

**DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER  
WHEN USED ACCORDING TO DIRECTIONS**

2551. Misbranding of Gomco ring pessaries. U. S. v. 6 Devices, etc. (F. D. C. No. 25549. Sample No. 29003-K.)

**LIBEL FILED:** September 9, 1948, District of Colorado.

**ALLEGED SHIPMENT:** On or about August 17, 1948, from Buffalo, N. Y., by the Gomco Surgical Mfg. Corp.

**PRODUCT:** 6 *Gomco ring pessary devices* at Denver, Colo., together with 6 circulars entitled "Technique For The Use Of The Gomco Intrauterine Silver Ring Pessary." Examination showed that the device was a metallic ring, approximately one inch in diameter, which was fashioned from a spring, the coils of which were approximately  $\frac{3}{32}$  inch in diameter.

**NATURE OF CHARGE:** Misbranding, Section 502 (j), the article was dangerous to health when used with the frequency and duration recommended and suggested in its labeling, namely, "Patient lies in the Gynecological position on the examination table. The Speculum is inserted and antiseptic wet swabs are applied to the Os in order to remove any mucous. The Tenaculum Forceps used to seize the anterior lip is held in the left hand to steady the cervix and bend it down. A Sound is introduced in order to establish the position, size and direction of the Uterine Cavity and also to determine the caliber of the cervical canal. The Speculum is then pressed posteriorly. It is most important to establish the length of the uterine cavity as the ring must be placed so as to be in contact with the upper end of the cavity. The bend in the cervical canal is straightened by pulling gently on the Tenaculum. Occasionally projecting folds in the mucous membrane of the cervical canal (especially in hypo-plastic uteri) causes some difficulty. This can be overcome by dilating the cervical canal with a Hegar's Dilator so that the introducing instrument can be passed after the dilation. This is quite easy if a No. 6 dilator can be passed. If No. 5 goes in easy it is not necessary to try No. 6 as this is wide enough for the introducing instrument. The latter is pushed in until the resistance of the fundus uteri is encountered. The ring which is compressible adapts itself to the canal while passing through it and resumes its circular shape when it gets into the uterine cavity. You can see this from an X-ray plate of the ring in situ. On withdrawing the introducing instrument, the walls of the uterus at the internal os detach the ring from the instrument and the latter comes out easily, leaving the ring behind. The Tenaculum Forceps are then removed, any blood clots are swabbed up, the Speculum is removed and a swab left on the vaginal entrance. \* \* \* Care must be taken that the lower pole of the ring is within the cavity. \* \* \* The ring may be left in for at least one year."

**DISPOSITION:** October 29, 1948. The Gomco Surgical Manufacturing Corp. having executed an acceptance of service and authorization for taking of final decree, judgment of condemnation and destruction was entered.