

DESCRIPTION

LUBRICATING VAGINAL SPECULUMS AND PROCTOSCOPES

Field of the Invention

1. In obstetric and gynaecological practice, possibly the most common disposable device used during clinical examination is the vaginal speculum. During use, the blades of the speculum are inserted into the vaginal canal and then widened to allow adequate visualization of the cervix, vaginal fornices and vaginal walls.
2. In the examination of the anal canal and distal rectum a disposable proctoscope is an indispensable device to determine the cause of anorectal bleeding, pain or constipation. The device consists of two parts: an inner obturator with an olivary tip and the outer speculum proper. The purpose of the obturator is to dilate the anal orifice so that the entire instrument can be introduced into the anal canal.

Description of the Prior Art

3. For both devices, prior to insertion the outer surfaces must be lubricated with a proprietary lubricating gel that is dispensed from a tube or a sachet. The amount of gel used varies from patient to patient depending upon the difficulty of insertion. Generally, about 5ml – 15ml of the viscous lubricant is used to facilitate the process.

Description of the Invention

4. A lubricant made from biocompatible hydroxyl-propyl cellulose is thinly and uniformly applied to the surfaces of both devices and allowed to dry on them. When presented after the drying process the lubricant is not visible to the user. The unique property of the lubricant is its highly hydrophilic character. During insertion, contact with the fluid secretion of the vagina will create a smoothly lubricated surface that easily slides into the vaginal canal. For insertions into the anal canal and vagina, that are dry, the speculums can be dipped into water to lubricate their surfaces.
5. The hydroxyl-propyl cellulose coating that is applied does not undergo a change in physical property after the device have undergone ethylene oxide sterilization, and retains the lubricating effect for which it was intended.



The device aims at eliminating the following disadvantages associated with prior inventions:

- (i) Copious application required of current proprietary gels. At the end of the examination or treatment procedure, residual lubricant is left at the orifice of the anal canal or introitus. This has to be wiped away before the patient wears his or her underwear. The examiner usually performs the wiping process. Patients often do this themselves in the presence of their doctors. Whichever the procedure, the cleaning up is a cause of embarrassment to every patient.
- (ii) In the presence of infection, the doctor may want to take a specimen of the vaginal or anal discharge for a culture and sensitivity test. Proprietary lubricants generally contain an antiseptic to prevent product deterioration. The presence of this antiseptic will interfere with the accuracy of the culture results as the antiseptic can have a biocidal effect on the microorganisms collected.
- (iii) The invention allows for a much cheaper lubricant than what is being offered by current products in the market.

Description of the Drawings

6. **Figure 1:** is a perspective view of a Speculum. The lubricant is spread on the shaded region.

Figures 2 & 3: are the perspective views of the proctoscopes. The lubricant is spread on the shaded region of the devices.

CLAIMS

Claim 1: Protection of Method:

1. The method of applying the devices with a lubricant made from biocompatible hydroxyl-propyl cellulose comprising:
 - (i) Application and spreading of the lubricant thinly and in a uniform manner on the surface of the vaginal speculums and proctoscopes;
 - (ii) The process of drying the applied lubricant on the devices and ensuring that the lubricant is not visible to the user;
 - (iii) The method of Claim 1 allows the devices to be inserted into the vaginal canal and then widened to allow adequate visualization of the cervix, vaginal fornices and vaginal walls more easily than the present method available and is in practice in the area of obstetric and gynaecology.

Claim 2: Protection of Process:

2. The process of applying lubricant mentioned in Claim 1 to vaginal speculums and proctoscopes comprising:
 - (i) The application of the lubricant made from biocompatible hydroxyl-propyl cellulose on the devices;
 - (ii) The device to undergo 'ethylene oxide sterilization';
 - (iii) Ensuring that the hydroxyl-propyl does not undergo a change in physical property after the device has undergone ethylene oxide sterilization;
 - (iv) Ensuring that the devices retain its smooth and lubricated character for insertions into anal canal and vagina that are dry.
 - (v) The process in Claim 2 allows for a smoother insertion as described in Claim 1.