

NOVA T[®] BAYER MIDDLE EAST

Intrauterine Device

Presentation

Packs of 1 Intrauterine Device

For further information on the I.U.D, especially the technical information on its insertion and removal, please consult our scientific literature.

Indication

The IUD provides protection against pregnancy. Its reliability is less than that of ovulation inhibitors. IUDs are less effective in preventing extrauterine pregnancies than they are in preventing intrauterine pregnancies. Therefore, there is a risk that a pregnancy occurring with an IUD in situ may be extrauterine.

The I.U.D is particularly recommended for women who for medical reasons cannot use hormonal contraceptives, who decline to use them or who cannot take these preparations regularly for one reason or another.

In very young women and nulliparae, the benefit/risk ratio must be weighed particularly carefully, since reports exist on higher failure rates and complications. Epidemiological studies suggest that nulliparous IUD wearers may be at an increased risk of pelvic infection and consequent infertility. Also women with a multiplicity of sexual partners seem to be more affected in this respect.

Contraindications

The NOVAT Schering is not to be used during an existing or assumed pregnancy; malignomas or suspected malignancy in the genital area; acute, subacute and chronic pelvic inflammatory disease (including a history thereof); extremely profuse menstrual bleeding; congenital or acquired anatomical changes of the uterus or cervix; endometriosis; hypoplasia or extreme positional anomalies of the uterus; genital bleeding of unknown origin; clotting disorders; conditions which can lead to or promote bacteraemia (e.g. valvular defects, congenital heart disease); severe anaemia; conditions associated with a weakened

immune defence; Wilson's disease; copper allergy; a history of extrauterine pregnancy.

The benefits of inserting an I.U.D must be carefully weighed against the risks in status after surgery on the uterine body or in the pelvic and abdominal cavity-and particularly on the tubes -, since there have been isolated reports of an increased risk of extrauterine pregnancy and uterine perforation.

In cases of preceding infected abortion, the I.U.D should be inserted only after adequate treatment.

Reasons for premature removal of the I.U.D

Should pregnancy occur with an I.U.D in situ it is recommended that it be removed by pulling on the threads, since this reduces the increased risk of secondary symptoms (e.g. abortion, general bacterial infection).

A desire for children and the following symptoms: irregular and more copious monthly bleeding, persistent cramp-like lower abdominal pain, inflammation*) in the region of the uterus or pelvis minor, in order to avoid exacerbating these symptoms and a possible threat to fertility.

If the I.U.D has moved into the cervix, has penetrated into the wall or is completely outside the uterus it should likewise be removed because of reduced or absent protection against conception and possible complications.

Side effects

Initially the IUD can cause dragging pain in the lower abdomen or sacral area, but this usually soon subsides. Very rarely, a brief loss of consciousness or decelerated pulse rate may occur during insertion or removal of intrauterine devices. Menstruation is sometimes stronger and of longer duration than normal or painful. Iron deficiency anaemia may then occur in individual cases. Slight intermenstrual bleeding, often in the form of spotting, usually subsides, of its own accord. Lower abdominal infections with the risk of subsequently becoming infertile occur more frequently in IUD wearers than in other

women. Isolated cases of skin reactions, possibly attributable to copper allergy.

Technical data

The intrauterine device (IUD) NOVAT Schering is made of plastic material approx. in the shape of a T. Polyethylene threads are attached to the lower portion. The vertical portion of the T is wound round with thin copper wire stabilized with a silver core (107-141 mg copper and 11-29 mg silver, surface about 200 MM²).

Special notes

Before any insertion of an I.U.D the patient should be given a thorough gynaecological examination. The size and position of the uterus should be established and pregnancy or other contraindications (see "Contraindications") excluded. Gynaecological examinations are recommended 1, 3, 6 and 12 months after insertion and subsequently at yearly intervals, cytological smears every 6-12 months.

*Bacteriological examinations and, where applicable anti biotic therapy are indicated even in discrete symptoms indicative of inflammatory changes (e.g. discharge). 11 actinomyces are found in cytological smears, consideration must be given to removing the I.U.D as a precaution-particularly after it has been in situ for some time ~ even in asymptomatic patients, and to giving appropriate treatment.

Women who are taking anticoagulants, must be supervised particularly closely because of the increased tendency to haemorrhage.

Reports have been published that the contraceptive effect of intrauterine devices appears to be diminished in patients under chronic treatment with non-steroidal antiinflammatory drugs (particularly acetyl salicylic acid) and with corticoids or antibiotics (particularly tetracyclines).

According to experience to date, however, contraceptive protection is not reduced during short-term treatment of dysmenorrhoea with non-steroidal anti inflammatory drugs.

Extrauterine pregnancy must be considered in the presence of vague lower abdominal complaints associated with irregular cycles (especially amenorrhoea after persistent bleeding).

Following delivery or abortion an I.U.D should only be inserted when the uterus has reverted to its normal size, i.e. after 4-6 weeks. If inserted earlier there is an increased risk of the device being expelled or of perforation of the uterus.

Because of the reduced fragmentation risk of the copper wire it appears that the NOVAT Schering can be left inserted for longer periods (up to 5 years). After removal a new Schering can usually be inserted at once.

Caution should be exercised when performing therapy of the sacral or abdominal region (short or microwave, diathermy), since heating of the copper with subsequent damage cannot be ruled out.