

# Speculite®

## VAGINAL ILLUMINATION FOR PAPSURE®

### PACKAGE INSERT

Revised: August 2010

### Rx only

2-1501012401

**DEVICE DESCRIPTION:** Speculite is a chemiluminescent illumination source that is attached to the upper dilator blade of a vaginal speculum to be used during screening gynecologic examination as a procedure known as speculoscopy.

Speculoscopy is intended to be an adjunctive procedure to routine pelvic examination and Pap smear in the diagnosis of cervical and vaginal abnormalities. The procedure consists of visualization of acetowhite areas using low power (4-6x) magnification.

#### INDICATIONS FOR USE:

- Speculoscopy is indicated for use in those women who are currently recommended for cervical screening with pelvic examination and Pap smear.
- Speculoscopy is only to be used as an adjunct to the Pap smear, and only the combination of the two tests affords the clinician improved sensitivity in identifying women with mucosal abnormalities visualized on colposcopy.
- The combined results of the Pap smear with speculoscopy in the screening examination, designated PapSure, can allow for the identification of more women who are appropriate referrals for colposcopy or close follow up than Pap smear alone.

#### PERFORMANCE CHARACTERISTICS:

- PapSure significantly increases the sensitivity (from 40% to 90%) of detection, as determined by cervical punch biopsy, of Squamous Intraepithelial Lesions low grade and above (LGSIL+) as compared with Pap smear alone. Most of this increase is related to improved detection of LGSIL lesions.
- PapSure significantly decreases the specificity (from 95% to 80%) in identifying women without disease as compared with Pap smear alone.
- A negative PapSure more accurately predicts the absence of cervical pathology than Pap smear alone (increased negative predictive value from 94% to 99%)\*.
- A positive PapSure less accurately predicts the presence of cervical pathology than Pap smear alone (decreased positive predictive value from 44% to 28%)\*.
- \* These predictive results are from a study of approximately 3,300 screening patients (see *Clinical Studies*) in which the prevalence of disease in the population was 8.2%.
- Based on data from prospective clinical trials (in approximately 3,300 women) in which all women undergo colposcopy (see *Clinical Studies*), one could expect - in a standard screening population of 1,000 women - that 180 additional women would have an acetowhite lesion seen on colposcopy when a positive PapSure was compared with a positive Pap smear alone (83 for Pap positive and 262 for PapSure positive). If all 180 women were biopsied, one could expect to find approximately 40 additional LGSIL+ lesions, 39 of which would be LGSIL and one of which would be HGSIL.
- PapSure is reliably performed both by physicians and by nurse practitioners.

#### CONTRAINDICATIONS:

Speculoscopy should NEVER be used without Pap smear.

#### WARNINGS / PRECAUTIONS:

- Speculoscopy is only to be used as an adjunct to Pap smear and only the combination of the two test results in improved sensitivity in identifying women with cervical abnormalities.
- Speculoscopy is not intended to grade acetowhite lesions or direct biopsies.
- Women with abnormal Pap smear, even in the presence of a negative speculoscopy, should be referred for additional evaluation.

#### ADVERSE EVENTS:

None known

#### CLINICAL STUDIES:

**Study 1. Comparison of the Papanicolaou Smear and Speculoscopy Compared With the Papanicolaou Smear Alone in Screening for Cervical Precancer.**

#### Results of a Prospective Multi-Center Clinical Trial.

**Conclusions:** PapSure detected significantly more disease than the Pap smear used alone (92.2% versus 40.7%), however, the increase in sensitivity was accompanied by a decrease in specificity from 94.7% to 79.6%. The prevalence of disease was 8.2%. This study also demonstrated that a negative PapSure can more reliably predict the absence of disease than the Pap smear, however, a positive speculoscopy does not indicate the presence of disease as reliably as the Pap smear.

Clinical trial protocol required that all women in this study have colposcopy and biopsy. Since PapSure can more accurately identify women appropriate for referral to colposcopy or for closer follow up than the Pap smear alone, the clinical decision to immediately colposcope or closely follow women with a normal Pap smear and a positive speculoscopy is a clinical decision that should be made based on that woman's clinical history including risk factors for cervical cancer and reliability for follow up.

**Investigators:** Physicians at 34 Italian gynecologic centers.

**Purpose:** The purpose of the study was to prospectively examine screening patients to evaluate the effectiveness of adding speculoscopy to the routine Pap smear in the identification of cervical pathology (LGSIL+).

**Design:** All screening patients presenting at any of the study sites were prospectively evaluated. No selection of patients took place.

**Description of Patients:** 3,309 screening patients (mean age 33 years) with no history of cervical abnormality enrolled. For 30% of these patients, this was their first screening exam.

**Methods:** The participants all underwent a Pap smear, speculoscopy, and colposcopy examination. When a colposcopic abnormality was observed, a targeted biopsy was performed for histologic evaluation. In each center the accuracy of the screening tests was evaluated independently by a cytopathologist (Pap smear), by a colposcopist, and by a non colposcopist (speculoscopy). In women undergoing biopsy, the results of the screening tests evaluated were compared against histologic results as a gold standard.

**Results: Table 1. Statistical results of the Pap smear versus PapSure in the detection of LGSIL+ (on biopsy) (N=3309).**

|                           | Pap smear alone | PapSure |
|---------------------------|-----------------|---------|
| Sensitivity               | 40.7%           | 92.2%   |
| Specificity               | 94.7%           | 79.6%   |
| Positive predictive value | 44.3%           | 28.7%   |
| Negative predictive value | 94.8%           | 99.1%   |

**Sensitivity** =  $\frac{\# \text{ patients with (+) test and (LGSIL+)*}}{\text{total \# patients with (LGSIL+)*}}$

**Specificity** =  $\frac{\# \text{ patients with (-) test and no (LGSIL+)*}}{\text{total \# patients with no (LGSIL+)*}}$

**Pos. pred. value** =  $\frac{\# \text{ patients with (+) test and (LGSIL+)*}}{\text{total \# patients with (+) test}}$

**Neg. pred. value** =  $\frac{\# \text{ patients with (-) test and no (LGSIL+)*}}{\text{total \# patients with (-) test}}$

\*LGSIL or worse on biopsy

#### Study 2. Cervical Screening with Papanicolaou Smear Plus Speculoscopy by Nurse Practitioners in a Health Maintenance Organization.

**Conclusions:** PapSure found more than twice as many LGSIL+ (79% LGSIL, 21% HGSIL) as the Pap smear alone. Since all women did not have colposcopy and biopsy (per the protocol), the true prevalence of disease in the population cannot accurately be known, but it is at least 6.2% (43/689). The positive and negative predictive values cannot be accurately calculated since all women did not have all tests. PapSure is reliably performed by Nurse Practitioners.

**Investigators:** Nurse Practitioners staffing screening clinics in a Health Maintenance Organization.

**Purpose:** To evaluate the utility of speculoscopy as an adjunct to the Pap smear in the detection of cervical pathology (LGSIL+) by Nurse Practitioners in a Health Maintenance Organization.

**Design:** A prospective study of patients presenting for routine screening. No selection took place.

**Description of patients:** 689 patients (mean age 33.7 years), with no prior history of cervical abnormality were enrolled. For less than 5% of the patients, this was their first screening exam.

**Methods:** Patients who presented for routine screening received a Pap smear and speculoscopy examination by a nurse practitioner. If the Pap smear or the speculoscopy result was positive, colposcopy was performed and biopsies were obtained from women with positive colposcopies. In women undergoing biopsy, the results of the screening tests evaluated were compared against histologic results as a gold standard.

**Results: Table 2. Number of Cases Detected by Pap Smear and PapSure® Screening Tests.**

|                      | # of Cases detected by Pap smear | # of Cases detected by PapSure |
|----------------------|----------------------------------|--------------------------------|
| Total Cases detected | 10                               | 43                             |
| # of Cases of LGSIL  | 4                                | 34                             |
| # of Cases of HGSIL  | 6                                | 9                              |

**INSTRUCTIONS FOR USE:**

**NOTE:** WHILE THE WOMAN IS IN THE LITHOTOMY POSITION FOR A PELVIC EXAMINATION, PREPARE THE SPECULITE®.

**NOTE:** OPTIMALLY, A PAP SMEAR SHOULD BE TAKEN BETWEEN THE 12TH AND 16TH DAY OF THE WOMAN'S MENSTRUAL CYCLE. PRIOR TO THE PAP SMEAR EXAMINATION, WOMEN SHOULD BE INSTRUCTED NOT TO DOUCHE, OR USE VAGINAL MEDICATIONS, LUBRICANTS, OR CONTRACEPTIVE PRODUCTS, SUCH AS SPERMICIDE, FOR 2 TO 3 DAYS PRIOR TO THE PAP SMEAR TEST. SEXUAL INTERCOURSE SHOULD BE AVOIDED FOR 1 TO 2 DAYS PRIOR TO THE PAP SMEAR TEST.<sup>1,2</sup>

PERIODIC CYTOLOGIC SCREENING FOR VAGINAL NEOPLASIA AFTER REMOVAL OF THE CERVIX FOR BENIGN DISEASE IS WARRANTED, BASED ON RISK FACTORS.<sup>3</sup>

**ACTIVATE AND ATTACH SPECULITE USING THE FOLLOWING INSTRUCTIONS:**

1. Remove Speculite from foil packet.
2. Firmly bend Speculite capsule until you feel a "snap."
3. Vigorously shake capsule.
4. Peel one side of the two-sided adhesive strip (supplied) and apply to illuminated Speculite.
5. Remove remaining strip from adhesive strip.
6. Attach Speculite with adhesive strip to inside upper dilator blade of speculum (metal or plastic).

**NOTE:** THE BRIGHTEST ILLUMINATION PRODUCED BY SPECULITE IS DURING THE FIRST FEW MINUTES AFTER CAPSULE ACTIVATION. IF SPECULOSCOPY EXAMINATION IS NOT COMPLETED WITHIN FIFTEEN MINUTES, FOR OPTIMAL VIEWING, THE SPECULITE CAPSULE SHOULD BE REPLACED.

**PERFORM EXAM USING THE FOLLOWING INSTRUCTIONS:**

1. With the woman in lithotomy position, insert the speculum with Speculite; a water-based lubricant may be used. If speculum is removed after Pap smear is taken, speculum may be reinserted with a lubricant.
2. Visually examine the vaginal and cervical mucosa with normal illumination to check for lesions and/or discharge prior to taking the Pap smear or performing speculscopy.
3. Perform routine Pap smear screening examination with any approved Pap smear tray/kit supplies. Pap smear kit components may vary. Please refer to the specific instructions in your selected Pap smear kit for directions on the use of the selected Pap Smear components in your kit. The use of a brush to obtain endocervical sample may result in slight bleeding. Any blood will be washed away when the cervix is washed with acetic acid and will not alter the results of the speculscopy examination.
- 3.a) If indicated, obtain cervical cultures prior to acetic acid (vinegar) washing of the cervix and vaginal walls.
4. Liberally wash the vagina and cervix with 5% acetic acid (common table vinegar) using a large cotton swab or 4 x 4 gauze squares held with ring forceps.
5. Dim room lights.

**NOTE:** FAILURE TO DIM THE ROOM LIGHTS MAY COMPROMISE YOUR ABILITY TO OBSERVE ACETOWHITE AREAS.

**PERFORM THE SPECULOSCOPY EXAMINATION USING THE FOLLOWING INSTRUCTIONS:**

1. With any approved low power (4-6x) optical magnification source perform the visual speculscopy examination. These optics can include 4-6x magnification, handheld monocular, glasses mounted monocular and binocular loupes of 4-6x magnification. Refer to manufacturer's instructions for use.

**NOTE:**

WAIT AT LEAST SIXTY (60) SECONDS AFTER ACETIC ACID WASH BEFORE VISUAL EVALUATION.

2. Inspect for the presence of acetowhite areas. Look for bright whitening and sharp, defined borders.

**NOTE:**

- You may reapply the 5% acetic acid to the cervix to help distinguish acetowhite lesions from mucous.
- On occasion, light from the Speculite may reflect from the cervix. To distinguish between a reflection and an acetowhite area, move the speculum slightly. White areas that appear to move may be a reflection from the Speculite.

- Alternatively, a small cotton swab can be used to press gently on a potential acetowhite lesion. Changing the contour of the cervix in this way may help differentiate light reflections from a true acetowhite lesion.

3. Resume normal room lighting.
4. Remove the speculum from patient.
5. Remove adhesive strip and Speculite from speculum (necessary only for metal speculum).
6. Discard Speculite and adhesive strip per institutional procedures.
7. Document/record speculscopy findings on the speculscopy data form or in patient chart.
8. Complete the pelvic examination.

NOTE: Speculite and PapSure are registered trademarks of Watson Diagnostics, Inc., Corona, CA 92880.

**References:**

1. American College of Obstetricians and Gynecologists Patient Education Pamphlet AAP085 ("The Pap Test")
2. Berlex Laboratories, 1991, Patient Education Series #4 #92-430-0530 ("Exploring the Pap smear")
3. American College of Obstetricians and Gynecologists Committee Opinion, Number 152 - March 1995 ("Recommendations on Frequency of Pap Test Screening")

**Rx only**

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**WARRANTY AND LIMITATIONS OF LIABILITY**

Watson Diagnostics, Inc. ("Watson") warrants that the Speculite ("the Product"), when delivered, will conform to the manufacturer's then current version of the published specifications for such Product in all material respects and shall be free from defects in material or workmanship for a period equal to the Product's expiration date. The exclusive remedy for any breach of this Warranty shall be the replacement of the non-conforming Product, which is returned to Watson. For Product returned which is not under warranty, Watson's standard replacement charges then in effect shall apply. This Warranty does not apply to normal wear and tear, or to defects, malfunctions or failures that result from the abuse, neglect, improper handling or maintenance, alteration, modification, accident or misuse of the Product. THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. WATSON SHALL NOT BE RESPONSIBLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES SUFFERED BY ANY PARTY, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. The Warranty set forth above may not be extended, enlarged or otherwise modified by any Watson agent or employee, and Watson does not assume any liability or make any Warranty except as stated above.