MANUAL FOR THE STANDARDIZATION OF COLPOSCOPY FOR THE EVALUATION OF VAGINAL PRODUCTS

C O N R A D

WORLD HEALTH ORGANIZATION

STEPS TO BE CARRIED OUT WHEN PERFORMING COLPOSCOPY

Prior to the examination: Everything needed for the procedure should be in place before the study participant is brought into the room. This includes working equipment, spare bulbs, and adequate specula that have been inspected to make sure there are no rough edges that could induce epithelial injury. A Standard Operating Procedure written by each site helps ensure that these steps are taken.

1. PARTICIPANT POSITIONING:
The participant should lie on a soft examination table in the lithotomy position with leg supports so that the perineum and vulva can be inspected. At all times, the physical and emotional comfort and privacy of the woman should be ensured.

2. NAKED EYE AND COLPOSCOPIC EXAMINATIONS OF EXTERNAL GENITALIA:
Examine the external genitalia with the naked eye and record findings. Then, using appropriate magnification (usually 4-10X), examine the external genitalia again and record findings.

3. INSERTION OF SPECULUM:
Use a speculum with sufficiently long blades to permit adequate visualization of the vagina and cervix. If necessary, apply a small amount of the lubricant specified in the protocol to the external surfaces of the blades. Gently insert and open the speculum so as to prevent trauma and position it so that the cervix and upper vagina can be seen clearly.
The position of the cervix relative to the vagina and the least traumatizing type/size of speculum should be recorded on the source document during the first examination for reference at later examinations. This information should be reviewed prior to subsequent examinations to reduce the chance of causing iatrogenic injury.

4. NAKED EYE EXAMINATION OF VISIBLE EPITHELIUM:
Naked eye inspection of visible epithelial surfaces should be performed without manipulation. Record findings.

5. AUXILIARY VAGINAL TESTS:
If a vaginal specimen, such as a wet preparation, pH test, or vaginal microbiological test is collected, the sample should be obtained after the speculum is placed and initial visual examination is made, but prior to lavage. The sample should be taken from the vaginal pool or lateral vaginal wall (or as directed by the protocol) away from any apparent abnormal areas. The area from which the wet preparation is taken should be excluded from the subsequent examination, or findings should be noted as "probably iatrogenic - wet preparation site."

6. LAVAGE:
Using a syringe, gently lavage the cervix and vaginal walls with normal saline to remove mucus and cellular debris. Avoid contact between the tip of the syringe and the epithelium. The lateral fornices may be lavaged without manipulation by directing the stream into them.
Aspirate the fluid with the tip of the syringe against the inner surface of the posterior blade of the speculum. Do not permit contact between the syringe and the epithelium. Dry swabs may be used to remove obscuring fluid from the posterior blade that cannot be removed by aspiration. (Do not use dry swabs in any other manner during the colposcopic exam.)
If the product obscures findings, it should be lavaged away as gently and completely as possible using a medium specified in the protocol. All unobscured epithelial surfaces should be examined. If lavage alone does not adequately remove the study product, a saline-soaked swab may be used. Record any observations not noted on previous naked eye examination.
Some protocols may require collection of lavage fluid for measurement of inflammatory markers. If this is felt to be of higher priority than collection of vaginal specimens, it may be collected first; this should be specified in the protocol.

7. COLPOSCOPIC EXAMINATION OF CERVIX:
Inspect the cervix under appropriate magnification (usually 4-10X) and record findings.

8. AUXILIARY CERVICAL TESTS:
Cervical specimens are generally collected after colposcopic examination of the cervix since their collection is likely to induce minor trauma which may be erroneously attributed to product use.

9. COLPOSCOPIC EXAMINATION OF FORNICES:
Under appropriate magnification (usually 4-10X), examine the anterior, right lateral, left lateral, and posterior fornices and adjacent cervical trunk and record findings. Additional irrigation and/or slight manipulation of the speculum may be necessary to clearly visualize the fornices. The lateral fornices are best exposed by placing a saline-moistened swab in the contralateral fornix and pressing toward the head and laterally. For example, to view the right lateral fornix, place a saline-soaked swab in the left lateral fornix and press gently toward the woman's head and left side. Record findings.

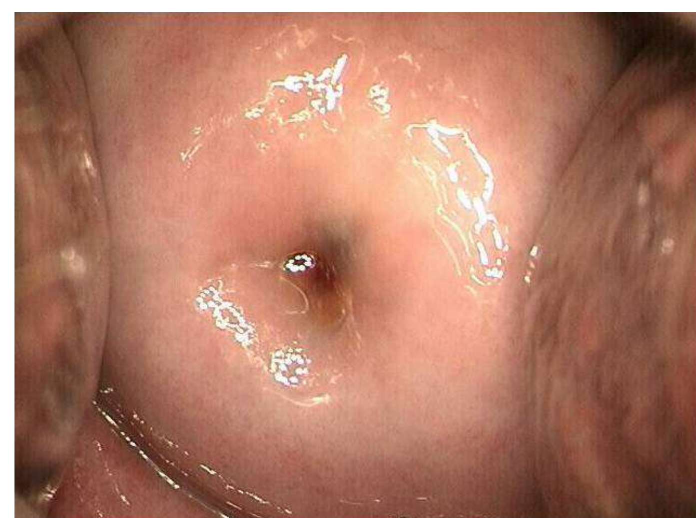
10. COLPOSCOPIC EXAMINATION OF VAGINA:
To examine the rest of the vagina, move the colposcope to bring the lateral vaginal walls into focus. Slowly withdraw the speculum, relaxing the blades as necessary for the comfort of the woman and refocusing as needed, to view the anterior and posterior vaginal walls. Record findings.

TABLE 1. TERMINOLOGY FOR COLPOSCOPIC FINDINGS

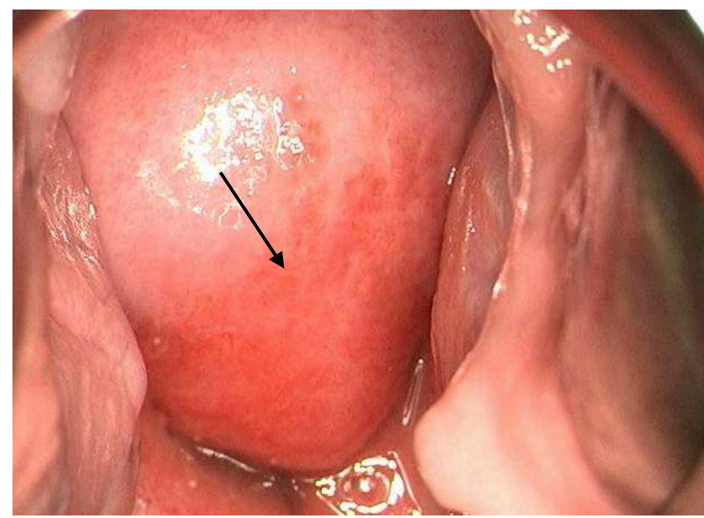
The results of the colposcopic examination should be documented using the terms in Table 1 and by recording the status of the epithelium and blood vessels for each numbered finding.

Term	Status of epithelium*	Status of blood vessels	Comments
Erythema	Intact	Intact	Distinguished by color (erythema being redder than normal, edema either normal or paler than normal, and grossly white findings being white). Grossly white findings are sharply demarcated whereas edema and erythema may be sharp or diffuse.
Edema	Intact	Intact	
Grossly white finding	Intact	Intact	
Petechiae	Intact	Disrupted	≤ 3mm; Color of finding is red or purple.
Ecchymosis	Intact	Disrupted	> 3mm
Peeling	Disrupted, superficial	Intact	Fragment of disrupted epithelium may remain attached to the area from which it has peeled off. Generally has well demarcated outline. Underlying epithelium looks normal.
Ulcer	Disrupted, superficial or deep	Intact or disrupted	May include sloughing at base. Generally round or oval with sharply demarcated outline. Superficial ulcers are more accurately called erosions.
Abrasion	Disrupted, superficial or deep	Intact or disrupted	Distinguished from other findings in this class by diffuse or poorly demarcated outline
Laceration	Disrupted, superficial or deep	Intact or disrupted	Sharply demarcated linear finding. Includes fissures. Lacerations appear to be the result of trauma. Fissures appear to be linear "pulling apart" or wearing away of tissue.

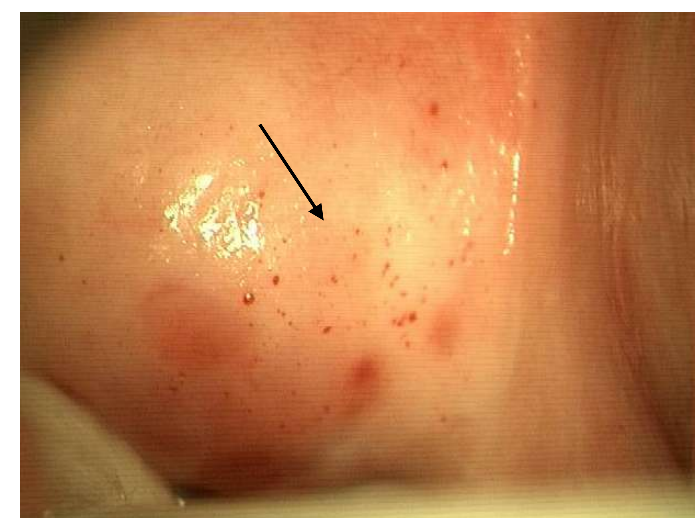
*Superficial epithelial disruption does not penetrate into the subepithelial tissue. Deep epithelial disruption penetrates into and exposes the subepithelial tissue and possibly blood vessels. If bleeding from the finding is present, the disruption should be recorded as deep.



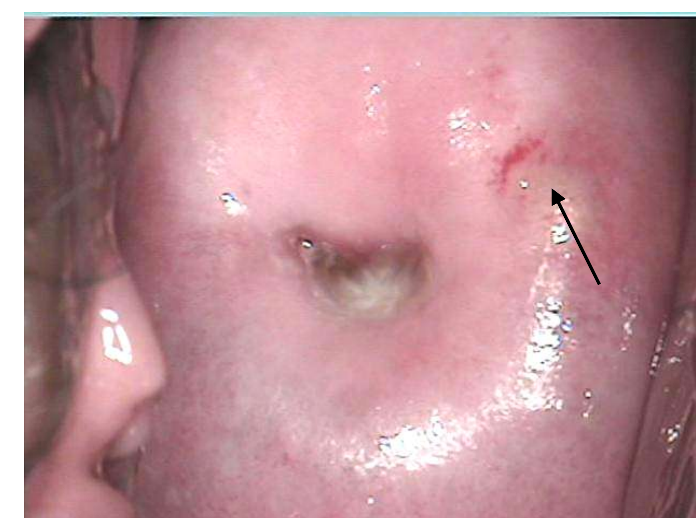
Normal



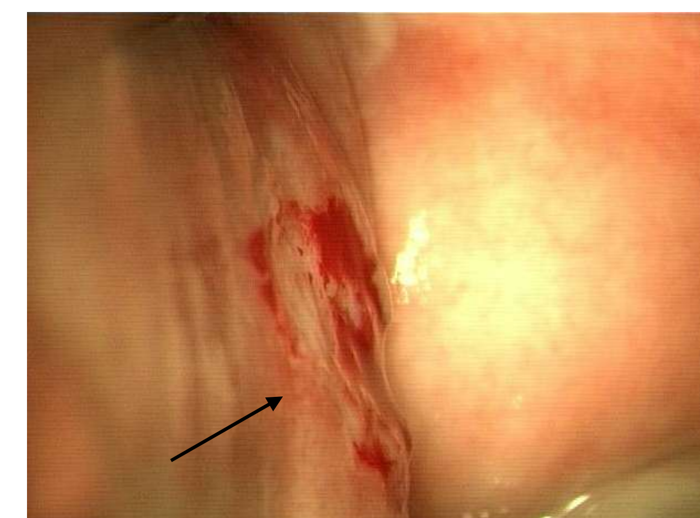
Erythema



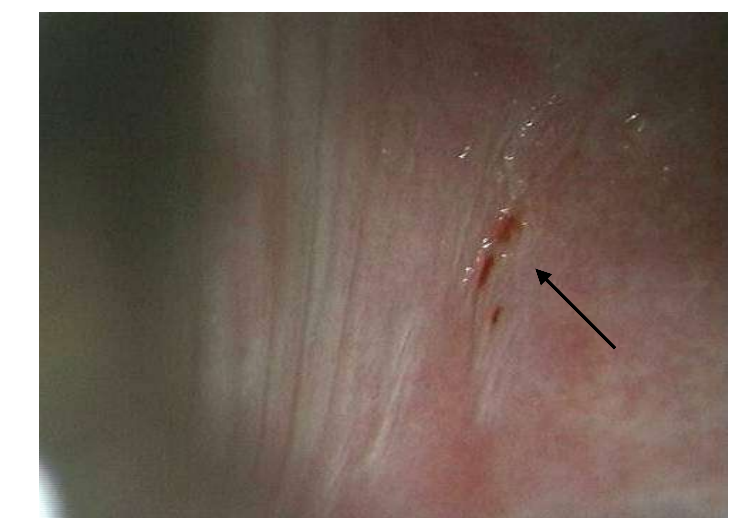
Petechiae



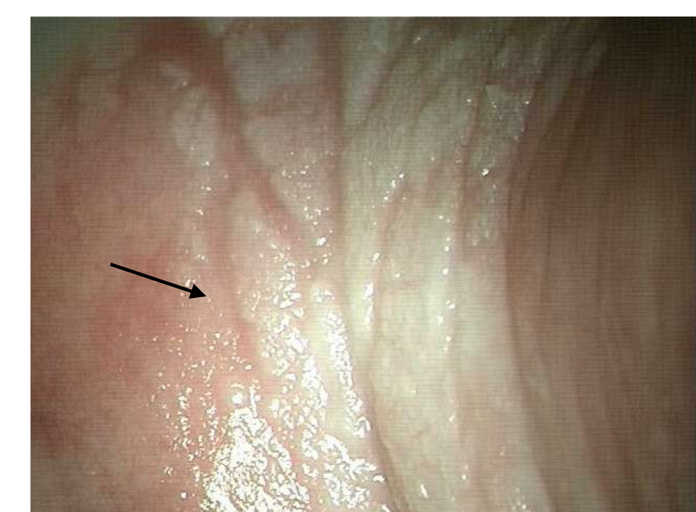
Ecchymosis



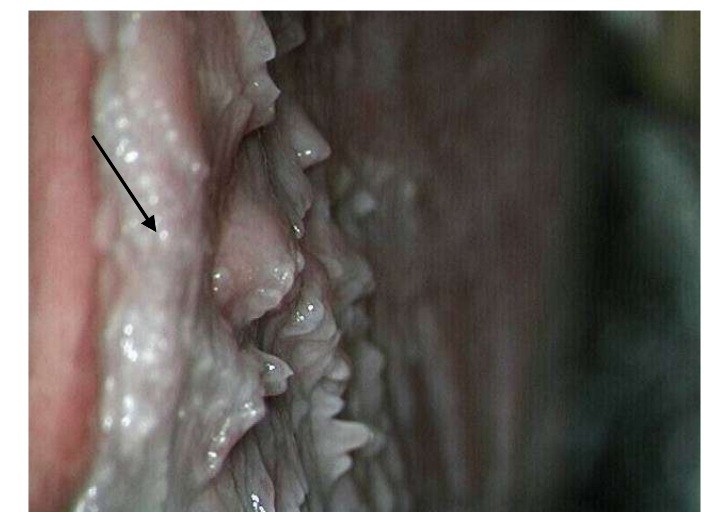
Abrasion



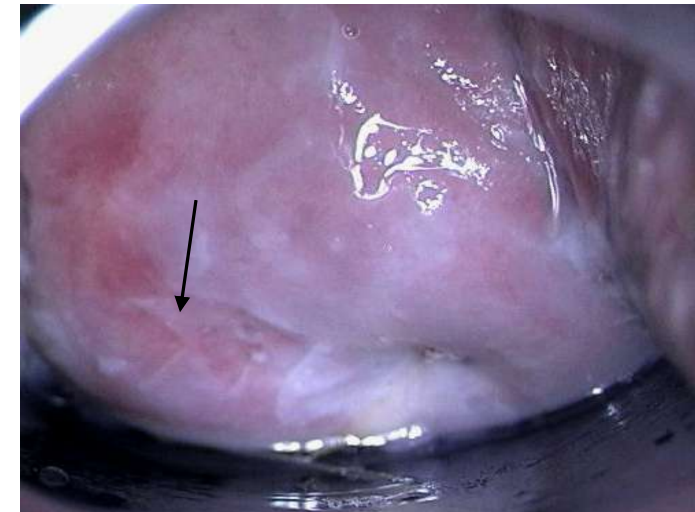
Laceration



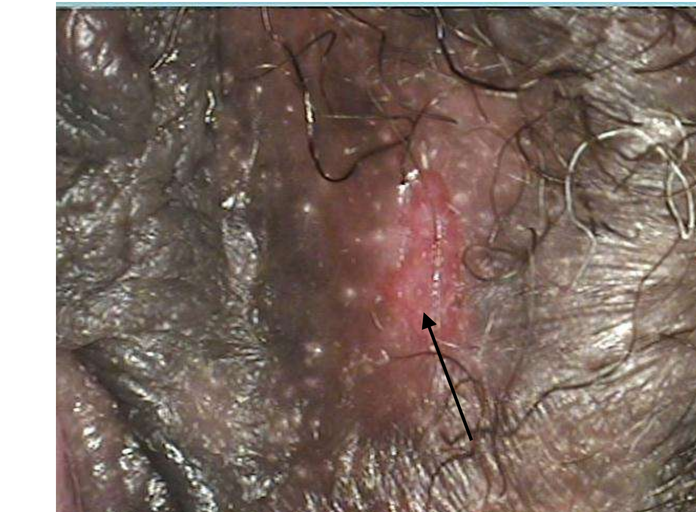
Edema



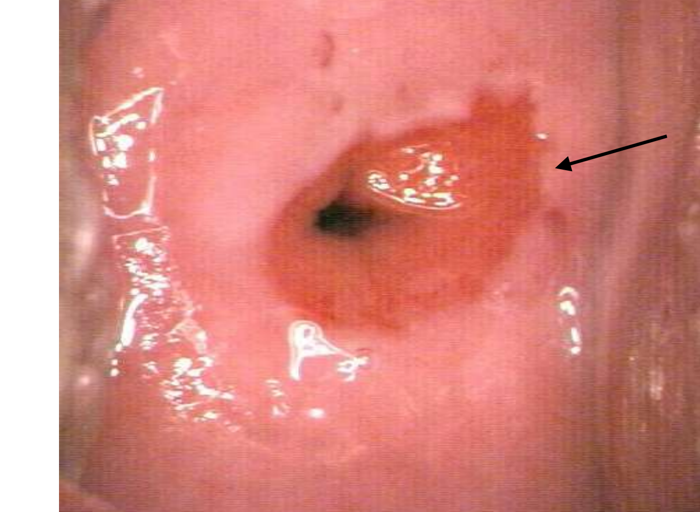
Grossly White Finding



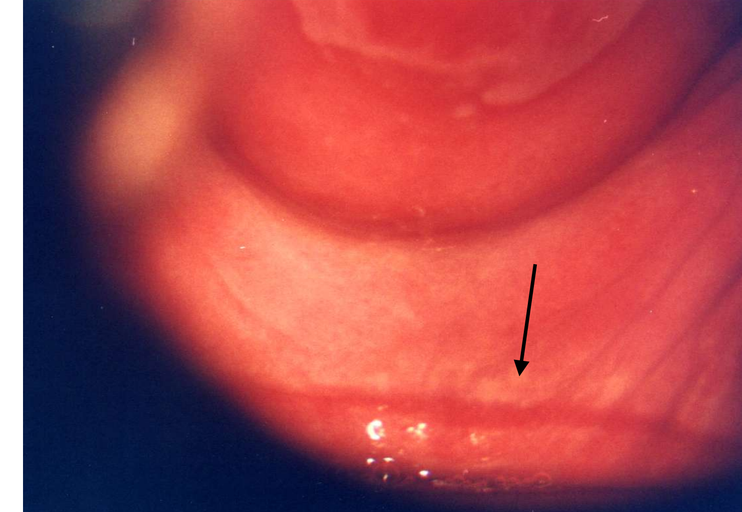
Peeling



Ulcer



Ectopy



Speculum Trauma