

Dalkon Shield IUD advertisement.

[s.l.]: [s.n.], 1972

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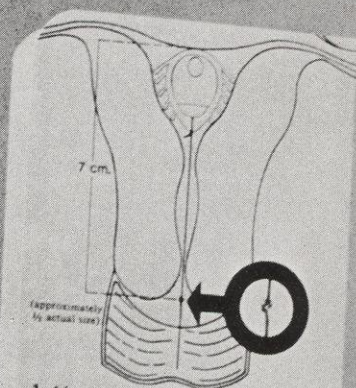
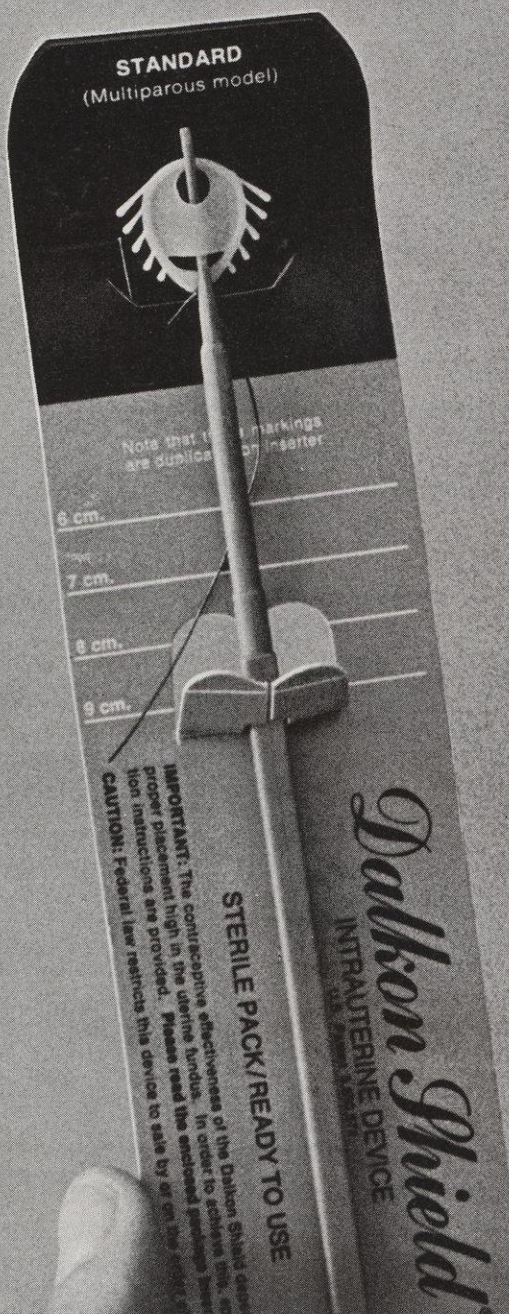
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Q. Which part of the Dalkon Shield® package is as important as the Dalkon Shield itself?

A. The insertion instructions! (follow them carefully)



1. After performing bimanual examination to check normality and position of uterus, cleanse cervix with cotton and antiseptic solution.
2. Apply tenaculum securely through anterior lip of cervix.
3. Sound uterus to determine axis of canal and measurement from external cervical os to highest fundal position. Record measurement on patient's chart.
4. Insert Dalkon Shield to FULL depth in the plane of the uterine cavity. Use knot on tail (which is 7 cm from top of device) to assure proper placement. Examples: If depth determined by sounding is 7 cm, knot should be at cervical os; if depth is 6 cm, knot should be approximately 1 cm outside cervical os; if depth is 8 cm, knot should be approximately 1 cm inside cervical os.
5. Disengage inserter from Dalkon Shield by turning it 90° (1/2 turn) and withdrawing gently.
6. Check high fundal positioning of device by observing knot as explained above. Record on patient's chart the location of the knot in relation to external cervical os.

Removal Procedure

1. Apply tenaculum to anterior lip of cervix to align cervical canal.
2. Grasp the string securely with sponge forceps or other suitable instrument and extract with steady, even traction.

A. H. Robins Company, Richmond, Va. 23220

A-H-ROBINS

TECHNICAL

Rev. Jan. 1973

Full Disclosure:

IMPORTANT

The contraceptive effectiveness of the Dalkon Shield depends upon its proper placement high in the uterine fundus. In order to achieve this, specific insertion instructions are provided. Please, follow these instructions carefully!

Indication

Prevention of Pregnancy.

Contraindications

Pregnancy. Distortion of uterine cavity by myomata or congenital septum. Severe retroverted or anteverted uterus. Menometrorrhagia, acute or subacute pelvic inflammatory disease, endometritis, suspected neoplasia, stenosis of the cervical canal. Uterine sounding of less than 5 cm. from external cervical os to uterine fundus.

Warnings

1. As with all IUD's, perforation (partial or complete) is a recognized risk. Insertion before 8-12 weeks postpartum (or postabortion) may be attended by a higher risk of uterine perforation.
2. The Dalkon Shield exhibits a relatively low level of radiopacity because of its thin construction, and in some patients, particularly the obese, soft-tissue technique may be needed to achieve visualization.
3. Spontaneous complete or partial expulsion of this device may occur. Reports indicate that a Dalkon Shield not in its high fundal position may not provide anticipated contraceptive effect.

Precautions

1. Close adherence to the recommended insertion procedure is considered essential for maximal contraceptive effectiveness.
2. The standard size Dalkon Shield should be used in women who have borne children unless it is found by trial not to be tolerated. The small size Dalkon Shield should be used primarily for nulliparous patients and the occasional multi-

parous patient who does not tolerate the standard size.

3. Aseptic technique should be used during insertion.
4. Insertion during the menstrual flow facilitates insertion and provides greater assurance that the patient is not pregnant.
5. In selected patients, particularly nulliparas, premedication with an analgesic and/or paracervical block may aid insertion and removal. Post-insertion syncope may be avoided by the use of atropine prior to insertion.
6. The risk of accidental pregnancy with IUD's may be higher during the first two or three menstrual cycles following insertion. Therefore, the use of a supplemental contraceptive method, such as spermicidal foam or gel, during this interval is recommended.
7. The need for removal and/or replacement of the Dalkon Shield is dictated largely by patient tolerance.
8. The patient should be instructed to check presence of string, particularly after each period. Re-examination by the physician is recommended after the first menses, at six-month intervals thereafter, and at any other time that the patient has reason to suspect that the Dalkon Shield is not in proper position.
9. At each follow-up examination, the location of the knot in relation to the external cervical os should be compared to its location noted on patient's chart at the time of insertion. Upward displacement of knot may indicate string has retracted into cervical canal, or perforation and/or accidental pregnancy has occurred. Displacement of the knot downward indicates a low-lying device. Recognition and correction of this are important to the maintenance of expected efficacy. A device not in its high fundal position should be replaced.

Adverse Effects

Inter-menstrual spotting and prolongation and increase in the menstrual flow, particularly during the first few cycles following insertion. Lower abdominal cramping, usually transient. Post-insertion syncope, particularly in nulliparas. Infection.

Supply

A package contains 8 Dalkon Shields individually sterile packed and preloaded on disposable inserters ready to use. Available in standard and small sizes.

Dalkon Shield®

A. H. Robins Company, Richmond, Virginia 23220

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