Cu7 advertisement.

[s.l.]: [s.n.], 1975

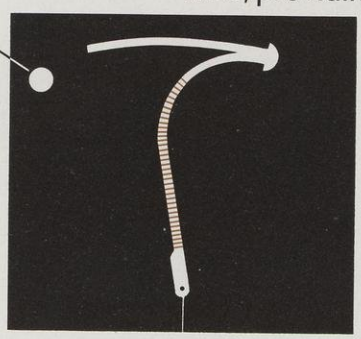
A new dimension in contraception with Cu-7®

brand of

intrauterine copper

This is the actual diameter of the Cu-7 inserter.

This is the actual size of Cu-7.
Supplied with an inserter and a patient identification card, each Cu-7 is wound with 89 mg. of copper wire, providing 200 mm² of exposed copper surface area.



Seven reasons for selecting Cu-7

1. Mode of action: Intrauterine copper is an important contraceptive component of Cu-7. How copper enhances the contraceptive effect of the tiny plastic figure 7 has not been conclusively demonstrated, but the most common hypothesis is that the copper prevents pregnancy by altering the function of the enzymes participating in the implantation process. Copper may also interfere with intrauterine sperm transport.

2. Size and shape: The plastic figure 7 is a very small carrier which will flexibly conform to the shape of the uterine cavity yet provide a 200 mm² surface area of copper.

3. Ease of insertion: Because of its unique size, shape and flexibility, Cu-7 usually may be inserted without dilatation of the cervix. The Cu-7 inserter has a diameter approximately half that of inserters presently in use.

4. Suitability for most women of childbearing age: Cu-7 may even be inserted with ease into the uterus of most normal nulliparous women. Perforations are rare, cramps and bleeding are minimal.

5. Time of insertion: Cu-7 may be inserted at any time of the menstrual cycle and during any office visit convenient to the patient. Possibility of pregnancy prior to insertion, of course, should be considered. The Cu-7 should not be inserted post partum or post abortion until involution of the uterus has been completed.

6. Uterine retention: Spontaneous expulsion of a properly inserted Cu-7 may occur. When it does it most frequently happens within the first six months (in about six percent during the first year). The device should be replaced every two years, because contraceptive effectiveness for longer periods has yet to be established. (Replacement at the two-year interval also provides another opportunity for patient follow-up.) Removal of the Cu-7 is usually painless.

7. Effectiveness: Cu-7 has proved to be an exceedingly effective intrauterine contraceptive. Cu-7 use experience, based on 133,941 woman-months, including 12 months completed by 5,672 women and 24 months completed by 736 women, produced a pregnancy rate of less than one per 100 women per year by life table analysis.

SEARLE **Searle & Co.**
Division of G.D. Searle & Co.
Box 5110, Chicago, Illinois 60680

Practical because it's small. Increased effectiveness because of copper content.

contraceptive

Description: The plastic component of the Cu-7 is composed of pharmaceutical grade polypropylene homopolymer with barium sulfate added to render it radiopaque. Its shape approximates the number 7; it is substantially smaller than previously available intrauterine devices.

Coiled around the vertical limb is a pure, virgin electrolytic copper wire. This wire provides a surface area of 200mm^2. A polypropylene retrieval thread is fastened to the free end of the vertical limb of the Cu-7.

The Cu-7 is supplied with a simple tubular polypropylene inserter. All components are sterile.

Action: Available data indicate that the contraceptive effectiveness of the Cu-7 is enhanced by a minute quantity of copper being released continuously from the copper coil into the uterine cavity. The exact mechanism by which metallic copper enhances the contraceptive effect of an IUD has not been conclusively demonstrated. Various hypotheses have been advanced, the most common being that copper placed in the uterus interferes with enzymatic or other processes that regulate blastocyst implantation.

Animal studies suggest that copper may play an additional role by reduction of sperm transport within the uterine environment.

Indication: The Cu-7 is indicated for contraception.

Contraindications: The presence of any of the following, at the time of insertion, constitute contraindications: pregnancy, abnormalities of the uterine cavity, acute pelvic inflammatory disease or a history of repeated pelvic inflammatory disease, postpartum endometritis or infected abortion in the past three months, endometrial disease such as hyperplasia or carcinoma and a known or suspected allergy to copper.

Warnings: Recent reports suggest an increased incidence of septic abortion associated in some instances with septicemia, septic shock and death in patients becoming pregnant with an IUD in place. In some cases, initial symptoms have been insidious and not easily recognized. If pregnancy should occur with a Cu-7 in situ, the Cu-7 should be removed if the string is visible or, if removal proves to be or would be difficult, interruption of the pregnancy should be considered and offered as an option. If the patient elects to maintain the pregnancy and the Cu-7 remains in situ, she should be warned of the suggested incidence of increased risk of sepsis and followed with close vigilance.

The long-term effects on the offspring of the presence of copper in the uterus during pregnancy are unknown.

Perforations of the uterus have occurred. If this occurs the device should be removed immediately.

The use of microwave therapy in patients with metal prosthetics may cause heat injury to the surrounding tissue. Therefore, microwave therapy to the abdominal and sacral areas should not be used on patients wearing a Cu-7.

Additional amounts of copper available to the body from the Cu-7 may precipitate symptoms in women with undiagnosed Wilson's disease, the incidence of which is one in two hundred thousand.

Precautions: A pelvic examination should be done.

Sound the uterus prior to insertion and exercise care to avoid perforation. Do not use excessive force. The possibility of insertion in the presence of an existing undetermined pregnancy is reduced if insertion is performed shortly following a menstrual period. The Cu-7 should not be inserted post partum or post abortion until involution of the uterus has been completed. Occasional perforations of the uterus (.03%) have been reported, usually during insertion into patients who were less than two months post abortion or post partum. If penetration into abdominal cavity occurs, laparotomy should be performed and the device recovered. Local inflammatory reaction with abscess formation is a possibility if a device is left in the abdomen.

If any patient with a Cu-7 suddenly develops overt clinical hepatitis or abnormal liver function tests, appropriate diagnostic procedures should be initiated.

The Cu-7 should be removed if pelvic infection which is unresponsive to treatment occurs.

The device should be replaced every two years. There is no evidence of decreasing effectiveness with time before two years, but the contraceptive effectiveness of the Cu-7 has yet to be established after two years.

The patient should be told that some light bleeding or cramps may occur during the first few days after insertion, but if these symptoms continue or are severe she should report to her physician. She should be instructed on how to inspect periodically to make certain that the thread still protrudes from the cervix and cautioned that there is no protection if the device has been expelled. She should also be cautioned not to pull on the thread and displace the device and told to return for replacement of the device in two years.

A report has appeared in the literature suggesting that a copper induced urticarial allergic skin reaction developed in a woman wearing a copper IUD. If symptoms of such an allergic response occur the patient should be instructed to tell the consulting physician that a copper bearing device is being worn.

Adverse Reactions: Perforation of the uterus has occurred.

The incidence of spontaneous abortion, when conception occurs with intrauterine devices in situ, appears to be increased over that in unprotected women.

Insertion cramping, usually of no more than a few seconds duration, may occur; however, some women may experience residual cramping for several hours or even days. Transient spotting or bleeding or prolongation of menstrual flow may occur in the first few cycles. Uncommonly, pelvic infection has been reported. Complete or partial expulsion may occur in some patients, particularly those with uteri measuring less than 6.5 cm. by sounding. The following complaints have also been reported although their relation to the Cu-7 has not been established: amenorrhea or delayed menses, backaches, cervical erosion, cystic masses in pelvis, vaginitis, leg pain or soreness, weight loss or gain, nervousness, dyspareunia, and cystitis.

Dosage and Administration: A single Cu-7 is to be inserted into the uterine cavity (see Precautions section). The small diameter of the Cu-7 enables easy insertion into the nulliparous as well as the multiparous uterus. Present information indicates that the efficacy is retained for at least 24 months. Until accurate data indicating a longer effective life become available, the Cu-7 should be removed and a new one inserted on or before 24 months from the date of insertion. If partial expulsion occurs, removal is indicated, and a new Cu-7 may be inserted. Removal of the Cu-7 may also be indicated in the event of heavy or persistent bleeding.

How Supplied: Each carton contains 6 or 30 sterile units (Cu-7 with an inserter) and patient identification cards.

Clinical Studies: Different event rates have been recorded with the use of different intrauterine contraceptive devices. Inasmuch as these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision. Furthermore, event rates tend to be lower as clinical experience is expanded, possibly due to retention in the clinical study of those patients who accept the treatment regimen and do not discontinue due to adverse reactions or pregnancy. In clinical trials conducted by Searle Laboratories with the Cu-7, use-effectiveness was determined as follows for parous and nulliparous women, as tabulated by the life table method. (Rates are expressed as events per 100 women through 12 and 24 months of use.) This experience is based on 133,941 women-months of use including 5,672 women who completed 12 months of use, and 736 women who completed 24 months of use.

	12 Months		24 Months	
	Parous	Nulliparous	Parous	Nulliparous
Pregnancy	0.97	0.99	1.40	1.97
Expulsion	4.77	6.44	5.61	7.70
Medical Removal	7.37	10.67	12.49	19.32
Continuation Rate	83.5	77.5	63.8	53.2