

Current Practice

Intrauterine Contraceptive Devices

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In recent years there has been an upsurge of interest in the intrauterine contraceptive devices (I.U.C.D.) both as a means of controlling the world population explosion and as another contraceptive for use in routine family planning. The characteristic of the intrauterine device method which distinguishes it from all other methods of contraception is that its effectiveness is largely independent of the continual vigilance of the couple using it. This, together with the fact that the plastic devices now available can be manufactured very cheaply,

Mode of Action

Although the precise mode of action of the I.U.C.D. has yet to be determined, it is almost certain that it does not work by producing early abortions. Possible modes of action include increased tubal or uterine motility and alteration in the normal cycle through which the endometrium passes.

Types of Device

Many different shapes and sizes of device have been made, but only the three on which the most data have accumulated will be described. They are illustrated in Fig. 1.

LIPPES LOOP.—This is an open-ended device in the shape of a double "S." It is made in three different thicknesses of plastic. Loop A is the finest and loop C the thickest. A fourth loop, loop D, is of the same thickness as loop C but is more rigid. All the loops have a cervico-vaginal extension consisting of two fine nylon or polyethylene threads.

MARGULIES SPIRAL.—This is an open-ended device in the shape of a coil. It is made in different thicknesses of plastic, size 5 being the thickest. When in situ within the uterine cavity an extension made of polyethylene traverses the cervical canal. The end of this extension, which is quite rigid, is fitted with small beads which protrude from the external cervical os into the vagina.

BIRNBERG BOW.—This is a collapsible closed-end device, shaped like an hour glass, which can be obtained in different sizes. It has no cervico-vaginal extension.

Selection of Device

A good I.U.C.D. should be easy to insert, have a low rate of spontaneous expulsion, be easy to identify in situ, produce a minimum of side-effects and complications, give reliable contraception, and be easily removed when it is no longer required. Only the three devices already described will be compared with regard to these criteria.

Fig. 2 shows a Lippes loop with its introducing cannula and plunger. The cannula possesses a flange which is situated 4.5 cm. from its distal end so that this length of it can be passed into the cervical canal. Another flange is situated at the proximal end of the cannula to enable the operator to depress the plunger more easily. After the loop has been loaded into the cannula, the cannula is inserted into the cervical canal. The plunger is then used to expel the loop into the uterine cavity. The more rigid the loop the more difficult it is to load into the introducing cannula and the thicker the loop the wider the cannula required for its introduction.

The Margulies spiral is inserted in a similar way, but the Birnberg bow requires a more elaborate instrument for its insertion, which is not often possible without previous dilatation of the cervix.

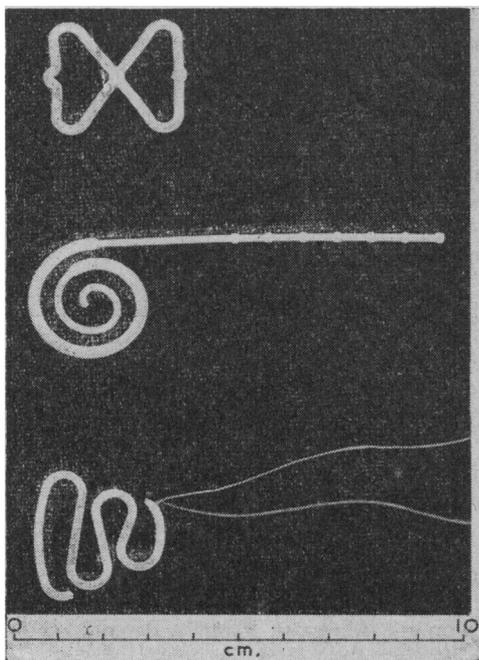


Fig. 1.—Birnberg bow (top); Margulies spiral (centre); Lippes loop (bottom).

makes it especially suitable for use in massive population control programmes and not unattractive for use by many individual patients. Doctors with some gynaecological experience may wish to offer this method of contraception to selected patients in their practices. In this paper we will endeavour to provide some measure of guidance on most of the practical problems involved in the use of I.U.C.D.s in Britain today.

The legal position relating to the occasional but inevitable serious complication, the possibility of the device being held responsible for an abortion, and the necessity or otherwise of obtaining the written consent of the patient's husband before inserting the I.U.C.D. are not yet clear. Doctors who feel uneasy about the legality of fitting I.U.C.D.s should consult their defence union or protection society.

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In general, the bigger and more rigid the device the less frequently will it be expelled from the uterus. Thus the Lippes loop D is less often expelled than any of the other Lippes loops, and the Margulies spiral size 5 less often than any of the other sizes of the Margulies spiral. The expulsion rate for the large Birnberg bow is lower than that for the small Birnberg bow.

The National Committee on Maternal Health¹ states that the initial annual rates (per 100 women) of expulsions of the Lippes loop D, the Margulies spiral size 5, and the large

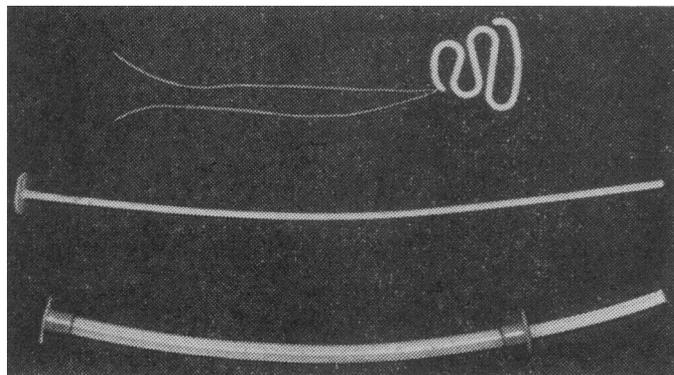


FIG. 2.—Lippes loop with cannula and plunger.

Birnberg bow are 11.3 ± 0.4 , 22.3 ± 0.9 , and 4.5 ± 0.5 respectively. Expulsions during the second year of use are much less common for all three devices. I.U.C.D.s fitted during the puerperium are more prone to spontaneous expulsion than those fitted several months after delivery.

The Lippes loop and the Margulies spiral both have extensions which pass through the cervix into the vagina, where they may be seen or felt. With these devices the patient may be able to determine for herself that the I.U.C.D. is in place. The Birnberg bow lies entirely within the uterine cavity, where its presence can be confirmed only by probing with an instrument or by radiography.

Side-effects

Bleeding

Most patients experience some uterine bleeding for a few days after an I.U.C.D. has been fitted. Menorrhagia and intermenstrual bleeding or "spotting" commonly follow, but the severity of these symptoms tends to decrease with the passage of time.

In our experience, 60 per cent. of women who have worn a Lippes loop D for more than six months say that their menses are still heavier and last a little longer than before they were fitted. Hall² has shown that the bow causes slightly less uterine bleeding and the spiral much more uterine bleeding than the loop.

Pain

Although the patient may experience some pelvic discomfort during and shortly after the fitting of an I.U.C.D., it is unusual for this symptom to persist. Severe pain is seldom encountered, except as an exacerbation of pre-existing dysmenorrhoea, and should alert the doctor to the possibility of a serious complication (see later). In Hall's² comparison, the bow produced less pain and the coil more pain than the loop.

Discharge

Most patients fitted with an I.U.C.D. notice an increase in vaginal discharge, but the increase is seldom enough to be troublesome.

Complaints by Husband

The rigid vaginal extension of the Margulies spiral has caused complaints by some husbands. The nylon or polyethylene threads of the Lippes loop become soft after insertion and tend to curl up around the cervix, so that few husbands are aware of them during intercourse. The Birnberg bow is free from this side-effect because it is entirely intrauterine.

The side-effects discussed above constitute the principal medical reasons for device "removals." The National Committee on Maternal Health¹ states that the initial annual rates (per 100 women) of removals for medical reasons for the Lippes loop D, the Margulies spiral size 5, and the large Birnberg bow are 11.1 ± 0.4 , 16.0 ± 0.9 , and 10.5 ± 9.7 respectively. Removals for medical reasons during the second year of use are much less common for all three devices.

Complications

Pelvic Inflammatory Disease

The relationship between pelvic inflammatory disease and the I.U.C.D. is not unlike that which exists between thromboembolic disease and "the pill." Cases of salpingitis occur for which no other cause can be found except that the patient was using an I.U.C.D., but there is as yet no evidence that the incidence of salpingitis is higher in I.U.C.D. users than it is in women comparable in all respects other than their mode of contraception. Laboratory investigations are apt to be more confusing than illuminating. Thus Mishell *et al.*³ have found positive endometrial cultures to be common within days of insertion but to be rare only a month after insertion.

The National Committee on Maternal Health¹ states the initial annual rates (per 100 women) of pelvic inflammatory disease associated with use of the Lippes loop D, the Margulies spiral size 5, and the large Birnberg bow are 2.1 ± 0.2 , 3.5 ± 0.5 , and 3.2 ± 0.4 respectively. During the second year of use, pelvic inflammatory disease is slightly less common with all three devices.

Migration

Migration into the pelvic cavity is theoretically possible with any device, but is a serious problem only with the Birnberg bow. Thus, of the 885 bow insertions reported by Hall² the bow was subsequently found embedded in the myometrium in seven cases and lying free in the peritoneal cavity in five cases. For this reason the American Planned Parenthood Federation have advised against the use of the bow.

Ectopic Pregnancy

As I.U.C.D.s are believed to act by preventing not fertilization but implantation of the fertilized ovum within the uterine cavity it is not surprising that cases of ectopic pregnancy have been reported in women using a device.⁴ However, there is as yet no evidence that the likelihood of ectopic pregnancy is increased in I.U.C.D. users or that any one device is associated with more ectopic pregnancies than any other.

Cancer

To date, there is no evidence that the I.U.C.D. is an aetiological factor in the production of uterine cancer. Ishihama⁵ found no evidence that even long-term use of the I.U.C.D. increased the likelihood of the development of endometrial cancer. Lippes⁶ performed 2,730 cervical smears in a two-year follow-up of patients using the intrauterine loop. The incidence of positive smears did not exceed that anticipated from the accepted norms for his group of patients.

Reliability of Contraception

Despite the fact that it is better retained than the other devices discussed in this paper, the Birnberg bow is associated with the highest pregnancy rate. The Margulies spiral, which is the least well retained, is associated with the lowest pregnancy rate.

The National Committee on Maternal Health¹ states that the initial annual rates (per 100 women) of unintended pregnancies in users of the Lippes loop D, the Margulies spiral size 5, and the large Birnberg bow are 2.9 ± 0.3 , 1.8 ± 0.4 , and 5.9 ± 0.5 respectively.

Ease of Removal

The Lippes loop and Margulies spiral are removed by traction applied to the vaginal extension. The procedure is usually quite painless. The Birnberg bow requires a special hook for its removal; this may be both painful and traumatic, especially if the bow has become embedded in the myometrium. Fragmentation of the bow during an attempt at removal may also occur.

In our clinic at Queen Charlotte's Maternity Hospital we use the Lippes loop C or D. Information about the cost and availability of some of the I.U.C.D.s is given in an appendix to this paper.

Selection of Patients

Patients for whom an I.U.C.D. is not advisable

NULLIPAROUS WOMEN.—In the present state of knowledge it is prudent to assume that any intrauterine device may be an aetiological factor in the development of pelvic inflammatory disease. In addition it should not be overlooked that, although overt pelvic sepsis is unusual with a device in situ, subtle changes occur in the endometrium of the majority of patients using an I.U.C.D.⁷ and may also occur in the Fallopian tubes, leading to a permanent impairment of reproductive function. For these reasons we consider that nulliparous women should seldom be fitted with an I.U.C.D.

UNMARRIED MOTHERS.—The natural inclination felt by many doctors to advise unmarried mothers to have an I.U.C.D. fitted should generally be resisted. In most cases the woman will not be keeping the child and is therefore "socially" nulliparous. Furthermore, the doctor's action in fitting a device might be misconstrued by the patient's family or by society as an endorsement of promiscuity. The patient herself should not be underestimated. Her illegitimate pregnancy may have been carefully planned and certainly cannot be assumed to indicate that she is incapable of using a method of contraception requiring a greater degree of co-operation on her part or that she needs any method of contraception at all. Few unmarried mothers go on to have a second illegitimate child.

SALPINGITIS.—The well-known tendency of salpingitis to recur and the possibility that a recurrence may be provoked by the presence of an I.U.C.D. are contraindications to the fitting of a device in these patients.

MENORRHAGIA.—The patient who is already distressed by heavy periods is unlikely to be able to tolerate the additional increase in menstrual loss which can be expected with the use of an I.U.C.D.

Patients for whom an I.U.C.D. is particularly suitable

GRAND MULTIPARA.—These women often have such a strong maternal instinct that any method of contraception which requires their continual co-operation is doomed to failure. Not infrequently they are quite young, and for them the I.U.C.D. is a very acceptable alternative to sterilization.

ORAL CONTRACEPTIVE FAILURES.—It is well known that most of the failures that occur with oral contraception are "patient failures" rather than "pill failures." The reasons why some women desiring contraception should fail to take their tablets are often obscure. The presence of severe side-effects, the fear of toxic effects or long-term hazards, preoccupation with other things, overtiredness, simple forgetfulness, or confusion about the tablet regimen caused by breakthrough bleeding may account for some cases, while others may be due to the patient's inability to suppress her instinctive desire for pregnancy all the time. As the cause of failure can seldom be determined, and as the patient's confidence in the oral method of contraception will usually have been lost, the fitting of an I.U.C.D. can be recommended.

SOCIAL PROBLEMS.—Some of the patients fitted in our clinic at Queen Charlotte's Maternity Hospital have been sent to us from the almoner's department. These referrals comprise four main types of patient. (a) The patient who has had more than one illegitimate child and who cannot be persuaded to lead a more responsible sexual life. (b) The West Indian woman who finds other methods of contraception unacceptable. (c) The poor woman who cannot afford either another child or another method of contraception. (d) The mental defective or psychotic who needs a method of contraception requiring a minimum of patient responsibility.

A trained social worker should always be consulted before a patient is fitted with an I.U.C.D. for social reasons.

Other Patients

WOMEN OF LOW PARITY.—These women may be fitted with a device provided that both they and their husbands are informed of the likely side-effects and possible complications.

ORAL CONTRACEPTIVE REFUSALS.—A detailed discussion of the various factors affecting the acceptability of "the pill" would be out of place in this paper. Suffice it to say that many women who previously have been satisfied with the oral method of contraception are asking to be fitted with an I.U.C.D. Provided that no contraindication exists, these women may be fitted, but not before both they and their husbands have been made aware of the higher pregnancy rate and the other ways in which an I.U.C.D. may be inferior to "the pill." The condom, the diaphragm, and the rhythm method still have a place in advice on contraception to patients.

Insertion of the Device

Optimum Time

In puerperal patients the best time for insertion is at the postnatal examination six weeks after delivery. Insertion before this time may be associated with an increased risk of uterine perforation. The more weeks that elapse after this time the more likely is the patient to become pregnant before fitting, and the cervix may become difficult to cannulate.

In normally menstruating patients the best time for insertion is during a period. The cervical dilatation that occurs at this time greatly facilitates the procedure and both patient and doctor can feel certain that pregnancy has not occurred already. Insertion during the first week after a period is acceptable, but insertion during the premenstrual week is contraindicated because of the risk of introducing a device into an already gravid uterus. Bad timing of the insertion is a potent cause of apparent failure of the device to prevent conception.

Optimum Position

As in all gynaecological procedures it is imperative that the doctor should be able to see clearly what he is doing, and the

lithotomy position is ideal for this purpose. The left lateral and other positions will usually suffice but are less satisfactory.

Equipment

The equipment that we use for the insertion of the Lippes loop D at Queen Charlotte's Hospital is shown in Fig. 3. It

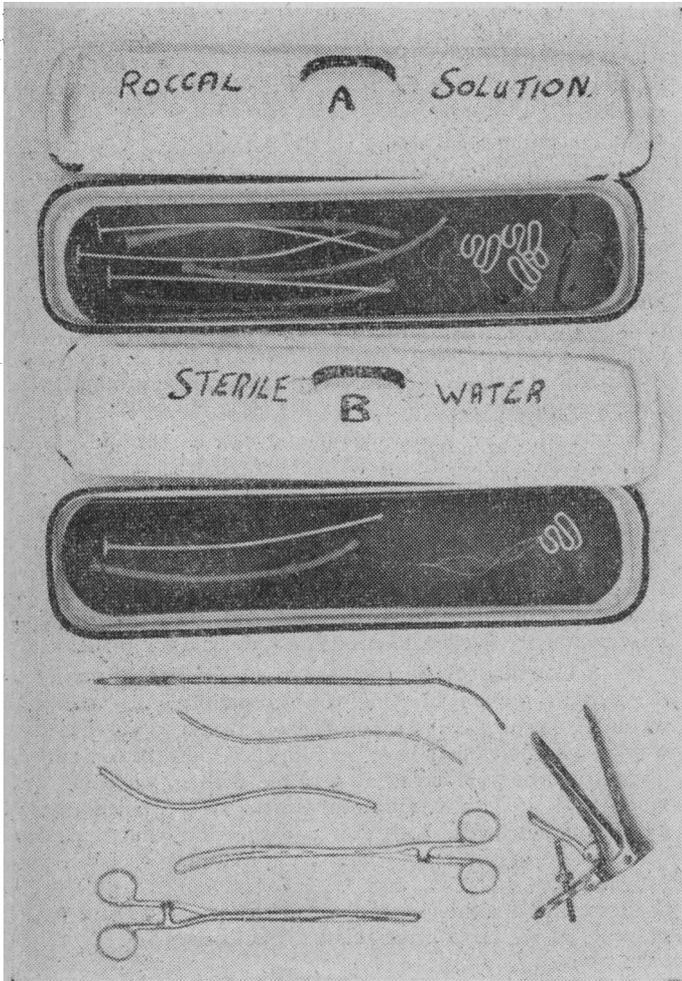


FIG. 3.—Equipment for insertion of Lippes loop.

will be remembered that loop D is the largest and most rigid of the Lippes loops.

The loops and introducers are sterilized by immersing them in an aqueous solution of benzalkonium chloride 1:750 for at least two hours. Immediately before use the loops and introducers are washed in sterile distilled water. Prepacked sterile sets are available, but these are of course more expensive, because, apart from the cost of sterilization and packing, a new introducer has to be purchased with each new loop.

The self-retaining bivalve speculum allows the doctor to have both his hands free to perform the insertion after the cervix has been visualized. An additional advantage of this type of speculum is that the doctor can use it to steady the cervix and dilate the external cervical os by traction on the adjacent vaginal walls. Wide non-tapering blades are recommended to prevent the flabby vaginal walls of the multiparous and puerperal patient from obscuring the field of vision.

The uterine sound and small cervical dilators are malleable so that they can be shaped to traverse any cervical canal.

The vulsellum forceps are of the single-toothed variety to minimize the discomfort caused to the patient when it is necessary to use them.

Paper gloves are more convenient than rubber gloves. We do not cleanse the vulva or vagina prior to insertion.

Method

A bimanual examination is performed to ensure that the patient is not pregnant and that there is no gross pelvic lesion. During this examination the position of the cervix and body of the uterus are noted.

The bivalve speculum is inserted so as to visualize the cervix and is then locked in position.

The length and direction of the uterine cavity are confirmed by passage of the uterine sound.

The cervix is gently dilated to a No. 5 or 6 Hegar. This procedure is not always necessary but often facilitates insertion. It is usually quite painless and takes only a few seconds to perform.

The Lippes loop is loaded into the introducing cannula. No instruments are needed for this. The plunger is then used to push the loop along until its free end almost reaches the distal end of the cannula. The loading of the introducer is delayed until this stage to reduce to a minimum the time for which the loop is straightened out.

The cannula is passed through the cervical canal until its distal flange reaches the external cervical os. The plunger is then fully depressed so as to extrude the whole of the loop itself into the uterine cavity, leaving only the nylon or polyethylene threads lying beside the plunger within the cannula.

If difficulty is experienced in passing the cannula through the cervical canal owing to excessive anteversion or retroversion of the uterus, depressing or elevating the handle of the bivalve speculum is preferable to exerting traction with the vulsellum forceps on the anterior lip of the cervix to straighten out the cervical canal.

If difficulty is experienced in extruding the device into the uterine cavity it will probably be due to the plane of the loop being at right angles to the plane of the uterine cavity. Rotating the cannula through a right angle will facilitate extrusion.

The cannula is withdrawn, leaving only the threads protruding through the cervix. If any of the device itself is still visible, the insertion needs to be repeated.

The speculum is withdrawn, after which the patient is given a vulval pad and helped down from the lithotomy position.

Advice to the Patient after Insertion

The patient is reminded of the menstrual disturbances that she can expect. If she asks if she can continue using internal tampons she should be advised that her period may be too heavy for this during the first few months after insertion but that there is no contraindication to her using them after this time. It is important that the patient should inspect all her used tampons before discarding them lest the device, which she should be shown, has been extruded on to one of them. The patient should also be encouraged to check that the device is in situ by digital self-examination from time to time and especially after any bleeding. We do not usually advise our patients to use any other form of contraception once we have fitted a device.

Follow-up after Insertion

At least one follow-up examination one month after insertion is essential to check that the device is in situ and that the patient is not suffering excessively from side-effects. Thereafter each patient should be seen six months after insertion of the device and then annually.

Treatment of Side-effects and Complications

Bleeding

Severe bleeding which does not soon stop should be treated by removal of the device. Most I.U.C.D. users will benefit from the prescription of iron and folic acid tablets.

Pain

Severe pain during insertion is a signal to the doctor to abandon the attempt before any serious harm is done. Another attempt at insertion can be made at a later date.

Sometimes the device has to be removed soon after insertion because of the onset of severe colicky pain. A smaller device or a differently shaped one might prove more satisfactory.

Pain occurring at a later time may be associated with loop expulsion, salpingitis, or ectopic pregnancy.

Spontaneous Expulsion

At Queen Charlotte's Hospital we treat our loop expulsions by the insertion of another loop as soon as possible. The loop is usually retained, but if it is not we advise the patient to use another form of contraception.

Salpingitis

This is treated by bed rest and antibiotics. It is our practice to remove the loop in accordance with our views on the contraindications to its use.

"Absent Tails"

Occasionally the threads of the Lippes loop cannot be seen or felt in the absence of a history of spontaneous expulsion or removal. There are five possible explanations. The patient may be pregnant and the tails have been carried up into the enlarging uterus. The tails may have passed up into the non-gravid uterus, in which case they will usually come down again during the next period. Occult expulsion of the device may have occurred. The device may have migrated through the wall of the uterus. The threads may have become detached from the loop. Investigation may include uterine probing or radiography.

A loop which is in situ but has lost its tail should be replaced

by another loop. If migration is thought to have occurred the patient should be referred for specialist treatment.

Pregnancy

It has been suggested that the physician's responsibility in this method of contraception is so great that termination should be offered to any patient in whom the method fails. The authors do not endorse this view, and feel that each case should be judged on its own merits. If no indication for termination exists, the device should be left in situ, as there is no evidence that it harms the mother or foetus, whereas removing the device may produce sufficient disturbance to provoke a miscarriage.

Removal of Device

The mode of removal of these devices has already been described. No one knows how long these devices may be left in the uterus with safety, but it would seem reasonable that they should be changed every two or three years and that they should be removed altogether when the patient no longer wishes or needs contraception, or when side-effects or complications make their presence undesirable.

Appendix

Ortho Pharmaceuticals Limited manufacture the Lippes loop and the Margulies spiral (Gynecoil). The devices can be obtained direct from Ortho at about 10s. each and the introducers at 34s. each. There is a medical discount and a discount for large orders.

London Rubber Industries Limited provide a less well known but promising device called the Saf-T-Coil. This comes pre-sterile complete with introducer and costs 25s. if a dozen are ordered direct from the Company.

The devices may be obtained from some retail chemists and sellers of medical instruments. Prices are variable, so economies may be effected by "shopping around."

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ANY QUESTIONS?

We publish below a selection of questions and answers of general interest.

Excretion of Disulfiram

Q.—*Is there a simple urine or blood test to show whether or not a patient is taking his Antabuse (disulfiram) tablet?*

A.—Though small quantities of the unchanged substance are detectable in the urine, disulfiram is excreted mainly as a diethyldithiocarbamate. Precise methods have been described for the determination of both unchanged disulfiram and the diethyldithiocarbamate produced in blood, serum, and urine.¹

Under appropriate conditions diethyldithiocarbamate will react with cupric salts to form a product which dissolves in an organic solvent such as amyl alcohol to produce a yellow-coloured solution. This is the basis of methods that have been used extensively for the determination of copper in biological

materials.² This reaction may be used as a test for the presence of diethyldithiocarbamate in urine. The test is carried out as follows:

To 10 ml. of urine add the following in order, mixing thoroughly after each addition: 1 ml. aqueous sodium citrate (10% w/v); 1 ml. 10% ammonia (ammonia, S.G. 880, diluted 10 times); 1 ml. aqueous cupric sulphate (5% w/v); 5 ml. amyl alcohol. After adding the amyl alcohol shake vigorously for two minutes and centrifuge.

The presence of diethyldithiocarbamate is indicated by the amyl alcohol layer (top layer) assuming a yellow colour. The omission of cupric sulphate from the test results in the production of a colourless amyl alcohol layer. As a reference substance, sodium diethyldithiocarbamate may be purchased from British Drug Houses Ltd., Poole, Dorset. Only freshly prepared solutions should be

used, since this compound is unstable in solution.

This test for diethyldithiocarbamate in urine is in effect the reversal of the usual method for the determination of copper in biological materials.

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Pendulous Breasts

Q.—*What can be done for large, full, and pendulous breasts in women who are past the menopause and when diuretics, diet, and exercises have not achieved anything?*

A.—The safest operation for large pendulous breasts in women past the menopause is subtotal amputation with transposition of the nipples as a free graft.