please receive the device or the following.</p> <p>Contact information</p> <p>TAISEI MEDICAL CO.,LTD. tel.: 072-640-2125 Time: 9-16 o'clock (excluding holidays and public holidays)</p>	

Manufacturer and distributor

TAISEI MEDICAL CO.,LTD.

〒567-0054 2-11-6 Fujinosato, Ibaraki City, Osaka Pref.