AN ATLAS OF Intrauterine Contraception

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Preface

Contraception, it might be said, is a subject that, with its myriad aspects, encompasses all humanity for all time. It is well-documented history that contraception—specifically its basic nonexistence—has been a frustrating enigma for all past generations of the earth. However, it is now an accepted conclusion that contraception as a science, an individual practice, and a compelling need of society will occupy all future generations.

In a developing pattern of study and application it has become both the necessity and privilege of those living in the 20th century to stand at the vortex of past contraceptive failure and modern contraceptive advances. Those knowledgeable about contraceptive study understand that the compiled research, clinical application, and plans for future contraceptive developments combine to form whole libraries. But in a narrower sense, the development of intrauterine contraceptive devices (IUDs), one band in the spectrum of contraceptive techniques, has itself produced virtual libraries of research data, findings from clinical testing, and descriptions of complications. With few exceptions all the material produced about IUDs has appeared since the resurgence of the modern IUD, about 1960.

As an example of the magnitude of scientific literature published about intrauterine contraception, the bibliography in a

report about IUDs prepared for the U.S. Food and Drug Administration in August 1975 contains over 2,500 individual references. And, it is far from complete.

It is apparent that no single text can adequately cover the subject of intrauterine contraception. It is equally apparent that with the proliferation of both interest in and information about IUDs there arises the need for basic reference works. These can readily provide specific information that could only be obtained elsewhere by time-consuming and often fruitless searches through the scientific literature.

This book has been written to provide such a basic reference work about IUDs. There is a pictorial and descriptive listing of a majority of those IUDs that either have been conceived by the inventor, tested clinically, or obtained limited or wide-scale commercial use. This comprehensive listing will be of invaluable help to not only the historian, but also to the researcher, the manufacturer, and the practicing physician.

The nucleus of the book is based on a unique collection of IUDs, inserting and removal instruments for IUDs, and associated paraphernalia that has been assembled by the author. This is the largest single collection of such devices, and it is used for scientific exhibit and many other purposes within the broad scope of medical education and research. The collection will continue to be developed to reflect the growth and development of intrauterine contraception.

While the book presents a comprehensive listing of IUDs, its value as a source book is enhanced by descriptive material and selective bibliographies.

A chronological survey of the history of intrauterine contraception precedes the atlas. Individual descriptions accompany the photographs of the IUDs, and where available, selected references are given for the pictured devices. A listing of patent information for most of the IUDs patented in the United States is also included and a comprehensive index allows for the rapid location of each IUD in the atlas.

It would be difficult to acknowledge and thank all of those whose contributions have made the collection of IUDs and this atlas a reality. While in no way wishing to slight the many individual contributions to the collection, I feel that it is appropriate to give special credit to the following individuals who have made contributions of great value: Hans Lehfeldt, Jack A. Lippes, Tenrei Ota, Samuel Soichet, Howard Tatum, Michael S. Burnhill, Silas S. Smith, Jr., Robert G. Wheeler, John F. Williford, John L. Marco, and R. P. Husemeyer.

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Russel J. Thomsen

AN ATLAS OF

Intrauterine Contraception

A History of Intrauterine Contraception

Antiquity	Quaintly fecund with fancy and maybe fact is the legend that a camel driver invented the intrauterine contraceptive device. Uncharted as to which past millennium or barren desert was involved, the story credits the observant camel master with placing stones in the uteri of his camels to protect them from the fruits of their follies during the boredom of the long caravan treks. Whatever facts this legend might contain, such are for both learning and enjoyment!
400 BC	Hipprocrates hinted at a mechanism for intrauterine contraception. Or, was it for abortion?
5–4 BC	Emperor Augustus ruled the mighty Roman Empire. Christ was born in a sleepy village called Bethlehem. And only 250 million people inhabited planet Earth.
1830	The Earth comfortably held one billion people.
1909 AD	Dr. Richard Richter reported the use of intrauterine dried silkworm gut for contraception. Pub-

lished in *Deutsche Medizinische Wochenschrift*, his article was bravely titled, "A means of preventing pregnancy." It can be considered as the first modern report of IUD use for contraception.

1923 Also published in the above German journal was a series about 453 women using an IUD similar to Richter's but containing a silk cervical tail. The inventor, Dr. Karl Pust, claimed *no* pregnancies and *no* complications!

1929 A Berlin gynecologist, Dr. Ernst Gräfenberg, reported the use of a silver ring IUD subsequently called the Gräfenberg Ring. His work set the foundation of scientific claims by which widescale IUD use eventually became a part of medicine. He can rightly be called the father of the modern IUD even though many contemporaries in Europe decried his use of IUDs. He and other European physicians skilled in IUD use came to the United States as the Nazi storm engulfed Europe. Writers of IUD history intimate that criticism of Gräfenberg and his ring was hysterical. But it is a fact that in the pre-antibiotic era major IUD complications were often disasters.

1930 Doubling in just a century, the population of planet Earth stretched to two billion.

1931 At their annual congress held in Frankfurt am Main, leading German gynecologists condemned intrauterine contraception in general and the Gräfenberg ring in particular. This effectual ban was to last three decades.

1934 Dr. T. A. Ota in Japan claimed somewhat better results with his new IUD than had Gräfenberg. The Ota Ring was basically like Gräfenberg's except for a central disc attached to the outer ring by spokes. Both IUDs continue to be used on a limited basis.

1934 Progesterone was isolated, bringing the "Pill" one step closer to reality.

1956 G. D. Searle and Company began the first human testing of a birth control pill in April at San Juan, Puerto Rico. The pill used was Enovid.

1959 Reports from Israel and Japan of long-term use of the Gräfenberg and Ota rings gave support for a reconsideration of IUD use.

1960 The 1959 IUD reports had a profound effect on Dr. Alan Guttmacher, the chief of obstetrics and gynecology at Mt. Sinai Hospital in New York City. Once having stated that IUDs should be "thoroughly condemned," Guttmacher now gave his permission for Mt. Sinai to become the first U.S. institution to allow IUD testing. In August, 1960, Dr. Lazar Margulies inserted his first spiral IUD in his own wife. Unique in its molding of barium sulfate into the plastic to give the IUD radiopacity, the Margulies Spiral was sold by Ortho until at least 1973 as the Gynekoil. It was the first of the straw-inserted linear devices.

1962 The Population Council, founded for population studies in 1952, sponsored the first of several international conferences on IUDs.

1962 The Lippes loop IUD was introduced to the 1962 IUD conference by Dr. Jack Lippes, its inventor. Its early and major use and promotion made it the standard by which other IUDs are judged. More than 25 million Lippes Loops have been used since 1962. It was the first plastic IUD to utilize transcervical nylon strings to check placement and facilitate its removal.

1965 Limited marketing of Saf-T-Coil IUDs began as a product of Deseret Pharmaceuticals, the fledgling Utah "penny stock" company. Late that year it was sold nationally through Julius Schmid, Inc., a giant in the field of condom manufacturing. The Saf-T-Coil has, like the Lippes Loop, become a standard in IUD use. It was the first IUD to be marketed in a sterile, ready-to-use pack.

1960s — Scores of IUDs were invented during this decade. Though given euphemistic names such as the heart, bow, anchor, and butterfly, few were tolerated by the harsh realities of uterine physiology. Rampant IUD invention at this time thrived on nonregulation by the Food and Drug Administration. About the only FDA involvement with IUDs during the 1960s was the 1968 advisory committee's *Report on Intrauterine Contraceptive Devices.*

1968 — Working with rabbits, Dr. Jaime Zipper from Chile demonstrated the effect of copper as an intrauterine contraceptive. His use of copper IUDs in women started in 1969.

1970 — In January, the Subcommittee on Monopoly of the Select Committee on Small Business of the United States Senate conducted the much publicized "Birth Control Pill Hearings." It is estimated that up to one million women in the United States stopped using the Pill because of the hearings. IUD sales jumped by nearly 500,000 units over the number of sales in 1969.

1970 — The February 1 issue of the *American Journal of Obstetrics and Gynecology* published the developer's article proclaiming the new Dalkon Shield IUD to be "a superior modern contraceptive." Rates of 1.1 for pregnancy and 94 percent for continuation were claimed. The A. H. Robbins Company bought the shield in June, and sales began nationally in January, 1971. Massive promotion gave the shield 66 percent of the U.S. IUD market by the end of 1971. It also came to be sold in 41 other nations.

1970s — Unrealistic claims for IUDs, IUD over-promotion, and wishful thinking propelled the IUD into an unofficial status symbol for the "liberated woman." IUDs were worn as earrings even as bras were being burned. As facts about non-testing of IUDs and the Dalkon Shield fiasco became known, the love affair between the Women's Liberation Movement and the IUD cooled.

1973 Medical Device Legislation hearings by committees of both houses of the United States Congress publicized the non-drug status of IUDs. After a decade of congressional debate, a medical device law was finally passed in 1976.

1974 Adverse publicity, plummeting sales, and legal and FDA pressure forced sale of the Dalkon Shield to stop after 4 million had been used. The CU-7 became the first copper IUD to obtain FDA new drug sale status.

1975 World population reached four billion. Despite its checkered history, the IUD has arrived as one of the means with which to help defuse the "population bomb."

1976 The Progestasert became the first progesterone IUD approved for sale. The Copper-T also obtained FDA approval for open marketing.

1979 Fifty years have passed since Dr. Gräfenberg unveiled his ring IUD.

1980 An International Symposium on Medicated IUD Systems in mid-1979 in Amsterdam and the IUD Technology, International Symposium in July, 1980, lent state-of-the-science status to IUD research and worldwide IUD use for the 1980s.

The Golden Year of the Silver Ring: Ernst Gräfenberg and His Ring

On a windy, cold winter night not too many months past I sat in a small room in an ancient castle on northern Germany's flatland near Münster. Not far away is the German village where my grandfather had been born, raised, then lured to the exciting appeal of 19th century America. Time and its recall seem blurred in such a setting. And it was in that castle near Münster, steeped as it were in history, that to me was unfolded in detail the medical saga of Dr. Ernst Gräfenberg and the famous intrauterine Ring contraceptive device which bears his name. Settings of such ancient rapproachment are ideally suited for historical outpourings. Near to my right sat Dr. Jack Lippes, the paternal figure behind the Lippes Loop, another IUD classic. He, too, was but a listener that night, excepting his occasional interjection of a choice morsel to the conversation. For across the room, fondling an assortment of antique contraceptive devices as if to pull from them hidden details and legends, was Dr. Hans Lehfeldt. Even the air seemed vivid with fact and pregnant with memory as Dr. Lehfeldt regaled Dr. Lippes and myself with anecdotes about the life of Dr. Gräfenberg and the days when only the farsighted and

A speech presented by the author to the Taunus Medical Society in Frankfurt am Main, West Germany, on February 14, 1979.

daring were brave enough to seek effective contraception technology for women under their care. Fifty years is a mere speck from the exponential view of eternity. But it can be a long time, nonetheless, as we mortals chart our endeavors. This year, 1979, marks one such epoch. It marks a half-century of importance to humanity for which it benefited, medicine from which it sprang, and German-American history amidst which it became inexorably tangled, then woven.

The year 1979—irrespective of IUD history—is certainly a year of introspection for both Germany and the United States. Apparent are the traumas our two great countries face in a world apparently beyond our control in its unbridled passions and unforgiving in its recall of past wrongs. In the context of today it does not seem inappropriate to allude to the reality of the past fifty years—five of history's most turbulent decades. For in the history of intrauterine contraception political and medical developments have often crossed. Turning, then, to Dr. Gräfenberg and his time, I first spotlight the year 1929. The location was London. There before the International Sexual Reform Congress Gräfenberg spoke, backed by the years of contraception research he had been quietly performing. He had first publicly discussed his Ring intrauterine contraceptive device in 1928 at the Berlin postgraduate course chaired by Dr. Margaret Sanger. Also participating in it was Dr. Lehfeldt, already a junior colleague and admirer of Dr. Gräfenberg. But it was the status of the September, 1929 international platform in London whereupon Dr. Gräfenberg fathered intrauterine contraception and from which its golden anniversary should be dated. His third presentation of the subject was at the Seventh International Birth Control Conference meeting in Zurich in September, 1930, adding but inadequately to the acceptance needed to assure the method's survival.

For tainted by pre-antibiotic disasters rightfully attributed to the cervico-uterine pessaries foisted upon women about the turn of the century, Gräfenberg's ring was hardly received with enthusiasm by the leading lights of German gynecology. Their reaction was soon to come. Before detailing the rise and fall of the Gräfenberg Ring, a flashback covering the highlights of Dr. Gräfenberg's busy early life must be attempted. Ernst Gräfenberg was born in 1881 at Adelebsen, a small community in the green hills some 40 kilometers from the old university town of Göttingen. The family name was taken from a nearby hill, Gräfenberg (Count's Hill) when 19th-century German Jews were permitted to bear family names. With underschooling finished in 1900, Gräfenberg went on into medicine, studying at the universities in Göttin-

gen and Munich. His doctoral thesis, "Die Entwicklung der Knochen, Muskeln und Nerven der Hand," (The Development of Bones, Muscles and Nerves of the Hand), was lauded and reputably published. His studies first led him to practice opthalmology, working in that department at the University of Würzburg. As if to give encouragement to those of us who find it difficult to choose among the many interests and rewards life presents, Gräfenberg again acutely changed his professional interests. Gynecology thereafter became his work, studying under Dr. Richard Werth and Dr. J. Pfannenstiel at the University of Kiel, where his training was completed in 1910. Thereafter, for the next three decades, the multiple facets of Dr. Gräfenberg's professional pursuits eminated from Berlin. There he maintained a private practice of obstetrics and gynecology in addition to being the chief of gynecology at a city hospital. From observation and investigation of those patients Gräfenberg produced medical publications on a widely varied spectrum of subjects including: seriological tests for pregnancy and venereal disease, pelvic anatomy, tuberculosis, dysmenorrhea, syphilis and associated congenital anomalies, and obstetrical anesthesia. He was the pioneer in elucidating the cyclical variation of vaginal secretory acidity as related to ovulation. Dr. Hans Lehfeldt's extensive review of Gräfenberg's contributions attests to wide clinical interests in addition to his classic, founding contribution to intrauterine contraception.

Gräfenberg's writings and clinical interests manifest themselves as an extension of his early and growing concern for the medical emancipation of women. Abortion, birth control, sexual realization; each claimed an ordinate amount of his thought and professional effort. Typically relevant were the thoughts he expressed during the 1929 London presentation of the Ring IUD: "A satisfactory contraceptive method is most important in dealing with psychosexual disturbances in women. By removing fear and the necessity for objectionable preparations, many physical and mental inhibitions are removed." Lest we forget, the sexual and medical rights of women in this century's first third were only cosmetically different than those under which their sisters of the Middle Ages suffered, slaved, or died. Still in the world's pre-antibiotic history and with but rudimentary anesthesia and surgical support from our modern perspective, women in the 1920s could often anticipate infective morbidity or death as a consequence of sex and childbirth. Hemorrhage added to the grim toll. From this perspective is Gräfenberg's work best appreciated. Whether in the charity ward or among the socialites of his practice on Berlin's fashionable Kurfurstendamm, Gräfenberg acutely

perceived the plight of women and sought to alleviate it. Of additional credit to Dr. Gräfenberg's pioneering contribution to intrauterine contraception is that it was done in the face of the inherent opposition of German medicine to both change and invasion of the uterus.

The bias of gynecology against intrauterine devices was not irrational in that pre-antibiotic, patent medicine milieu. From late in the 19th century a plethora of various cervico-uterine pessaries had been espoused for everything from hysteria and dysmenorrhea to abortion and even contraception. Typical of the devices in Gräfenberg's Germany was the wishbone spring pessary patented in 1902 by Dr. Carl Hollweg. A possible slight improvement of the 1920s was the device of Dr. Karl Pust. His cervico-uterine pessary made of silkworm gut attached to a cervical glass button was eventually distributed for use in over 20,000 women. In a 1923 issue of *Deutsche Medizinische Wochenschrift*, Pust claimed that there were no pregnancies among the 453 women in whom he had inserted his silkworm pessary. Candidly titled, "Ein brauchbarer Frauenschutz," (A Useful Protection for Women) Pust's report further claimed—somewhat increduously—no serious complications for the method. Unconvinced, other gynecologists denounced the Pust device.

Tangentially, intrauterine silkworm gut was first reported for use as an intrauterine contraceptive by Dr. Richard Richter. A German doctor in the small town of Waldenberg near Breslau, Richter plainly titled his report, "Ein Mittle zur Verhutung der Konzeption" (A Means of Preventing Conception), frankly audacious at a time when it was illegal to prescribe birth control. Aware of both the valid objections to intrauterine tampering and the earlier use of silkworm, Gräfenberg's first efforts utilized silkworm gut in a star shape. That gave way to a silkworm gut ring which was further refined and made visible on x-ray by wrapping it with a wire of "German Silver." Finally evolved as the device called the Gräfenberg Ring, the circle of tightly wound German Silver has been analytically studied in modern times and found to contain nickel, zinc, and 26 percent copper. Ten years of systematic evaluation involving hundreds of insertions predated Gräfenberg's 1929 report of the Ring IUD. Shortly thereafter, a scattering of other European physicians added statistics verifying both the increased clinical use of the Ring and the mounting number of damaging reports of pelvic infections associated with its use. The demise of Gräfenberg's Ring swiftly followed his original optimistic reports. His fourth and last public presentation of the subject was in 1931 at the German Congress of Gynecology meeting in

Frankfurt am Main. Composed of but seventeen printed lines, the report was denounced by virtually all of the attending leading lights of German gynecology including Dr. Ludwig Fraenkel, professor and chairman of gynecology at Breslau and Dr. S. Aschheim. So damning was the denouncement and so authoritative the denouncers that for all practical purposes the Gräfenberg Ring was banished. The nearly concurrent Nazi ban on contraception in promotion of national fertility soon assured the total disappearance of intrauterine contraception from German medical practice.

Despite the ignoble treatment the Ring was afforded in its demise, the attribution to Dr. Gräfenberg as the father of the intrauterine contraceptive device is based not on first use of the method, but on the scientific thoroughness by which he investigated and reported the use of the Ring. In elucidating its effectiveness, complications, physiological impact on the uterus, and safe insertion and removal techniques, Gräfenberg contributed a scientifically valid foundation upon which the method could be resurrected under the changed atmosphere of medical practice and population problems facing the world as it approached the sixth decade of the 20th century. The unfinished character of the Ring's story was akin to many aspects of Dr. Gräfenberg's life subsequent to the 1931 Frankfurt confrontation. The cloud of National Socialism fell ever more darkly on Germany's Jews as the uncertainties of the early 1930s turned into terrible realities. Many Jewish doctors fled Germany including some who would become prominent in supporting IUD resurgence in the 1960s. Drs. Hans Lehfeldt left in 1934, encouraging a similar course for his friend Gräfenberg. Seemingly insulated by his position as gynecologist to the wives of the rich, and high placed Nazi politicians and diplomats. Gräfenberg was misled about his safety and stayed in Berlin. Possibly augmenting his hopeful presumption of safety was his patriotic credential of having served in World War I as a German medical officer on the Russian front. In 1937 he was imprisoned near Berlin. Surviving—as Dr. Lehfeldt conjectures—because the warden's wife was his patient, Gräfenberg languished in prison until his release was ransomed by Dr. Margaret Sanger for a large sum in U.S. dollars in 1940. Gräfenberg arrived in New York City in 1941 subsequent to a circuitous path from the German prison, through Siberia and Japan, and with a short professional stop in Chicago, he assumed a busy life of obstetrical and gynecological practice. His continued interest in contraception was manifest in his work at the Margaret Sanger Research Bureau. And he helped Dr. Herbert Hall in the development of a stainless

steel ring IUD eventually marketed as the Inhiband. Texts tracing IUD history state that warnings given Dr. Gräfenberg not to attempt the use of his Ring were so effective as to preclude his ever again utilizing this method. This is not correct. Dr. Hans Lehfeldt asserts as "irrefutable" his personal knowledge that his friend Gräfenberg used modified Ring IUDs made in the strict confidentiality of his private New York practice.

But scant public notice and no professional accolades marked the death of Dr. Gräfenberg on October 28, 1957, after a prolonged, debilitating struggle against Parkinsonism. An unfortunate irony of human existence is the frequency at which deserved recognition for a person's noteworthy accomplishments is withheld until after his death. Dr. Gräfenberg's death predated by but two years the modern rebirth of intrauterine contraceptive research, use, and general acceptance. In 1959, Dr. Alan Guttmacher—having adamantly opposed IUDs during Gräfenberg's life—condoned the experimental use of handmade IUDs at Mt. Sinai Medical Center by Dr. Lazar Margulies. Dr. Gräfenberg had himself practiced at Mt. Sinai for a decade and a half. Guttmacher's change of mind was precipitated by his alarm over the world's burgeoning population, and reinforced by the late 1959 publication from Israel and Japan of studies documenting Gräfenberg and Ota Ring IUD insertions in thousands of women. By 1960, Margulies was marketing his plastic spiral, the Gynekoil, through Ortho Pharmaceutical Company. It was the first of the deluge of devices that flooded gynecological practices in the 1960s. The rapidity of the acceptance of intrauterine contraception can only be compared to the precipitous decline of the Gräfenberg Ring after its condemnation in 1931 at Frankfurt.

To IUD or Not to IUD: Intrauterine Contraception Comes of Age

In the United States, the evolutionary nature of the modern IUD was guided as much by the marketplace as by astute medical practice because of a major, but little understood, oversight in the regulation of medical modalities. Even those of us who chafe under the specter of excessive and indolent governmental red tape can now recognize that the total lack of regulation in the testing, promotion, or clinical use of IUDs prior to 1976 led to grievous trauma to both patients and their physicians.

I, like most physicians trained during the resurgence of IUD use, never questioned that the product we commended to and used in patients had not passed the most rigorous scientific inquiry and regulatory scrutiny. Certainly after the tightening of U.S. food and drug laws in the wake of the thalidomide disaster, the average gynecologist had little reason to question the propriety of IUD use. All IUDs came in packages blatantly labeled, "Caution: Federal law restricts this device to sale or dispensing by or on the order of a physician." It was not until preparing to testify before a U.S. Congressional committee about IUDs in 1973 that I discovered that there was no such law. How it became a standard pronouncement on IUD packages I still do not know. But it is patently false. Not only did no federal laws restrict the sale and usage of IUDs, but until 1976 IUDs remained completely outside

the pale of any legally delegated observation. Medical devices, regardless of their complexity or potential for good or evil, had virtually no more regulation than did false teeth, glass eyeballs, crutches, or horse-hair wigs until the passage of the Medical Devices Act of 1976. This aura of nonregulation might appear to be the capitalistic dream. And it certainly was democratic, leaving equally unfettered the concerned medical investigator and the charlatan.

Throughout the watershed of enthusiastic IUD invention in the 1960s and early 1970s, it would have been perfectly legal in the United States (and virtually all other non-U.S. jurisdictions) to advertise, market, and insert paper clips as intrauterine devices. Frankly, no premarket testing would have been required, grandiose advertising claims for paper clip IUDs could have been made, and no requirements existed to report injuries or deaths caused by the paper clip IUD.

That era motivated each gynecologist to solve the mysteries of intrauterine contraception. What gynecologist could deny lying awake fitfully fantasizing a design for the "perfect IUD"? And out of such inspirations of the night has come a mind-boggling variety of IUD shapes, sizes, and incidental appendages.

Added to these scores of devices has been an equivalent variety of inserting and removal instruments, uterine depth probes, and procedures bent on locating errant IUDs.

Occasionally out of all this has come a truly remarkable breakthrough. Concerning one such epic advance in intrauterine contraception, it is fitting to pay tribute to Dr. Jack Lippes for his great contribution to IUDs: the perfect tail. When introduced in 1960, the first commercial plastic IUD, the Margulies Spiral (Gynekoil), was equipped with an elongated plastic tail that protruded down through the cervix. There it was to be trimmed by the inserting physician. Always a difficult problem because of the vagaries of cervical anatomy and minor movement of the device following insertion, the stiff plastic tail often ended up protruding a short distance beyond the cervix. This accounted for somewhat of a public outcry in consequence of the resultant penile agony during intercourse. The Gynekoil was, however, inserted in tens of thousands of women during a marketing course of over a decade. With the 1962 commercial introduction of the Lippes Loop, this problem was remedied by abandoning the stiff plastic tail for pliable nylon threads.

It is appropriate to recognize the unique contributions women have made to the development of intrauterine contraception. For instance, it is to be recalled that the first Margulies Spiral

(Gynekoil) was inserted by Dr. Lazar Margulies into his own wife. It went on to become commercially the first of the plastic IUDs. In that context it becomes conjectural whether the Margulies Spiral was named after Dr. Margulies or in honor of his brave wife.

This illustrates that the hands that have molded, twisted, and shaped IUDs have been connected to men. In surveying the history of some 200 IUDs, I have found only one that was invented by a woman: the Ahmed device designed by Dr. Mary Aftad Ahmed of Karachi, Pakistan.

There are implications for the future of intrauterine contraception that have compelling importance for both the medical profession and women using the method:

1 The implant nature of intrauterine contraception and its ability to create or enhance infection can cause infertility or other pelvic disorders. Uniquely possible in the changing milieu of the 1980s will be the woman, rendered sterile because of an intrauterine contraceptive device, who becomes pregnant through intrauterine ovum transplantation. Another delayed-discovery IUD complication that I predict will be encountered in this decade is Dalkon Shield uterine perforation discovered at the time of attempted elective removal. The massive use of this difficult-to-insert device (4.5 million sold in the United States and additional marketing in 40 other countries) led to a significant number of perforations at the junction of utero-cervical flexure, often with the Dalkon Shield tail appearing to show correct placement of the device.

2 The modern use of IUDs now enters its third decade and its use has been massive around the world. It must be remembered that among such a large group of users will be those women who never really understood the goings-on of the procedure that gave them the IUD. Many other women will age healthfully with a device that, for more than a decade, gave them such uneventful protection that they do not seriously question its need for removal. Inevitably we will find many women entering menopause with intrauterine devices still within their bodies. The atrophied, noncycling, postmenopausal, IUD-containing uterus certainly carries the potential for multiple types of pathology and clinical manifestations.

3 The ultimate solution for many problems facing humanity today is rational population control. Within the realm of such family planning must be intrauterine contraception. Despite its successes and failures and its checkered history, intrauterine contraception must be continually perfected to maximize its usefulness and minimize its side effects.

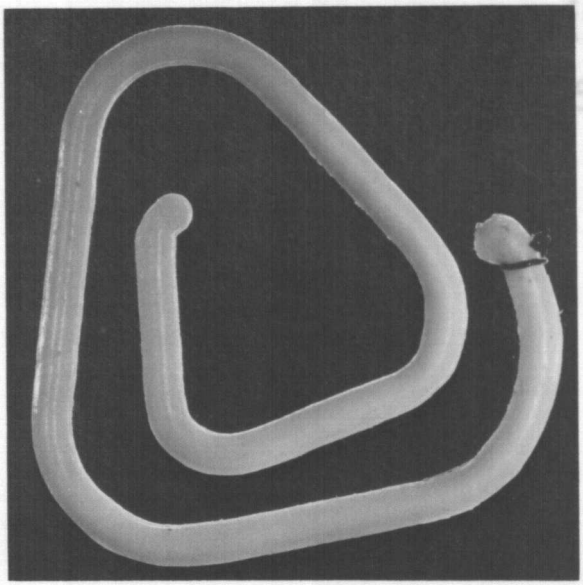
Atlas

Intrauterine Contraceptive Devices

In the following section of the atlas are depicted the majority of the world's important intrauterine contraceptive devices from the viewpoints of medical history, bioengineering, and clinical use. Except for minor variations, they have been arranged alphabetically by their common, trade, or medical journal names. No effort has been made to imply importance of a particular IUD or its own approval or disapproval by the author on the basis of its location in the listing.

Also, the reader's attention is drawn to the index, which gives a separate listing for those intrauterine contraceptive devices that contain drugs.

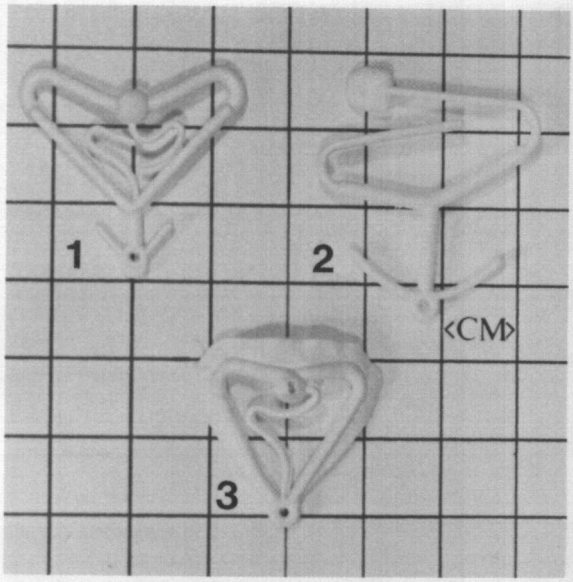
Unless otherwise specified, photographs were taken by the author.



(Photo courtesy of R. P. Husemeyer, M.D.)

AHMED

Apparently never attaining widespread use, the Ahmed IUD still maintains a historically unique place in the continuing saga of intrauterine contraception. Developed by Dr. Mary Aftad Ahmed of Karachi, Pakistan, it is most likely the only IUD developed by a woman. It was patented in Pakistan and was also granted United States patent 3,306,286 in 1967. Little is known of the statistics pertaining to its use.



ANCHOR

SF-Bow (Anchor Bow) (1)

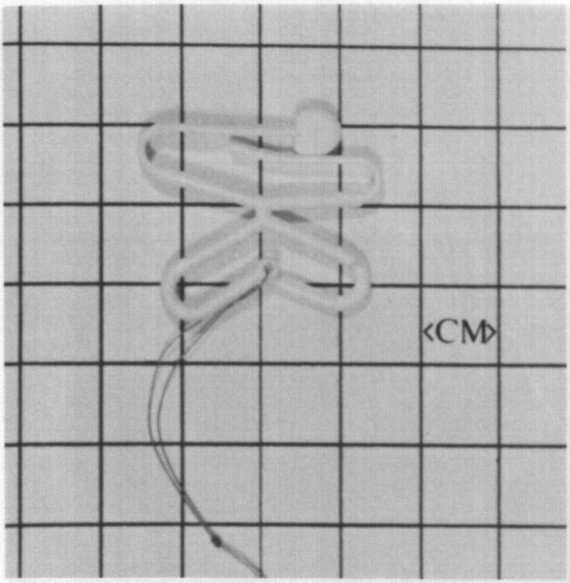
This little used or tested IUD is a variation of the Anchor IUDs invented by Dr. Michael S. Burnhill. It was commercially sold by American Caduceus Industries, Inc.

Regular Anchor (2)

Invented by Dr. Michael S. Burnhill, the regular size Anchor IUD was sold commercially by American Caduceus Industries, Inc.

Anchor (Prototype) (3)

A molding variant of the Anchor IUDs, this was not likely used clinically.

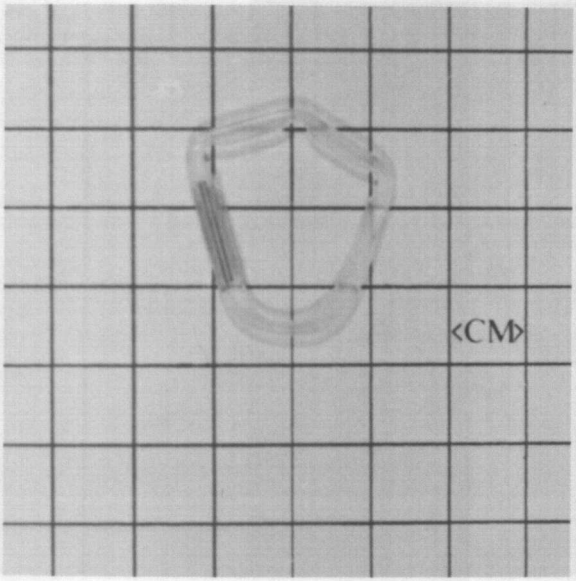


LARGE ANCHOR

The large Anchor IUD was invented by Dr. Michael S. Burnhill and is covered by United States Patent 3,537,445. It was sold on a small basis by American Caduceus Industries, Inc., of New York City.

REFERENCE

Burnhill, MS: The Anchor—principles of designing and testing an IUD. In: *Advances in Planned Parenthood*, edited by AJ Sobrero, C. McKee, vol. 5, pp. 110–116. Amsterdam: Excerpta Medica, 1970.

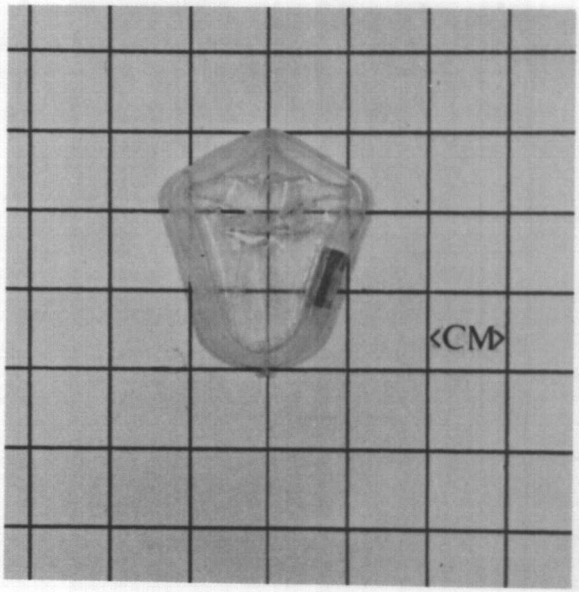


ANTIGON

The Antigon IUD was developed by Dr. Poul Lebech and Dr. Mogens Osler in Copenhagen, Denmark. Unique is the magnetic metal strip placed in one side of the device for location by a galvanometer. The Antigon is made from polyethylene without barium and is classified as a "closed ring." A modified IUD, the Antigon-F closes the ring with a membrane and has a cervical tail of two nylon threads. The "F" stands for Dr. Fritz Fuchs of the United States who modified the Antigon.

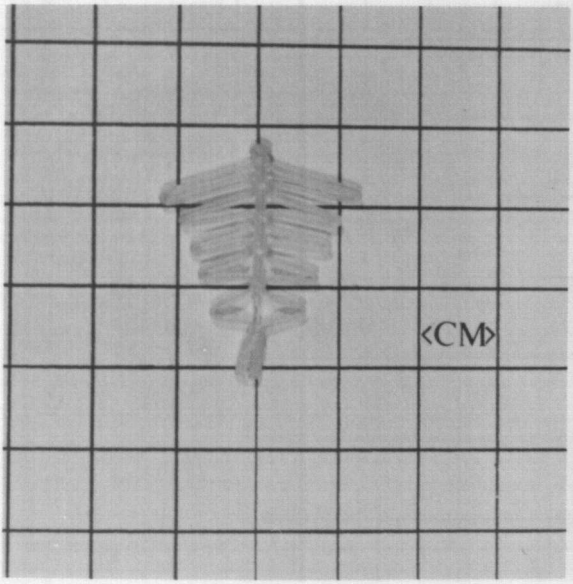
REFERENCE

Fuchs F, Risk A: The Antigon-F, an improved intrauterine contraceptive device. Contraception 5:119-127, 1972.



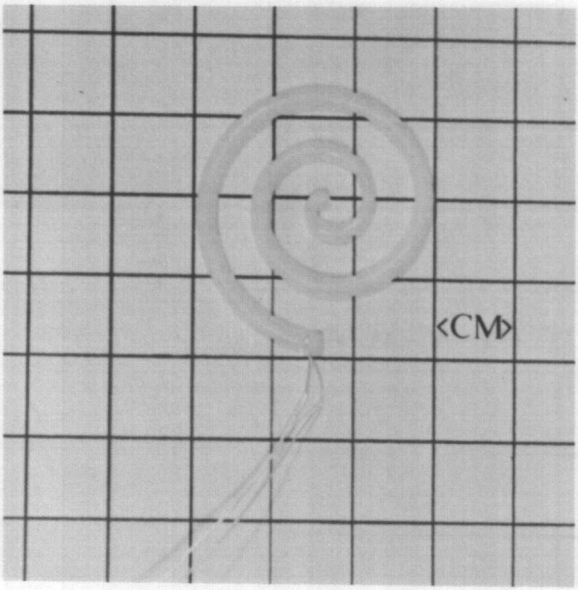
ANTIGON F

As is explained in the description of the Antigon IUD, Dr. Fritz Fuchs modified the basic Antigon ring by adding a central membrane and a double, nylon cervical tail. This Antigon F was inserted in a patient in New York City in 1968, and removed in Frankfurt am Main, West Germany in 1978. The cervical threads broke off during the removal. The slits in the membrane have become foci for calcium deposits.



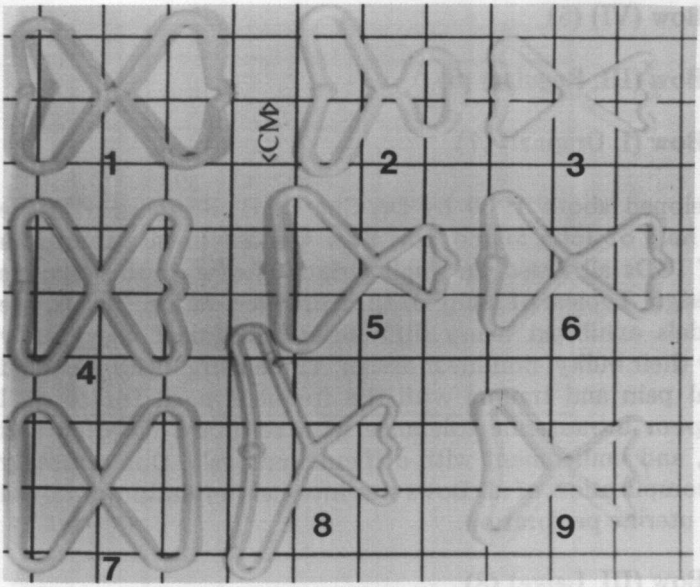
BATTELLE EXPERIMENTAL IUD

Made by Battelle Laboratories, this "thinker's IUD" is a test model developed so as to be linear for insertion, but to expand while in the uterine cavity for maximum coverage of the endometrium. Too stiff for actual use, it remains an intriguing IUD for those who attempt to think of the "perfect" IUD.



BEOSPIR

Made in Yugoslavia, the Beospir IUD is constructed of barium impregnated plastic. It has a diameter of 27 mm and two white cervical threads. It is a virtual duplicate of the original spiral plastic IUD invented by Dr. Lazar Margulies in 1959.



BIRNBERG BOW

Birnberg Bow (IV, Postpartum) (1)

This large Bow is typical of those used in small clinical scale for postpartum insertion.

Birnberg Bow (III, Small) (2)

Birnberg Bow (II, Small) (3)

Not widely used, this smaller Bow was made in early 1963. Patent claims and information for the Bows are found in United States Patents 3,253,590 and 3,230,953.

Birnberg Bow (V) (4)

About 1961, minor molding changes were made in the original Bow to help its flexibility for placement into an insertion tube. Such placement was still difficult, and the necessary inserting straw was a large diameter. This Bow had no cervical threads.

Birnberg Bow (VI) (5)

Birnberg Bow (III, Regular) (6)

Birnberg Bow (I, Original) (7)

First developed about 1960 by Dr. Charles H. Birnberg with the technical help of John Marco, this Bow was the lineal parent of a family of IUDs all based on small variations of a double-triangle "bow" design. Typical of many of the "first generation" IUDs, the Bow models exhibited many difficulties in clinical use mostly caused by their bulky, nonlinear design. These difficulties included insertional pain and trauma with the frequent need for cervical dilation, poor intrauterine tolerance with resultant bleeding and cramping, and embedment with difficult removals. One remotely possible complication of all Bows was internal herniation of bowel following uterine perforation.

Birnberg Bow (III, Large) (8)

This Bow variation was made in mid-1962. It had limited clinical testing or usage.

Birnberg Bow (II, Regular) (9)

In early 1962, the lower triangle of the Bow was narrowed in an attempt to make the Bow useful in nulliparous women. Still too bulky and rigid, the Bow required cervical dilation for insertion and had excessive side effects.

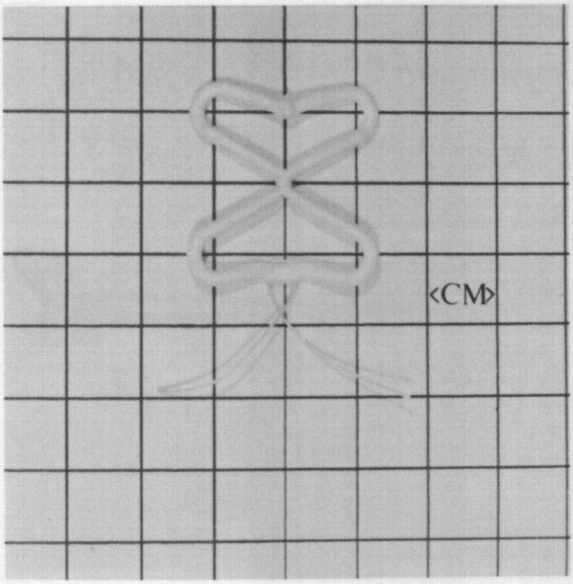
REFERENCES

Birnberg CH, Burnhill MS: A new intrauterine contraceptive device. Am J Obstet Gynecol 89:137–138, 1964.

Burnhill MS, Birnberg CH: Superimposition hysterography as a tool in the investigation of intrauterine contraceptive devices: Preliminary report. In: Intra-Uterine Contraceptive Devices, edited by SJ Segal et al., International Congress Series, No. 86, pp. 127–134. Amsterdam:Excerpta Medica Foundation, 1964.

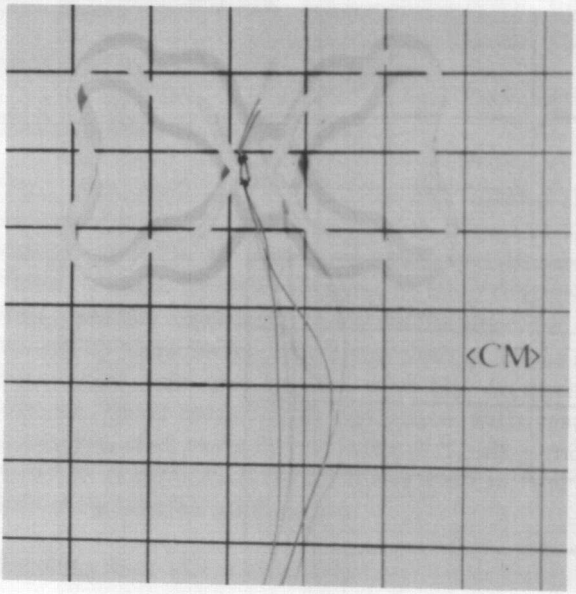
Burnhill MS, Birnberg CH: Contraception with an intrauterine bow inserted immediately post partum. Obstet Gynecol 28:329–331, 1966.

McCammon, RE: The Birnberg Bow as an intrauterine contraceptive device. Obstet Gynecol 29:67–70, 1967.



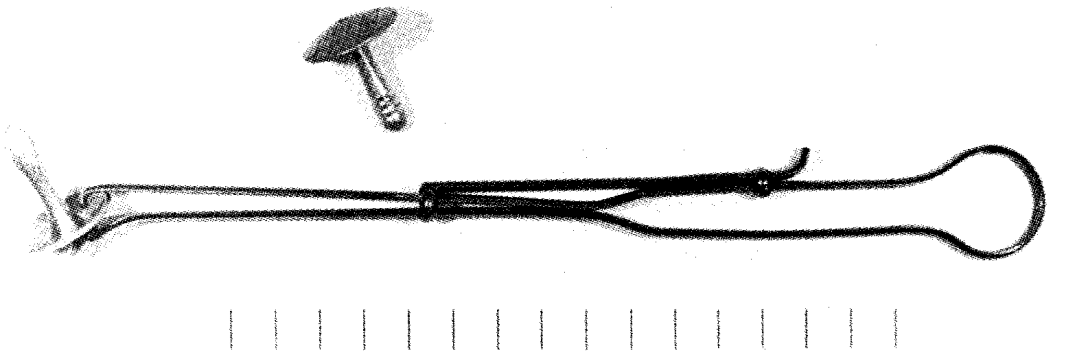
BIRNBERG BOW (V, REGULAR)

Minor alterations of the type V Bow included the addition of this woven cervical thread. This became the most widely used commercial Bow sold from the mid-1960s to the early 1970s. Its rigidity gave it a high medical removal rate.



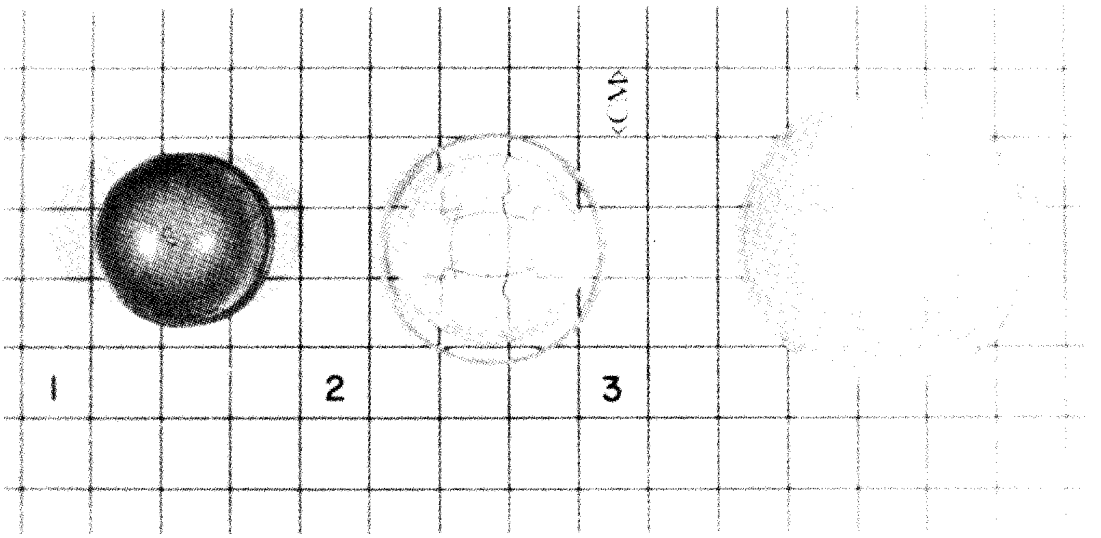
BUTTERFLY

Described in its advertising as having "lowest expulsion, lowest removal, and lowest failures," there were actually no studies to support these claims. Sold by Graham-Field Surgical Company in New York, some 20,000 Butterfly IUDs were distributed before the FDA urged the discontinuance of sales in the United States. It was claimed that the Butterfly had a unique "three-dimensional" design that would increase its effectiveness. Actually, such an IUD is bulky, difficult and dangerous to insert, and generally poorly tolerated by the uterus.



CERVICAL BUTTONS AND INSERTER

Shown here are two of the large variety of cervical button type of pessaries. These have a rather short stem, and as such cannot be considered true cervico-uterine pessaries. As with the cervico-uterine pessaries, these cervical buttons were fitted for the correction of a variety of pelvic ills in women. The results were equally varied. The ingenious applicator facilitated placement into the cervix while a suture was placed through the cervical tissue and secured through a small hole in the rim of the button.



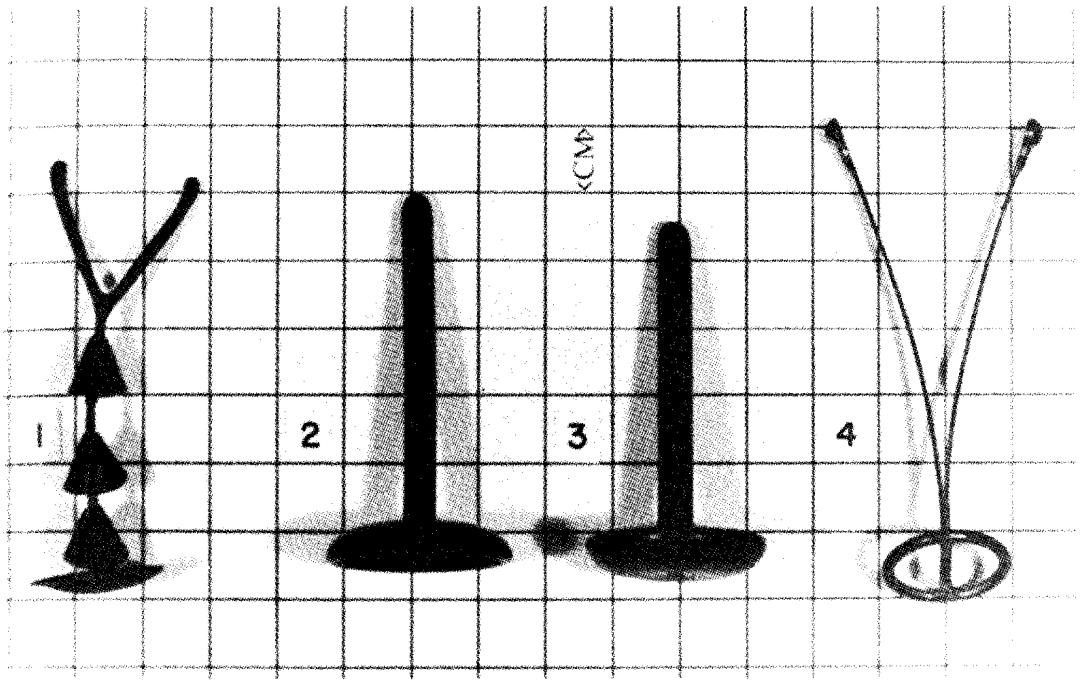
CERVICAL CAPS

Shown here for completeness and historical perspective are three types of the many different cervical caps that have been used as barrier contraceptives. Modern gynecology has also utilized similar caps as an adjunct to performing artificial donor insemination. Type number 1 is metal; 2 and 3 are plastic. A rubber cap, the Prencap, is manufactured in England.

A variety of widths were made of most types of cervical caps to accommodate the various widths and shapes of the cervix. The physician fitted the woman for the optimal size. She then had the difficult task of attempting to place it on the cervix in conjunction with her contraceptive needs. Understandably, the use of cervical caps has been virtually relegated to history except for occasional surges of local promotion and popularity.

Barrier contraceptives—in addition to the widely used modern diaphragm—reach far back into contraceptive history. Through the centuries a wide variety of materials have been recommended for vaginal packing to prevent conception. Included have been animal dung, leaves, sponges, paper, and beeswax. Casanova, the renowned paramour, urged women to use half a lemon rind as a cervical cap.

The specific history of the cervical cap dates back to the development of the "cautchuk pessarium" by Dr. Friedrick Adolphe Wilde, a German gynecologist, in 1838.



CERVICO-UTERINE PESSARIES

Remotely related to intrauterine contraceptive devices were the intracervical or cervico-uterine stem pessaries. These "devices of the devil" were inspired through combinations of wishful thinking, ignorance, and even patent medicine hucksterism. They were promoted for the cure of most female problems including those of libido, infertility, and dysmenorrhea. They were often used to induce abortions in the hands of quacks and the desperate. In the pre-antibiotic era the frequent severe pelvic infections caused by these devices could be fatal. The ill repute of the stem pessaries because of the infections they produced caused most doctors to doubt the safety of any intrauterine device. Historically, it must be realized that this was not an unwarranted assumption, for it is a fact that before antibiotics even an apparently mild pelvic infection caused by an intrauterine object could result in a catastrophe of life-threatening proportions.

Wishbone (1)

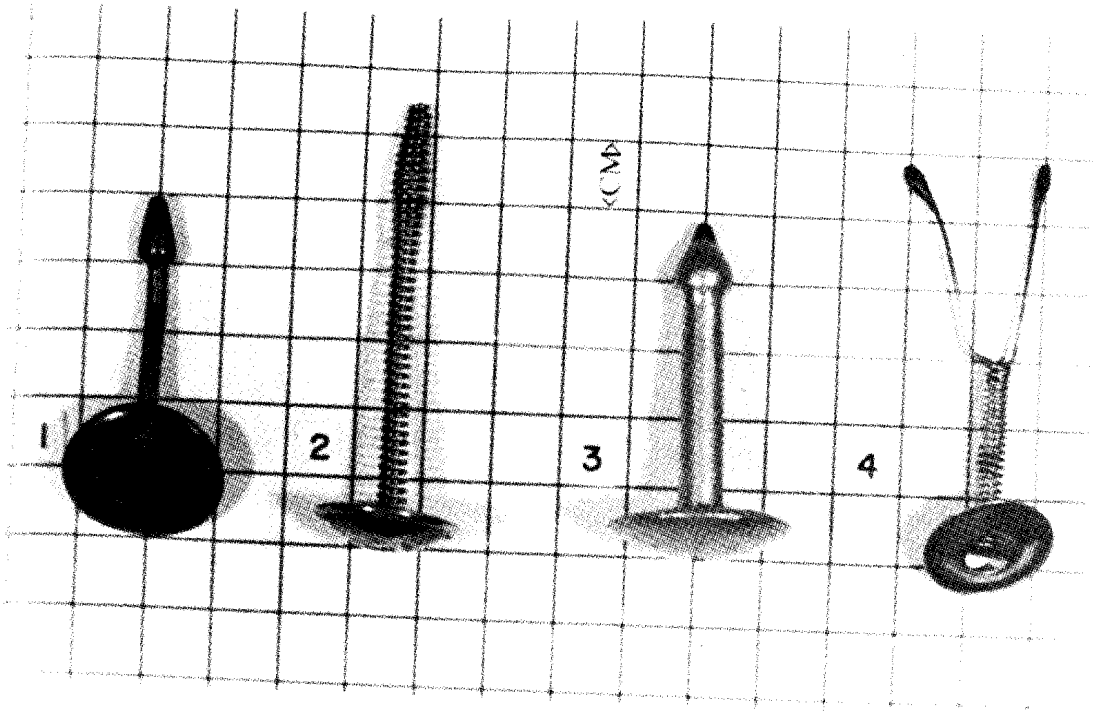
This pessary had a cervical button, three conical fixtures on the stem for the purported need to keep the cervix open, and the wishbone intrauterine portion. It is made of an early celluloid-like substance. It would have been, of course, very painful for most women.

Stem Pessaries (2 and 3)

Typical of the simple stem pessaries are these two slightly varied hard rubber models.

Hollweg (4)

This cervico-uterine pessary was invented by a Dr. Hollweg in Germany and used in the 1920s and 1930s. It is made of a malleable metal covered with silver.



CERVICO-UTERINE PESSARIES

German (1)

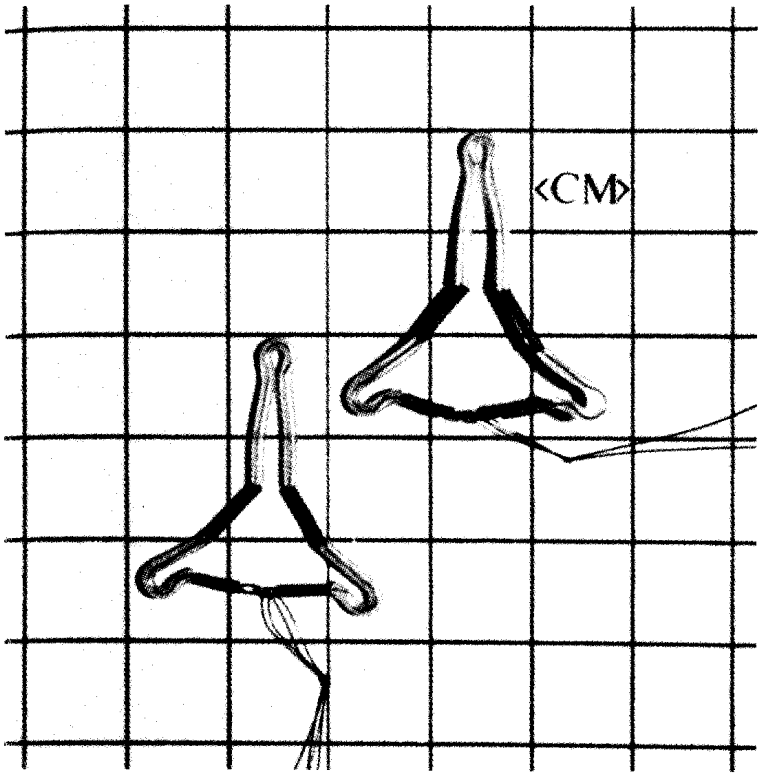
Bley Uterector (2)

With United States Patent Number 1,917,870, issued on July 11, 1933, this cervico-uterine pessary achieved the status of a truly patented medical device. "It is well known to physicians, surgeons and many others that barrenness, painful menstruation and other similar ills of women are frequently the result of malposition of the uterus," states the patent for the Bley Uterector. It was designed to be the best remedy for such problems. Its genius resided in the screw-like nature of its spring stem. Continues the patent, "The invention provides a device which can be inserted into and removed from a uterus having any degree of malposition or deformation, merely by manipulating the device in the same manner that a screw is threaded into or removed from a close fitting aperature . . . ." Of course, the conjecture that this was the best of the cervico-uterine pessaries still did not make it a safe idea.

Cervical Button (3)

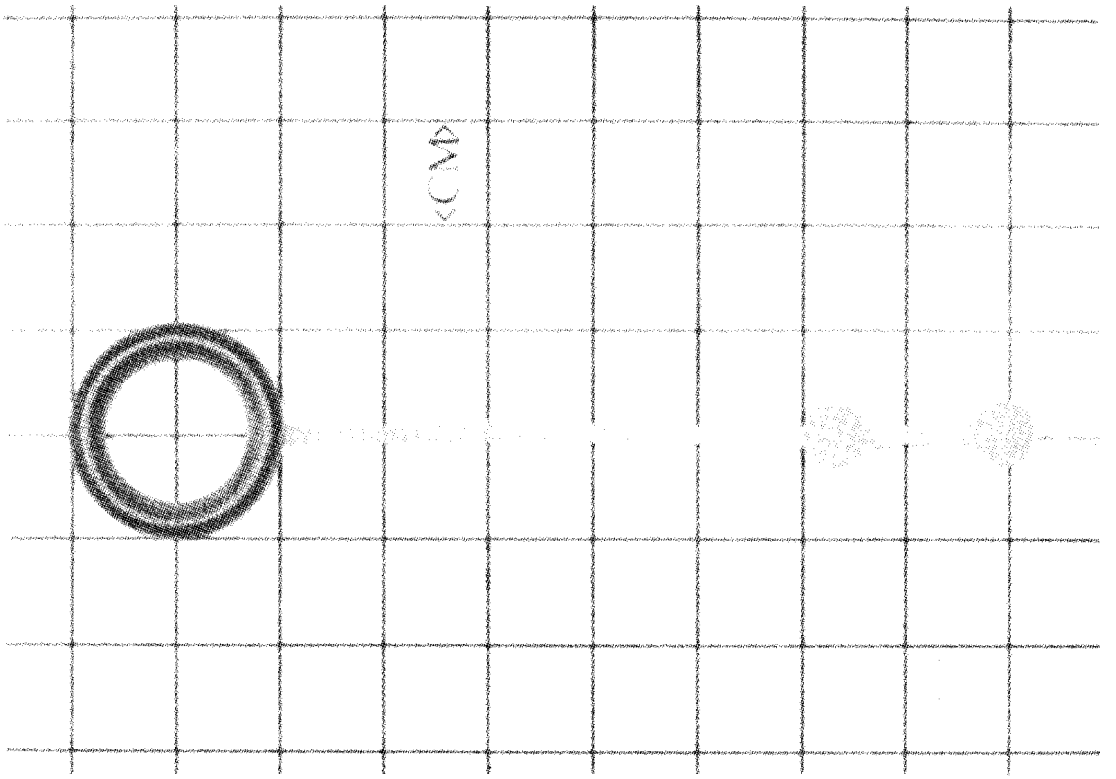
Refer also to the separate photograph of cervical buttons along with their inserter, p. 31.

German, Gold (4)



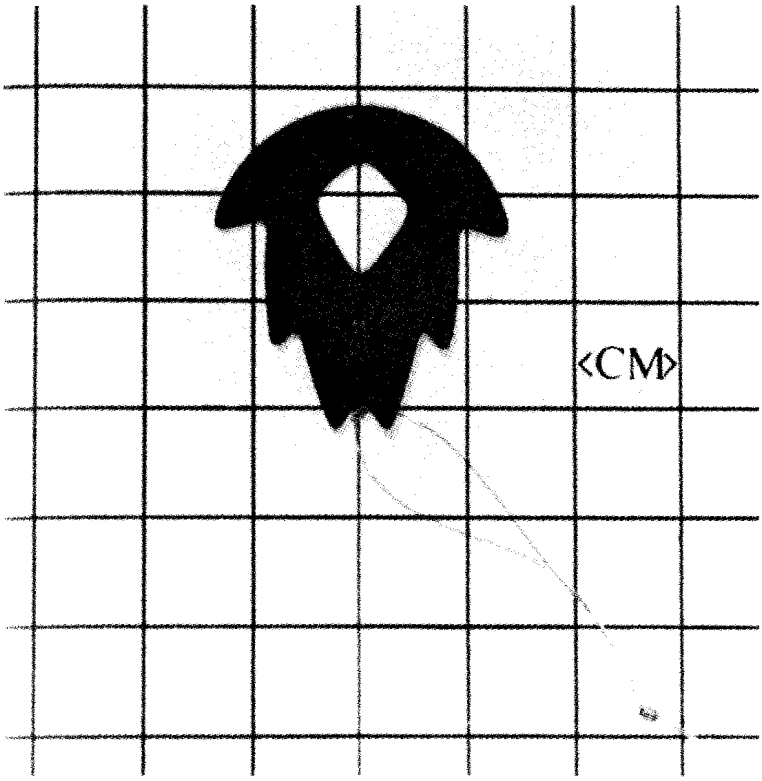
CHINESE COPPER IUDS (TWO SIZES)

It is estimated that some 40-50 million women use IUDs in the Peoples Republic of China (1980). These are two sizes of a copper bearing IUD currently used in China. No specific "event rates" are available.



COMET

Developed by Dr. Jerome Schwartz and Dr. Franklin C. Reyner, the Comet IUD was conceived as a blending of the historically tried ring design and newer biologically inert materials. As such it is comprised of a stainless steel spring formed into a ring and covered with Silastic. It is covered by U.S. Patent 3,256,878. It was originally made by Skye-Ray Medical Supply Corporation, 88-61 76th Avenue, Glendale, New York 11227, but is now of limited availability.

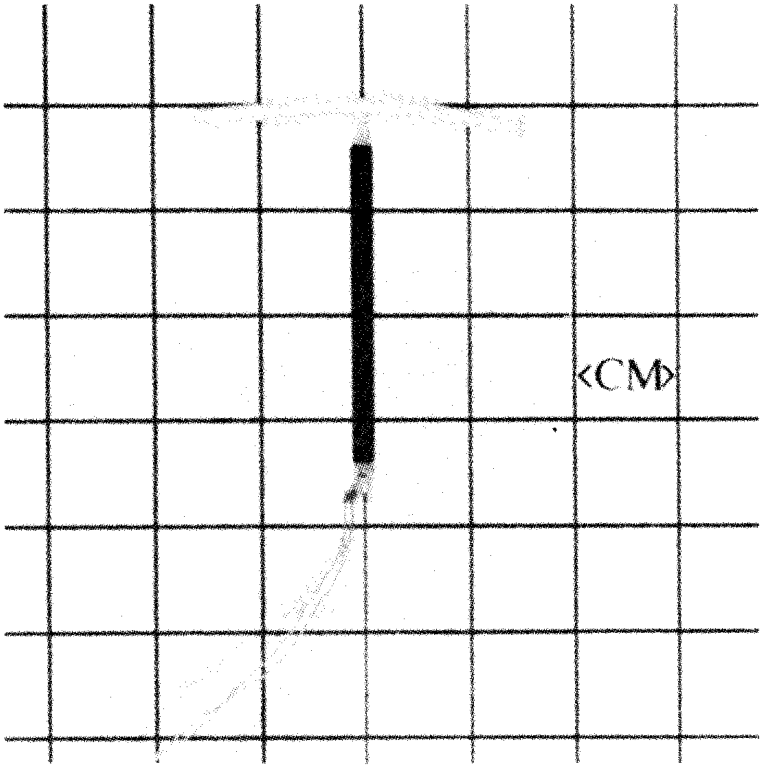


CONTRALEAF

This IUD has been given the trade name of Contraleaf. However, it is variously called the Leaf, Latex Leaf, and Anderson Leaf in the medical literature. Developed in Australia by Dr. Ian Anderson, the pliable silicone Leaf incorporates copper and zinc powders as 21 and 17 percent of its weight. It has undergone study in India, Malaysia, and Australia.

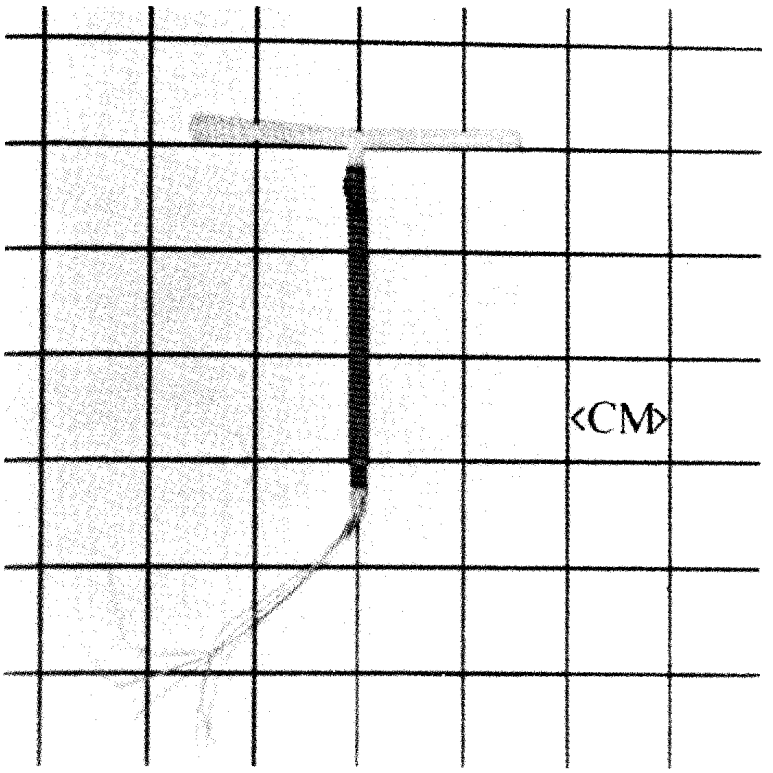
REFERENCE

Anderson I: The Leaf IUD. In: Intrauterine Devices—Development, Evaluation and Implementation, edited by RG Wheeler, GW Duncan, JJ Speidel, pp. 199-202. New York: Academic Press, 1974.



COPPER T 30

A surface area of 30 mm^2 of copper is exposed by the sheath on the vertical stem of this T IUD. It has been found to be less than the optimal amount of copper for best contraceptive effect. Also, this type of copper placement on the T gives the stem much more rigidity than is desirable, allowing for a stronger possibility of retrograde penetration of the stem into the lower uterine segment or the cervix.



COPPER T 200

The addition of 30 mm^2 of copper to the plain plastic T IUD dropped the rate of pregnancy from 18.3 to about 5 per 100 woman-years of use. Based on this finding the Copper T 200 was developed. It has 200 mm^2 surface area of copper. Studies have shown that 30-50 μg of copper are lost each day by the intrauterine TCU 200. Serum copper and ceruloplasmin do not change in the woman using the IUD.

Patent rights, disputes, and negotiation about the use of copper delayed generalized marketing of the Copper T device in the United States until the beginning of 1980 although its use had already become widespread throughout Europe and elsewhere. As marketed by Searle Laboratories under the registered trade name Tatum-T, the device sold in the United States incorporates 120 mg copper wire wrapped on the vertical portion of the Tatum-T providing 210 mm^2 of intrauterine surface copper exposure area.

REFERENCES

Cooper DL et al.: The Copper T 220C: A new long-acting copper intrauterine contraceptive device. Am J Obstet Gynecol 124:121-124, 1976.

Fortier L et al.: Canadian experience with a copper-covered intrauterine contraceptive device. Am J Obstet Gynecol 115:291-297, 1973.

Mishell DR et al.: A study of the copper T intrauterine contraceptive device (TCu 200) in nulliparous women. Am J Obstet Gynecol 116:1092–1096, 1973.

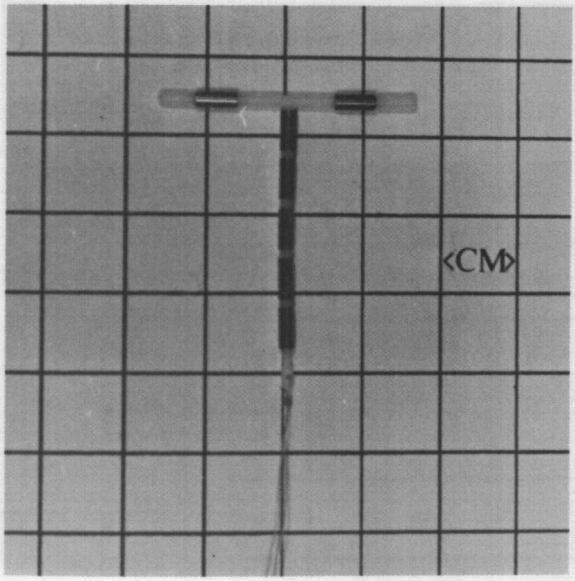
Roy S et al.: Experience with three different models of the Copper T intrauterine contraceptive device in nulliparous women. Am J Obstet Gynecol 119:414–417, 1974.

Tatum HJ: Metallic copper as an intrauterine contraceptive agent. Am J Obstet Gynecol 117:602–618, 1973.

Tatum HJ et al.: Management and outcome of pregnancies associated with the Copper T intrauterine contraceptive device. Am J Obstet Gynecol 126:869–879, 1976.

Timonen H et al.: Use-effectiveness of the copper-T300 during the first year. Am J Obstet Gynecol 120:466–469, 1974.

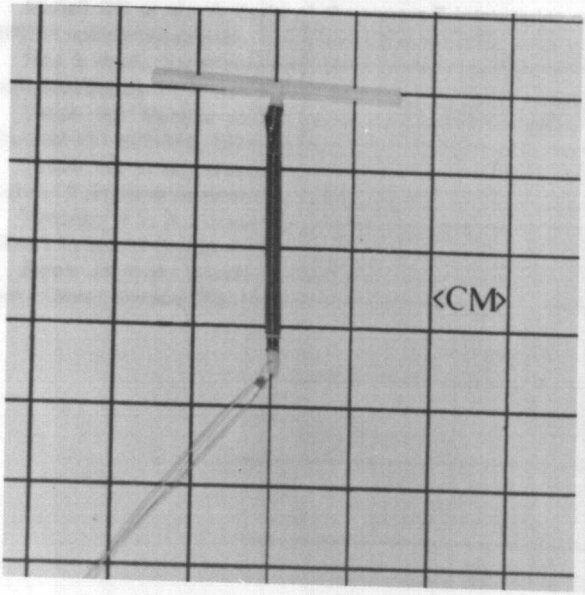
Zipper JA et al.: Metallic copper as an intrauterine contraceptive to the "T" device. Am J Obstet Gynecol 105:1274–1278, 1969.



COPPER T 220C

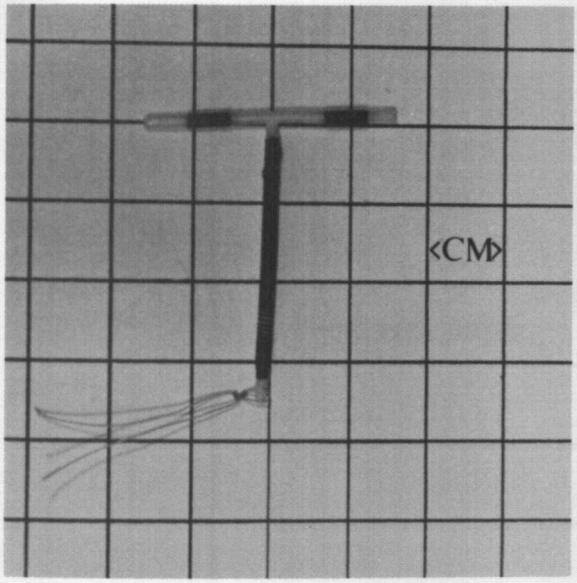
Copper sleeves give this research model Copper T 220 mm^2 surface area exposed to copper.

Information concerning all models of the Copper T can be obtained from The Population Council, 245 Park Avenue, New York, New York 10017. The Copper T 200 is internationally available through a number of commercial distributors. A listing of these distributors can also be obtained from The Population Council.



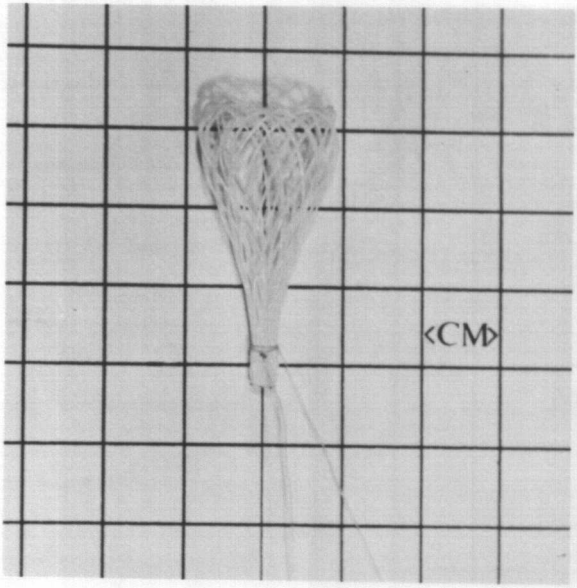
COPPER T 300L

This research model of the Copper T series bears enough copper wire to provide 300 mm^2 surface area of copper.



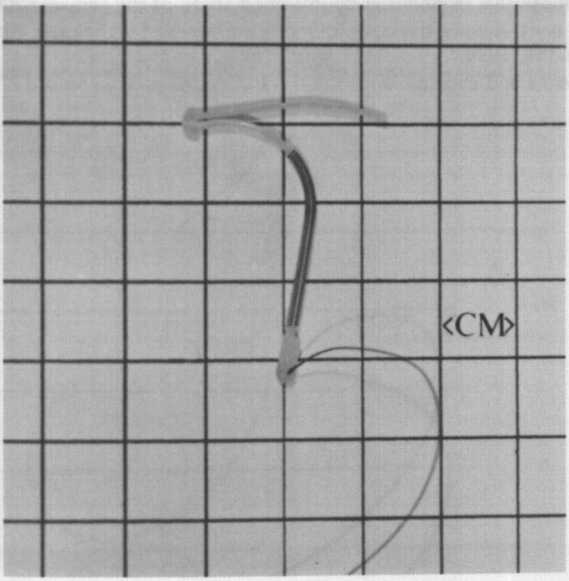
COPPER T 380A

This growing family of Copper T IUDs marks attempts to increase their effectiveness and intrauterine lifespans. In addition to 380 mm^2 surface area of copper, the sleeves of copper on the arms of the T were added to give a longer lifespan for the copper. It is claimed that these sleeves can effectively release copper in the uterus for up to 20 years.



COROLLE

Dr. Jean Cohen of Paris, France, is the developer of this multiple loop IUD designed to cover a large portion of the uterine cavity. It is distributed by A. T. N., 156 rue Oberkampf, Paris. Little else is available concerning this device. It is made of a type of plastic, has two nylon cervical threads, and comes with a straw type inserter in a sterile package.



CU-7 (GRAVIGARD)

In 1968 Dr. Jaime Zipper of Chile showed the contraceptive effect of intrauterine copper in rabbits. He first used copper IUDs in women in 1969. G. D. Searle and Company was given FDA approval to market the CU-7 in the United States in 1974. It was the first IUD to be marketed in the United States after having undergone "new drug" studies. Outside of the United States it is marketed under the tradename, Gravigard. It bears 200 mm^2 of "pure, virgin electrolytic copper wire," and compares with the Copper T 200.

For information concerning the CU-7, write to Searle Laboratories, Division of G. D. Searle & Company, Chicago, Illinois 60680.

REFERENCES

Nebel WA et al.: Clinical experience with the Copper-7 intrauterine contraceptive device. Am J Obstet Gynecol 126:586-589, 1976.

Newton J et al.: Intrauterine contraception with the Copper 7: Evaluation after two years. Brit Med J 2:447-450, 1974.

Patchell RD: Rectouterine fistula associated with the Cu-7 intrauterine contraceptive device. Am J Obstet Gynecol 126:292-293, 1976.

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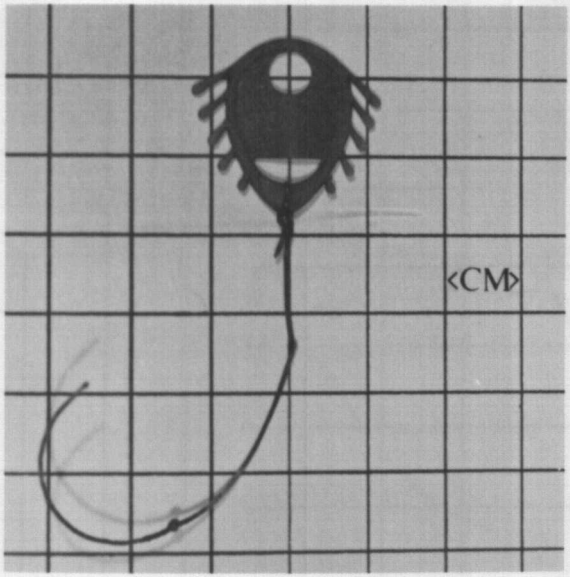
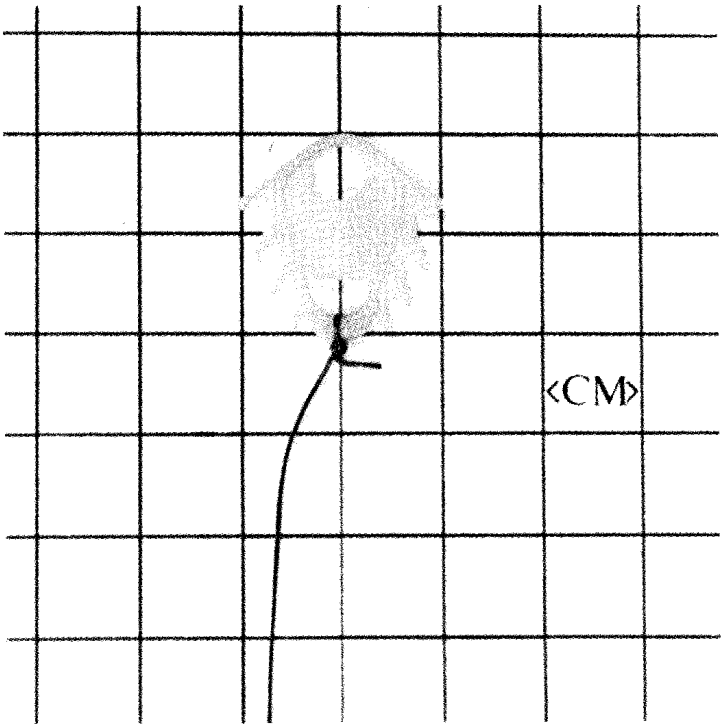
Viechnicki MB: Septicemia and abortion with the Cu-7. Am J Obstet Gynecol 127: 203, 1977.



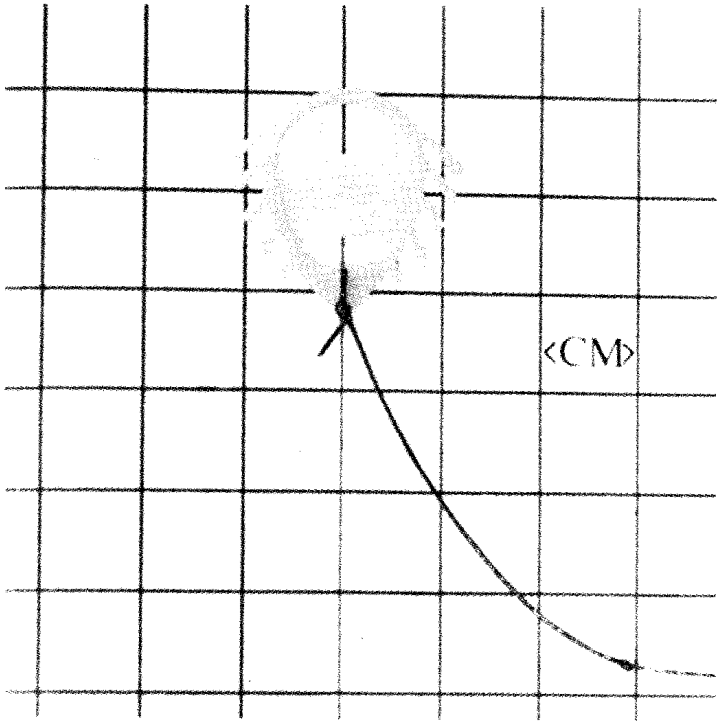
DALKON SHIELD (COPPER, BLACK)

Inserted in 1973, this standard size Dalkon Shield was removed after 27 months of use. It had turned dark because of the oxidization of the $CuSO_4$ and metallic copper in its matrix. No listing of copper IUDs should fail to include the Dalkon Shield. About 1 mg of elemental copper dust and $CuSO_4$ was added to its plastic matrix. The low release rate of the copper never helped the contraceptive effectiveness of the Shield. However, it might have increased the inflammatory reaction caused by the Shield in those cases of uterine perforation.



DALKON SHIELD (NULLIP)

By simply lessening the dimensions of the Standard Dalkon Shield, the developers of the Nullip model claimed to have developed a nearly perfect form of IUD for the woman who had never been pregnant. On the basis of a major advertising effort, over 600,000 Nullip Dalkon Shields were sold in the United States in the first two years of marketing. It had not been scientifically tested. While tolerated by some women, many others found its insertion to be an agonizingly painful experience contrary to the claims of its advertising. And problems associated with its overall performance helped assure the demise of both the Nullip and Standard models of the Dalkon Shield.

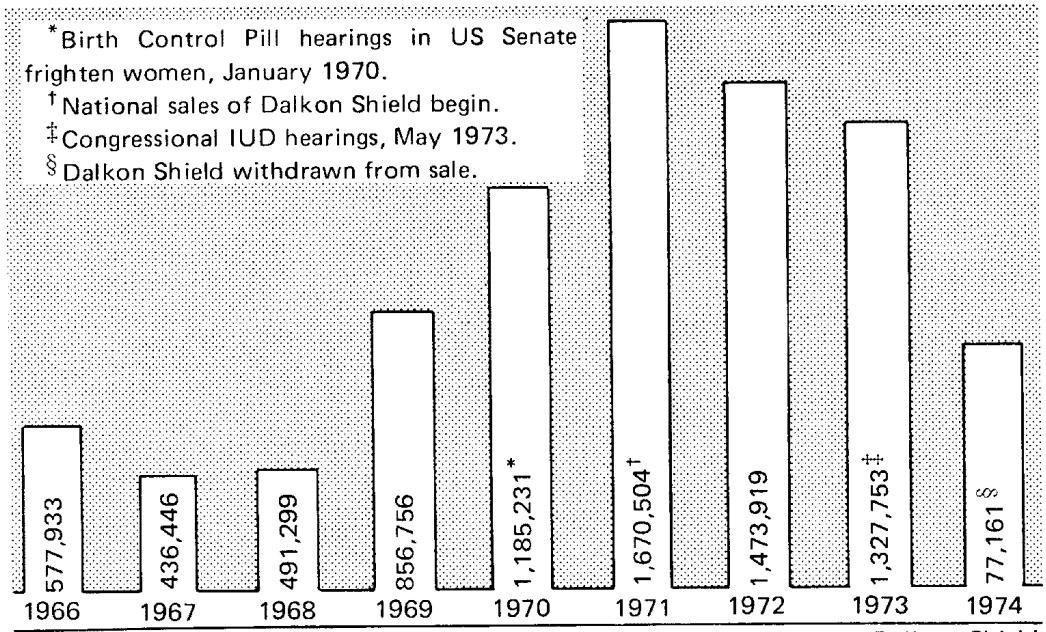


DALKON SHIELD (STANDARD)

In many ways, the Dalkon Shield was the most important IUD since the Gräfenberg Ring. Certainly the Lippes Loop, Saf-T-Coil, and other plastic and metal IUDs had established respectability for intrauterine contraception during the 1960s. But it was the short, traumatic history of the Dalkon Shield that emphasized the need for developing "physiologic" IUDs, and doing so within the realm of regulated research.

Based on ideas developed by work on the Incon Ring IUD, the medical inventor of the Dalkon Shield proposed the shape and size of the Shield ideally to fit the "average" uterine cavity. To this theoretically perfect IUD were added a central membrane and laterally projecting fins. The latter were meant to promote the "fundal seeking" quality of the device and its resistance to expulsion.

The Dalkon Shield was originally marketed by a small Connecticut corporation, the Dalkon Corporation. However, in June 1970, its ownership was taken over by the A. H. Robbins Company, a large Virginia-based drug company with no prior experience in the study or sales of contraceptives—least of all IUDs. Two significant events surrounded the marketing of the Dalkon Shield by Robbins. First, its marketing coincided with the notorious "Birth Control Pill" hearings of the U.S. Senate. These hearings were given



1966 through October 1974, US IUD sales: 8,795,002. Lippes Loop, Dalkon Shield, and Saf-T-Coil mostly used. Scores of lesser-known IUDs accounted for only about 5 percent of IUD use.

massive media coverage, with the resultant furor prompting possibly up to several million women in the United States to discontinue use of the birth control pill. Significantly, the "Pill" hearings were visibly and vocally supported by the primary backer of the Dalkon Shield.

The second significant factor in the advance of the Dalkon Shield was its massive promotion by a company bent on taking marketing control of IUDs.

By the time the Dalkon Shield was withdrawn from the market in 1974, about 4.5 million of the devices had been sold in the United States and 43 other countries.

The marketing significance of the Dalkon Shield can be seen in the graph of U.S. IUD sales from 1966 through 1974.

The greater significance of the Dalkon Shield on intrauterine contraception is that its medical and promotional history were prominantly featured in oversight hearings of subcommittees of both houses of the U.S. Congress and of the Food and Drug Administration. These hearings, in turn, led to the long delayed passage of a medical device regulation act in 1976. This act places IUDs and other medical devices under basically the same legal requirements by which the FDA regulates the testing and sales of drugs.

While no longer marketed, information about the Dalkon Shield can be obtained from the A. H. Robbins Company, Richmond, Virginia 23220.

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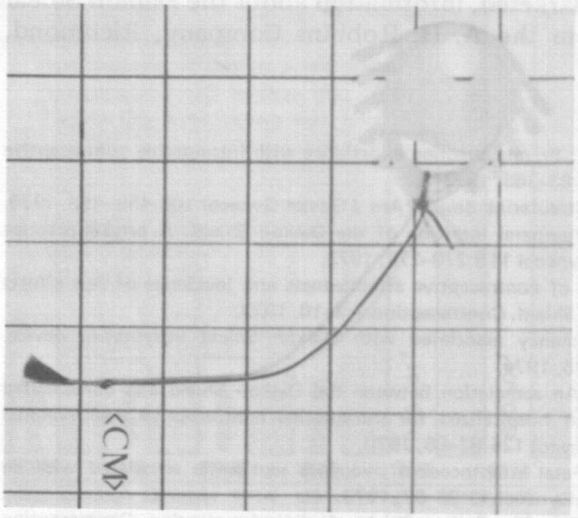
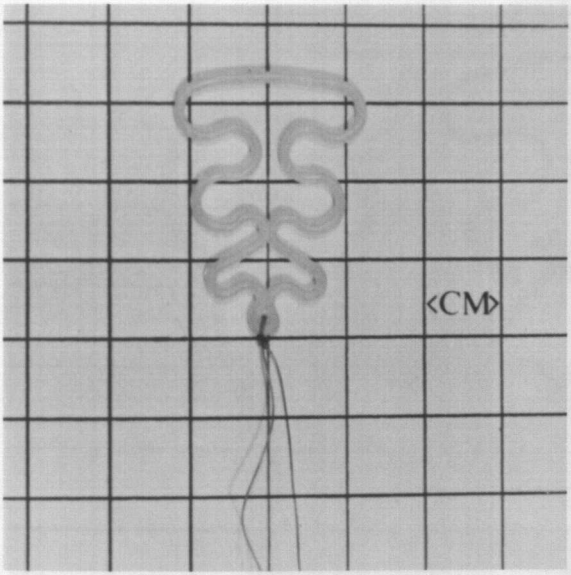


DALKON SHIELD TAIL

About 400 fibers were sheathed into the tail of the standard size Shield with somewhat fewer fibers being present in the tail of the smaller Nullip Shield. It is proposed that the fibers acted as a capillary wick for the conduit of bacteria to pass from the vagina to the uterine cavity. This was proposed as one of several possible factors in the observed increase of pelvic inflammation associated with the use of the Dalkon Shield. For demonstration, the sheath surrounding the tail fibers was opened at the end of the tail of this Dalkon Shield.

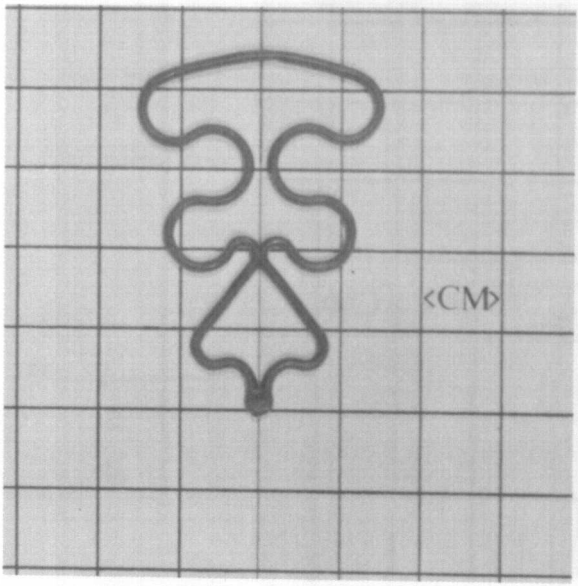
REFERENCE

Tatum HJ et al.: The Dalkon Shield controversy, JAMA 231:711-717, 1975.



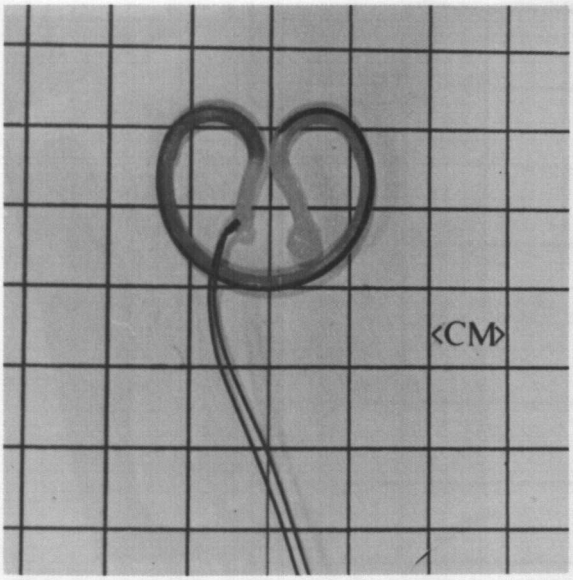
DANA SUPER LUX

There are four sizes of Dana Super Lux in this series of IUDs produced by the State Textile Research Institute, Centre for the Application of Radioactive Isotopes in the Textile Industry, Brno-Vaclavska 6, Czechoslovakia. They are made of barium sulphate impregnated ethylene vinyl acetate. A heart-shaped Dana Cor in three sizes is also produced by the same company (not shown here). The cervical threads are nylon.



DANA SUPER LUX COPPER

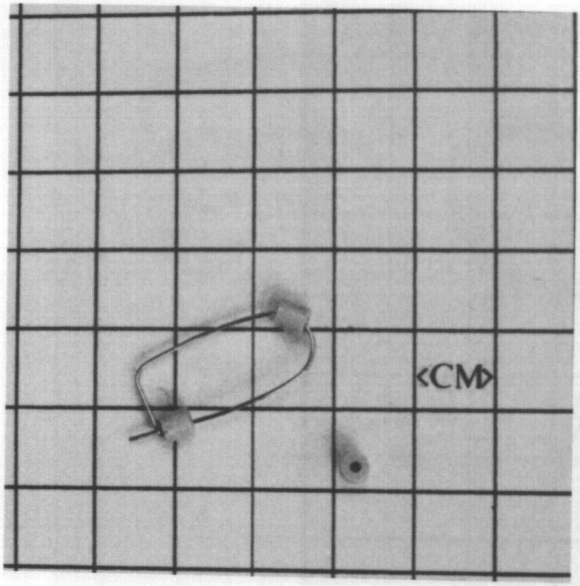
Studied predominantly in Czechoslovakia and the German Democratic Republic, the Dana IUDs are injection molded from ethylene vinyl acetate with barium sulphate added. In this Dana Super Lux model copper has also been molded into the plastic in an attempt to increase contraceptive effectiveness. However, studies done at Münster University in West Germany on the release of copper from various IUDs indicates that very little copper is released from the plastic matrix of this Dana device.



D.I.U. PHARMATEX (STERILE M)

This French IUD is available in four sizes ranging from 25 to 30 mm in width. The sizes are color coded by means of the double, colored cervical tail. The tail is made of a multifilament, woven string that might be implicated as having the capacity to harbor bacteria. The IUD is made of a non-radiopaque plastic into which a radiopaque filament has been molded. The Sterile M is available through Laboratoires Pharmelac, 40 rue de Paradis, Paris 75010, France, or Laboratoires Fandre of Nancy and Paris.

The following is the color code for the tails of the various sizes of Sterile M IUDs: yellow tail = 25 mm diameter size; blue tail = 27 mm diameter size; green tail = 28.5 mm diameter size; red tail = 30 mm diameter size.



FALOPE RING TUBAL OCCLUDING DEVICE

Developed primarily to be used as a method of permanent tubal occlusion for sterilization via placement through the laparoscope, the Falope Ring has the added advantages of eliminating the potentially complicating problems associated with electrocoagulation of the tubes via the laparoscope. It is made of medical grade, biologically inert silicone. Its inner 1 mm diameter is stretched to 6 mm over a special applicating instrument for application over a mid-portion loop of the uterine tube. Problems associated with the procedure include difficulties of application, slippage, and manipulative trauma to the tube and associated structures. Some observers point to an apparently increased incidence of prolonged pain at rates greater than anticipated in other forms of tubal sterilization. Use of the procedure in the United States started in 1973. One manufacturer of the Falope Ring is K. L. I., Inc., of Ivyland, Pennsylvania.

REFERENCES

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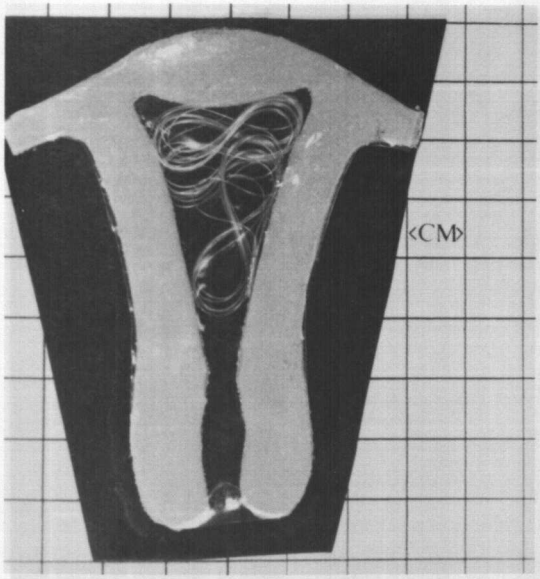
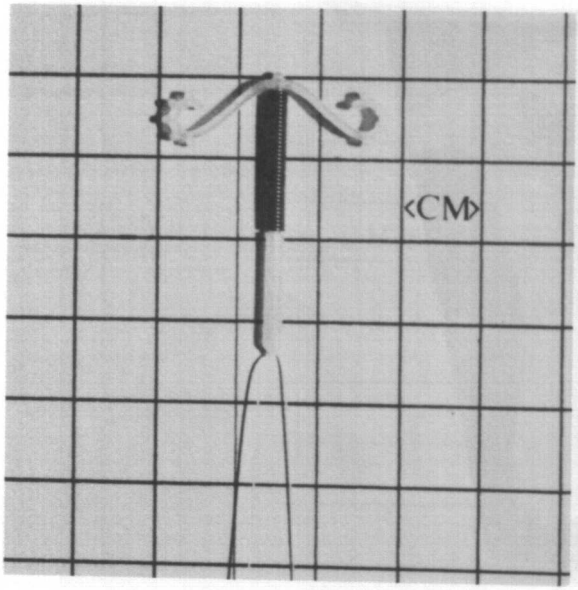


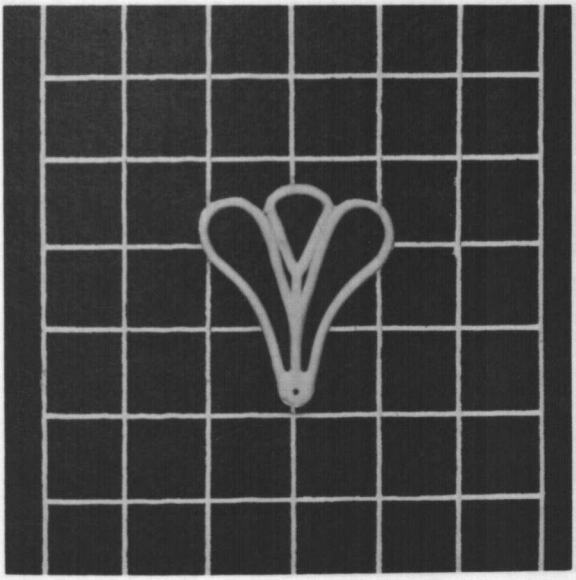
FILAMENT

Made of long loops of nylon, it is doubtful that the Filament IUD would be long tolerated by a live uterus. Little is known about this model. A 1971 compilation of IUDs by the Massachusetts Institute of Technology indicates that the Filament IUD was developed by John Stroop of Products Developments, 25 Broadway, New York, New York 10004.



FINCOID COPPER 350

The Fincoid Copper 350 IUD contains a 350 mm^2 surface area of 0.5 mm diameter copper wire. Its design variations from the standard T-shape are meant to reduce expulsion and perforation. Manufactured in Finland by H. Stahlberg Oy, it is marketed in that country by Neofarma Oy. It has also been granted United States Patent 4198966.



Photograph courtesy of the Population Information Program of The George Washington University, Washington, D.C.

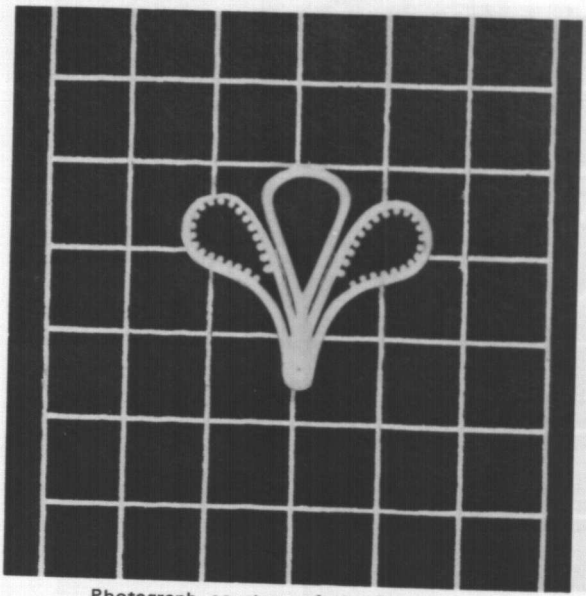
FLOWER OF CANTON (OLD)

This polyethylene IUD is from the collection of the Population Information Program of The George Washington University. It is the older of two models of Flower of Canton IUDs that are used in the Peoples Republic of China. In addition to the Flower of Canton devices, investigators report that a number of ring shaped IUDs made from stainless steel are also used in the Peoples Republic of China.

REFERENCES

Berliner D et al.: Family planning and birth control programs in the People's Republic of China. In: Intrauterine Devices—Development, Evaluation and Implementation, edited by RG Wheeler, GW Duncan, JJ Speidel, pp. 33-36. New York: Academic Press, 1974.

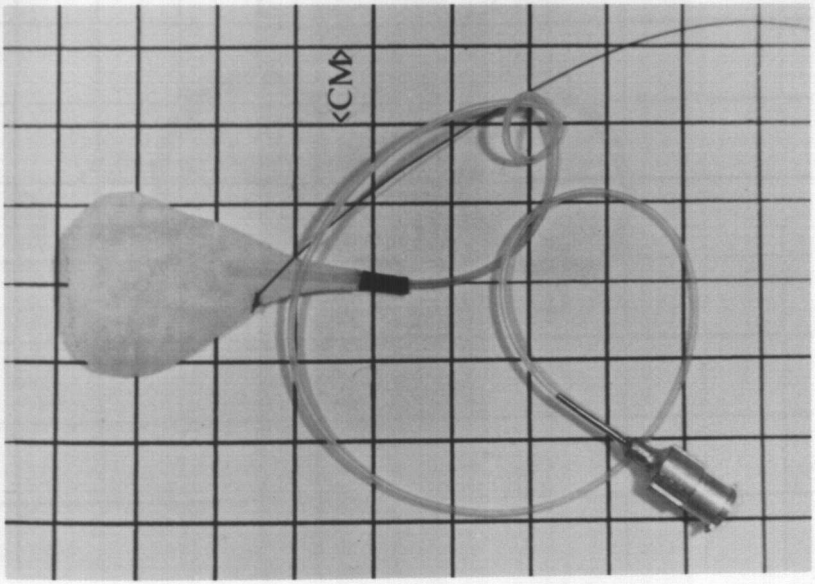
Heber SC et al.: IUDs reassessed. A decade of experience. Population Reports, series B, no. 2, pp. 21-48. Washington, D.C.: George Washington University Medical Center, Department of Medical and Public Affairs, 1975.



Photograph courtesy of the Population Information Program of The George Washington University, Washington, D.C.

FLOWER OF CANTON (NEW)

The same sources that are referenced for the Old Flower of Canton describe this IUD from the Peoples Republic of China as the New Flower of Canton. It is also made from injection molded polyethylene. No other information is readily available.



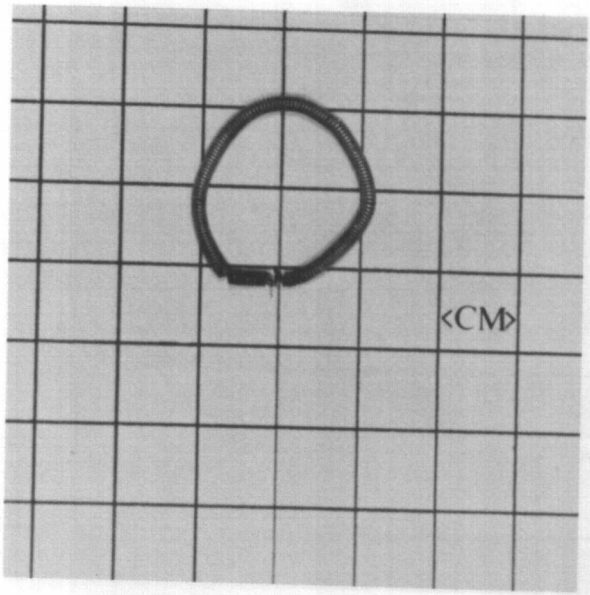
FLUID-FILLED IUD

Developed by Dr. Jack M. Futoran, the Fluid-Filled IUD is a heart-shaped balloon with its largest dimensions being 28 by 35 mm. Its thickness depends on the amount of fluid placed in it, but is stated to be between 0.4 and 3.8 mm. It is made of a silicone polymer, Dacron mesh wall, with injection of saline accomplished through a tubular tail. The tail is closed by simple tying. It seems that this technical aspect is a major flaw in design as it does not seem likely that long-term obstruction of this tail could be obtained by single ligature. Though increased effectiveness over other IUDs has not been proved for the Fluid-Filled IUD, it does mark a logical attempt to produce an IUD that would have ease of insertion, be pliable, and fill the uterine cavity.

REFERENCES

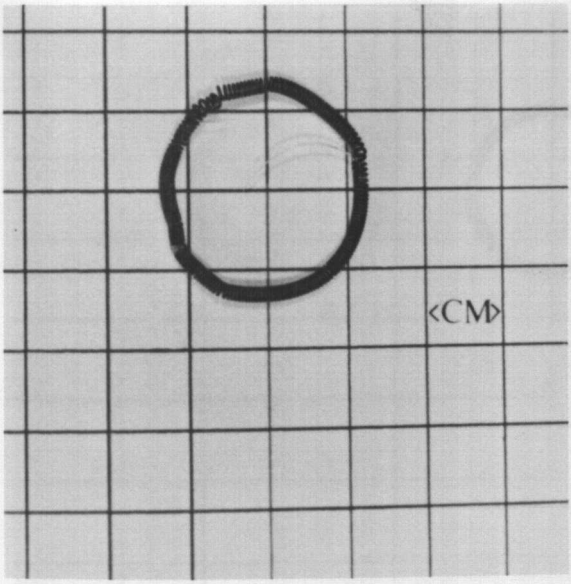
Futoran JM, Kitrilakis S: Experience with a Fluid-Filled intrauterine device. Obstet Gynecol 43:81–86, 1974.

Margolis AJ: A Fluid-Filled intrauterine device: Initial clinical trials. Am J Obstet Gynecol 122:470–475, 1975.



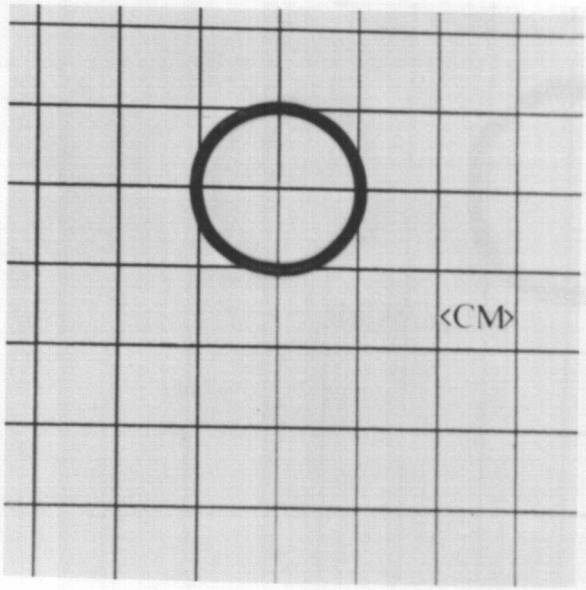
GRÄFENBERG RING (MODERN, GOLD)

This gold Gräfenberg Ring was inserted in a patient in 1960 by Dr. H. Kretschmar at his Gieserbrescht Strasse office in Berlin. It was removed in New York City in 1964 by Dr. Hans Lehfeldt.



GRÄFENBERG RING (ORIGINAL, LARGE)

This original Gräfenberg Ring is dated back to the late 1920s or early 1930s. Slightly damaged, it demonstrates the silk strands that Dr. Gräfenberg threaded into the IUD to prevent separation of the spring in case of its breakage. Several sizes of Rings were tried by Dr. Gräfenberg ranging from 15 to 30 mm in diameter. He settled on a diameter of 17.5 mm for the "average" patient. The wire of the Ring was made of "German Silver" (an alloy of copper, zinc, and silver). In this respect, the Gräfenberg Ring can be considered the first of the copper IUDs.



GRÄFENBERG RING (ORIGINAL, SMALL)

Dr. Ernst Gräfenberg, a Berlin gynecologist, first began to use primitive, modified silkworm IUDs in the late 1920s. He reported his early results to the 1930 Zurich International Birth Control Conference. It was about 1928 that he first utilized the model of IUD that bears his name and has made him known as the father of the modern IUD. This original Gräfenberg Ring was made in Germany in the late 1920s or early 1930s.

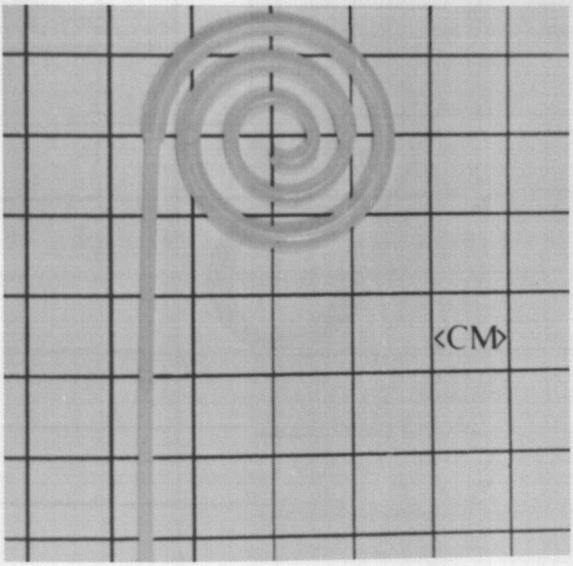
REFERENCES

Gräfenberg E: An intrauterine contraceptive method. In: The Practice of Contraception (Proceedings of the 7th International Birth Control Conference, Zurich, Switzerland, September, 1930.), edited by M Sanger, HM Stone, pp. 336–356. Baltimore: Williams & Wilkins, 1931.

Hall HH, Stone ML: Observations on the use of the intrauterine pessary, with special reference to the Gräfenberg Ring. Am J Obstet Gynecol 83:683–688, 1962.

Lehfeldt H: Experience with intrauterine devices: 1928–1962. In: Intra-Uterine Contraceptive Devices, edited by C Tietze, S Lewit, International Congress Series, no. 54, pp. 45–47. Amsterdam: Excerpta Medica Foundation, 1962.

Tietze C: Intrauterine contraceptive rings: History and statistical appraisal. In: Intra-Uterine Contraceptive Devices, edited by C Tietze, S Lewit, International Congress Series, no. 54, pp. 9–20. Amsterdam: Excerpta Medica Foundation, 1962.



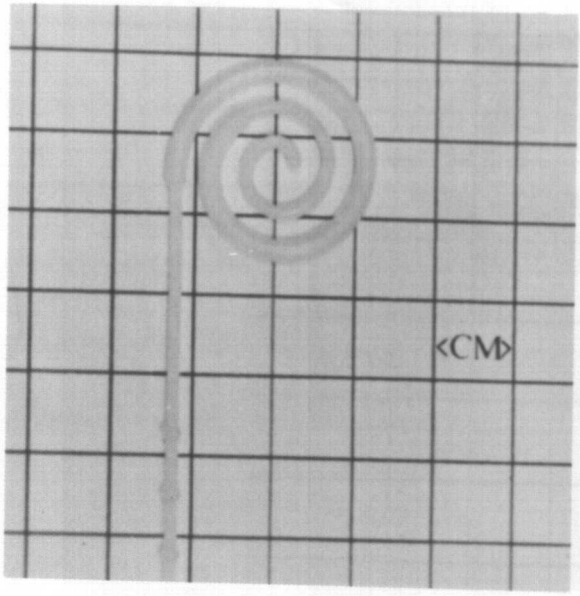
GYNEKOIL (LARGE)

With the hesitant approval of Dr. Alan Guttmacher at Mt. Sinai Hospital in New York City, Dr. Lazar Margulies started inserting handmade IUDs in 1959. In August, 1960, Dr. Margulies inserted the first prototype Spiral in his own wife. Unique in its molding of barium sulfate into the plastic to give the IUD radiopacity, the Gynekoil became the first commercially sold, plastic IUD. It was sold by Ortho until the early 1970s. It was also the first of the plastic, linear IUDs meant to be inserted through the straw inserter.

REFERENCES

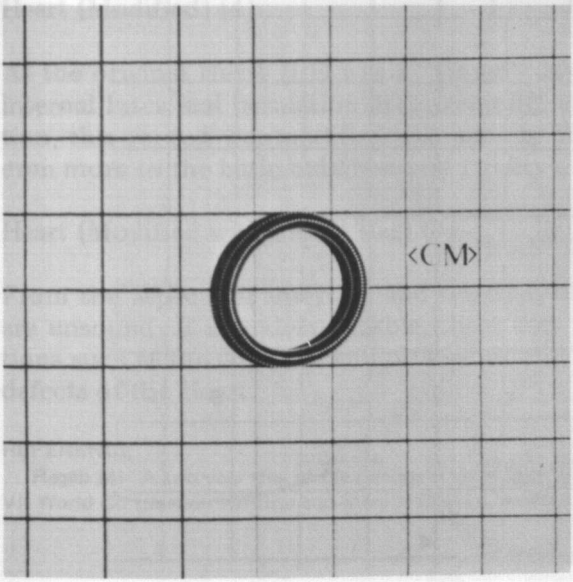
Margulies LC: Permanent reversible contraception with an intra-uterine plastic spiral (Perma-spiral). In: Intra-Uterine Contraceptive Devices, edited by C Tietze, S Lewit, International Congress Series, no. 54, pp. 61–68. Amsterdam: Excerpta Medica Foundation, 1962.

Margulies LC: Intrauterine contraception: A new approach. Obstet Gynecol 24:515–520, 1964.



GYNEKOIL (SMALL)

Sold in two sizes by Ortho Pharmaceutical Company, the Gynekoil (Margulies Spiral) had a beaded tail that descended down the cervical canal, on occasion giving rise to penile agony. With a complication rate of 50 percent, only a few Gynekoil IUDs remain in use today.

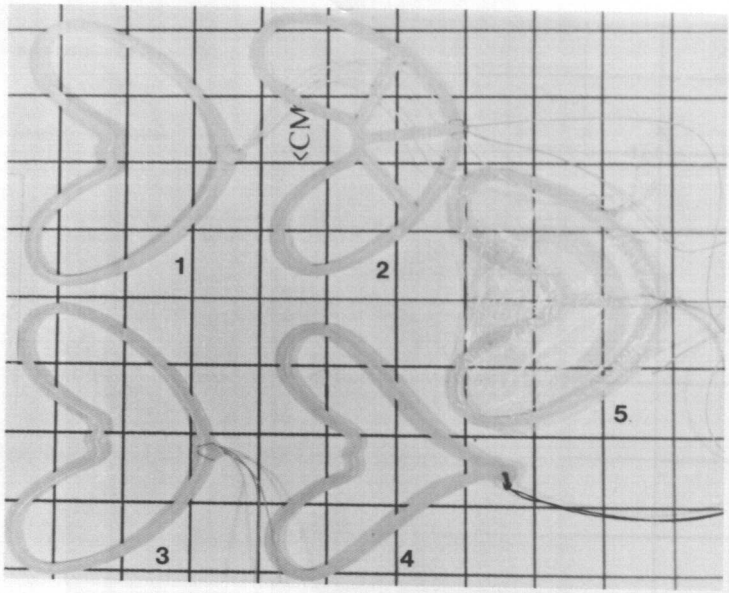


HALL-STONE RING

Dr. H. H. Hall and Dr. M. L. Stone, professional associates of Dr. Ernst Gräfenberg in the New York City area, basically duplicated the original Gräfenberg Ring. The main difference between the Hall-Stone Ring and its predecessor was that it was made from medical grade stainless steel instead of "German Silver," a copper, zinc, and silver mix. A later modification of the Hall-Stone Ring became the Inhiband.

REFERENCE

Hall HH, Stone ML, Sedlis A, Chabon I: The intra-uterine ring for conception control. Fertil Steril 15:618–624, 1964.



HEART IUDS

Heart (1)

Developed by Dr. Walter J. Gamble, a director of The Pathfinder Fund, the Heart IUDs underwent few trials. Bulky, the Heart devices were hard to insert. Insertion was attempted by wrapping the outside rims of the Heart around a Lippes Loop inserter with the depressed center portion of the Heart pushed into the lumen of the inserter.

Heart (High Barium Content) (2)

Comparing this IUD with (1) demonstrates well the difference in opacity caused by increasing the amount of barium. Such an increase of barium also increases the rigidity of the plastic, and adds to its brittleness.

Heart (3)

Modified to conform more closely to the size and shape of the uterine cavity, this Heart is also too bulky and difficult to insert.

Heart (Modified) (4)

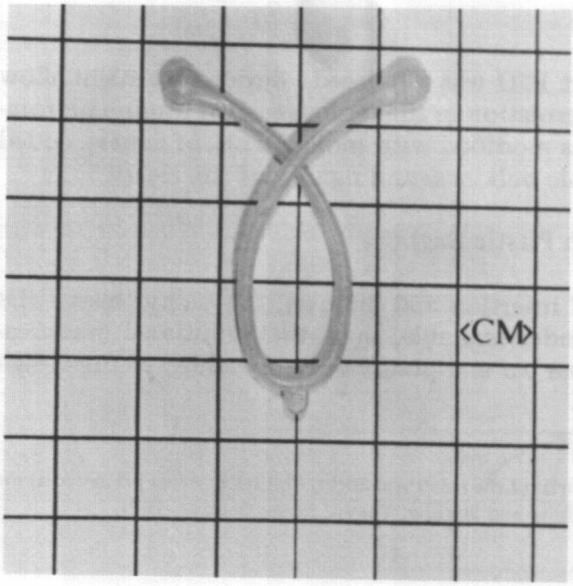
As the original Heart IUD was a "closed" device that might allow internal intestinal herniation in the remote case of uterine perforation, this version was modified with spokes. This, of course, added even more to the basic bulkiness and rigidity of the Heart.

Heart (Modified with Plastic Bag) (5)

From the aspects of insertion and removal, the bulky Heart IUDs are unsound. It is understandable, then, that additional modifications such as the cross bar and plastic bag only added to the design defects of the Heart.

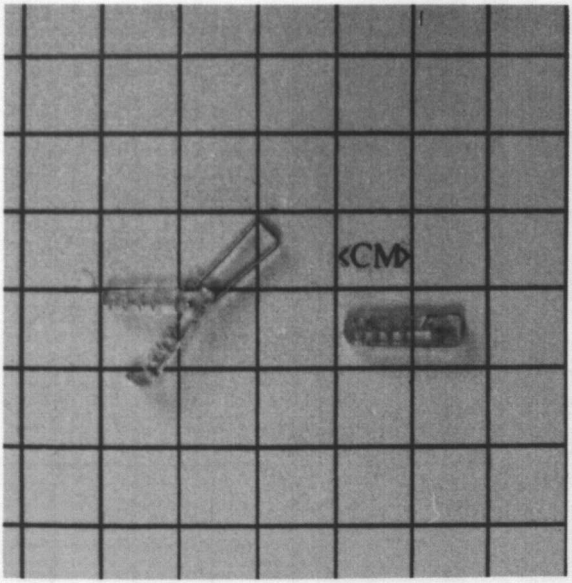
REFERENCE

Ragab MI: A two-year trial of the Heart and Spring Coil IUDs. Paper presented at the VII World Congress on Fertility and Sterility, Tokyo, Japan, October, 1971.



HULKA

Typical of well-intentioned attempts by physicians to invent an improved IUD is the Hulka device patented by Dr. J. F. Hulka in 1966. Inserted in 50 women, it was discontinued because of problems caused by bulkiness.



HULKA TUBAL CLIP

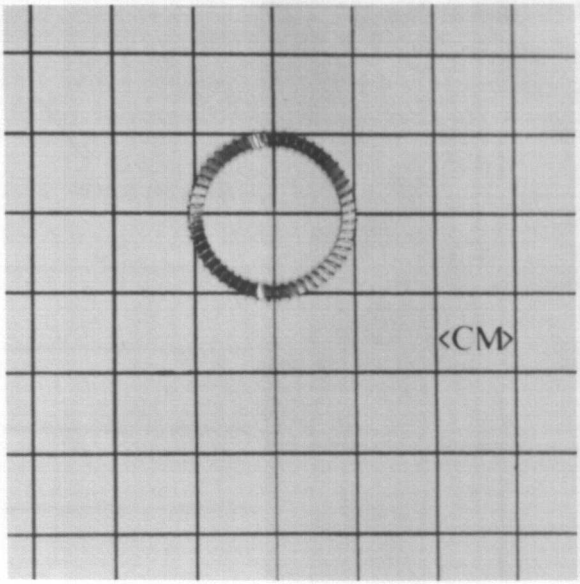
First reported on in the medical literature in 1973, the use of a spring-loaded clip, via laparoscopic application to the uterine tubes, has subsequently been investigated with widening interest. Sometimes called the Hulka-Clemens Clip, the spring clip has been primarily investigated by Dr. Jaroslav F. Hulka. The Hulka Tubal Clip is now made and sold internationally through Richard Wolf Medical Instruments, Rosemont, Illinois 60018, USA, and Rocket of London, Imperial Way, Watford, WD2 4XX, England.

Although the primary indication for use of the Hulka Tubal Clip is nonfulguration sterilization by laparoscopic tubal occlusion, it is a peripheral hope that it will be found that the method is of such limited trauma to the uterine tubes that fertility can be restored when elected, and that this can be done at a favorable rate of success.

REFERENCES

Hulka JF, Fishburne JI, Mercer JP, et al.: Laparoscopic sterilization with a spring clip: A report of the first fifty cases. Am J Obstet Gynecol 116:715–718, 1973.

Hulka JF, Omran K, Lieberman BA, et al.: Laparoscopic sterilization with the spring clip: Instrumentation development and current clinical experience. Am J Obstet Gynecol 135:1016–1020, 1979.



INHIBAND

Dr. Herbert Hall came to the United States about the same time as did Ernst Gräfenberg. As European colleagues, they shared an interest in IUD contraception. Dr. Hall invented the Inhiband, which was very similar to the Gräfenberg Ring, and Ayerst Laboratories sold about 100,000 of them before they were discontinued in 1973. The Inhiband is made from stainless steel.

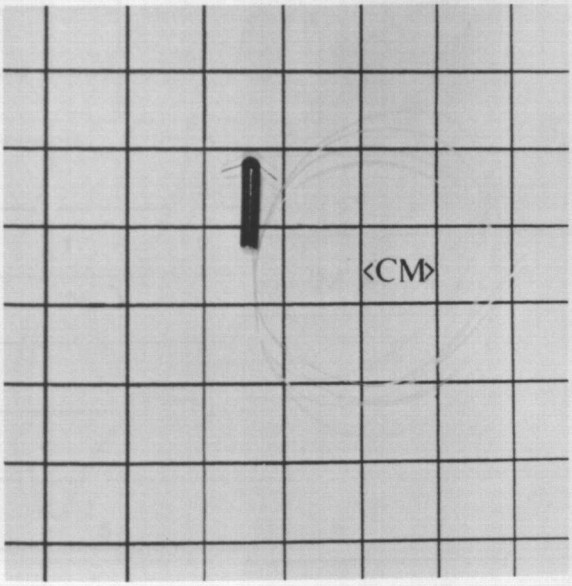
REFERENCES

Hall HH et al.: The intra-uterine ring for conception control. Fertil Steril 15:618-624, 1964.

Hall HH et al.: Effect of intrauterine stainless steel ring on endometrial structure and function. Am J Obstet Gynecol 93:1031-1041, 1965.

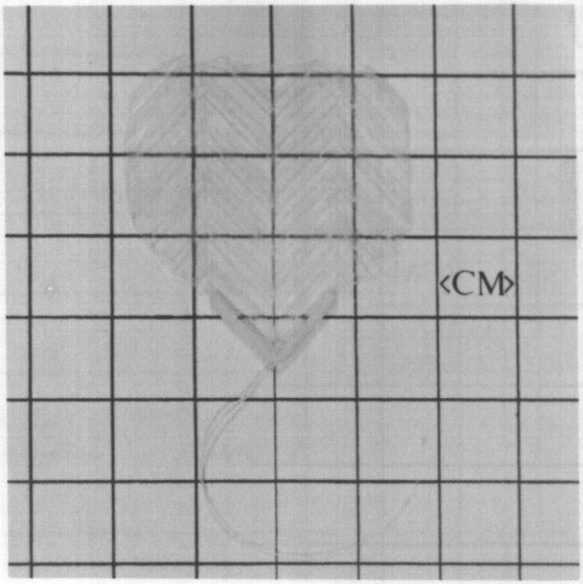
Hall HH: The band, a new intrauterine contraceptive device. Am J Obstet Gynecol 95:879-880, 1966.

Lehfeldt H et al.: Comparative study of intrauterine contraceptive devices. Obstet Gynecol 26:679-688.



INTRATUBAL CONTRACEPTIVE DEVICE

Dr. Jaime Chargoy-Vera of Puebla, Mexico, developed this device for intratubal occlusion. It is meant to be placed by hysteroscope into the uterine tubes. Dr. Chargoy-Vera reported on the device at the October 1976 meetings of the VIII World Congress of Gynecology and Obstetrics, held in Mexico City. The device is removed by traction on the nylon tail, which comes down through the cervix like the typical IUD tail.

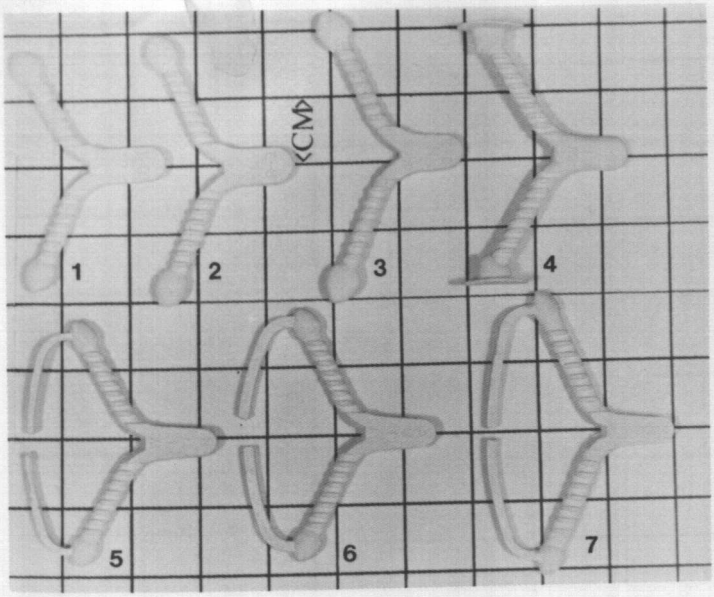


INTRAUTERINE MEMBRANE (IUM)

Developed by Battelle Laboratories as a model testing the theories of optimal IUD effectiveness and potential lowered complication rates, the IUM is made of corrugated Alathon-20 polyethylene. Barium in the plastic "V" at the base of the IUD gives radiopacity.

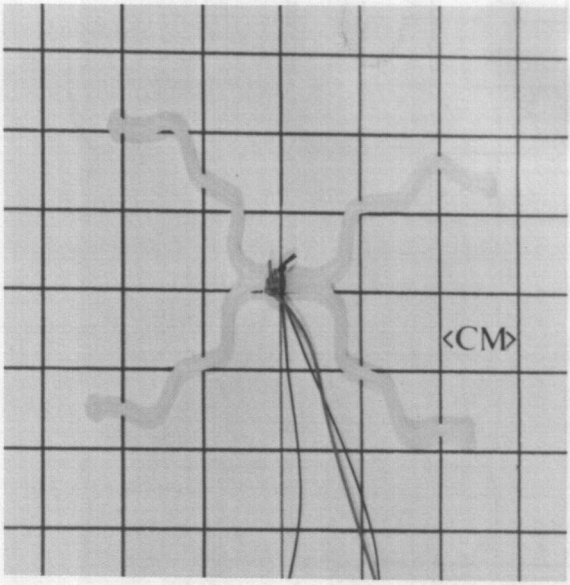
REFERENCE

Wheeler RG: The Intrauterine Membrane. In: Intrauterine Devices—Development, Evaluation and Implementation, edited by RG Wheeler, GW Duncan, JJ Speidel, pp. 199-202. New York: Academic Press, 1974.



K. S. WING

The K. S. Wing intrauterine contraceptive devices are actually a series of variations of the same basic design, seven of which are pictured here. The devices numbered 1–4 have widths of 37, 40, 44, and 38 mm, respectively. All of the devices are natural rubber molded over stainless steel wire. They contain no barium, relying on the wire for radiopacity. They contain no cervical threads and are meant to be removed by means of a hook. The inserter supplied for the K. S. Wing IUDs is a wide diameter stainless steel straw-plunger device that would require cervical dilation to allow completion of most insertions. Mainly used in Japan, they are available from K. S. Wing Laboratory, 123 Hase, Kamakura, Kanagawa, Japan.

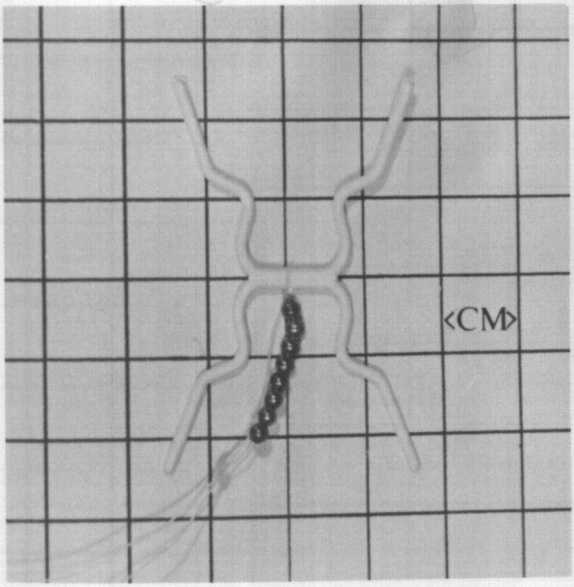


LEM

In what was a major marketing error, Searle Laboratories brought out the LEM in 1972 in an effort to capture the postabortion IUD market (if such, indeed, exists). Unfounded claims included, "for postpartum or postabortion use, no other IUD is comparable." Euphemistically named after the lunar landing module, the LEM was designed for retention in the enlarged, boggy, postpartum or postabortive uterus. However, the same legs that caused retention also caused uterine perforation. Under Food and Drug Administration pressure, Searle Laboratories backed away from the LEM, and by 1974 it was effectively off the market.

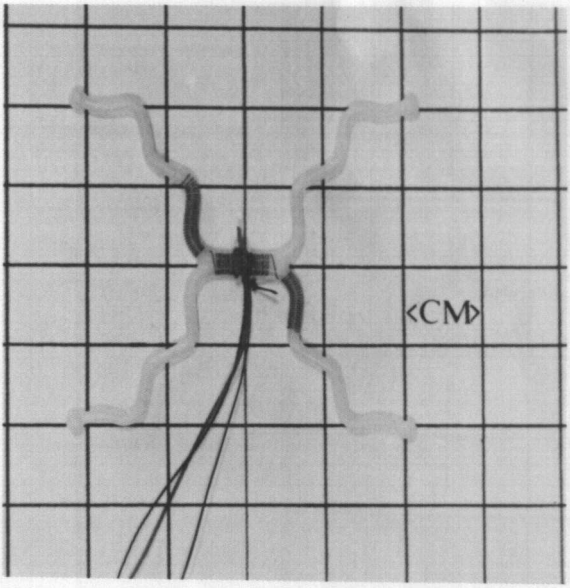
REFERENCE

Rashbaum WK, Wallach RC: Immediate postpartum insertion of a new intrauterine contraceptive device. Am J Obstet Gynecol 109:1003-1004, 1971.



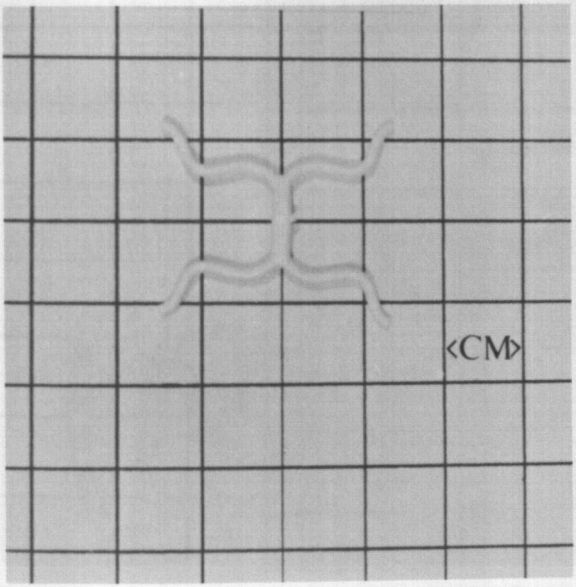
LEM (COPPER, BEADED TAIL)

This IUD is the result of another attempt to make the LEM an acceptable IUD. Of course, the addition of copper could not overcome the basically unphysiologic design of the LEM. If it had been used clinically, the tail could have broken allowing the copper beads to drop from the vagina. This would have been a surprising new IUD complication.



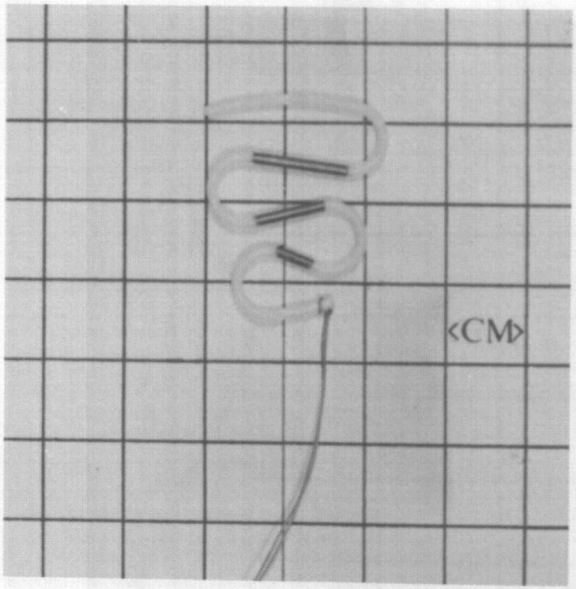
LEM (COPPER, WIRE)

The addition of copper wire to the LEM could in no way decrease the complications of this IUD caused by its bulk and the penetrating nature of its protruding arms. It has not been tested clinically.



LEM (NULLIPAROUS)

Molded in mid-1970 and used on a limited clinical basis, the "nullip" LEM was made by simply cutting off part of each leg of the regular LEM.



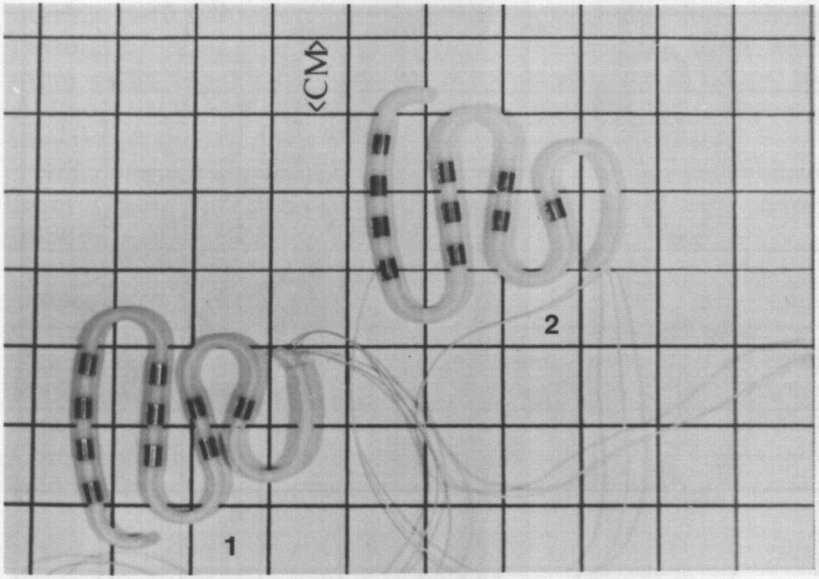
LIPPES LOOP

Lippes Loop A (Copper)

Dr. Jack Lippes modified the smallest of his Loops, the "A" size, to carry either 135 or 200 mm^2 surface area of copper in the form of copper sleeves. This modified Loop is the Copper A-200. The sleeves are placed into the mold prior to the injection of the plastic. Preliminary findings of a study by Dr. Lippes and associates indicated an improvement of pregnancy rates by adding copper to the A-Loop, but a worsening of the successful rates of removal because of bleeding and pain. Dr. Lippes has also advocated the small Lippes Loop Copper A as a possible form of "morning after" contraception. This idea, however, is to be regarded as highly contemplative at this time.

REFERENCE

Lippes J et al.: The effect of copper on Loop A. J Reprod Med 10:166-168, 1973.



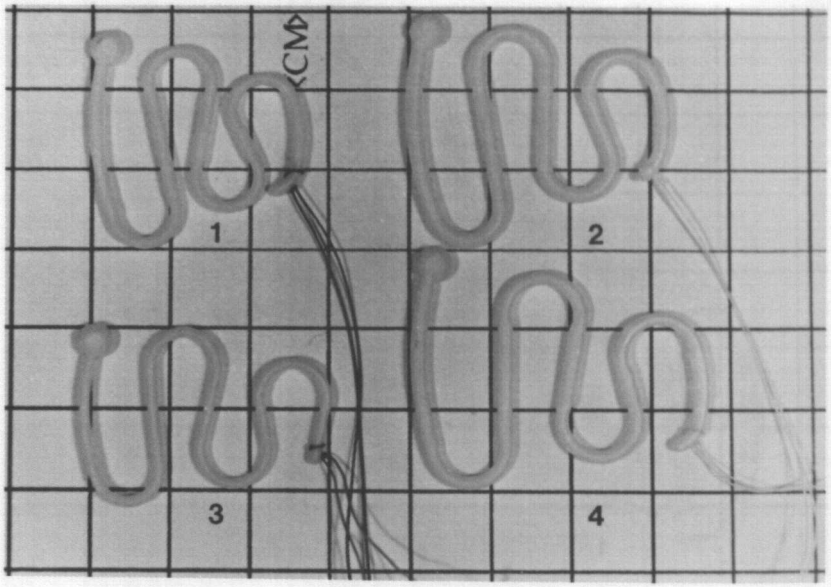
LIPPES LOOP

Lippes Loop C (Copper) (1)

This Lippes Loop "C" has been modified to bear about 200 mm^2 of exposed surface area of copper by the placement of small sheaths of medical grade copper. It had a rate of pregnancy of 3.2, slightly better than the plain Loop but worse than the CU-7 or the Copper T Cu-200.

Lippes Loop D (Copper) (2)

Contributed to the collection by Dr. Jack Lippes, the developer of the famous Lippes Loop, this experimental "D" Loop has also been plated with thin strips of medical grade copper. About 200 mm^2 surface area of copper is thereby exposed to the endometrium. Virtually every inert IUD can be so treated, but improved performance of the bulky IUDs on the basis of simply adding copper is questionable.



LIPPES LOOP (NEW)

Lippes Loop B (1)

Probably the most reasonably sized Loop, the B Loop has had far less use than the C or D sizes, which have been more thoroughly studied and promoted.

Lippes Loop D (2)

Adding to the continued use of the Loop is the fact that a whole generation of medical personnel around the world have been trained in its use—especially its insertion. This is a positive advantage both in sales and in practical clinical management over other IUDs. However, the Loop D has probably been overly used as its bulk is less physiologic than some of the other available IUDs. It is probably time to stop thinking of the Lippes Loop D as the standard by which other IUDs are gauged or as the IUD of first choice for most patients.

Lippes Loop A (3)

Current Loops differ from the four early models by the addition of the nob at the tip, which is meant to decrease the chance of