



## Memorandum

Date SEP - 5 1996

From Director, Office of Device Evaluation (HFZ-400)  
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Richard Wolf Medical Instruments Corporation  
Hulka Clip Tubal Occlusion Device and Applicator System - ACTION

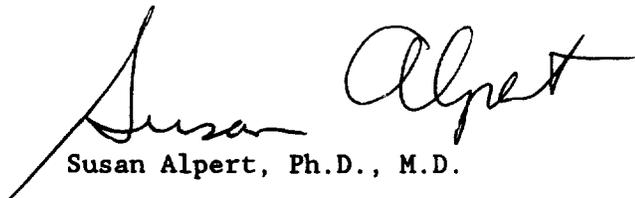
To The Director, CDRH  
ORA \_\_\_\_\_

**ISSUE.** Publication of a notice announcing approval of the subject PMA.

**FACTS.** Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

**RECOMMENDATION.** I recommend that the notice be signed and published.

  
Susan Alpert, Ph.D., M.D.

**Attachments**

Tab A - Notice  
Tab B - Order  
Tab C - S & E Summary

**DECISION**

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_

Prepared by Miin-Rong Tsai, Ph.D., CDRH, HFZ-470, 1/31/96, 594-1180

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

**DRAFT**

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. \_\_\_\_\_]

Richard Wolf Medical Instruments Corp.; PREMARKET APPROVAL  
of the Hulka Clip® Tubal Occlusion Device and Applicator  
System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is  
announcing its approval of the application by Richard Wolf  
Medical Instruments Corp., Vernon Hills, IL, for premarket  
approval, under the Federal Food, Drug, and Cosmetic Act  
(the act), of Hulka Clip® Tubal Occlusion Device and  
Applicator System. After reviewing the recommendation of  
the Obstetrics and Gynecology Devices Panel, FDA's Center  
for Devices and Radiological Health (CDRH) notified the  
applicant, by letter on September 5, 1996, of the approval  
of the application.

DATES: Petitions for administrative review by (insert date  
30 days after date of publication in the FEDERAL REGISTER)

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ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Colin M. Pollard,  
Center for Devices and Radiological Health (HFZ-470),  
Food and Drug Administration,  
9200 Corporate Blvd.,  
Rockville, MD 20850,  
301-594-1180.

SUPPLEMENTARY INFORMATION: On December 30, 1987, Richard Wolf Medical Instruments Corp., Vernon Hills, IL, 60061, submitted to CDRH an application for premarket approval of Hulka Clip® Tubal Occlusion Device and Applicator System. The device is a contraceptive tubal occlusion device (TOD) and is indicated for female sterilization (permanent contraception) by occluding the fallopian tubes.

On May 25, 1988, the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the

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application subject to the submission of the data from the long-term animal carcinogenic studies demonstrating the safety of the device materials.

On September 5, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

#### Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under



§10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Robert Casarsa  
Quality Assurance Manager  
Richard Wolf Medical Instruments Corporation  
353 Corporate Woods Parkway  
Vernon Hills, Illinois 60061

SEP - 5 1996

Re: P870080  
Hulka Clip® Tubal Occlusion Device and Applicator Systems  
Filed: December 30, 1987  
Amended: March 10, April 6, 11, 12 and 20, May 17 and 24, June 24, and  
December 22, 1988; January 4, 1989; July 31, 1990; October 23  
and December 23, 1991; April 29, July 16, September 28 and  
October 26, 1992; January 19, June 10 and November 12, 1993; March 29,  
May 25, July 3, September 12 and 22, and November 6, 1995; and  
July 24, 1996

Dear Mr. Casarsa:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Hulka Clip® Tubal Occlusion Device and Applicator Systems. This device is indicated for use for female sterilization (permanent contraception) by occluding the fallopian tubes. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may continue commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

The expiration dating for this device has been established and approved at 2 years. This is to advise you that the protocol provided in the Amendment dated May 25, 1995, is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

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Page 2 - Mr. Robert Casarsa

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Colin M. Pollard at (301) 594-1180.

Sincerely yours,



Susan Alpert, Ph.D., M.D.

Director

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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**CONDITIONS OF APPROVAL**

**APPROVED LABELING.** As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

**ADVERTISEMENT.** No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

**PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT.** Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effectuated" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effectuated" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effectuated." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
  - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

- (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

**ADVERSE REACTION AND DEVICE DEFECT REPORTING.** As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
  - (a) has not been addressed by the device's labeling or
  - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)  
Center for Devices and Radiological Health  
Food and Drug Administration  
1350 Piccard Drive, 340  
Rockville, Maryland 20850  
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)  
Center for Devices and Radiological Health  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

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## SUMMARY OF SAFETY AND EFFECTIVENESS

### I. GENERAL INFORMATION:

**Device Generic Name:** Contraceptive Tubal Occlusion Device (TOD) and Introducer

**Device Trade Name:** Hulka Clip Tubal Occlusion Device and Applicator System

**Applicant's Name and Address:**

Richard Wolf Medical Instruments Corporation  
353 Corporate Woods Parkway  
Vernon Hills, Illinois 60061

**Premarket Approval Application (PMA) Number:** P870080

**Date of Panel Recommendation:** May 25, 1988

**Date of Notice of Approval to Applicant:** September 5, 1996

### II. INDICATIONS FOR USE

The Hulka Clip Tubal Occlusion Device and Applicator system (hereinafter called the Hulka Clip) is indicated for female sterilization (permanent contraception) by occluding the fallopian tubes.

### III. DEVICE DESCRIPTION:

The Hulka Clip prevents fertilization by obstructing the isthmic portion of the fallopian tube. The Hulka Clip consists of two plastic jaws made of polycarbonate. The upper jaw is 0.130" wide and 0.534" long. The lower jaw is the same width but 0.065" longer. Each jaw has teeth (0.040" long) on the opposing surfaces. These teeth are hinged together 2 mm from one end of the assembled jaws by a stainless steel fulcrum pin which is 0.128" long and 0.031" in diameter. At the far end of the clip, a gold plated spring (0.473" long, 0.148" high, and 0.0625" wide) holds the clip's jaw in an open position. Interlocking teeth on the upper and lower jaws of the clip crush 0.5 - 0.7 cm of tissue, while the spring prevents expansion and dislodgement by the contractile movements of the tube. The device has not been demonstrated to be Magnetic Resonance Imaging (MRI) safe and compatible.

Hulka Clip Applicators have been developed for both single and double puncture laparoscopic techniques. The original single puncture applicator fits through a 10 mm sleeve housing a 5 mm optic which can be used separately for diagnostic work with a 5 mm sleeve. The double puncture

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technique utilizes a 10mm diagnostic scope with a separate 7 mm applicator. The equipment includes a channel for spraying topical anesthetic directly onto the tube at the time of clip application.

The Hulka Clip is held firmly in the jaw of the applicator such that repeated safe opening and closing is possible during insertion through trocars, testing of the application, and manipulation of the tube. Lateral manipulation of the uterus with a special tenaculum with cervical jaws and intrauterine extension puts the tube on a stretch during these procedures, providing maximum availability to the clip applicator.

#### **IV. Contraindications, Warnings and Precautions:**

Use of Hulka Clip is contraindicated in the presence of the following conditions: (1) significant peritubular adhesive disease obscuring the isthmic portion of the tube and impairing tubal mobility, (2) salpingitis isthmica nodosa or chronic isthmic induration, (3) acute pelvic inflammatory disease, (4) patient conditions which contraindicate surgery or the use of anesthesia, (5) significant hemoperitoneum, (6) pregnancy or suspicion of pregnancy, and (7) allergy to gold.

See the attached labeling for additional warnings and precautions (Attachment 1).

#### **V. ADVERSE EFFECTS OF THE DEVICE ON HEALTH:**

##### **A. Reported Adverse Effects**

The following adverse effects have been reported from the use of the Hulka Clip and Applicator System. The effects are not listed in order of frequency or severity.

tuboovarian abscess; pregnancy; ectopic pregnancy; pain and cramping; mesosalpingeal bleeding; misapplication to ovarian ligament, broad ligament, omentum, bowel, tubal serosa, or cornual; inadvertent discharge of the device into the peritoneal cavity; and allergic reactions to the gold.

Menstrual pattern changes (amount blood flow, duration of flow, cycle length, cycle regulatory, and pain) may occur following sterilization.

The following adverse effects have been reported from surgical procedures to implant the Hulka Clip:

omental emphysema; abdominal wall emphysema; cervical, omental, ovarian, uterine, or peritoneal laceration; incisional bleeding; bladder injury; excess blood loss/shock; incisional dehiscence; incisional infection; urinary tract infection; vaginal bleeding;

incisional keloids; omental blood vessel bleeding; pelvic infection; uterine perforation; and febrile morbidity.

## **B. Potential Adverse Events**

Intraoperative and postoperative complications, in the form of unintended major surgery, febrile morbidity and rehospitalization, may occur following laparoscopic tubal sterilization. Trauma and bleeding of the pelvic organs may occur during laparoscopic Hulka Clip procedures and result in major unwanted surgery (laparotomy).

Section VIII, Part B, of this summary discusses in greater detail the adverse effects associated with use of the Hulka Clip and their respective incidences.

## **VI. ALTERNATIVE PRACTICES AND PROCEDURES:**

Alternative permanent female sterilization methods include hysterectomy, surgical resection of fallopian tubes, tubal ligation or fulguration (cauterization) of the fallopian tubes, and application of tubal rings (bands) to the fallopian tubes.

## **VII. Marketing History of the Device**

The applicant submitted this application in response to the final rule published in the Federal Register of Oct. 1, 1987 (52 FR 36882) requiring the submission of PMA applications for Tubal Occlusion Devices (TODs) and applicators that were in commercial distribution before May 28, 1976, or those marketed after May 28, 1976 and found substantially equivalent to such TODs and applicators. On June 30, 1988, FDA determined that continued availability of the Hulka Clip Tubal Occlusion Device and Applicator was necessary for the public health. The Hulka Clip Tubal Occlusion Device and Applicator has been marketed in the United States, Canada, and Germany since 1976, in Belgium and Australia since 1977, and in England since 1980. Over 1 million devices have been distributed.

## **VIII. SUMMARY OF STUDIES:**

### **A. Preclinical Studies**

#### **1. Mechanical and Physical Properties**

The applicant submitted test data demonstrating the load/deflection functions of the Hulka Clip and the applicator. The force applied by the applicator to the clip was measured at under 0.607 lb. This is much less than the 20 lb required to damage a clip. The force applied by the clip to a fallopian tube when the free ends of the clip are held open at a distance of 2 mm ranges from 0.25 lb. to 0.36 lb.

The applicant examined 5 clips explanted from patients after implantation for 3.5 to 10.5 years. The explanted clips were mechanically functional in terms of their ability to open and close, as well as with respect to the locking spring tension. Under scanning electron microscopy there was evidence of the gold coating pitting and flaking. However, there were no other visual signs of deterioration to the clip.

## 2. **Biocompatibility**

The clip is composed of 3 materials: medical grade stainless steel, gold, and Lexan 124R-112. The biocompatibility of medical grade stainless steel and gold is well documented and these materials are known to not sensitize or irritate human tissue. The parts of the applicators which come into contact with human tissue are manufactured from medical grade stainless steel.

The biocompatibility tests on Lexan resin were conducted according to United State Pharmacopeia (USP XXI)<sup>1</sup>. The extracts of Lexan were tested for tissue culture cytotoxicity to evaluate their potential toxic effect to L929 mouse fibroblast cells. The results indicated that Lexan was nontoxic to the cell line studied. The extracts from Lexan were tested in 5 mice for acute systemic toxicity and in 2 rabbits for intracutaneous irritation. The results indicated that extracts from Lexan did not produce systemic toxic effects in mice and did not produce intracutaneous irritation reactions in rabbits. Lexan strips were investigated in 2 rabbits for intra-muscular implantation. The results showed that none of the test animals exhibited a significant inflammatory reaction.

The results from the above in-vitro and in-vivo studies revealed no evidence of cytotoxicity, acute systemic toxicity, intracutaneous irritation, or intramuscular tissue response.

## 3. **Long Term Tissue Toxicity**

### 1. **Mouse Study**

To evaluate the potential for chronic toxicity and tumorigenic responses, miniaturized Hulka Clips were surgically implanted in female mice. Surgery was successfully performed on four hundred and fifteen (415) outbred CD-1 (ICR) female mice. Of these, 207 were implanted with two devices, one attached to each uterine horn (Test group), and 208 were sham-operated with no devices implanted (Sham group). Two weeks after the last day of surgery, the size of the Test and Sham groups was reduced to 200 mice each, and the remaining animals were euthanized.

At the end of the 18 month study, 279 (69%) of the original 400 mice had survived:

	<u>Early Death/ Euthanasia</u>	<u>Survivors</u>
Test	74	126 (63%)
Sham	47	153 (77%)

None of the early deaths of the test animal were attributable to the device. Solid-state neoplasms occurred in 19 of 200 test mice at the implant sites. These were all of mesenchymal derivation, and were considered to have been associated with the Oppenheimer solid-state tumor effect. The occurrence of such solid-state neoplasms in the test group was an expected occurrence in this study, due to the physical size of the over-sized clips. Microscopic evaluations of the remaining non-neoplastic changes revealed no evidence of systemic toxicity from the implants. Results were similar in the two groups.

Under the conditions of this 18-month study in mice, there was no evidence of toxicological effects from the implanted clips. All pathologic changes noted were related to natural disease processes in the aging mice or to mechanical effects from the relatively large clips placed on the uterine horns of the mice. While neoplastic changes were noted at the implant site, they were believed related to the physical presence of the oversized samples and solid-state tumorigenesis.

## 2. Rat Study

To further evaluate the potential for chronic toxicity and tumorigenic response, miniaturized Hulka Clips were surgically implanted in female rats. Surgery was successfully performed on four hundred (400) female rats. Of these, 200 were implanted with two devices, one attached to each uterine horn (test group), and 200 were sham-operated with no devices implanted (sham group).

After 24 months, 151 (38%) of the original 400 rats had survived:

	<u>Early Death/ Euthanasia</u>	<u>Survivors</u>
Test	119	81 (40%)
Sham	130	70 (35%)

None of the early deaths of the test animal were attributable to the device. At termination, except for implant site changes in the test rats, the necropsy observations were similar in number and type between test and sham animals. Microscopically, there were 18 foreign body, solid-state neoplasms noted at implant sites, while none were noted in the sham surgical animals at the uterine sites. These neoplasms were usually well-differentiated fibrosarcomas or

osteosarcomas representative of solid-state tumorigenesis. As noted previously, these neoplasms are believed to result from the presence of the over-sized implants.

Under the conditions of this test, it was concluded that there was no systemic effect of the implanted device on body weight, general health, mortality, or tissue organ weights. There was no evidence of local tissue toxicity associated with the device. The occurrence of solid-state neoplasms in 18 of 200 of the test animals was not an unexpected finding. These neoplasms have been well described in rodents in association with implanted foreign bodies and apparently have little, if any, relevance concerning human safety.

## **B. Clinical Studies - Overview**

The applicant submitted clinical data from two different sources to demonstrate the safety and effectiveness of the Hulka-Clip for permanent female sterilization: 1) controlled clinical trials conducted by Family Health International (formerly the International Fertility Research Program (IFRP)), and 2) investigations reported in the scientific literature.

The IFRP Study was a multicenter study of 1,151 women who underwent permanent sterilization with a clip identical to the Hulka Clip between 1975 and 1982 (Table 1). Long-term follow-up, generally for one to three years post-sterilization, was conducted. Data on the occurrence and outcome of pregnancies that occurred following sterilization was collected.

The safety of the procedure was evaluated by the number and type of complications and complaints that occurred. These were analyzed according to the time of occurrence: during the sterilization procedure; during the recovery period before discharge; within the first 30 days after hospital discharge; and at 6, 12, 24, and/or 36 months after the sterilization procedure.

### **a. Pregnancy Rate - Failure Rate**

#### IFRP Study

The primary measure of effectiveness of the clip is the resulting pregnancy rate. Pregnancy rates based on a life table analysis for IFRP Study are presented in Tables 1A through 1F.

IFRP results represented final data pooled across all centers that participated in clinical studies of the clip. Actuarial charts for pregnancy rates are presented for data pooled across all sites and by patient type and surgical approach.

A total of 13 post-sterilization pregnancies were reported for the 1,151 women sterilized. Four of these pregnancies were luteal phase pregnancies that occurred before sterilization and are excluded from the analysis. Thus, the actuarial analyses are based on the 9 non-luteal phase pregnancies.

Eight pregnancies occurred within the first year. One occurred during the first month, 6 occurred within the first 6 months and 1 occurred between 7 and 12 months. The 12 month cumulative pregnancy rate is 0.86% (95% confidence limits are 0.26% to 1.45%). An additional pregnancy occurred after 36 months. The 48 month cumulative pregnancy rate is 1.34% with 95% confidence intervals of 0.22% to 2.46%.

The twelve month cumulative post-sterilization pregnancy rate was slightly higher among the minilaparotomy patients (Table 1B) than the laparoscopy patients (Table 1C) (1.23% vs. 0.68%), but this difference was not statistically significant, (Mantel-Haenszel chi-square was 0.867). Although the 12-month cumulative post-sterilization pregnancy rate was slightly lower among the interval patients (Table 1D) than the post-abortion patients (Table 1E) (0.85% vs. 0.90%), this difference was not statistically significant (Mantel-Haenszel chi-square was 0.006).

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Study Description	Location	Total	Patient Category	Surgical Approach	Required follow-up	Cumulative			
						Follow-up		Distribution	
Comparative Evaluation of Sterilization with Rocket Clips and Tubal Rings	England	101	Interval	101 Laparoscopy	12 month	1+ month	99	98%	
						6+ month	92	91%	
						12+ month	72	71%	
						24+ month	1	1%	
	Belgium	20	Interval	20 Laparoscopy	6 month	1+ month	20	100%	
						6+ month	11	55%	
Comparative Evaluation of Minilaparotomy with Rocket Clips and Tubal Rings	Egypt	29	Interval	29 Minilaparotomy	24 month	1+ month	8	28%	
						6+ month	2	7%	
	El Salvador	148	Postabortion	148 Minilaparotomy	24 month	1+ month	141	95%	
						6+ month	127	86%	
						12+ month	57	39%	
						24+ month	6	4%	
	Costa Rica	147	Interval	147 Minilaparotomy	24 month	6+ month	147	100%	
						24+ month	145	99%	
Evaluation of Sterilization using laparoscopy and Rocket Clips	England	41	Interval	47 Laparoscopy	12 month	1+ month	41	87%	
		6	Postabortion						
		47	Total						
	England	287	Interval	299 Laparoscopy	12 month	1+ month	299	100%	
	12	Postabortion				6+ month	278	93%	
	299	Total				12+ month	227	76%	
						24+ month	2	1%	
	England	100	Interval	108 Laparoscopy	24 month	1+ month	108	100%	
		6	Postabortion			6+ month	101	94%	
		2	Postpartum			12+ month	90	83%	
		108	Total			36+ month	72	67%	
	England	45	Interval	55 Laparoscopy	12 month	1+ month	55	100%	
		10	Postabortion			6+ month	51	93%	
		55	Total			12+ month	37	67%	
Comparative Evaluation of Sterilization Using Laparoscopy and Minilaparotomy with Rocket Clips	England	191	Interval	98 Laparoscopy	12 month	1+ month	196	99%	
		2	Postabortion	99 Minilaparotomy		6+ month	192	97%	
		4	Postpartum			12+ month	188	95%	
		197	Total			36+ month	134	68%	
Summary		961	Interval	728 Laparoscopy		1+ month	1114	97%	
		184	Postabortion	423 Minilaparotomy		6+ month	1003	87%	
		6	Postpartum			12+ month	816	71%	
		1151	Total	1151		24+ month	360	31%	
						36+ month	206	18%	

## ACTUARIAL CHART FOR PREGNANCY RATE

Interval Since Sterilization	Number at Start of Interval	Pregnancies During Interval	Number Withdrawn	Effective Number at Risk During Interval	Percent Pregnant	Percent Not Pregnant	Cumulative Percent Not Pregnant from Sterilization or Through End of Interval	Standard Error
0 - 1 month	1147*	1	140	1077	0.0929	99.907	99.907	
2 - 6	1006	6	82	965	0.6218	99.286	99.286	
7 - 12	918	1	424	706	0.1416	99.145	99.145	0.30
13 - 24	493	0	289	348.5	0.0000	99.145	99.145	
25 - 36	204	0	0	204	0.0000	99.145	99.145	
37 - 48	202	1	0	204	0.4902	98.659	98.659	0.57
49+	203	0						

\* 4 luteal phase pregnancies excluded

12-Month Pregnancy Rate: 0.86%  
 95% Confidence Interval: 0.26% to 1.45%  
 48-Month Pregnancy Rate: 1.34%  
 95% Confidence Interval: 0.22% to 2.46%

**ACTUARIAL CHART FOR PREGNANCY RATE**  
**Minilaparotomy**

Interval Since Sterilization	Number at Start of Interval	Pregnancies During Interval	Number Withdrawn	Effective Number at Risk During Interval	Percent Pregnant	Percent Not Pregnant	Cumulative Percent Not Pregnant from Sterilization or Through End of Interval	Standard Error
0 - 1 month	421	0	78	302.0	0.0000	100.0000	100.0000	
2 - 6	343	4	35	325.5	1.2289	100.0000	98.771	
7 - 12	304	0	81	263.5	0.0000	100.0000	98.771	0.61
13 - 24	223	0	154	146.0	0.0000	100.0000	98.771	
25 - 36	69	0	0	69.0	0.0000	100.0000	98.771	
37 - 48	69	1	0	69.0	1.4493	98.5507	97.339	1.54
49+	68	0						

12-Month Pregnancy Rate: 1.23%  
 95% Confidence Interval: 0.26% to 1.45%  
 48-Month Pregnancy Rate: 1.34%  
 95% Confidence Interval: 0.22% to 2.46%

ACTUARIAL CHART FOR PREGNANCY RATE  
Laparoscopy

Interval Since Sterilization	Number at Start of Interval	Pregnancies During Interval	Number Withdrawn	Effective Number at Risk During Interval	Percent Pregnant	Percent Not Pregnant	Cumulative Percent Not Pregnant from Sterilization or Through End of Interval	Standard Error
0 - 1 month	726	1	62	695.0	0.1439	99.8561	99.856	
2 - 6	663	2	47	639.5	0.3127	99.6873	99.544	
7 - 12	614	1	343	442.5	0.2260	99.7740	99.319	0.35
13 - 24	270	0	135	202.5	0.0000	100.0000	99.319	
25 - 36	135	0	0	135.0	0.0000	100.0000	99.319	
37 - 48	135	0	0	135.0	0.0000	100.0000	99.319	0.35
49+	135	0						

12-Month Pregnancy Rate: 0.68%  
 95% Confidence Interval: 0.0% to 1.37%  
 48-Month Pregnancy Rate: 0.68%  
 95% Confidence Interval: 0.0% to 1.37%

*of*

**ACTUARIAL CHART FOR PREGNANCY RATE**  
Interval Patients

Interval Since Sterilization	Number at Start of Interval	Pregnancies During Interval	Number Withdrawn	Effective Number at Risk During Interval	Percent Pregnant	Percent Not Pregnant	Cumulative Percent Not Pregnant from Sterilization or Through End of Interval	Standard Error
0 - 1 month	957	1	85	914.5	0.1093	99.8907	99.891	
2 - 6	871	5	47	847.5	0.5900	99.4100	99.301	
7 - 12	819	1	352	643.0	0.1555	99.8445	99.147	0.32
13 - 24	466	0	272	330.0	0.0000	100.0000	99.147	
25 - 36	194	0	0	194.0	0.0000	100.0000	99.147	
37 - 48	194	1	0	194.0	0.5155	99.4645	99.636	0.60
49+	193	0						

12-Month Pregnancy Rate: 0.85%  
 95% Confidence Interval: 0.22% to 1.48%  
 48-Month Pregnancy Rate: 1.365%  
 95% Confidence Interval: 0.18% to 2.54%

**ACTUARIAL CHART FOR PREGNANCY RATE**  
**Postabortion Patients**

Interval Since Sterilization	Number at Start of Interval	Pregnancies During Interval	Number Withdrawn	Effective Number at Risk During Interval	Percent Pregnant	Percent Not Pregnant	Cumulative Percent Not Pregnant from Sterilization or Through End of Interval	Standard Error
0 - 1 month	184	0	55	156.5	0.0000	100.0000	100.000	
2 - 6	129	1	35	111.5	0.8969	99.1031	99.103	
7 - 12	93	0	70	58.0	0.0000	100.0000	99.103	0.89
13 - 24	23	0	17	14.5	0.0000	100.0000	99.103	
25 - 36	6	0	0	6.0	0.0000	100.0000	99.103	
37 - 48	6	0	0	6.0	0.0000	100.0000	99.103	0.89
49+	6	0						

12-Month Pregnancy Rate: 0.90%  
 95% Confidence Interval: 0.0% to 2.64%  
 48-Month Pregnancy Rate: 0.90%  
 95% Confidence Interval: 0.0% to 2.64%



TABLE 11  
**ACTUARIAL CHART FOR PREGNANCY RATE**  
**Postpartum patients**

Interval Since Sterilization	Number at Start of Interval	Pregnancies During Interval	Number Withdrawn	Effective Number at Risk During Interval	Percent Pregnant	Percent Not Pregnant	Cumulative Percent Not Pregnant from Sterilization or Through End of Interval	Standard Error
0 - 1 month	6	0	0	6.0	0.000	100.000	100.000	
2 - 6	6	0	0	6.0	0.000	100.000	100.000	
7 - 12	6	0	2	5.0	0.000	100.000	100.000	
13 - 24	4	0	0	4.0	0.000	100.000	100.000	
25 - 36	4	0	0	4.0	0.000	100.000	100.000	
37 - 48	4	0	0	4.0	0.000	100.000	100.000	
49+	4	0						

Literature Report

Pregnancy rates for different laparoscopic tubal occlusion techniques including electrocoagulation, tubal ring and clips<sup>2</sup> were collected in a study by Bhiwandiwalla et al. The study pooled results from clinical investigations conducted at 64 sites in 27 countries, with 24,439 sterilizations.

**Summary of Pregnancy Rates and Follow-Up Rates**

Method	12-Month Pregnancy Rate (with Standard Error)	12-Month Follow-Up Rate
Electrocoagulation	0.26% (0.07)	26.5%
Tubal Ring	0.47% (0.10)	38.8%
Clip	0.18% (0.18)	67.5%

Pregnancy rates for clips implanted by either laparoscopy or minilaparotomy are comparable to those observed for other tubal occlusion devices

**b. Ectopic Pregnancy**

No ectopic pregnancies were reported in the IFRP Study. Most patients (71%) were followed for 12 or more months, and follow-up of 24 months or more was available for 360 (31%) patients. The incidence of ectopic pregnancy was 0.0%, 95% confidence intervals based on the Poisson distribution are 0.0% to 0.3%.

While the chance of pregnancy after sterilization is small, the proportion of such pregnancies that are ectopic is reported in the literature as ranging from 7.7% to 63.3%<sup>3,4, & 5</sup>.

**c. Abnormal Menstrual Patterns**

Data collected for the IFRP Study included information on the patient's menstrual cycle both before and after sterilization. Information was collected on changes in cycle length, cycle regularity, flow duration, dysmenorrhea, intermenstrual pelvic pain, and intermenstrual bleeding. None of the changes reported are remarkable.

There are conflicting reports in the literature about menstrual pattern changes following sterilization. Some publications reported increased incidence of irregular bleeding and pain while other publications reported no change<sup>6 & 7</sup>.

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**d. Infections**

In the IFRP Study (1,151 patients), uterine infections were reported for 2 patients (0.2%) seen during the long-term follow-up period. Four other infections (0.4%) were reported from sterilization to discharge (recovery period) and one other infection (0.1%) was reported during the early follow-up period (within 30 days).

**e. Pain**

In the IFRP Study (1,151 patients), pelvic pain was reported for 150 patients (13.0%) during the immediate postoperative period and for 111 patients (11.2%) during the early postoperative follow-up period. Two of the patients (0.2%) seen for long term follow-up reported adnexal pain. During the recovery period, pelvic pain was reported for 15.5% of the interval patients and for 0.5% of the post-abortion patients. At the early follow-up visit, 12.0% of the interval and 1.5% of the post-abortion patients reported pelvic pain. One interval (0.1%) and 1 post-abortion patient (0.5%) reported adnexal pain at long-term follow-up.

Chi and Cole <sup>8</sup> compared incidence of abdominal and pelvic pain among patients sterilized with Hulka Clip, electrocoagulation, and tubal ring methods. They reported that during the sterilization procedure, the incidence of moderate to severe abdominal or pelvic pain is lower among the Hulka Clip patients. During the recovery and early follow-up visits the incidence of moderate to severe pain is comparable between Hulka Clip and tubal ring patients, but slightly higher among Hulka Clip patients than electrocoagulation patients.

**f. Trauma - Bleeding**

In the IFRP Study (1,151 patients), tubal or mesosalpingeal injury without bleeding was reported for 7 clip patients (0.7%) and tubal or mesosalpingeal bleeding was reported for 3 clip patients (0.3%). Incision-related bleeding was reported for one patient (0.1%) and 8 patients (0.8%) reported vaginal bleeding other than menses or lochia during the recovery period. During the early follow-up evaluation vaginal bleeding other than menses or lochia was reported for 16 (1.6%).

**g. Allergic Reactions**

No reports of allergy to the gold plate in the clinical study. One allergic reaction to the gold plate in the Hulka Clip has been reported in the literature <sup>9</sup>.

**IX. Conclusions**

In-vitro assays and acute and subchronic animal studies revealed no evidence of acute systemic toxicity, intracutaneous reactivity or intramuscular tissue response. Results of cytotoxicity were negative. There has been one report of an allergic reaction to the gold plate in the clip. The stainless steel is not known to irritate or sensitize human tissues. Life-time implantation studies in

rats and mice provide no evidence of chronic toxicological effects from implanted devices. The neoplasms observed at the implant site in both rats and mice are related to the physical presence of the clip due to solid state phenomenon which is unique to rodent species.

In the multicenter clinical studies, the 12-month cumulative pregnancy rate was 0.86% (95% Confidence Intervals 0.26% to 1.45%) and the 48-month cumulative pregnancy rate was 1.34% (95% Confidence Intervals 0.22% to 2.46%). Pregnancy rates for the Hulka Clip were comparable to rates observed for other tubal occlusion devices. No significant incidence of adverse effects attributable to the applicator were reported.

In conclusion, the in-vitro and animal toxicity studies provide reasonable assurance of the safety of the device materials. The clinical studies provide reasonable assurance that the Hulka Clip is safe and effective for its intended use.

#### **X. PANEL RECOMMENDATIONS:**

The Obstetrics and Gynecology Devices, Panel met on May 25, 1988, to consider the safety and effectiveness of the Hulka Clip. The Panel considered data from: (i) investigations reported in the literature, and (ii) selected prospective comparative studies conducted by Family Health International. The Panel determined that there were sufficient data to provide reasonable assurance of the safety and effectiveness of the Hulka Clip for the stated indication. The Panel recognized that the results from the long-term animal implantation studies were not available at that time. However, based on the preliminary results from on-going studies, the Panel voted to approve the PMA with the condition that final approval of the device should be contingent upon the results from the long-term animal studies and labeling changes.

#### **XI. CDRH DECISION:**

CDRH concurred with the recommendation of the Obstetrics and Gynecology Devices Panel. On June 30, 1988 CDRH issued an approvable letter for the PMA which required that life-time animal implantation studies in rats and mice be performed, and the FDA notified the applicant that continued availability of the Hulka Clip was necessary for the public health. The applicant concurred with the conditions of approval and agreed to the study. The applicant conducted the comparative life-time animal implantation studies, and the results of these studies were subsequently submitted to CDRH. The results from the life-time animal implantation studies in rats and mice provided no evidence of chronic toxicological effects from implanted devices. Although neoplasms were observed at the implant site in both rats and mice, they were considered to be related to the physical presence of the clip due to solid state phenomenon which is unique to rodent species.

Inspections of the applicant's manufacturing facilities on July 21, and November 9, 1995 were found to be in compliance with the Good Manufacturing Practices (GMP) Regulation.

CDRH has determined that, based on the data submitted in the PMA, there is reasonable assurance that the Hulka Clip Tubal Occlusion Device and Applicator System is safe and effective for its intended use, and issued an approval order on September 5, 1996.

## **XII. Approval Specification**

Direction for Use: See the Labeling (Attachment 1)

Conditions of Approval: CDRH's Approval of this PMA is subject to full compliance with the conditions described in the approval order (Attachment B)

## References:

1. USP XXI, P.12335
2. Bhiwandiwalla, P. P., Mumbord, S.D., Feldblum, P. J., A comparison of different laparoscopic sterilization occlusion techniques in 24,439 procedures. *American Journal Obstetrics and Gynecology*. 144:319-331, 1982.
3. Chi I-C, Potts M., Wilkens L., Rare events associated with tubal sterilizations, *Obstet Gynecol Survey*, 41: 7 - 19, 1986.
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5. Huggins G. R., Sondheimer S. J., Comparisions of female sterilization: Immediate and delayed, *Fertil Steril*, 41: 337-355, 1984.
6. Hulka, J. F., *Textbook of Laparoscopy*, Orlando, Florida: Grune and Stratton, 1985.
7. Liebeman B.A., Belsey E., Menstrual patterns after laparoscopic sterilization using a spring-loaded clip, *Br. J. Obstet Gynecol*, 85: 376-380, 1978.
8. Chi C-I, Cole L.P., Incidence of pain among women undergoing laparoscopic sterilization by electrocoagulation, the spring-loaded clip, and the tubal ring, *American J. Obstet Gynecol* 135: 397-401, 1979.
9. Trathen W. T., Stanley R. J., Allergic reaction to Hulka Clips, *Obstet Gyn*, 66: 743-744, 1985.

PATIENT INFORMATION

**"CLIPPING THE TUBES"  
WITH HULKA CLIPS**

**Introduction**

The Hulka Clip is made with two "jaws" of inert plastic, each about a half inch long and narrower than a paper match. The plastic is hard, crystal clear Lexan, familiar as the plastic in some food containers. The two jaws are placed around the tube and are held together with a small gold-plated stainless steel spring, designed to let the jaws seal off the tube and gently divide it over the next few days. The entire clip is about a half inch long. The tubes are permanently divided and the clips are covered with a fine layer of cells as the only reaction to the material.

The procedure is performed using "laparoscopy," from the Greek words literally meaning "look into the abdomen." In this operation, the doctor uses an instrument like a small telescope, called a laparoscope to look at the pelvic organ and place the Hulka Clip on the fallopian tubes, thereby preventing pregnancy. The clip can be applied through one incision and the procedure can be performed under local anesthesia only.

**Information You Should Know  
Before Electing Sterilization**

A woman of child bearing age may decide she wishes never to become pregnant. This decision should only be entered into after careful consideration. All sterilization techniques should be considered permanent. If you might ever want more children in the future, possibly because of remarriage (the most frequent reason in the United States), you should not choose sterilization now because the success of reversing the sterilization may not be that great. The reported success rates of reversing sterilization vary widely. If, however, you decide you definitely want no more children, you are ready to consider sterilization as the best means of fertility control for you.

It is important to know that there are other means of contraception which, although not as effective as a sterilization operation, do afford you excellent protection against an unwanted pregnancy.

Alternate protection against pregnancy include:

- Oral contraceptives (birth control pills)
- Intrauterine device (IUD)
- Rhythm method
- Barrier methods, such as:
  - Condom
  - Diaphragm
  - Vaginal sponge
  - Spermicidal cream, jelly, foam, and/or suppositories

The advantages of sterilization are that you do not have to be concerned about becoming pregnant and you do not have to continue to use a contraceptive method. The procedure does not effect hormones, menstruation or sex activity. The psychological effect, in most instances, is freedom from the fear of an unwanted pregnancy. Rarely, however, a woman may suffer from temporary guilt or regret over her decision to elect sterilization.

The decision to have surgical sterilization performed must be entirely voluntary, made either by yourself alone or in conjunction with your spouse. To be able to make this decision you must be of legal age in the state in which the procedure is performed. You must also be of sound mind and mentally competent. If you are married it is important that you discuss this with your spouse, and vasectomy as an alternative form of sterilization should be considered. Local laws will be followed in regard to the necessity of the consent of the spouse for a sterilizing procedure.

---

**Sterilization offers no protection against sexually transmitted diseases (STD). Proper protection against STD must be used after sterilization.**

---

**Selection of Patients**

Patients asking about the procedure are first seen in the clinic, where the decision to have no more children is reviewed by the doctor and the couple.

A patient should ask the physician any questions about the procedure that come to mind. The patient may want to inquire how many patients and for how long the physician has been performing this particular procedure. In addition the physician may be able to inform you about his experiences with the procedure.

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The procedure is not recommended for all women who want no more children. Sometimes previous surgery, being overweight, or other medical problems may mean that another solution to her problem should be worked out. But for women with complete families who are sure they want no more children and do not want to use ordinary birth control methods for the rest of their reproductive years, this method is quicker and less expensive than the usual tubal ligation (tying and dividing the tubes) or hysterectomy (removing the womb). Both of these procedures are major surgery - requiring a large incision and several days hospitalization. The laparoscopy method, a 15 minute procedure, is much less complicated.

A doctor and nurse will discuss the details of sterilization and its alternatives, and will perform a complete medical history and physical examination. If everything is in order, sterilization and authorization papers are signed, routine laboratory work is done, and the patient is scheduled to return for surgery.

If couples are practicing no birth control methods, the operation will be scheduled during or just after a menstrual period to avoid the possibility of a fertilized egg getting caught in the divided tube and causing a serious medical problem later on.

### The Operation

On the day scheduled for the operation, the patient arrives in a special day room for outpatient surgery, puts on a hospital gown, and is brought to a holding area near the operating room where an intravenous infusion is started in bed. No special medication or shaving of any part of the body is required. In the operating room the patient is given medication to relax her. An instrument to control the uterus (womb) during surgery will be placed through the vagina.

The abdomen will then be cleansed and draped for the procedure. Legs will be in stirrups, and the table will be tilted slightly head-down for the best view of the pelvis. The abdominal wall will be numbed with local anesthesia in the area below the navel.

About two quarts of carbon dioxide gas are put into the abdomen through a special needle that is inserted just below the navel. This is to let the womb and tubes fall free from other structures so that they can be seen. This little opening in the skin is made slightly larger (about as wide as a fingernail). An instrument called a laparoscope, which is about as big

around as a fountain pen and twice as long, is inserted into the opening. The instrument brings bright light into the abdomen and has a lens system like a microscope so that the surgeon can see all the organs through the clear gas.

The tubes are between the womb and the ovaries and are smaller in size than an ordinary pencil. The Hulka clips will be placed, one on each tube, through this one incision while moving in the womb to get the tubes into the best possible view. Some doctors may make a second smaller opening into the abdomen to get the best possible view of the tubes, of course with more local anesthesia. When the clips are on, the instruments are removed, the gas is let out and the patient leaves in a few minutes with a stitch buried under her skin and a band-aid over her navel.

### Complications

The most serious known potential adverse effect is ectopic pregnancy. Other adverse effects are pregnancy, abnormal menstrual patterns, infection, pain, and trauma (bleeding).

The method failure rate through-out the world is currently 2-6/1,000, similar to that of other sterilization procedures.

Microscopic sections of the tubes of women who needed a hysterectomy after clips revealed normal tubes on either side of the clips, a complete sealing of the tube by the well applied clip, and no inflammatory or foreign body reaction other than the thin tissue covering the clip. Nevertheless, there is a minimal risk that the body might be allergic to such material as metal or plastic to cause an infection or adhesion.

At the time of surgery, about one woman in 100 has an unexpected finding (abnormally located blood vessel, adhesions between the tube and other abdominal contents, etc.) which may require a standard surgical incision to complete the operation safely. Of course, this would lengthen the hospital stay if this event occurred. About two women out of every 100 have to stay overnight, mostly for prolonged recovery from anesthesia. As with any surgical procedure, surgical errors are possible and could include mis-application of the clip, and cutting of unintended tissue or organs. Other unusual risks, including fatality, are always possible, but are as rare as with any common operation.

## After Effects

Afterwards, women may have mild nausea from the medication or procedure, pains in their neck and shoulders (from the gas irritation), pain where the instruments passed through the abdominal wall or discomfort and swelling where the intravenous infusion was started. These last a few hours and are usually gone in a day. Some women experience cramps at or after clip application like menstrual cramps for a day or two after surgery. This may be associated with a sensation of weakness and dizziness in about 5 women out of 100. This is temporary, and is usually gone or almost gone within 2 hours after the procedure. Most women are ready to leave the hospital two or three hours after local anesthesia wears off. There is a discharge like a menstrual flow for a day or two. By the next day, most of these minor symptoms will be gone, though some women will continue to be tired and have aches for a day or two more.

The abdomen may feel swollen for a few days because the muscles stay relaxed after being entered. The incision should be treated as an ordinary skin cut and kept dry for three or four days to assure good healing. A black and blue discoloration around the incision is a mark of a bruise from surgery and will fade away over a period of a week or two. If the incision appears infected, or if the black and blue spots are tender after three or four days, a doctor should look them over to see if the incision is infected. Of course, any other unusual or severe symptom should be reported to the doctor at the hospital immediately.

The sutures holding the small skin opening will dissolve by themselves a few days after surgery and will not need to be removed. Though a postoperative visit is not usually necessary, you may wish to be checked by the surgeon or your local doctor one week after surgery to check on external healing.

Intercourse can be resumed in a few days as soon as the minor symptoms are gone without fear of any complications or pregnancies, since the procedure is effective as soon as the tubes are clipped. There will be no change in your normal hormone function or menstruation since the ovaries are not damaged.

## Pregnancy Rates for Birth Control Methods

Each value given below is an estimate of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

“Lowest expected” rates indicate that the method was used correctly with every act of sexual intercourse but failed anyway. (e.g. remembered to take daily hormonal contraceptive pill, but became pregnant).

“Typical” rates indicate that the method either was used incorrectly, was not used with every act of sexual intercourse, or failed during use (e.g. forgot to take daily hormonal contraceptive pill, and became pregnant).

Method	Lowest Expected	Typical
<b>Sterilization:</b>		
Male sterilization	0.1%	0.15%
Female sterilization	0.4%	0.4%
<b>Hormonal Methods:</b>		
Implant (Norplant™)	0.09%	0.09%
Hormone shot (Depo Provera™)	0.3%	0.3%
Combined Pill (Estrogen/Progestin)	0.1%	3%
Minipill (Progestin only)	0.5%	3%
<b>IUDs:</b>		
Copper T	0.6%	0.8%
Progesterone T	1.5%	2%
<b>Barrier Methods:</b>		
Male Latex Condom	3%	12%
Diaphragm	6%	18%
Cervical Cap (no previous births)	9%	18%
Cervical Cap (previous births)	26%	36%
Vaginal Sponge (no previous births)	9%	18%
Vaginal Sponge (previous births)	20%	36%
Female Condom	5%	21%
Spermicide (gel, foam, film)	6%	21%
<b>Natural Methods:</b>		
Withdrawal	4%	19%
Natural Family planning (calendar, temperature, cervical mucous)	1-9%	20%
No Method	85%	85%

Data adapted from:

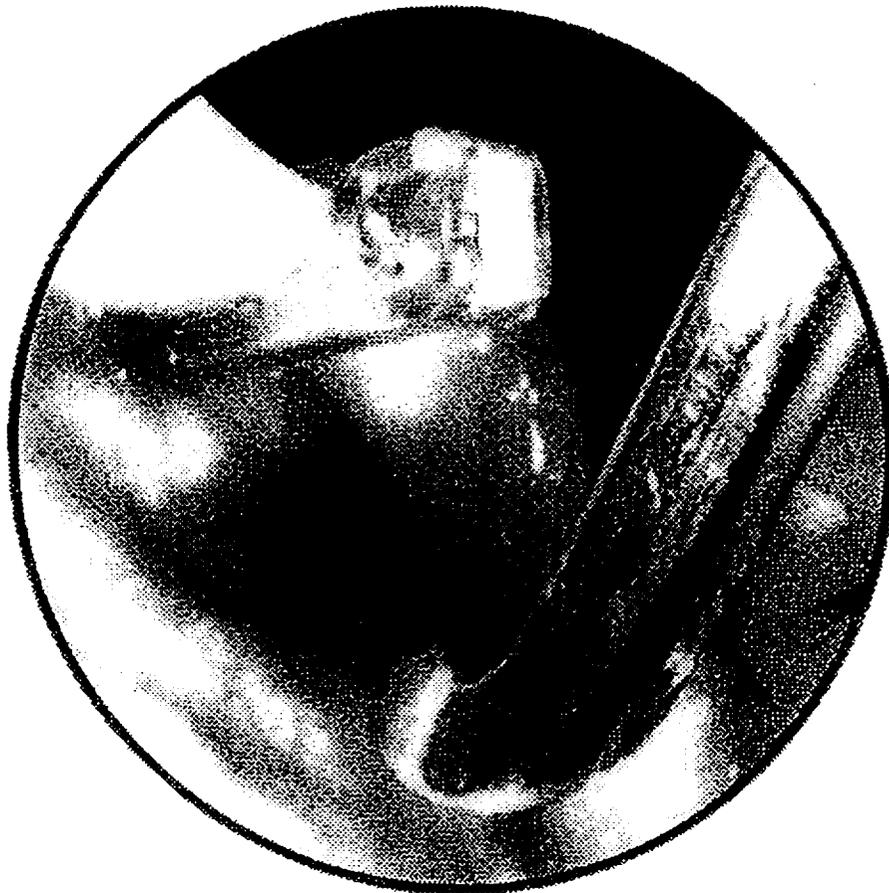
R.A. Hatcher, J. Trussell, F. Stewart, et al. (eds.), Contraceptive Technology, 16th Revised edition, New York, NY: Irvington Publishers Inc., Chapter 5 (1994).

# Laparoscopic Sterilization with Hulka Clips

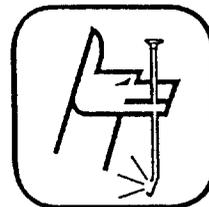
E31C-09-96

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# FORWARD

Tubal occlusion by means of the Hulka Clip, is a unique surgical procedure.

This manual illustrates the instrumentation needed to perform this surgical procedure, the function and application of the Hulka Clip, the applicators available and the technique in applying the Hulka Clip to the fallopian tube by means of simulation.

The following pages are intended as a guide and should not be regarded as a medical surgical procedure text.

Caution: Federal (USA) law restricts this device to sale, distribution, use by or on the order of a physician with appropriate training and experience.

**Our sincere gratitude to Jaroslav F. Hulka, M.D. for his contribution in the writing of this manual.**

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## DEVICE DESCRIPTION

The Hulka Clip Tubal Occlusion Device consists of two plastic jaws made of polycarbonate. The upper jaw is 0.534" long and 0.130" wide. The lower jaw is the same width but 0.599" long. Each jaw has teeth (0.040" long) on the opposing surfaces. These teeth are hinged together 2mm from one end of the assembled jaws by one fulcrum pin (stainless steel) which is 0.128" long and 0.031" in diameter. At the far end of the clip, a gold plated spring (stainless steel) which is 0.473" long, 0.148" high, and 0.0625" wide holds the clip's jaw in an open position. The compressive strength of the spring is 3 ounces. Hulka-Clip Applicator Systems are reusable after proper gas or steam sterilization.

Hulka Clip Applicators have been developed for both single and double puncture laparoscopic techniques. The original single puncture applicator fits through a 10mm sleeve, housing a 5mm optic which can be used separately for diagnostic work with a 5mm sleeve. The double puncture technique utilizes a 10mm diagnostic scope with a separate 7mm applicator. The equipment includes a channel for spraying topical anesthetic directly onto the tube at the time of clip application

Hulka Clip applicator Systems are reusable after proper gas or steam sterilization.

The Hulka Clip is held firmly in the jaw of the applicator such that repeated safe opening and closing is possible during insertion through trocars, testing of the application, and manipulation of the tube. Lateral manipulation of the uterus with a special tenaculum with cervical jaws and intrauterine extension puts the tube on a stretch during these procedures, providing maximum availability to the clip applicator.

## INDICATIONS FOR USE

The Hulka-Clip Tubal Occlusion Device and Applicator systems is a contraceptive tubal occlusion device (TOD) indicated for use for female sterilization (permanent contraception) by occluding the fallopian tubes.

## CONTRAINDICATIONS

The Hulka Clip should not be applied when the following conditions exist:

1. Significant peritubular adhesive disease obscuring the isthmic portion of the tube and impairing tubal mobility.
2. Salpingitis isthmica nodosa or chronic isthmic induration.
3. Acute pelvic inflammatory disease.
4. Patient conditions which contraindicate surgery or the use of anesthesia.
5. Significant hemoperitoneum or suspicion of ectopic pregnancy.
6. Pregnancy or suspicion of pregnancy.
7. Allergy to gold.

## WARNINGS

### 1. PELVIC DIATHERMY

Do not use pelvic diathermy for patients who have undergone sterilization with the use of Hulka Clips.

### 2. PREGNANCY

- a. Women sterilized postpartum or postabortion may be at increased risk of pregnancy. The pregnancy rate following tubal sterilization of postpartum patients is higher than that reported for interval patients
- b. Pregnancy, though infrequent may occur following Hulka Clip application. Women with pre-existing pelvic inflammatory disease (PID), and obesity may be at increased risk of sterilization failure.
- c. Pregnancies following this procedure are usually associated with applications which have not been completely placed across the isthmic portion of the fallopian tube.

### 3. ECTOPIC PREGNANCY

- a. Although rare, ectopic pregnancy has occurred following Hulka Clip sterilization.

Tubal sterilization is estimated to carry a small but higher risk of ectopic pregnancy than barrier contraception or oral contraceptives.<sup>1</sup> Patients who become pregnant following Hulka Clip sterilization should be carefully evaluated for the possibility of ectopic pregnancy.

- b. Special attention should be directed to patients with delayed menses, slight metrorrhagia and/or unilateral pelvic pain to determine if ectopic pregnancy has occurred.<sup>1</sup>

### 4. UNINTENDED MAJOR SURGERY

- a. Trauma to pelvic organs, though infrequent, may occur during laparoscopic Hulka Clip application.
- b. Trauma may result in unintended major surgical intervention (laparotomy) and repair. Unintended major surgery is more frequent among women with intra-abdominal adhesions, obesity, history of pelvic inflammatory disease, diabetes mellitus, prior intrauterine devices (IUD) use and lung disease. These patients should be carefully evaluated prior to implantation.

### 5. TECHNICAL FAILURES

- a. Technical failures have been associated with equipment malfunction. Both the operator and support personnel should be familiar with the operation, sterilization and maintenance of the Hulka Clip Applicator and associated devices prior to use.
- b. Technical failures resulting in the changing of the planned procedure to another sterilization procedure or abandonment of the sterilization procedure, though infrequent, may be required during a Hulka Clip procedure. Technical failures are more likely among women with enlarged uteri with pre-existing patient factors such as peritubular adhesive disease, obesity, or prior IUD use. These patients should be carefully evaluated prior to implantation.

### 6. INFECTION

- a. Pelvic infection may result in tuboovarian abscesses, endometritis, or salpingitis.
- b. Incisional infection may occur following tubal sterilization.
- c. Urinary tract infections may occur following tubal sterilization.

## 7. INJURIES

- a. Injuries to the fallopian tube, mesosalpinx and cornu, though infrequent, may result from Hulka Clip application. Mesosalpingeal or tubal injury is more likely among women with pre-existing peritubular adhesions, or thick edematous tubes. Caution should be used for patients with enlarged uterus, enlarged tubes, adhesions, or superior mesosalpinx.
- b. Transection of the fallopian tube, mesosalpinx or cornu, though infrequent, may result in bleeding and hematoma formation. If bleeding is uncontrolled, surgical intervention and repair or completion of the sterilization procedure using another tubal occlusion methodology may be required.

## PRECAUTIONS

1. For each procedure, use only clips enclosed in the sealed, sterile package. Do not allow the plastic of the clip to come in contact with cloth or talcum powder on gloves. The lint particles and talcum or starch particles adhere electrostatically to the plastic and will promote a granulomatous reaction on the surface of the clip during the healing process.
2. If the spring is dislodged from the plastic jaws, discard the clip and use another one. If the clip is closed before application, discard and use another one. If the spring is partially advanced over the jaws, it can be manually pulled back to the position where it opens the jaws. If the spring or jaws are damaged during loading or an attempt at application, discard the clip and use another one.
3. Check the operation of the applicator prior to use.
4. Improper loading and testing of the applicator may result in Hulka Clips being inadvertently discharged into the peritoneal cavity or an incorrectly placed clip. Refer to this Operating Manual for the proper insertion of clips into the applicator and recommended course of action for an incorrectly placed clip.
5. Confirm the location of the pelvic organs before the Hulka Clip application to prevent inadvertent application to an inappropriate anatomical structure.
6. This device has **not** been demonstrated to be Magnetic Resonance Imaging (MRI) safe and compatible.

## 7. LONG TERM SEQUELAE

- a. The inert Lexan resin, #316 stainless steel, and gold plating used in the manufacture of the Hulka Clip are generally regarded as safe materials for human implantation. Although no adverse toxic or tumorigenic effects due to the device or its materials have been reported, the effects of long term implantation are unknown.
- b. The long term effects of tubal sterilization on women is unclear. Several uncontrolled studies suggest that women undergoing tubal sterilization may be prone to gynecological problems.<sup>2,3</sup> Other recent controlled studies report that sterilization does not cause any long term effects.<sup>4</sup>

## 8. PATIENT COUNSELING

- a. Prior to sterilization, the physician or his designate should provide the patient with counseling and inform the patient of the risks and benefits of the procedure and alternate means of contraception. The patient should be given the opportunity to discuss fully any questions she may have concerning the Hulka Clip and the surgical procedure. The patient should be fully informed of the side effects of the procedure and potential complications during and following the procedure. The patient should be advised that if any postoperative symptoms are severe or persist she should see her physician.
- b. The patient should be informed that sterilization will not prevent sexually transmitted diseases (STD). Additional precautions against STD must be still be taken after sterilization.
- c. Richard Wolf provides a patient pamphlet that should be given to any patient considering sterilization with the Hulka Clip. These pamphlets are provided with each box of clips purchased. If additional quantities of the pamphlet are required please contact your local sales representative or Richard Wolf's customer service. The pamphlet may be copied as required.

## ADVERSE EFFECTS

In a clinical study of 1,151 subjects, the following adverse effects have been reported with the use of the Hulka Clip:

1. A total of 13 post-sterilization pregnancies were reported for the 1,151 women sterilized (1.12%).
2. Pelvic pain was reported for 150 patients (13%) in the immediate post-operative period. Pain, in the form of cramping, pelvic or shoulder discomfort, or headache may occur during the procedure and the initial postoperative period.
3. The effects of tubal sterilization on menstruation is unclear. Some publications reported increased incidence of irregularity and pain while other publications reported no change.<sup>4,5</sup>
4. Tubal or mesosalpingal injury without bleeding occurred in 7 out of 1,151 patients (0.7%) and tubal or mesosalpingeal bleeding occurred in 3 out of 1,151 patients (0.3%). Trauma and bleeding of the pelvic organs may occur during laparoscopy Hulka Clip procedures and result in major unintended surgery (laparotomy).
5. In the clinical study (1,151 patients), uterine infections were reported for 2 patients (0.2%) seen during the long term follow-up period. Four other infections (0.4%) were reported from sterilization to discharge (recovery period) and one other infection (0.1%) was reported during the early follow-up (within 30 days). Incisional, urinary tract, or pelvic infection may occur following the procedure and may result in the development of tuboovarian abscesses or general peritonitis.

The following adverse effects were not observed in the clinical study but have been reported with the use of the Hulka Clip.

6. Adverse tissue effects may occur as a result of a gold allergy or standard inert foreign body reaction. There has been one report of an allergic reaction to the gold plate in the literature.<sup>6</sup>
7. The following adverse effects have been reported from surgical procedures to implant the Hulka Clip:

omental emphysema; abdominal wall emphysema; cervical, omental, ovarian, uterine, or peritoneal laceration; incisional bleeding; bladder injury; excess blood loss/shock;

incisional dehiscence; incisional infection; urinary tract infection; vaginal bleeding; incisional keloids; omental blood vessel bleeding; pelvic infection; uterine perforation; and febrile morbidity.

8. The following adverse effects were not observed in the clinical study of the Hulka Clip, but have been reported with the use of the Hulka Clip. The adverse effects include ectopic pregnancy, misapplication to ovarian ligament, broad ligament, round ligament, omentum, bowel, tubal seosa or cornual; mesosalpingeal laceration; tube ovarian abscess; device migration through a tube ovarian and abdominal wall abscess. Other adverse effects related to laparoscopic application but not related to the Hulka Clip include death from myocardial infarction.
9. Intraoperative and postoperative complications, in the forms of unintended major surgery, febrile morbidity and re-hospitalization, were not observed in the clinical study, but may occur following laparoscopic tubal sterilization. Preoperative and operative factors associated with an increased incidence of complications include presence of diabetes mellitus, previous abdominal or pelvic surgery, lung disease, history of pelvic inflammatory disease, obesity, and use of general anesthesia. Though complications are more likely with the designated risk factors, the absolute incidence of complications is low and none of these conditions contraindicate sterilization with the Hulka Clip.

### CLINICAL TRIAL

The primary measure of effectiveness of the clip was the resulting pregnancy rate. To determine this effectiveness a controlled clinical trial was conducted by the International Fertility Research Facility (IFRP). This study involved 1,151 women who underwent permanent sterilization between 1975 and 1982.

A total of 13 post-sterilization pregnancies (1.12%) were reported by the participants. Four of these pregnancies were luteal phase pregnancies that occurred before sterilization and are excluded from the results. The pregnancy rate for the device was 0.78% (9 non-luteal phase pregnancies / 1,151 women).

Eight pregnancies occurred within the first year. One occurred during the first month, 6 occurred within the first 6 months and one occurred between 7 and 12 months. The 12 month cumulative pregnancy rate is 0.86% (95% confidence limits are 0.26% to 1.45%). An additional pregnancy occurred after 36 months. The 48 month cumulative pregnancy rate is 1.34% with 95% confidence intervals of 0.22% to 2.46%.

## References

1. Bhiwandiwalla PP, Mumford SD, Feldblum PJ. Comparison of different laparoscopic sterilization occlusion techniques in 24,439 procedures. *Am J Obstet Gynec* 1982; 144: 319-31.
2. Chi I-C, Potts M, Wilkens L. Rare events associated with tubal sterilizations: an international experience. *Obstet Gynecol Survey* 1986; 41: 7-19.
3. Chi I-C, Feldblum PJ, Higgins J. Ectopic pregnancies following female sterilization. *Acta Obstet Gynecol Scand* 1984; 63: 517-21.
4. Huggins GR, Sondheimer SJ. Complications of female sterilization: immediate and delayed. *Fertil Steril* 1984; 41: 337-55.
5. Hulka JF. *Textbook of Laparoscopy*. Orlando, FL: Grune and Stratton, 1985.
6. Lieberman BA, Belsey E, et al. Menstrual patterns after laparoscopic sterilization using a spring-loaded clip. *Br J Obstet Gynaecol* 1978; 85: 376-380.

## Pregnancy Rates for Birth Control Methods

Each value given below is an estimate of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

“Lowest expected” rates indicate that the method was used correctly with every act of sexual intercourse but failed anyway. (e.g. remembered to take daily hormonal contraceptive pill, but became pregnant).

“Typical” rates indicate that the method either was used incorrectly, was not used with every act of sexual intercourse, or failed during use (e.g. forgot to take daily hormonal contraceptive pill, and became pregnant).

Method	Lowest Expected	Typical
<b>Sterilization:</b>		
Male sterilization	0.1%	0.15%
Female sterilization	0.4%	0.4%
<b>Hormonal Methods:</b>		
Implant (Norplant™)	0.09%	0.09%
Hormone shot (Depo Provera™)	0.3%	0.3%
Combined Pill (Estrogen/Progestin)	0.1%	3%
Minipill (Progestin only)	0.5%	3%
<b>IUDs:</b>		
Copper T	0.6%	0.8%
Progesterone T	1.5%	2%
<b>Barrier Methods:</b>		
Male Latex Condom	3%	12%
Diaphragm	6%	18%
Cervical Cap (no previous births)	9%	18%
Cervical Cap (previous births)	26%	36%
Vaginal Sponge (no previous births)	9%	18%
Vaginal Sponge (previous births)	20%	36%
Female Condom	5%	21%
Spermicide (gel, foam, film)	6%	21%
<b>Natural Methods:</b>		
Withdrawal	4%	19%
Natural Family planning (calendar, temperature, cervical mucous)	1-9%	20%
No Method	85%	85%

Data adapted from:

R.A. Hatcher, J. Trussell, F. Stewart, et al. (eds.), Contraceptive Technology, 16th Revised edition, New York, NY: Irvington Publishers Inc., Chapter 5 (1994).

These instructions have been written to introduce you to the technique of laparoscopic clip sterilization. The whole exercise should take about 2 hours for an experienced laparoscopist, and will be an invaluable aid in familiarizing yourself with the applicators and their mechanisms, as well as with common clinical errors in practice and ways to avoid them.

These instructions are applicable when using the second puncture clip applicator, or with the single puncture clip applicator through the RICHARD WOLF 12 mm Operating Laparoscope.

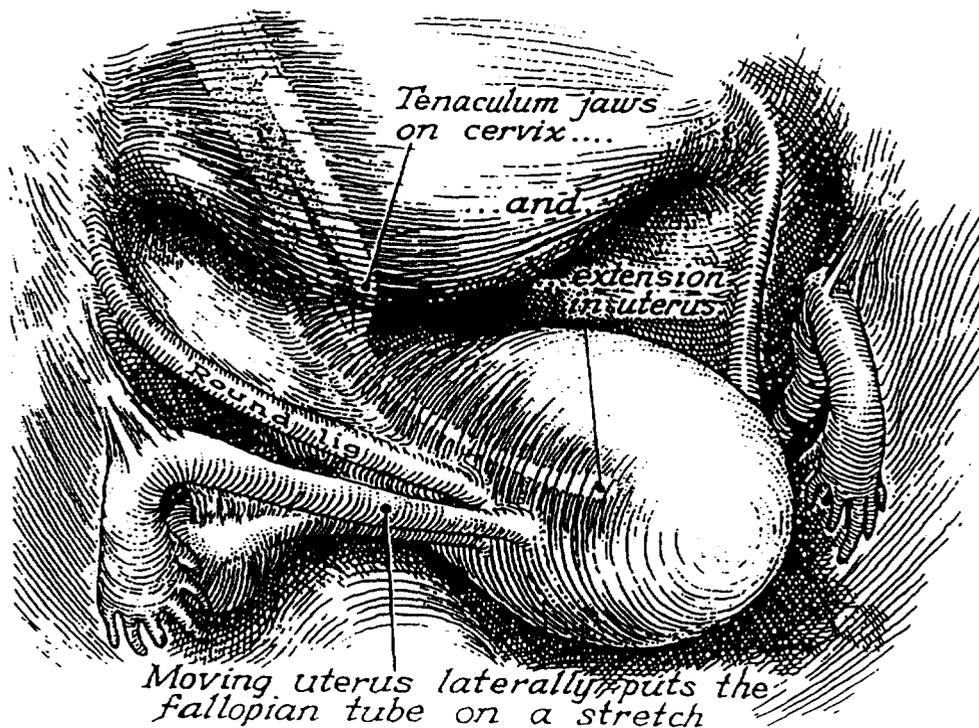
## LAPAROSCOPIC STERILIZATION WITH HULKA CLIPS

Clip application requires complete control of uterine mobility, so that the fallopian tube can be stretched across the true pelvis. This can be accomplished by angling and rotating the uterus from the lateral pelvic wall supports of the tube you wish to view and/or clip (Fig. 1).

FIGURE 1: Illustrates the technique of manipulating the uterus in order to put the tube on a stretch (for maximal clip application). A controlling instrument, with the features of a uterine sound and tenaculum, is inserted into the uterus and the uterus is anteverted. During surgery, the surgeon should move the uterus laterally with

the tenaculum in such a way as to put the fallopian tube on a stretch. In contrast to electrocauterization or band application, this often requires the uterus to be drawn down into the pelvis, so that the infundibulopelvic ligaments cause the tube to be stretched horizontally deep in the true pelvis, rather than protruding into the abdominal cavity at an angle oblique to the applicator. Thus, the most advantageous manipulation with the combined tenaculum-sound, is a downward and sideways displacement of the uterus into the true pelvis so that the tube is stretched across the midline.

FIGURE 1



## MECHANISM OF ACTION OF THE HULKA CLIP

The Hulka Clip has been designed to be applied onto the fallopian tubes in such a way as to prevent its being dislodged by peristalsis, to eliminate hemorrhage at the time of application, and to minimize the possibility of recanalization. The Hulka Clips are packaged in the open position (Photo 1). Each package contains two Hulka Clips.

The closed clip is shown in Photo 2. In this position, the clip measures a little over 1cm in length, and is 3x4mm in cross-sectional diameter. It cannot be opened after the spring is closed except by delicate disassembly of the clip. If this happens before application on a tube, discard the clip for human use. If for any reason the spring has been weakened so that it does not hold the jaws open by itself, discard the clip and use another one.

Each Hulka Clip consists of two plastic jaws (Made of inert Lexan resin) which are hinged together by a small medical grade stainless steel pin about 2mm from one end of the assembled jaws. Each jaw has teeth on the opposing surfaces, which penetrate the fallopian tube at the time of closure and prevent the tube from falling out of the clip. At the far end of the clip, beyond the pin, a gold plated, stainless steel spring holds the clip's jaws in an open position as shown in Photo 1.

This spring must not be bent beyond the limits described below, or it will lose its tension and effectiveness.

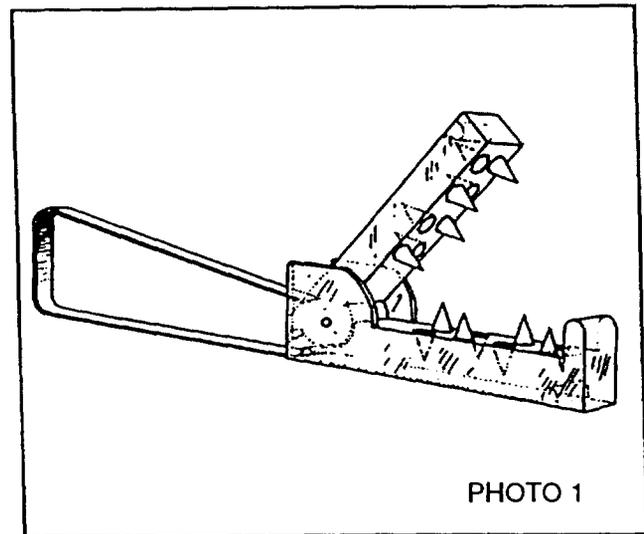


PHOTO 1

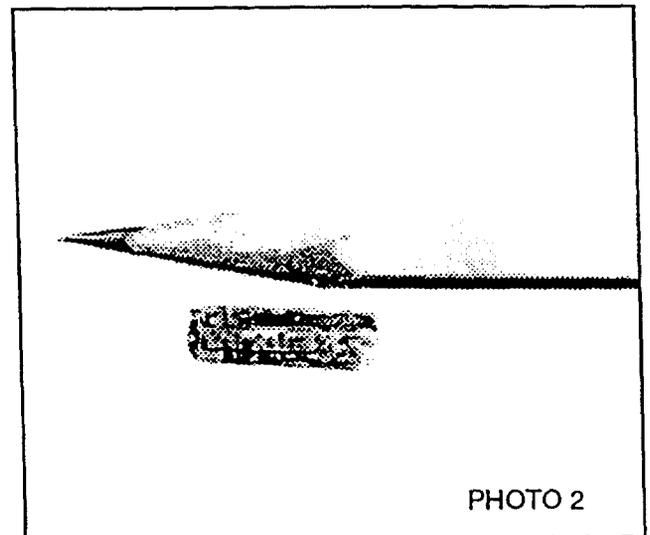
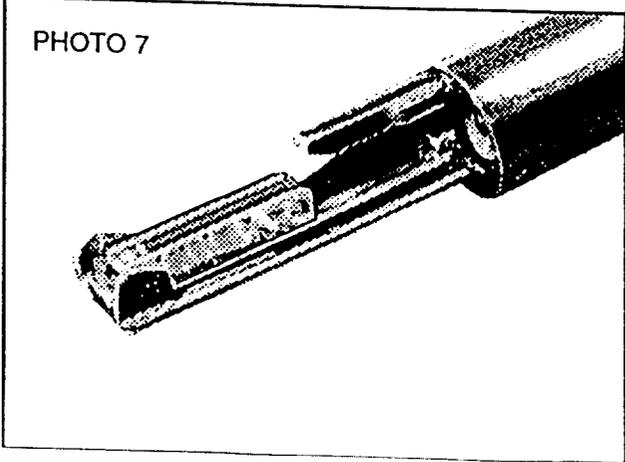
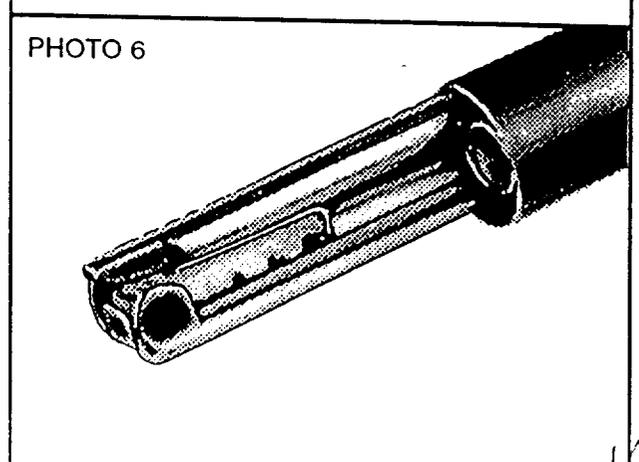
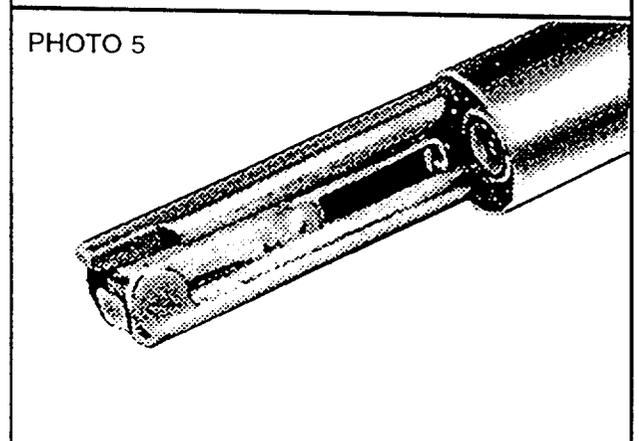
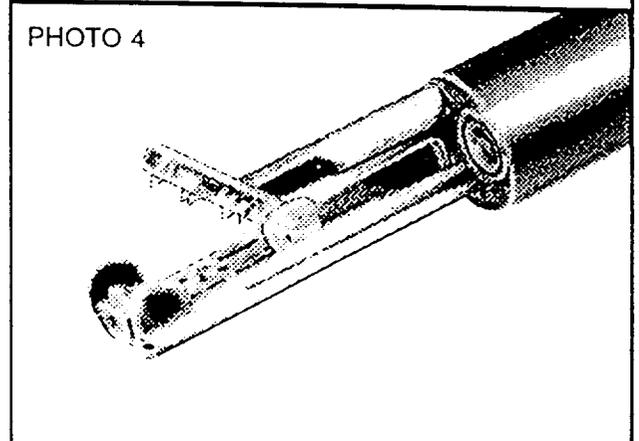
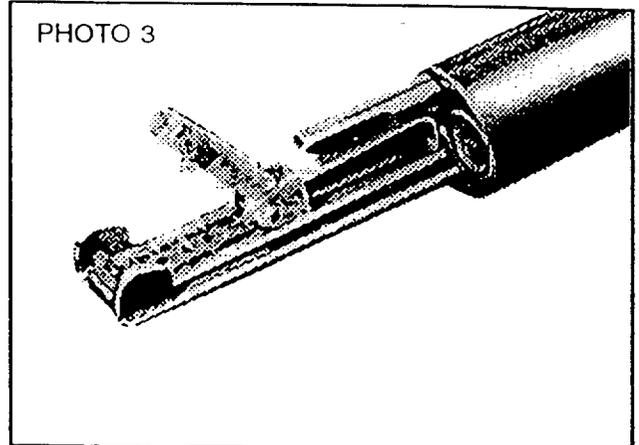


PHOTO 2

The clip is inserted into the applicator in the full open position as is shown (Photo 3). In the operation of the instrument, the upper ramrod is now advanced and holds the clip from falling out of the applicator in an open "safety" position (Photo 4). The upper ramrod is advanced to close the clip (Photo 5), allowing the instrument to be inserted through the sleeve. Just before inserting, however, open and close the jaws to make sure the clip will open inside the abdomen. In the abdomen, the clip is kept closed while studying the anatomy, and is opened again to the "safe open" position (Photo 5). After the clip is on the tube, the lower ramrod is pushed forward, advancing the spring over the clip (Photo 6).

At this point, the upper ramrod is pulled completely back (past the safety catch) and the lower ramrod is pushed back by its spring. This permits the clip to slide free from the clip applicator and remain on the tube (Photo 7 below). NOTE: Be sure to follow and practice these and all instructions to be certain that the placement of the Hulka Clip is an accurate one. At this point during your surgical procedure, should you place the clip incorrectly, you will not be able to retrieve the clip.

The instrument is held in the surgeon's right hand, (Photo 8, page 12) the thumb being the active finger which moves both the upper and lower ramrods; the other fingers mainly stabilize the instrument. The tip of the index finger is placed through the upper stabilizing ring, the third finger is placed above or below the laparoscope itself, and a fourth finger is placed in the lower stabilizing ring. The index finger activates the safety release to be described later. Please study this photograph of the correct hand application and practice it on the laparoscope.



SB

The photos on this page are arranged in the same sequence as are the photos of the clips on the previous page. Please use the applicator to compare the positions of the upper ramrod and lower ramrod as controlled by the hand (Photos 8-12) and see the effect these positions have on the upper and lower ramrods on the clip (Photos 3-7).

The upper ramrod has 3 important positions. The first photograph (Photo 8) shows the "full open" position. The safety catch consists of a curved metal hook which is spring-loaded. When the upper ramrod is advanced, it will fall within the safety catch as shown in Photo 9. Please study the first and second photographs comparing the "full open" position to the "safe open" position. The purpose of the safety catch is to assure that the clips will not accidentally fall out in the abdomen during manipulation.

The third position of the upper ramrod is completely forward which advances the upper ramrod over the upper jaw of the clip and closes it over the tube. This is done by pushing further forward with the thumb as shown in the third photograph (Photo 10). This ramrod should be fully advanced before the lower ramrod is moved.

When the clip is closed on the tube by the upper ramrod, the thumb should be taken out of the upper ring and placed onto the lower ramrod. This is shown in Photo 11. The ramrod is spring-loaded so that it normally assumes and maintains an open position. Push this completely forward.

At this point the clip is completely closed. Releasing the thumb will allow the spring-loaded lower ramrod to open again without further effort. At this point, the upper ramrod should be drawn back to its "safe open" position, and the safety latch released with the index finger as shown in Photo 12. The index finger can release this bar easily, allowing the upper ramrod to be drawn back to the "full open" position.

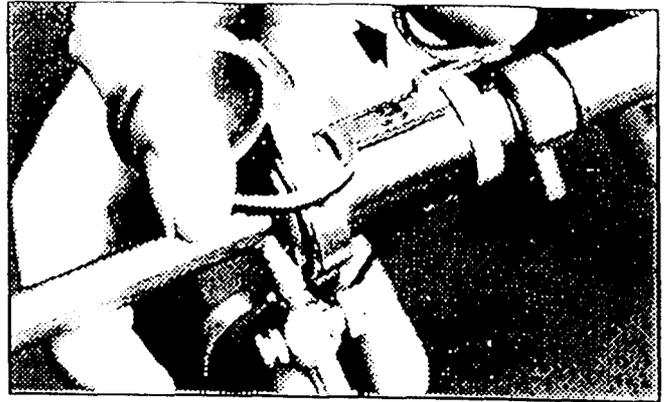


PHOTO 8

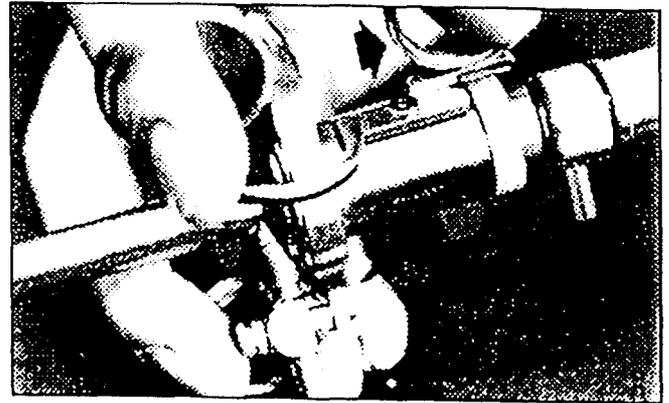


PHOTO 9

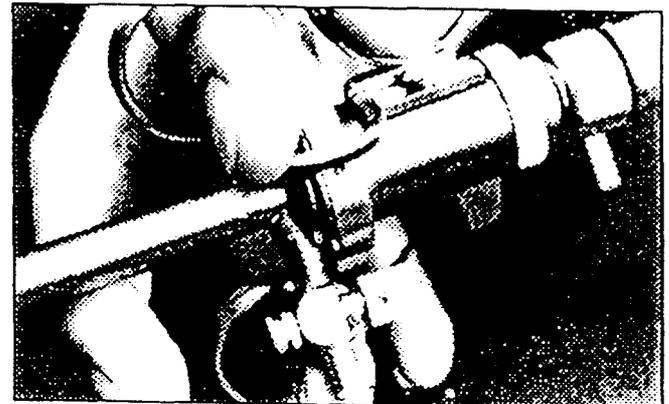


PHOTO 10



PHOTO 12

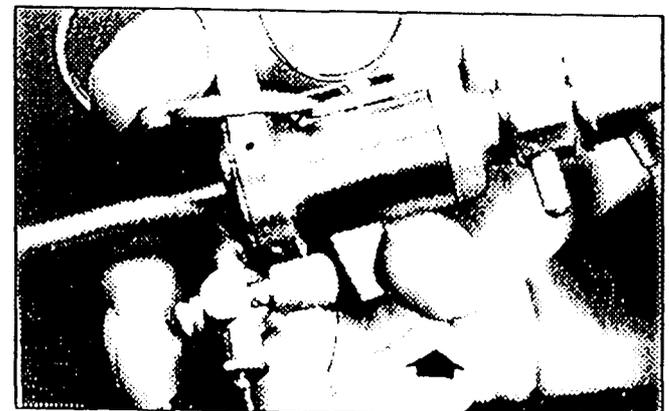


PHOTO 11

54

At the time of insertion of the laparoscope through the trocar, the upper ramrod must be closed with the clip in place. When the tube is positively identified, and the clip is about to be placed around it, the upper ramrod should be brought back to the safety position (but not beyond it) at which point the clip will open to its maximal position. If it does not, you may have accidentally pushed the lower ramrod forward, closing the spring. Remove the instrument and make sure the spring is not over the clip. If it is partially over, it can be pushed back to open the jaws of the clip again. When the tube is grasped by the open clip, the upper ramrod is pushed forward, closing the ramrod over the clip. The upper ramrod should remain closed on the clip until the lower ramrod is pushed forward.

Rarely, the clip may partially dislodge itself from the distal end and become stuck under the upper ramrod. Should this happen, drive the clip in Photo 13. This should free the clip applicator.

Photo 14 shows the hand and clip applicator as originally designed. With experience in the operating room moving the applicator through the different angles necessary for clip application, it will be seen that this is a comfortable way of holding the instrument.

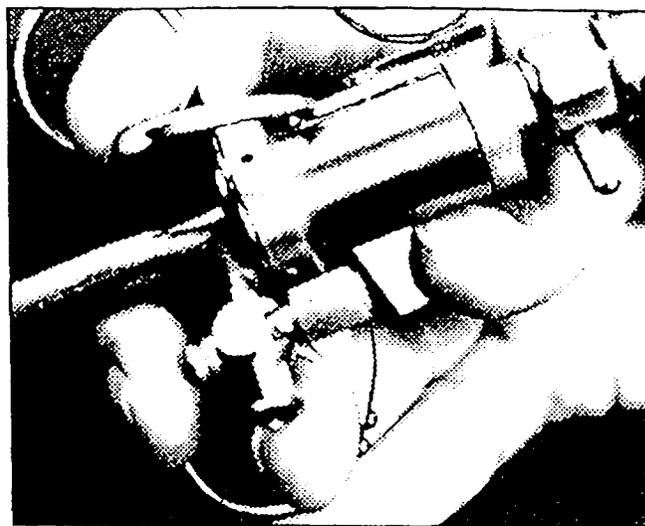


PHOTO 13

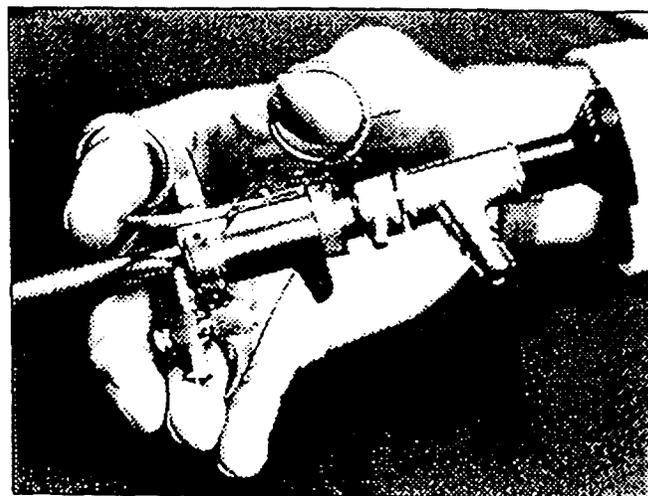


PHOTO 14

This technique is shown in diagrammatic form in the following series of photographs. As can be seen, the clip in the open position can get around most tubes (Photo 15). The metal holder for the tube is designed to prevent the tube from rolling out of the clip while the upper jaw is being pressed down. This is the grey semi-circular metal hook at the very end of the laparoscopic instrument. As the upper ramrod closes the jaw, there is a 1mm gap left between the upper and lower jaws of the clip (Photo 16). This gap is designed to prevent tearing of the tube, or any venous or arterial blood vessels which might be in the clip. This space will become obliterated by action of the spring over the next two or three day period, assuring maximal safety in terms of the prevention of hemorrhage and maximal effectiveness in terms of prevention of recanalization.

When the lower ramrod is advanced, the Hulka clip is caught in two notches on the upper and lower jaws in such a way that the clip cannot be accidentally dislodged. These notches are shown by the arrows on the diagram on the next photograph (Photo 17). Finally, when the clip is applied, both the upper and lower ramrods are retracted, permitting the applied clip to fall free into the abdominal cavity in the final position closed (Photo 18).

#### REVIEW OF MECHANISM OF ACTION:

A. Examine a practice Hulka clip (with metal bar at the end of the clip) in the open position. Review the workings of the clip itself, as well as the workings of the upper ramrod, the lower ramrod and the safety catch. Practice until you are able to perform these operations in sequence while looking at your hand and the end of the applicator.

1. Release safety latch and open the upper ramrod to the full open position.
2. Load a clip into the operating end of the instrument.
3. Close the upper ramrod to the safety position.
4. Close the upper ramrod to the closed position.
5. Move the upper ramrod to open and close the jaws of the clip.
6. Close the jaws of the clip and activate the lower ramrod by pushing the lower ramrod so as to bring the spring over the upper and lower jaws of the clip.
7. Release the lower ramrod, pull the upper ramrod back to its safety open position.
8. With the index finger, press the safety release so as to allow the upper ramrod to be pulled completely back to the full open position.

Please go through these steps sequentially, practicing them until they can be done automatically in approximately 30 seconds time.

B. When this is a comfortable operation, repeat all the steps in Part A while looking through the optic. You will probably notice your hand will have to shift position now that the clip applicator is near your eye. Practice so that your eye never leaves the scope while closing the upper ramrod, lower ramrod and releasing the upper ramrod to full open (steps 5-7 above).

PHOTO 15

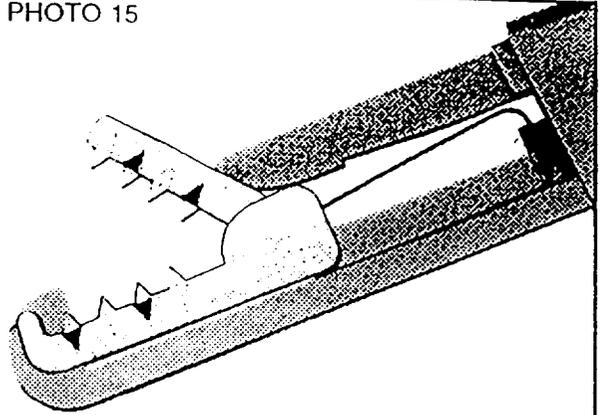


PHOTO 16

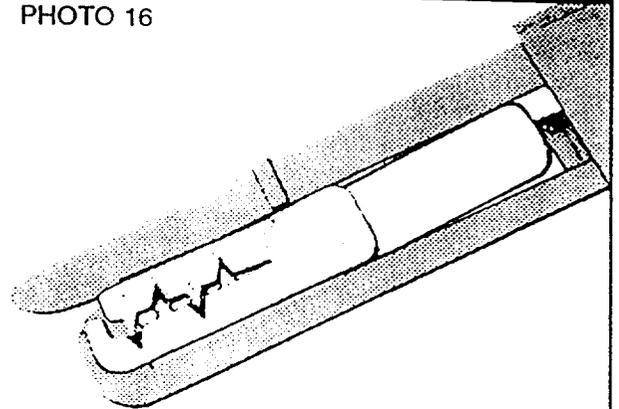


PHOTO 17

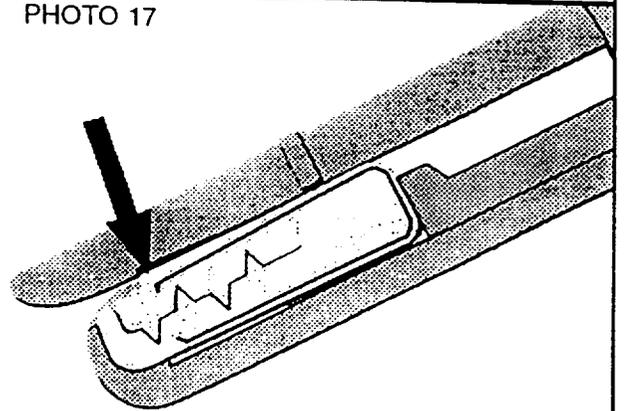
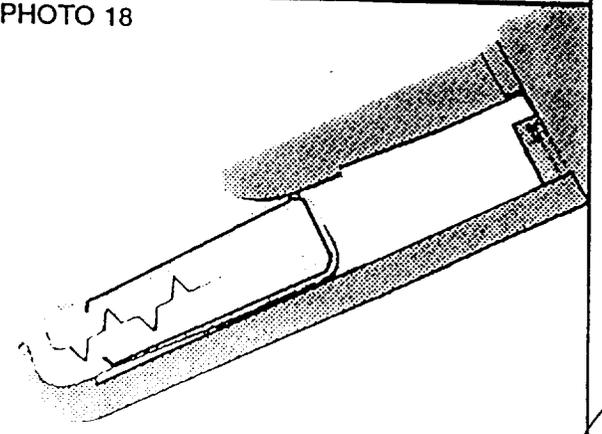


PHOTO 18



## INSTRUMENTATION

Downward and sideward displacement of the uterus into the true pelvis so that the tube is stretched can be accomplished, in the undilated uterus, with a special uterian mobilizer (Photo 19). With this combination sound, to antevert axis (see Fig. 1, page 9), the task is performed with ease.

For the recently evacuated uterus (us to 12 weeks size), a controlling forceps is needed to avoid perforation and accomplish the control in the larger, softer uterus (Photo 20).

To insert these instruments, a single hinge Graves speculum with a lateral opening is very convenient (Photo 21).

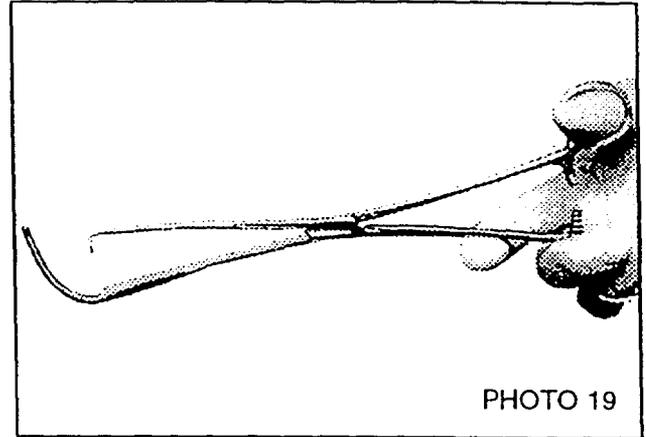


PHOTO 19

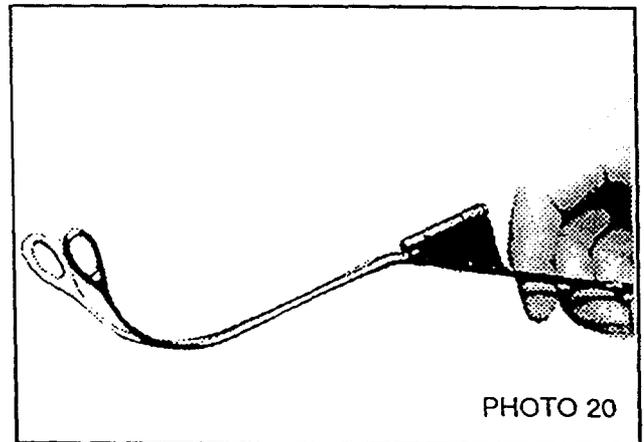


PHOTO 20

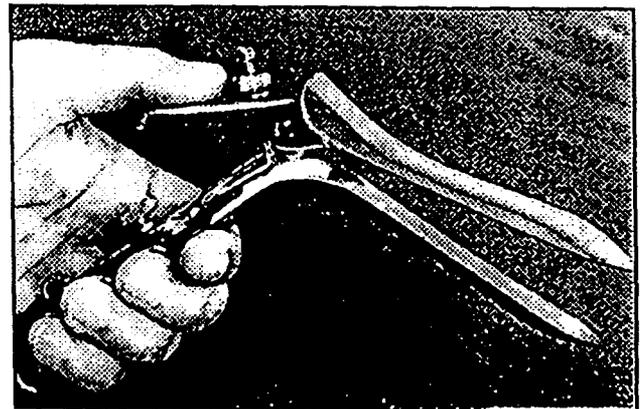
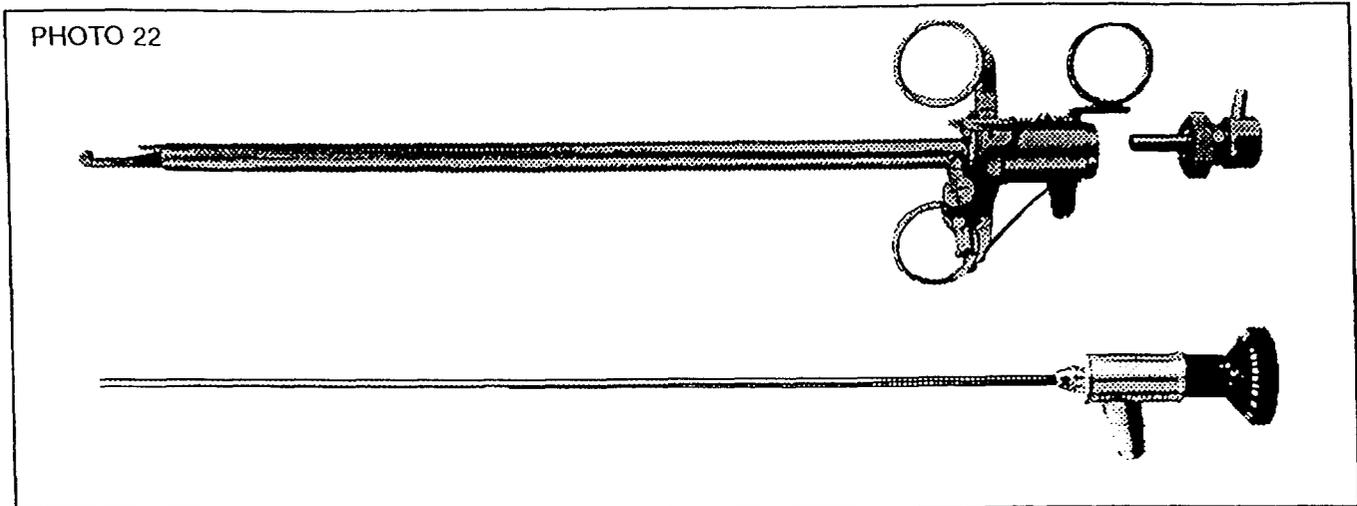


PHOTO 21

5

) SINGLE PUNCTURE HULKA CLIP APPLICATOR



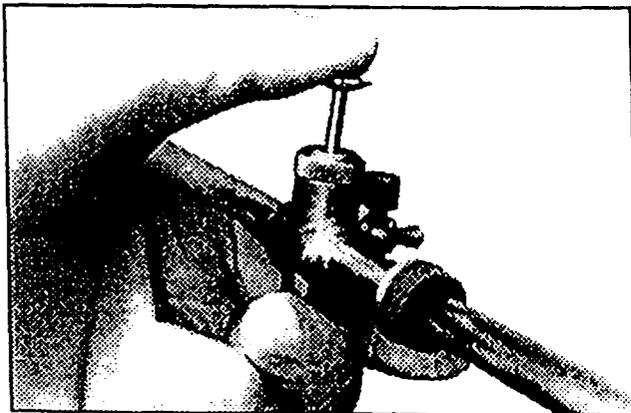
) The original Hulka Clip applicator consisted of two components: a standard 5mm optic components shown in the lower part of Photo 22, and the clip applying instrument shown in the upper part of Photo 4. The 5mm optic slides within a sleeve in the clip applicator, and is removable for separate use - (e.g. for diagnostic procedures through a 5mm trocar sleeve).

) When inserting the assembled clip applicator into a standard 10mm sleeve, it is first passed through the rubber gasket of the sleeve up to the trumpet valve as shown in the next photograph (Photo 23). The trumpet valve can now be depressed without excessive loss of gas.

) The laparoscope is now inserted so that it is within the portion of the sleeve between the trumpet valve and the

tip. It should not be pushed all the way through the sleeve, since the surgical parts at the end of the instrument may snag abdominal contents. The relative distance of insertion of the applicator into the sleeve is shown in the photograph (Photo 24).

After the scope is inserted this distance, the light cable should be connected and the scope advanced further through the sleeve under direct vision until it is certain that the abdominal cavity has been entered. Similarly, when the laparoscope is removed, it should be removed only under direct vision until it is well within the sleeve. Failure to do so may cause inadvertent snagging of bowel or omentum on removal.



) PHOTO 23

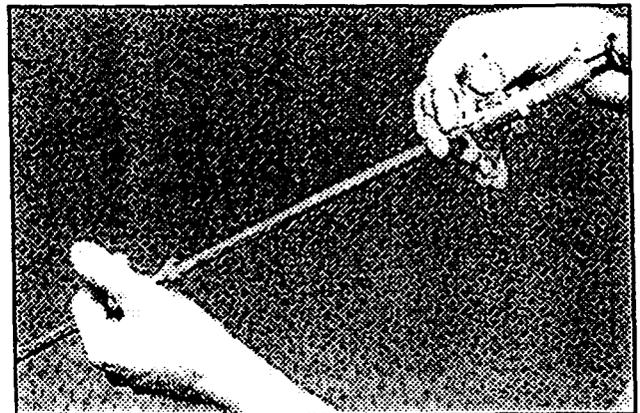


PHOTO 24

**HULKA CLIP APPLICATOR**  
**DOUBLE PUNCTURE APPLICATOR (7mm dia.)**

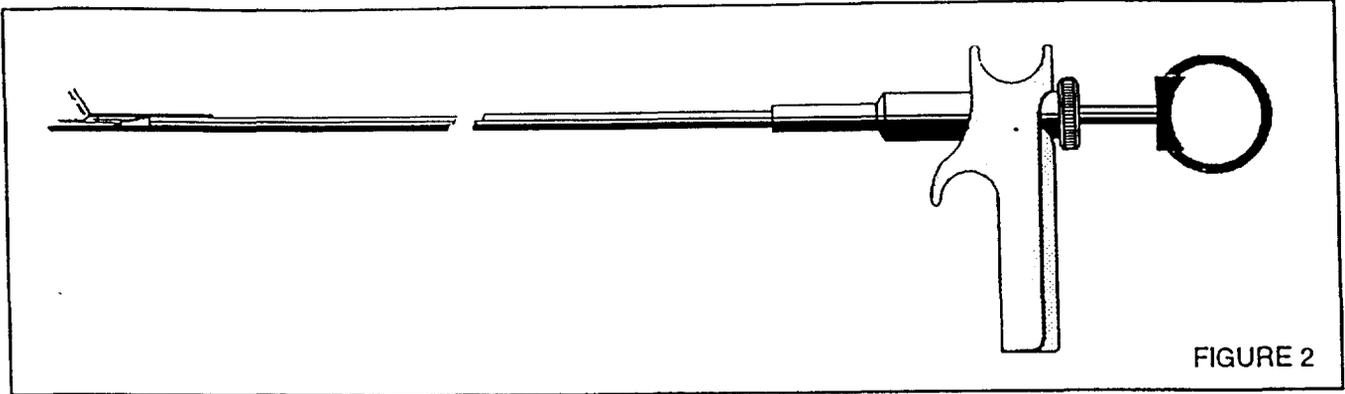


FIGURE 2

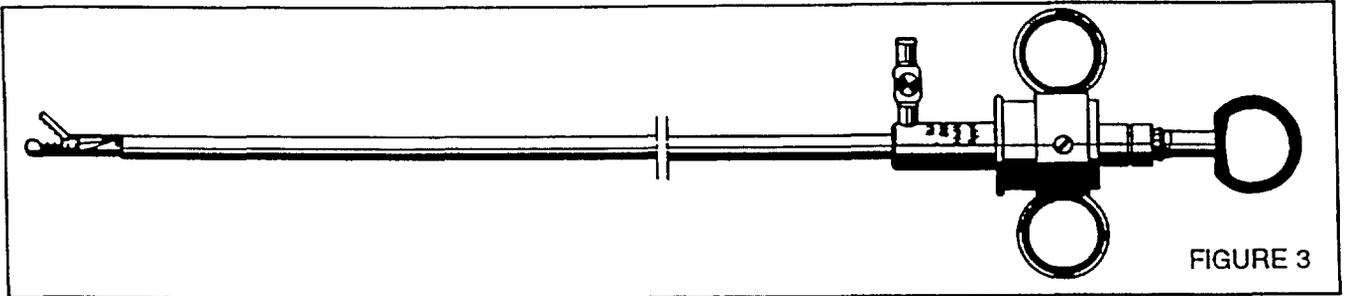


FIGURE 3

These Hulka Clip applicators are 32cm long and are introduced through the second puncture trocar sleeve. The instrument was designed for physicians who prefer the two puncture technique. (Fig. 3 illustrates a previously marketed applicator.)

**SINGLE PUNCTURE APPLICATOR (7mm dia.)**

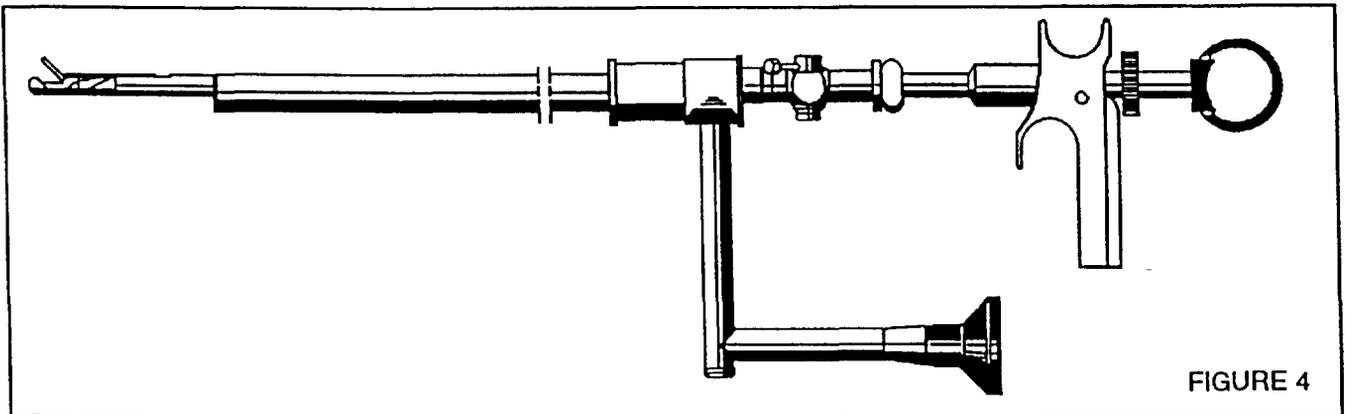


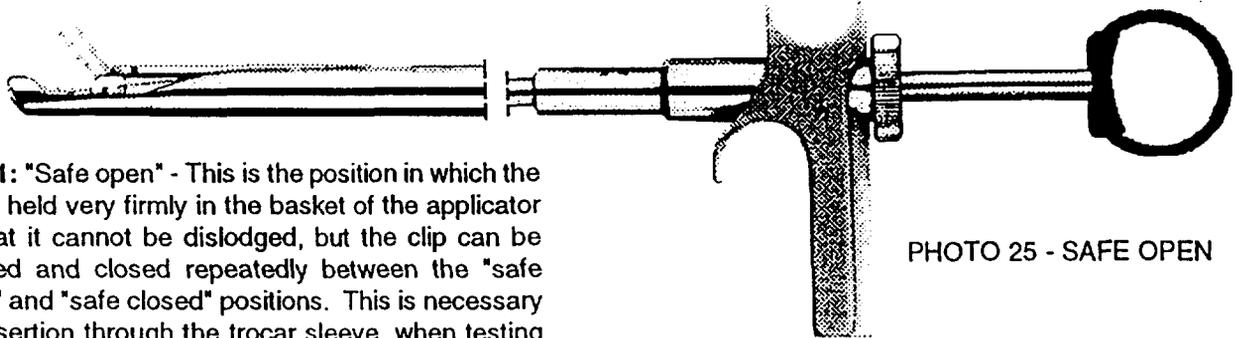
FIGURE 4

This Hulka Clip applicator is 45cm long and is introduced through an Operating Laparoscope. We offer one size of Operating Laparoscope to accommodate the Single Puncture Hulka Clip Applicator. 12mm O.D. with a 8mm operating channel, 10° viewing angle catalog number 8914.31 to be used with reducing sleeve E8388.98.

*Handwritten signature or initials.*

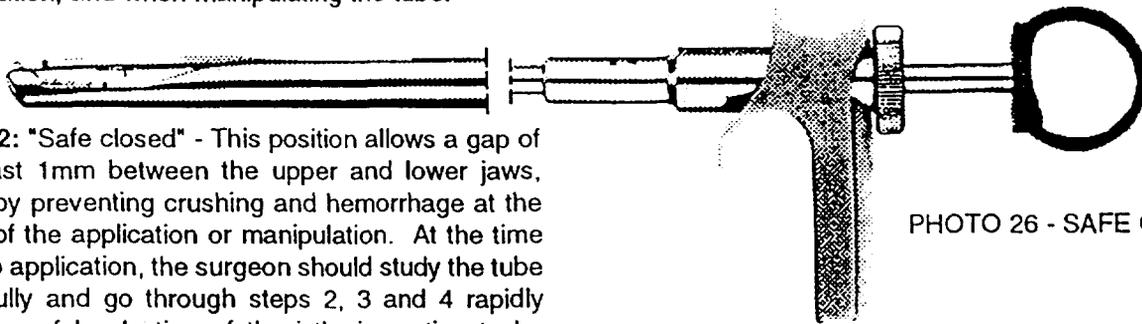
## Mechanical Movements

### A. Movement without resistance



**Step 1: "Safe open"** - This is the position in which the clip is held very firmly in the basket of the applicator so that it cannot be dislodged, but the clip can be opened and closed repeatedly between the "safe open" and "safe closed" positions. This is necessary for insertion through the trocar sleeve, when testing application, and when manipulating the tube.

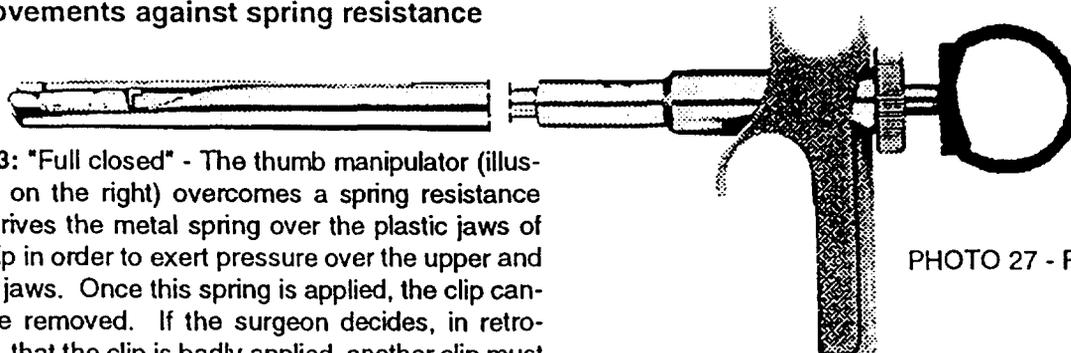
PHOTO 25 - SAFE OPEN



**Step 2: "Safe closed"** - This position allows a gap of at least 1mm between the upper and lower jaws, thereby preventing crushing and hemorrhage at the time of the application or manipulation. At the time of clip application, the surgeon should study the tube carefully and go through steps 2, 3 and 4 rapidly after careful selection of the isthmus portion to be clipped.

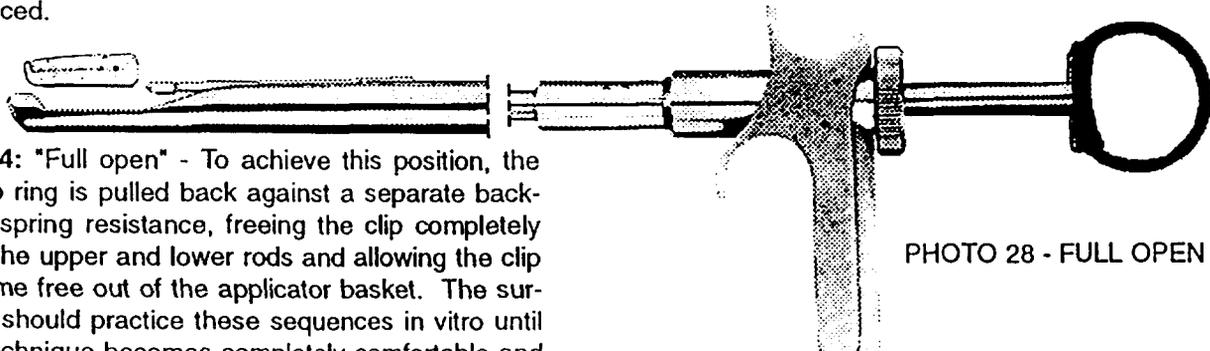
PHOTO 26 - SAFE CLOSED

### B. Movements against spring resistance



**Step 3: "Full closed"** - The thumb manipulator (illustrated on the right) overcomes a spring resistance and drives the metal spring over the plastic jaws of the clip in order to exert pressure over the upper and lower jaws. Once this spring is applied, the clip cannot be removed. If the surgeon decides, in retrospect, that the clip is badly applied, another clip must be placed.

PHOTO 27 - FULL CLOSED

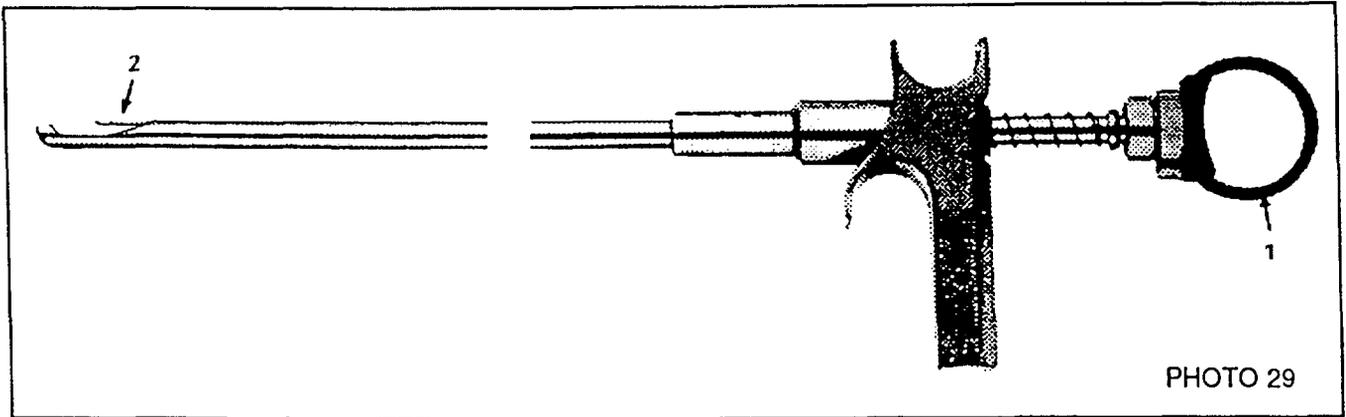


**Step 4: "Full open"** - To achieve this position, the thumb ring is pulled back against a separate backward spring resistance, freeing the clip completely from the upper and lower rods and allowing the clip to come free out of the applicator basket. The surgeon should practice these sequences in vitro until the technique becomes completely comfortable and automatic before attempting human clip application.

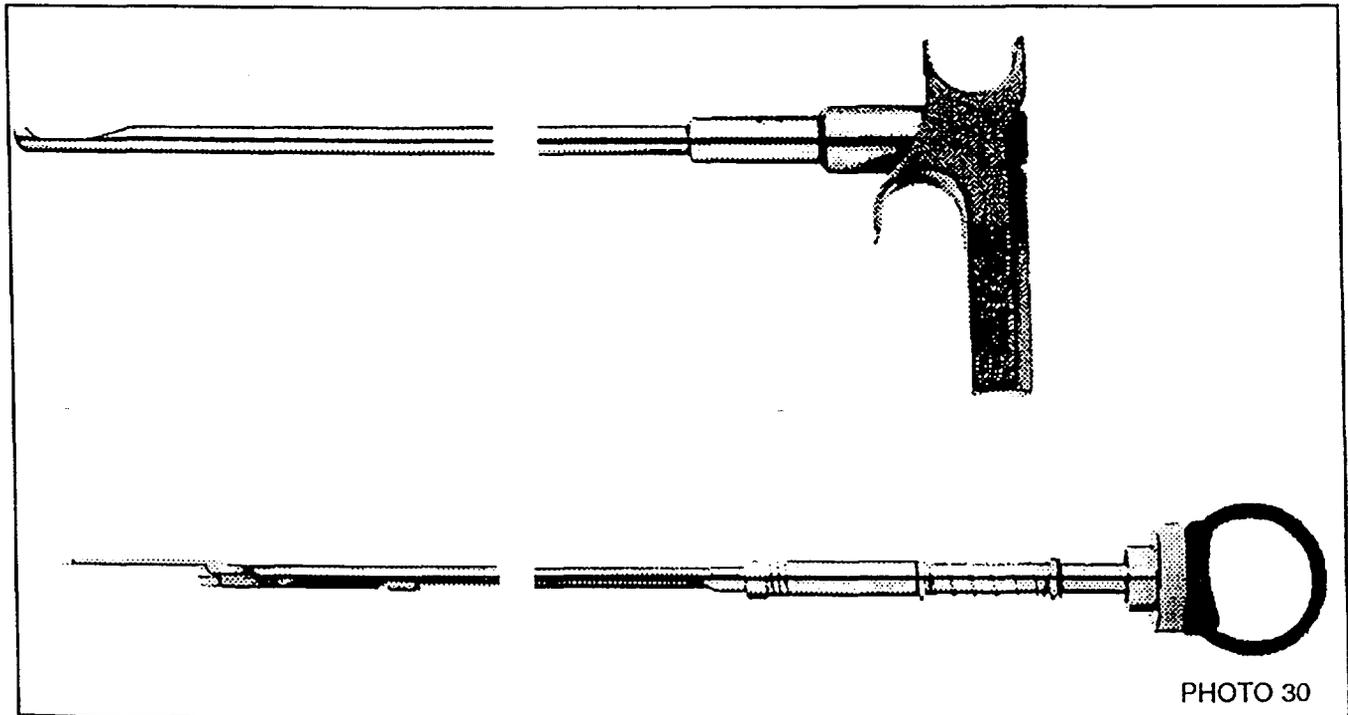
PHOTO 28 - FULL OPEN

## DISASSEMBLY OF APPLICATOR

Grasp the applicator around the thumb ring (1) with the right hand and move the left hand to the distal position of the applicator. With the thumb of the left hand, exert gentle downward pressure against the upper ramrod (2). Pull back on the thumb ring (1) and the entire inner shaft assembly is removed from the main outside housing (Photo 29).



You now have the applicator in two main parts as shown below. No additional disassembly is necessary (Photo 30).



## DESCRIPTION OF SYRINGE DESIGN APPLICATOR

The syringe design applicator has the upper and lower rod actions combined in a "syringe" type action of a single lever. The four interrelated positions of

this single lever are important and are shown in the figures 6 - 9 below. These actions are translated to the clip-holding end of the applicator as follows:

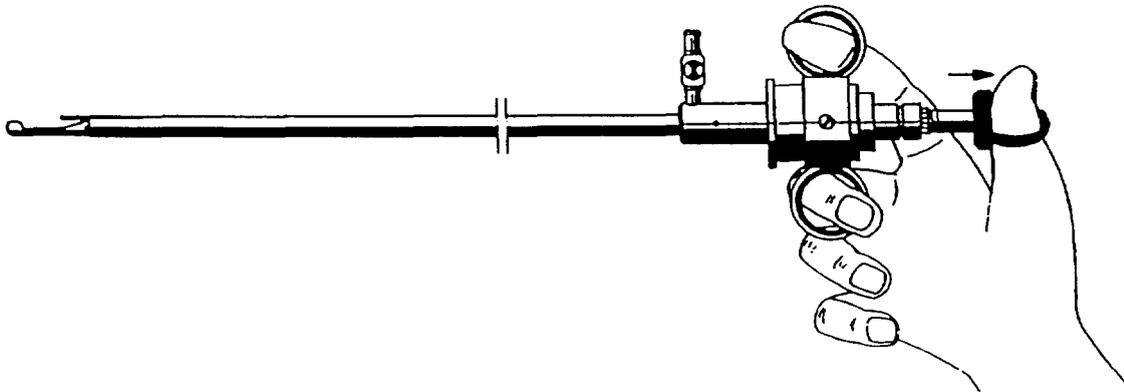


FIGURE 5

Step 1: "Safe open" - This is the position in which the clip is held very firmly in the basket of the applicator so that it cannot be dislodged, but the clip can be opened and closed repeatedly between the "safe open" and "safe closed" positions. This is necessary for insertion through the trocar sleeve, when testing application, and when manipulating the tube.

### A. Movement without resistance

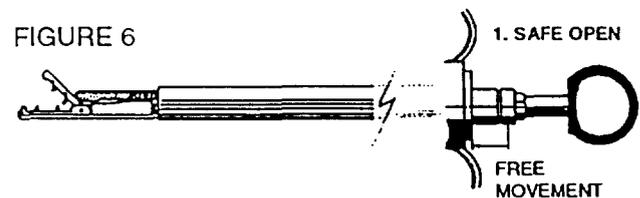


FIGURE 6

1. SAFE OPEN  
FREE MOVEMENT

Step 2: "Safe closed" - This position allows a gap of at least 1mm between the upper and lower jaws, thereby preventing crushing and hemorrhage at the time of application or manipulation. At the time of clip application, the surgeon should study the tube carefully and go through steps 2, 3 and 4 rapidly after careful selection of the isthmus portion to be clipped.

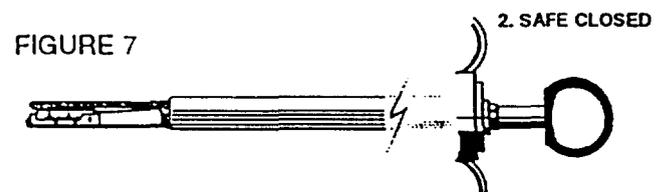


FIGURE 7

2. SAFE CLOSED

Step 3: "Full closed" - The thumb manipulator (illustrated on the right) overcomes a spring resistance and drives the metal spring over the plastic jaws of the clip in order to exert pressure over the upper and lower jaws. Once this spring is applied, the clip cannot be removed. If the surgeon decides, in retrospect, that the clip is badly applied, another clip must be replaced.

### B. Movements against spring resistance

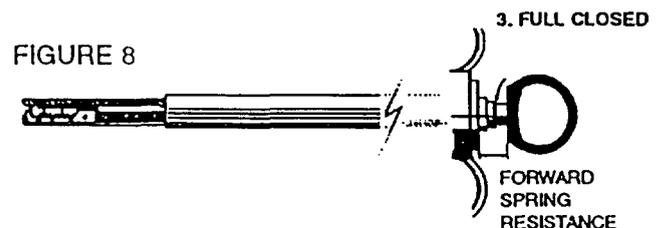


FIGURE 8

3. FULL CLOSED  
FORWARD SPRING RESISTANCE

Step 4: "Full open" - To achieve this position, the thumb ring is pulled back against a separate backwards spring resistance, freeing the clip completely from the upper and lower ramrods and allowing the clip to come free out of the applicator basket into the abdomen. The surgeon should practice these sequences in vitro until the technique becomes completely comfortable and automatic before attempting human clip application.

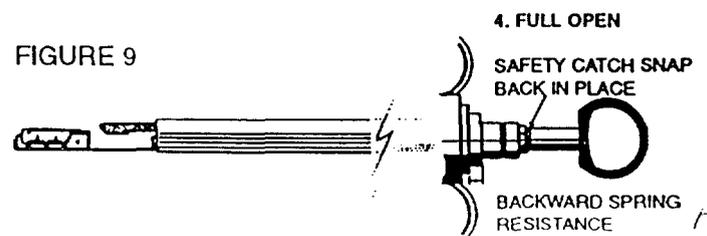


FIGURE 9

4. FULL OPEN  
SAFETY CATCH SNAP BACK IN PLACE  
BACKWARD SPRING RESISTANCE

## Application

The clip applicator, (loaded with the spring clip and with thumb ring pushed into the safe closed position), is inserted either through the 7mm trocar sleeve (second puncture technique) or through the 8mm operating channel (with reducing sleeve) of the 12mm Op-Scope.

Only after the tip of the forceps is in view and the tube is positively identified, should the clip be reopened.

With the jaws open (thumb ring backwards at safe open position) advance the instrument into a free falling part of the tube, about 2 to 3cm from the uterus. Figure 10.

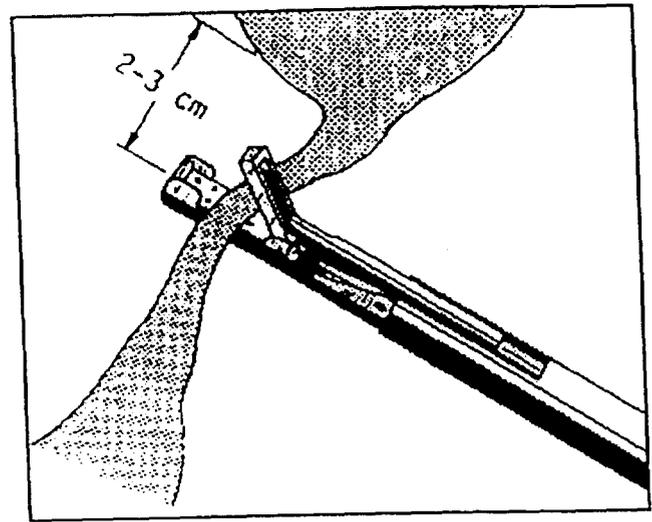


FIGURE 10

### To Lock the Clip

Locking of the clip begins by pushing the syringe plunger into the safe closed position, and should be done under optical control for assurance of proper clip placement. With proper placement assured the syringe plunger is advanced overriding the safety catch. Advance the syringe handle fully to the full closed position, placing the spring over the clip and permanently locking the clip in place.

Should the plunger accidentally be moved over the safety catch prior to assurance of proper clip placement and the clip is on the tube, the clip must remain where it is. The spring must be completely pushed over the clip into complete closed position, and a new clip placed next to the misplaced one.

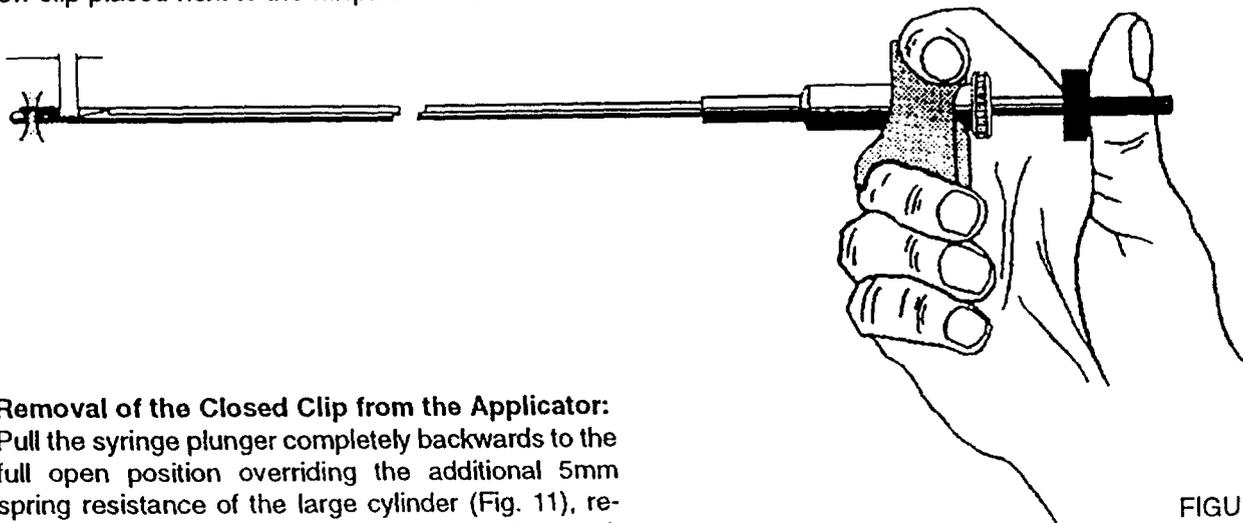


FIGURE 11

**Removal of the Closed Clip from the Applicator:**  
Pull the syringe plunger completely backwards to the full open position overriding the additional 5mm spring resistance of the large cylinder (Fig. 11), resetting the safety catch, listening for a click sound. Only in this position can the closed clip be released from the applicator.

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PRACTICING TECHNIQUE BY CLIPPING A RUBBER BAND MODEL

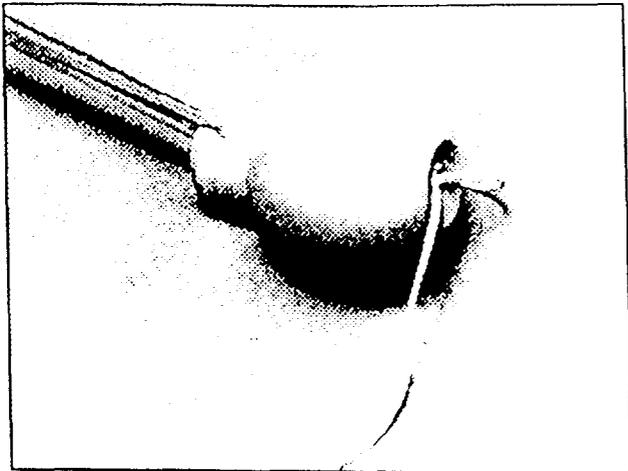


PHOTO 31

In the above photo is a "model uterus" and tubes consisting of a round plastic uterus with a rubber band attached to imitate a tube. Please take a controlling tenaculum and grasp the "cervix" of the model as is shown in Photo 31. In practice, it is usually necessary to maneuver the uterus so that the tube will be positioned correctly for clip application. Clip application differs significantly from electrocoagulation in that the tube is not picked up on a stretch, but rather remains in whatever anatomic position it is found in while the clip is applied. This plastic model will simulate many of the difficulties found in actual human clip application.

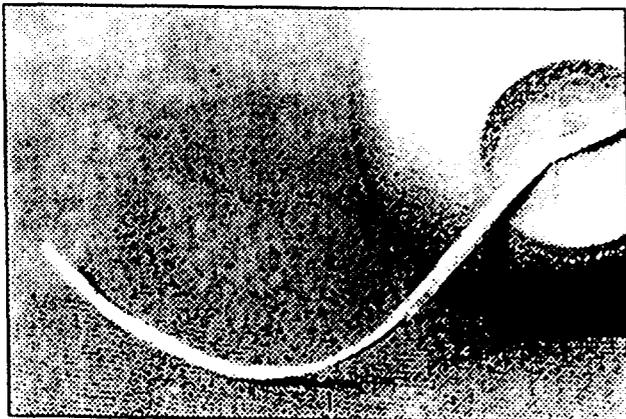


PHOTO 32

Place the "uterus" and "tube" on the table in such a way that the tube is partially stretched (Photo 32). Approach the rubber band with the optics and place the clip onto the rubber band looking through the optic. After you have applied it, inspect the application you have accomplished.

There are several common errors in clip application which can be eliminated after practice with the plastic model:

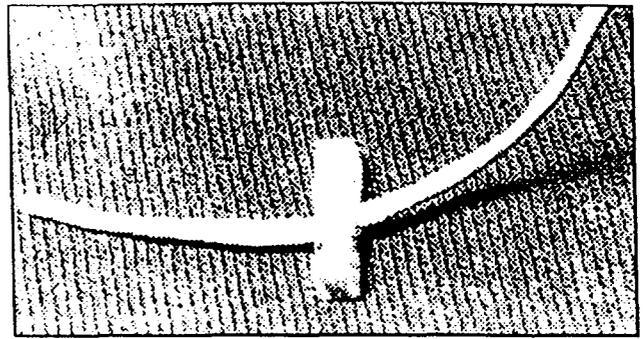


PHOTO 33

1. Clip too lateral (Photo 33): The clip is designed to be applied to the isthmus portion of the Fallopian tube. This corresponds to the first medial inch of the rubber band model. If the clip is applied too far laterally on the rubber band tube, pregnancy may occur because the ampullary portion of the tube is too wide for the clips to effect a complete closure. Make sure that your clip is within the first medial inch of the rubber band.

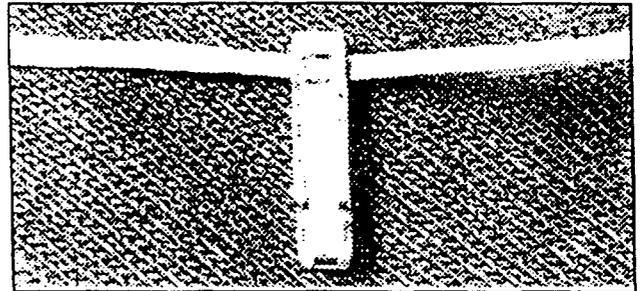


PHOTO 34

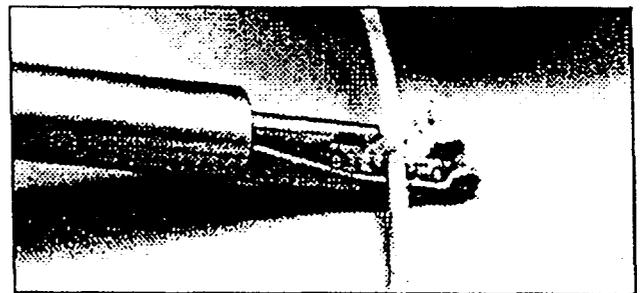


PHOTO 35

2. Tube is too near the end of the clip (Photo 34): In contrast to electrocoagulation, the tube should not be lifted and put on a stretch. If you do this, the clip application will look like Photo 34 where the tube has rolled down from the distal part of the clip. In practice, such an application, even if on an isthmus area, is incorrect and has resulted in recanalization. To avoid this, make sure that the rubber band (and tube) is right up against the inner angle of the jaw of the clip before the upper ram is closed. (Photo 35). This will assure that the teeth in the clip will prevent the tube from slipping out.

u4

) Have an observer watch you maneuver the applicator on the rubber band while you are applying the clip. You will not be aware of pushing or pulling the tube during application, but an observer will and can tell you about it.

While you are approaching the tube, "snuggle" the rubber band and tube up into the jaws by moving it back and forth over a quarter inch distance until the rubber band is right up in the angle of the jaws. This is more difficult in the model than in the patient.

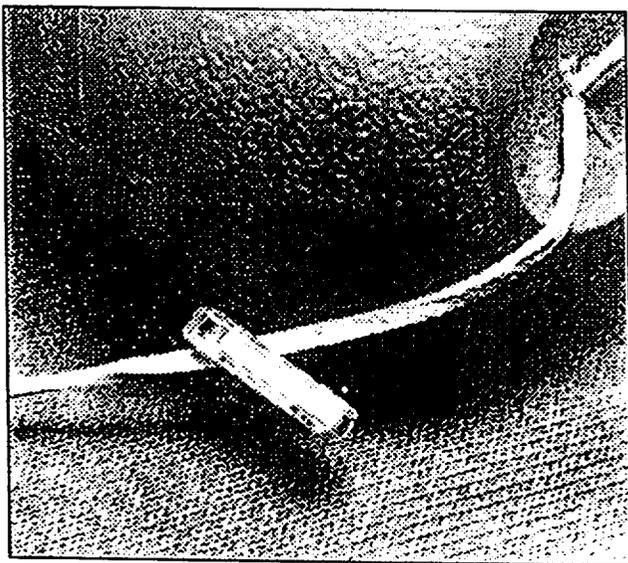


PHOTO 36

) **3. The clip is applied at an angle (Photo 36):** This usually occurs, despite the visual impression that the clip is within the angle of the jaws, because the tube is pushed inward by the applicator at the time of application (Photo 37).

When approaching the tube, make sure that:

a. the surface of the jaws is in the same place as the surface of the tube.

b. the tube is perpendicular to the applicator. This can be achieved by backing away from the tube, adjusting the uterus and drawing it into the pelvis, thus stretching the tube between its broad ligament attachments and pelvic uterus (Photo 38). This is in direct contrast to the usual instinct at electrocoagulation of pushing the tube up into the abdominal cavity in order to free it from surrounding structures. This can be demonstrated partially on the rubber band model by pushing the uterus towards you and pulling it away, the rubber band tubes fall on a more perpendicular plane (Photo 38) than if the uterus is pushed (Photo 37).

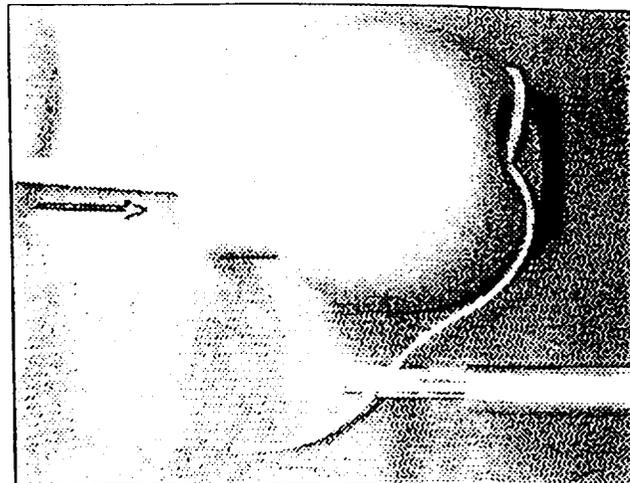


PHOTO 37

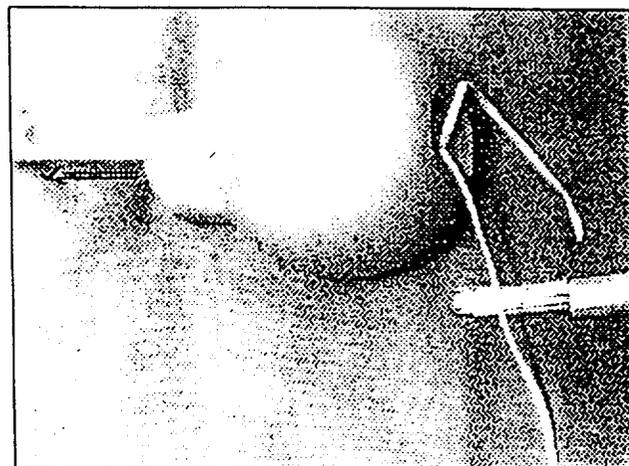


PHOTO 38

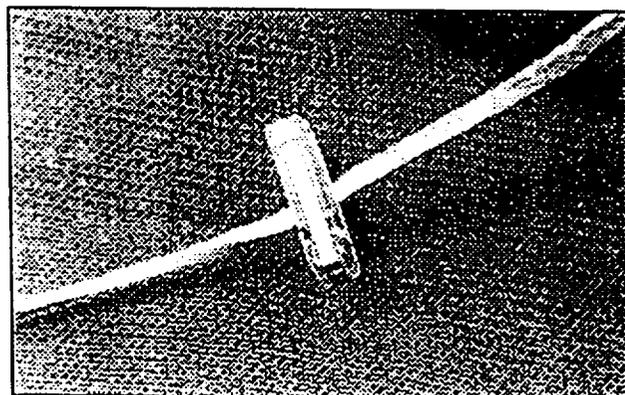


PHOTO 39

) Practice applying the clip onto a stationary uterus and rubber band, until you have properly applied the clip onto the first inch of the rubber band with the band deep in the jaws of the clip and the clip at right angles to the tube (Photo 39). This should take about half a dozen trials until you feel comfortable.

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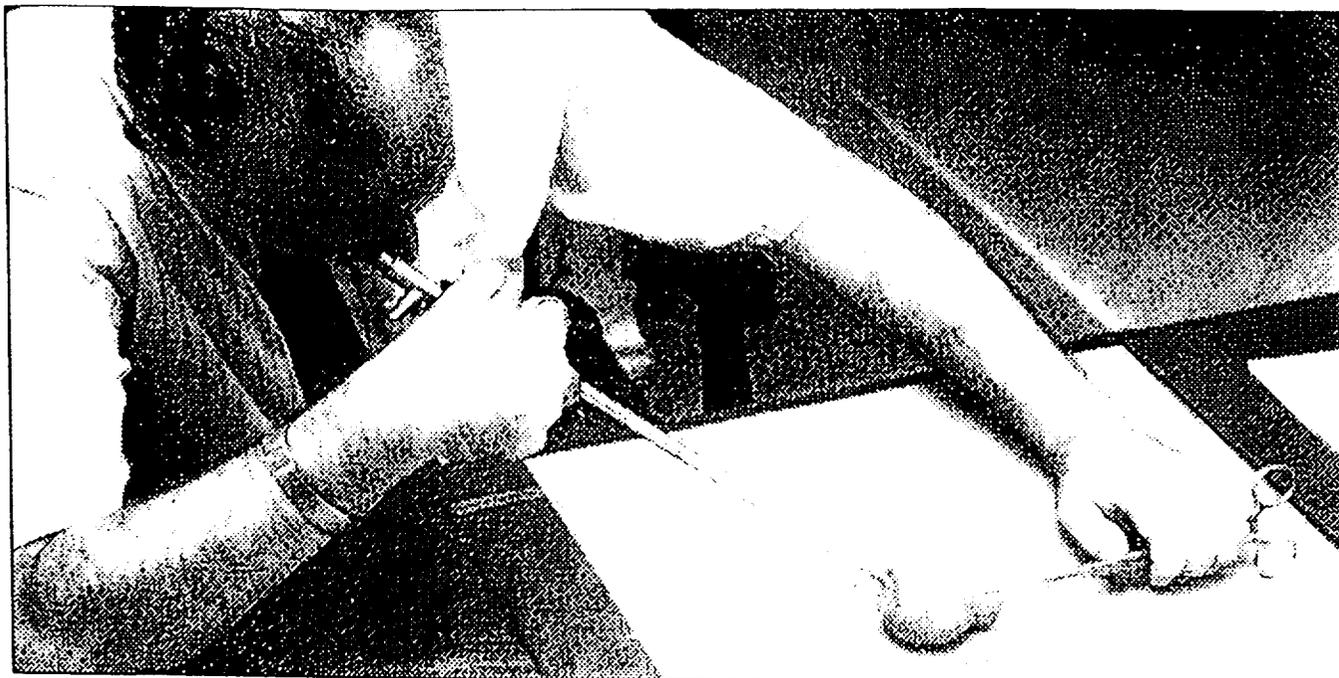


PHOTO 40

Repeat this maneuver holding the uterus by means of the controlling tenaculum in your left hand and the applicator in your right hand (Photo 40). You will find that this is far more difficult with the plastic model than with the patient, because the instrument is not supported by the trocar in the abdomen. Nevertheless, it is a good exercise to familiarize yourself with the technique of maneuvering both the left and right tubes so that they are stretched, rotating the laparoscope clock-wise and counter-clock-wise (learning how to maneuver your hand in these positions) until the applicator is in the same plane as the tube, and having a "delicate" touch on the tube so as not to distort it at the time of clip application.

#### REVIEW OF CLIPPING A RUBBER BAND MODEL

With an observer who can correct you if you are making one of the above mentioned errors, go through clip application on the practice model. The correct relative hand position for each tube is shown in Photos 41 and 42. For the left tube (Photo 41) the right hand is usually well over the laparoscope, which is usually almost 90° rotation off the vertical. For the right tube (Photo 42), similarly, the right hand is usually underneath the clip applicator somewhere between 50-90° off the vertical axis. Practice applying clip with hands in these two positions until the clip can be applied automatically. *Never take your eye off the operating field during clip application until the clip is free from the applicator*

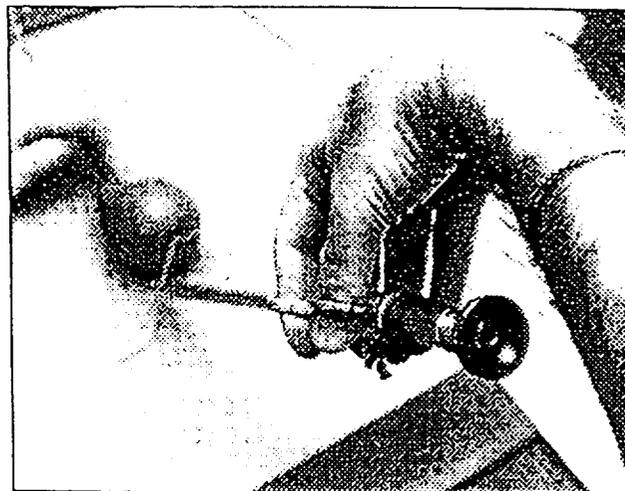


PHOTO 41

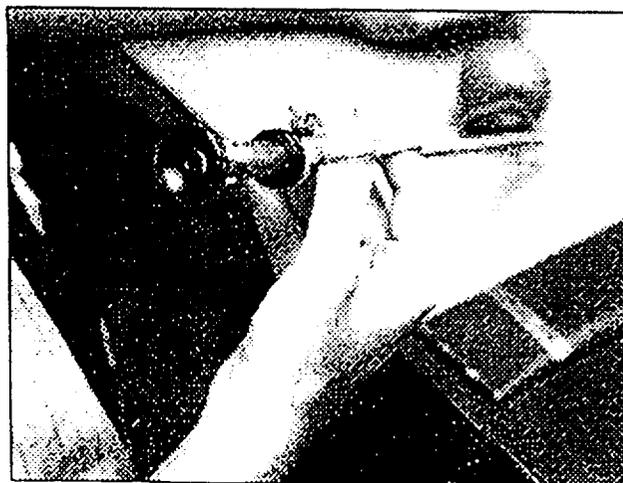


PHOTO 42

WLB

Practice doing this maneuvering with both right and left hands while looking through the optics, until the clip is properly applied onto both right and left tubes (as is shown in Photo 43).

When you apply clips in humans, take time after application to make sure both tubes are clipped properly as shown in Photo 43. If there is any question, always place another clip onto the tube. The current world's record is five clips in one patient, so don't be discouraged if at first you find yourself applying more than two clips per patient. No subsequent adhesions or hydrosalpinx have been noted.

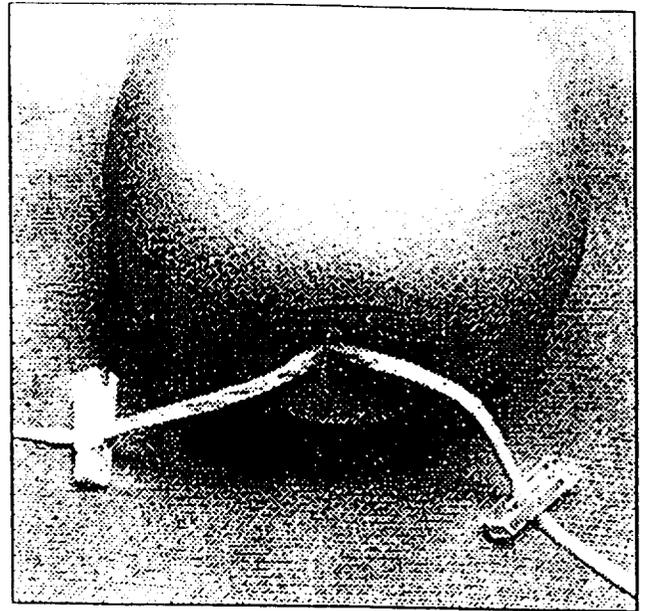
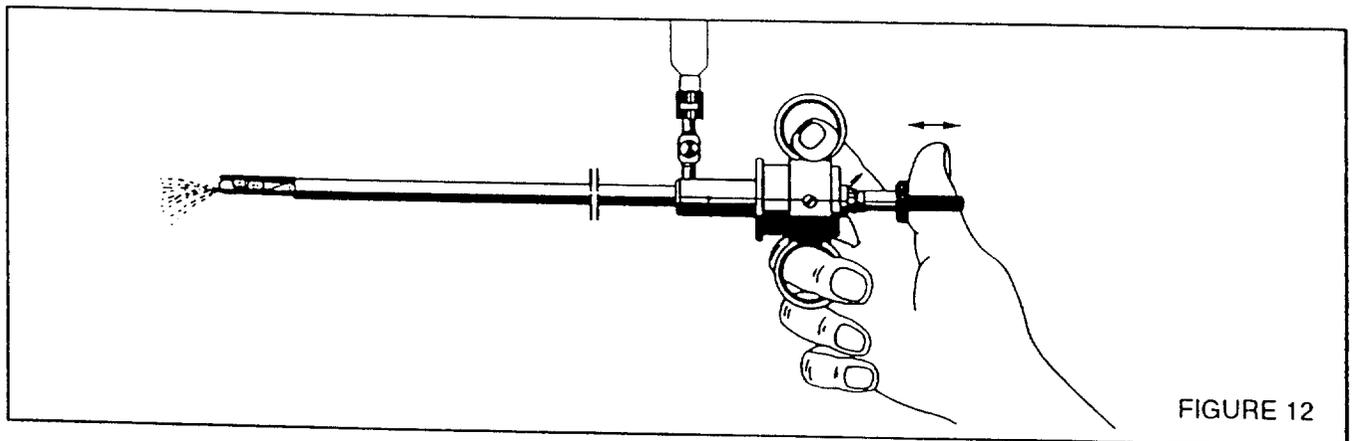


PHOTO 43

## DESCRIPTION OF SECOND PUNCTURE APPLICATOR

The abdominal wall can be well anesthetized for the second puncture 7mm trocar by selecting a site 4 to 8cm below the umbilicus.



Hulka clip applicators, catalog numbers 8387.85 and 8388.85 have an anesthesia channel. A luerlock syringe can be attached to the applicator and local anesthesia inserted through the laparoscope to come out at the distal tip of the applicator under direct vision. It is recommended that each tube receives 4cc of local anesthesia (0.5% Marcaine is rapidly resorbed and effective). Two cc should be on the upper surface of the tube from fundus to fimbria, and 2cc on the underportion, bathing the peritoneum between the tube and the ovary. Thus, a total of 8cc will be applied in the pelvis, well within toxic levels.

This application should be applied routinely under both general and local anesthesia, since this anesthesia will abort the pain reflex and reduce to a minimum the complaints of post-operative cramping which some patients find when the clip is applied without anesthesia. Figure 12 illustrates the placement of the syringe and where the anesthesia spray exits the applicator.

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## DESCRIPTION OF SPRING CLIP APPLICATION TECHNIQUE

For physicians who have been performing coagulation by grasping the tube and lifting, it is important to point out that the clip is not applied in this manner. Rather, the correct application requires very good perception of

of red to yellow is seen (tissue or fat). Also, overmagnification of small structures causes confusion (e.g. large tubes look like intestine). A good rule of thumb is to:

1. Remain just beyond the sleeve with the optics and
2. Move the uterus gently up and down.

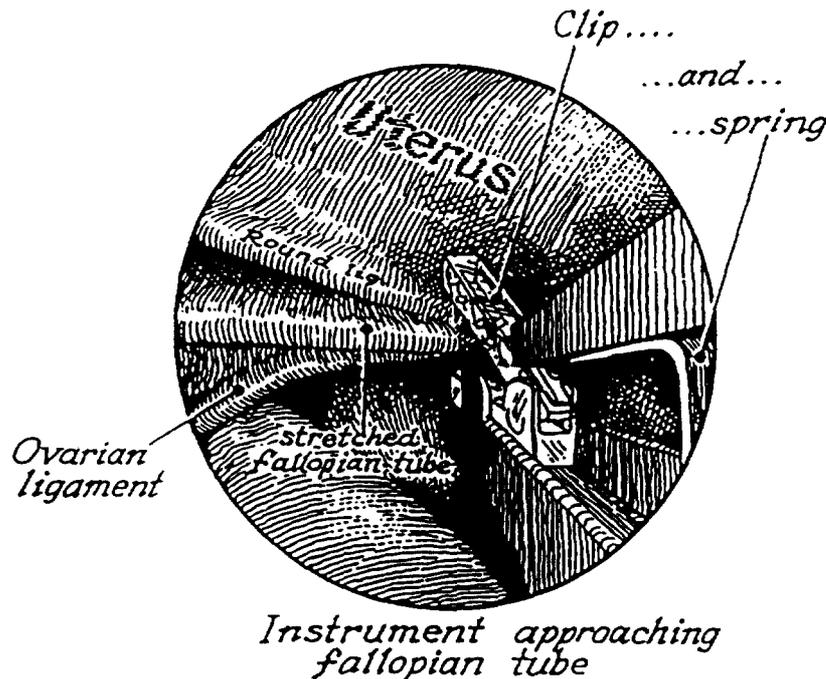


FIGURE 13

relations between the applicator and the tube. Specifically, the tube should be stretched for its maximum availability to the clip applicator. Misapplications, due to limited visibility, accounted for pregnancies in early experience with the clip.

The instruments should be maneuvered by the surgeon himself, manipulating the uterine instrument with one hand and the laparoscopic instrument with another.

Keep the scope as far away from the uterus and tubes as possible, so as to have the greatest visual field. Many beginning surgeons are so eager to get inside the pelvis that the optics are buried in peritoneal contents and a sea

The only structure that should be moving is the uterus. The tubes can then be identified starting at the uterus (as a landmark), and observing them laterally. Visualize the fimbria whenever possible and then move medially to identify the isthmus.

When the uterus is anteverted and stretched to the patient's right, her left tube will be visible and partially stretched as was seen in an earlier photograph. Visualize the entire adnexa to positively identify three structures:

(See Figure 13)

1. Round ligament
2. Tube
3. Utero-ovarian ligament

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Under local anesthesia, the isthmus portion of a normal tube may look remarkably flabby like a peritoneal fold. In the post-abortion patient, sometimes the broad ligament varicosities will look like convoluted tubes. Touch the structure you think is tube to see if it is mobile. Trace it to the fimbria if possible, although patient discomfort, loops of bowel, or adhesions may prevent the positive identification of fimbria. It helps to remember that the structure just over the ovary is usually tube.

When you have positively identified the tube, apply topical anesthesia onto its surface. To do so, have your assistant hold the uterus so that the tube is visible. Attach the 10cc syringe to the anesthesia spray nipple just above the lower stabilizing ring, open the valve, and spray about 5cc of 1% Xylocaine over each tube. The anesthetic will come out in a stream of spray just beyond the visible tip of the clip applicator. If no spray or stream is visible, touch the tube with the tip of the instrument and be assured that anesthetic to take effect, so that clips can be applied without discomfort.

To apply the clip:

1. Open and close the clip high in the abdomen, free of structures.
2. With the jaws open, advance the scope onto a free falling part of the tube about 2cm (1") from the uterus.
3. Snuggle the tube into the jaws of the open clip until what you see is as far into the angle of the jaws as possible. (see figure 14).

FIGURE 15. The upper ramrod is pushed forward by the thumb control, closing the clip into the "safe closed" position. Should the surgeon have any reservation as to the correct application of the clip, the upper ram can be pulled backward at this point into the "safe-open" position (seen in Photo 25, page 18) and a new application tried. When the clip is applied correctly, as illustrated here, the tube appears to fill the jaws of the clip all the way up to the hinge.

FIGURE 16. The lower ramrod is now moved forward, closing the C-shaped spring over the upper and lower jaws of the clip. At this point, the clip cannot be removed because it is permanently latched in place onto the tube. Care must be taken to push the lower rod completely forward until the spring snaps in place in the locked position over the jaws. Once the spring is in place over the jaws, both lower and upper rods can be rapidly drawn



*Tube pressed into angle of jaws of the clip*

FIGURE 14

*Upper ram forward*



*Jaws closed to within 1. mm*

FIGURE 15

*Lower ram forward*



*Spring engaged over clip.*

FIGURE 16

*W.C.*

back into the "full open" position, after which the clip will be free to disengage itself from the applicator. A "Japanese bow" of moving the applicator downward and away from the tube will assure easy disengagement of the clip from the applicator at this point.

FIGURE 17. The correct application of the clip across the isthmic portion of the tube is illustrated. One can see Doctor Kleppinger's "envelope" sign of the mesosalpinx on the surface of the tube pulled upward to resemble the flat triangular shape of an envelope flap. Again, the tube and its mesosalpinx occupy the entire clip all the way up to the hinge.

If you are unsure of the correct application (e.g. if you think the tube is incompletely caught or the wrong structure is clipped), by all means put *another* clip on more carefully in the right adnexa of this patient. The clip application should proceed swiftly, without motion of the laparoscope once the clip is applied onto the tube.

*The eye of the surgeon should never leave the operative field.* Failure to observe this may result in accidental avulsion of the tube while the surgeon is looking at part of the laparoscope or equipment.

After one tube has been clipped, the instrument should be removed, reloaded with a clip, reinserted through the sleeve, the uterus repositioned and held by the surgeon with the controlling tenaculum or forceps so as to make the other tube visible, and another clip applied.

FIGURE 18. Within six weeks of the operation, the clip is covered by mesothelium. The mesothelium is quite thin; the granulomatous reaction is minimal; and tubal endothelium is intact with 1mm of this peritonealization process on either side of the jaw. Adhesion formation is rare, since the materials of the clip have been selected for maximum inertness.

About 5% of patients will complain of crampy pelvic pain persisting after surgery. This is because the clip may have been applied onto a nerve which is then gradually crushed and may cause pain from a few hours up to two days. This pain is rarely severe in nature, and is usually controlled with aspiration. In our experience, this benign painful phenomenon does not indicate any hematoma or infection.

**Closure:** After the tubes have been clipped, the instrument should be partly withdrawn so as to positively identify for the last time the correct application of the clips on both the right and left Fallopian tube. When this is done, the operation is complete and the instruments can be withdrawn under direct vision.

The attachments of the light cable and the gas source are then removed and given to the assistant for immediate sterilization and preparation for the next case. We have performed 3 sterilizations an hour using the same instrument thoroughly washed

and soaked briefly between cases. The gas should be allowed to escape the abdominal

*Both rams withdrawn.*



*Clip released . . .  
... instrument withdrawn.*

FIGURE 17



*Spring clip epithelialized.*

FIGURE 18

cavity completely through the trumpet valve before the patient is taken out of the Trendelenberg position, to avoid the gas irritating the liver and diaphragmatic area and leading to shoulder pain later. After all gas has been removed, the surgeon should press on the abdomen and the sleeve should be withdrawn. This will prevent air from being drawn back into the peritoneal cavity as the sleeve is withdrawn. The vaginal instruments are removed and the skin closed with a single subcuticular suture.

A band-aid can then be placed on the abdomen and the patient sent to the recovery area; many patients have walked back if the sedation was light and no vagal hypotension developed.

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) PLACING THE HULKA CLIP

The following sequence of photographs show the Hulka Clip being placed on the fallopian tube (Photos 44-48).

Photo No. 49 shows a Hulka Clip in place on a fallopian tube for some nine months. As you see the Hulka Clip is completely covered by tissue.



PHOTO 44



PHOTO 45

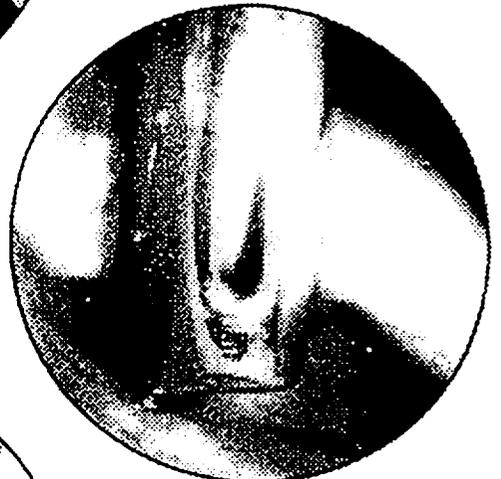


PHOTO 46



PHOTO 47



PHOTO 48

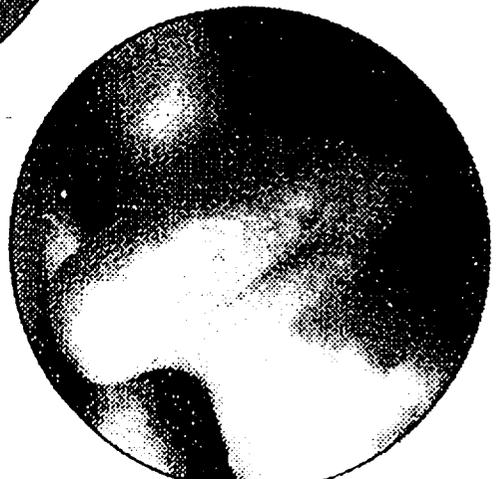


PHOTO 49

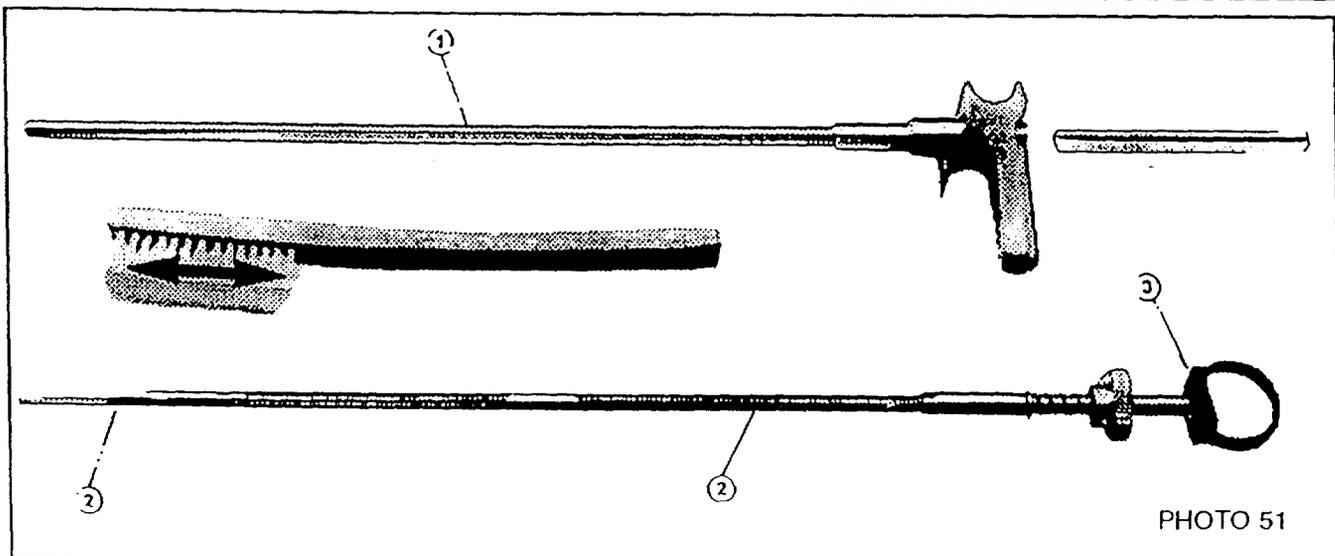
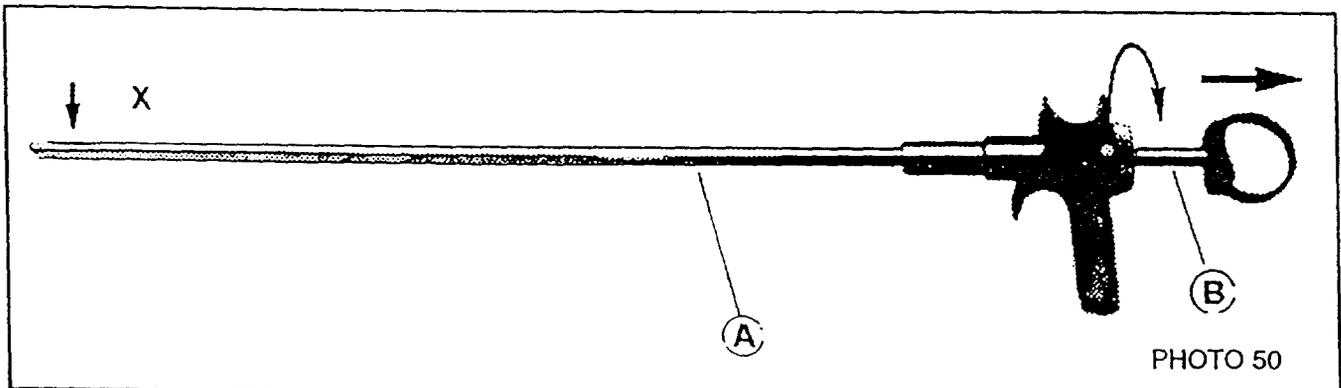
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## APPLICATOR CARE AND MAINTENANCE

Applicators are reusable devices, they are shipped from the factory non-sterile and must be sterilized prior to use. After each use the device must be cleaned, disinfected, and sterilized as described in the following instructions.

### CLEANING THE APPLICATOR

- 1) Disassemble the applicator, if possible, immediately after use. The applicator disassembles into two parts (A + B) as shown in Photos 50 and 51.
- 2) Thoroughly clean the applicator of all organic material with an Enzymatic Presoak Cleaner. The use of a soft bristle brush is recommended. Be sure to clean inside all shafts and openings. Observe all instructions provided by the manufacturer of the cleaning solution.
- 3) Rinse thoroughly with sterile water to prevent water spots and possible corrosion.
- 4) Lubricate the inside shaft with lubricating oil, ie. Richard Wolf WO51 oil or similar, as shown in Photo 52.



## DISINFECTION OF THE APPLICATOR

NOTE: Disinfection is recommended for safe handling of the device by facility employees.

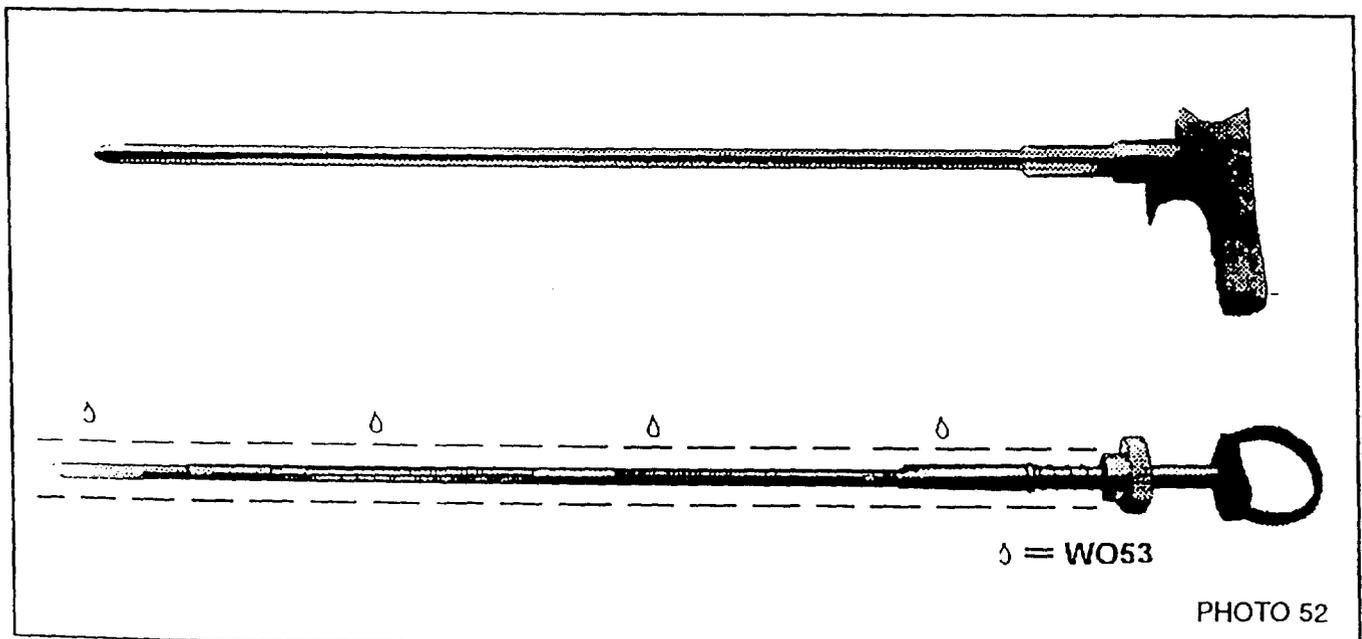
- 1) To achieve "High Level Disinfection" immerse applicator into an activated Glutaraldehyde solution. Manufactures and solutions vary, refer to the disinfectant instructions for information on required times and temperatures.
- 3) Remove and dry thoroughly.
- 4) The applicator must now be sterilized to assure a proper sterility level. EtO gas or steam sterilization must be used. Continue with all remaining steps.

example:

For Johnson and Johnson Medical's Cidex<sup>tm</sup>: use full strength and immerse for no less than 90 minutes at a temperature of 25C.

NOTE: Strictly follow all instructions from the disinfectant manufacturer.

- 2) Remove instrument from the disinfecting solution and rinse thoroughly with sterile water.



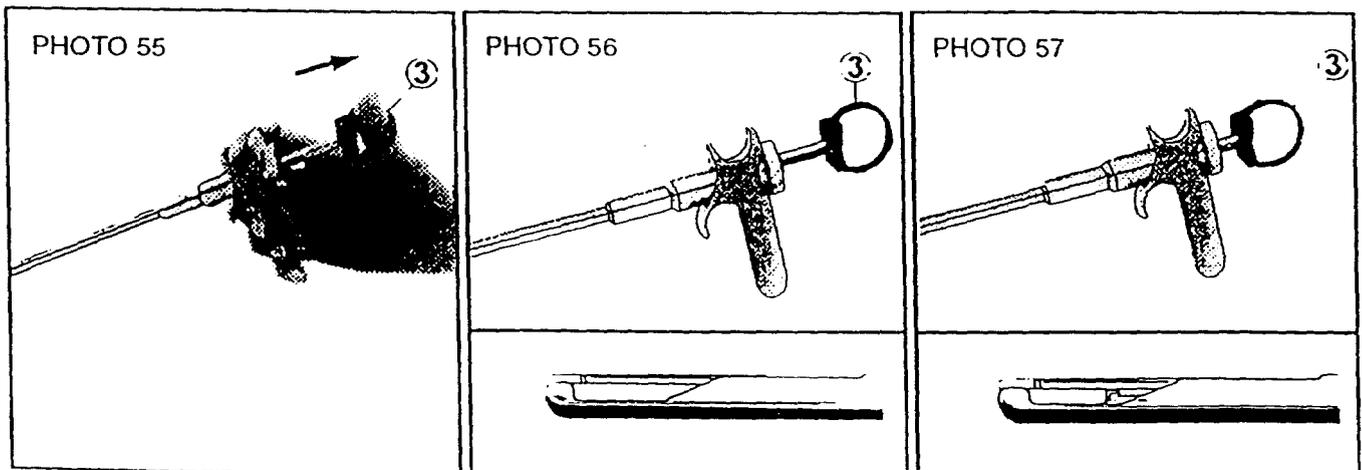
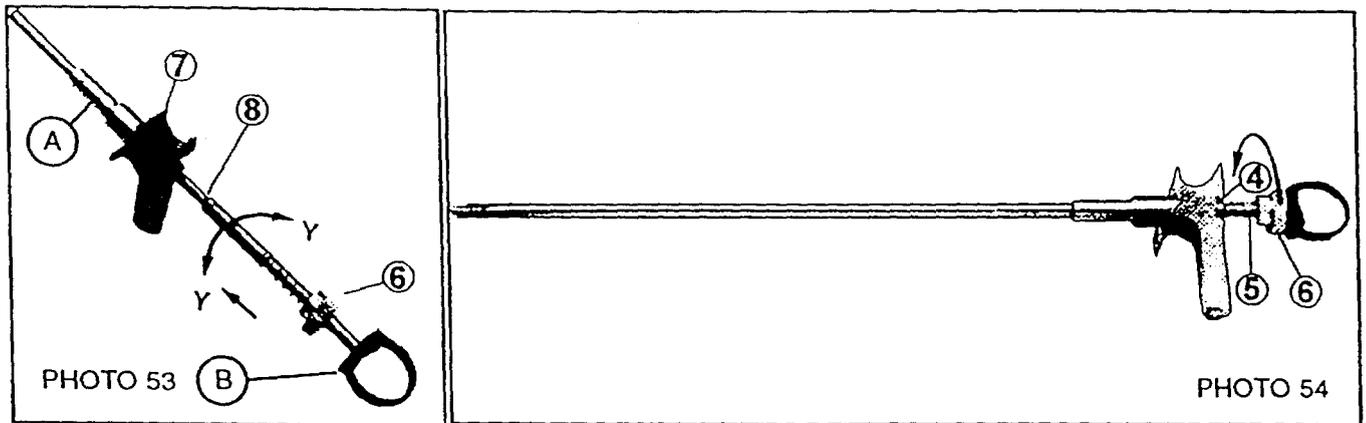
## RE-ASSEMBLY

- 1) Referring to Photo 53; the cleaned, disinfected and lubricated insert (B) is inserted into the external housing (A) so that the nose faces upwards.
- 2) Be sure that the insert (B) fits into the groove provided in the handle. DO NOT EXERT EXCESSIVE FORCE. If assembly proves difficult, remove insert and try again.
- 3) When fully inserted, screw knurled cap in direction indicated in Photo 54. Tighten securely but do not over tighten.

## FUNCTIONAL TEST

This functional test must be performed before each sterilization. This functional test must again be performed prior to the procedure to assure proper operation.

- 1) Correctly grasp the applicator and retract the thumb ring (3) until resistance is felt, Photo 55.
- 2) Push the thumb ring forward until it reaches the first stop. The upper push rod must reach the position shown in Photo 56. The pushing movement must be easy with no resistance.



- 3) Continue the forward movement, overcoming the resistance of the spring, as far as possible. This results in the lower locking pushrod reaching the position indicated in Photo 57.
- 4) Retract the thumb ring as far as possible overcoming all resistance. This should result in the upper push rod being in the position shown in Photo 58.
- 5) If the applicator does not perform as indicated, DO NOT USE THE DEVICE. Contact the Richard Wolf Service Department for further instruction.

## STEAM STERILIZATION - APPLICATOR

The applicator should be fully assembled and checked prior to sterilization.

- 1) The applicator must utilize some form of sterilizing packaging (ie. mesh bottom tray system). Follow AAMI - 'Good Hospital Practices' to assure dry sets.
- 2) Richard Wolf applicators must be steam sterilized using a cycle which has a slow heating and cooling phase (ie. with a "Prevacuum" or "High Vac" cycle). Recommended minimum exposure time of 3 minutes (5 minutes typical), an exposure temperature of 270-275F (132-135C) should be observed for the Richard Wolf applicator. Also follow AAMI - 'Good Hospital Practices' when sterilizing this instrument.
- 3) Instruments should be allowed to cool naturally to room temperature after removal from the steam sterilizer. DO NOT IMMERSE OR RINSE INSTRUMENT IN COLD WATER OR ANY OTHER LIQUID UNTIL COOL.

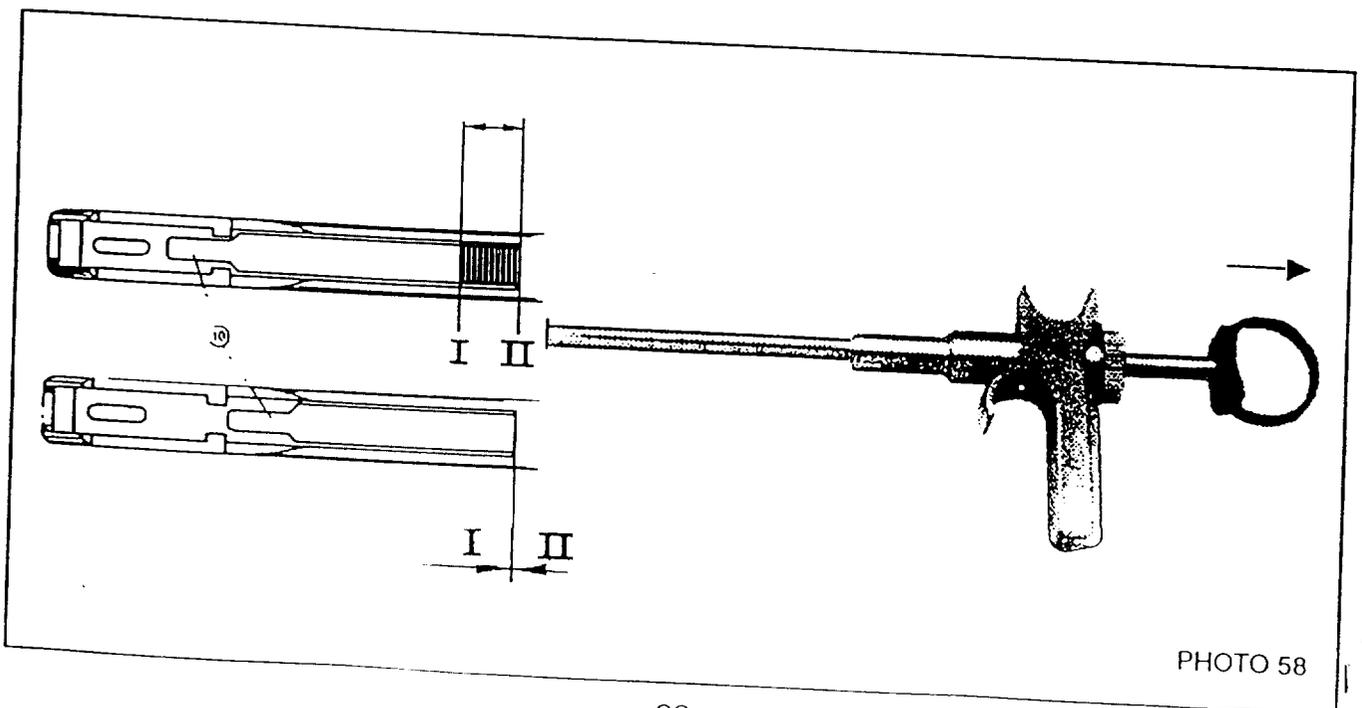


PHOTO 58