SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM

NOVA T 380

Intrauterine device (IUD)

COMPOSITION:

Nova T 380 is an intrauterine device made of polyethylene and wound with copper wire with a silver core. The surface area of the copper is 380 mm2. The polyethylene body, shaped as a modified T is impregnated with barium sulphate. Removal threads, pigmented with iron oxide are attached to the base of the vertical arm of the T.

PHARMACOLOGICAL CLASSIFICATION:

A 34 Other – intrauterine device

PHARMACOLOGICAL ACTION:

Copper IUDs prevent pregnancy by preventing fertilisation. This is based on the inhibition of sperm and egg transport and/ or the capacity of the sperm to fertilise eggs. This happens through cytotoxic and phagocytic effects before the egg reaches the uterine cavity. After the removal of Nova T 380 fertility is promptly restored.

The pregnancy rate with Nova T 380 has been 0.6 per 100 woman-years.

INDICATIONS:

Contraception.

CONTRA-INDICATIONS:

- Known or suspected pregnancy;
- Current or recurrent pelvic inflammatory disease;
- Lower genital tract infection;
- Postpartum endometritis;
- Infected abortion during the past three months;
- Untreated cervicitis;
- Untreated cervical dysplasia;
- Untreated uterine or cervical malignancy;
- Undiagnosed abnormal uterine bleeding;
- Congenital or acquired uterine anomaly including fibroids if they distort the uterine cavity;
- Copper allergy;
- Wilson's disease;
- Coagulation disturbances;
- Conditions associated with increased susceptibility to infections.

WARNINGS AND SPECIAL PRECAUTIONS:

Nova T 380 may increase menstrual blood loss and dysmenorrhoea. Nova T 380 may not be the method of first choice for women with excessive menstrual bleeding, anaemia, dysmenorrhoea or for women receiving anticoagulants. If these conditions develop during the use of Nova T 380, removal of the device should be considered.

Nova T 380 may be used with caution in women who have congenital heart disease or valvular heart disease at risk of infective endocarditis. Antibiotic prophylaxis should be administered to these patients when inserting or removing the intrauterine device.

Nova T 380 is not the method of first choice for young nulligravid women. In this group, the pregnancy rates and removal rates for expulsion, bleeding and/ or pain, and for infection have been reported higher than in other users.

Pelvic infection:
The insertion tube protects Nova T 380 from contamination with micro- organisms during the insertion. In users of copper IUDs, the highest rate of pelvic infections occurs during the first month after insertion and decreases later. Known risk factors for pelvic inflammatory disease are multiple sexual partners, frequent intercourse and young age. Pelvic infection may impair fertility and increase the risk of ectopic pregnancy.
Severe infection or sepsis(including group A streptococcal sepsis) can occur following insertion of IUDs such as Nova T 380.
If the woman experiences recurrent endometritis or pelvic infections, or if acute infection does not respond to treatment within a few days, the Nova T 380 must be removed.
Bacteriological examinations are indicated and monitoring is recommended.

Expulsion
Symptoms of the partial or complete expulsion of any IUD may include bleeding or pain. However, Nova T 380 can be expelled from the uterine cavity without the woman noticing it. Partial expulsion may decrease the effectiveness of Nova T 380. A displaced device should be removed and a new device inserted.
The woman should be advised how to check the threads of the IUD.

Perforation
Perforation or penetration of the uterus or cervix by the Nova T 380 IUD may occur, most often during insertion. In such cases Nova T 380 must be removed as soon as possible.
In a large European prospective comparative non-interventional cohort study in IUD users (N = 61448 women), the incidence of perforation was 1.3 (95 % CI: 1.1 - 1.6) per 1000 insertions.
Breastfeeding at the time of insertion and insertion up to 36 weeks after giving birth are associated with an increased risk of perforation (see table 1).

Table 1: Incidence of perforation per 1000 insertions stratified by breastfeeding and time since delivery at insertion (parous women).

	Breastfeeding at time of insertion	Not breastfeeding at time of insertion
Insertion ≤ 36 weeks after delivery	5.6 (95 % CI 3.9-7.9; n = 6047 insertions)	1.7 (95 % CI 0.8-3.1; n = 5927 insertions)
Insertions > 36 weeks after delivery	1.6 (95 % CI 0.0-9.1; n = 608 insertions)	0.7 (95 % CI 0.5-1.1; n = 41910 insertions)

The risk of perforation may be increased in women with fixed retroverted uterus.
Ectopic pregnancy
A pregnancy with an IUD in place is more likely to be ectopic than if pregnancy occurs without an IUD *in situ*. Women with a previous ectopic pregnancy, pelvic surgery or pelvic infection carry a higher risk of ectopic pregnancy. The possibility of ectopic pregnancy should be considered in the case of lower abdominal pain - especially in connection with missed periods or if an amenorrhoeic woman starts bleeding.

Lost threads
If the retrieval threads are not visible at the cervix on follow-up examinations, pregnancy must be excluded. The threads may have been drawn up into the uterus or cervical canal and may reappear during the next menstrual period. If pregnancy has been excluded, the threads may usually be located by gently probing with a suitable instrument. If they cannot be found, the possibility of expulsion or perforation should be considered. Ultrasound diagnosis may be used to ascertain the position of the IUD. If ultrasound is not available or unsuccessful, X-ray may be used to locate Nova T 380.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
There are no known effects on the ability to drive or use machines.

INTERACTIONS:
The limited available experience with Nova T 380 indicates that medicine effects interfering with Nova T 380's contraceptive efficacy are unlikely.

PREGNANCY AND LACTATION:
Pregnancy
Nova T 380 is not to be used during an existing or suspected pregnancy (See "Contra-indications").
If the woman becomes pregnant when using Nova T 380 removal of the device is recommended, since the IUD left *in situ* may increase the risk of abortion and preterm labour. Removal of the IUD or probing of the uterus may result in spontaneous abortion. If the device cannot be gently removed, termination of the pregnancy may be considered. If the woman wishes to continue the pregnancy and the device cannot be withdrawn, she should be informed about these risks and the possible consequence of premature birth to the infant.
In addition, ectopic pregnancy should be excluded and the course of such a pregnancy should be closely monitored. The woman should be instructed to report all symptoms that suggest complications of the pregnancy, like cramping abdominal pain with fever. She should be informed that, to date, there is no evidence of birth defects in cases where a pregnancy continues to term with Nova T 380 in place.

Lactation
Nova T 380 does not interfere with lactation.

DOSAGE AND DIRECTIONS FOR USE:

Nova T 380 is supplied sterile, sterilised by irradiation. It is for single use only.
Do not use if the pouch is damaged or open. Do not re-sterilise. Use before the date shown on the pouch label. To be inserted by a qualified healthcare professional.
Nova T 380 is inserted into the uterine cavity. It is effective for five years.

Insertion and removal/ replacement

Before insertion, the woman must be informed on the efficacy, risks and side effects of Nova T 380. A physical examination including pelvic examination and a cervical smear should be performed. Pregnancy, genital infection and sexually transmitted diseases should be excluded. The position of the uterus and the size of the uterine cavity should be determined. The instructions for insertion should be followed carefully. The woman should be re-examined 4 to 12 weeks after insertion and once a year thereafter, or more frequently if clinically indicated.

Insertion is recommended during or shortly following menstruation. If pregnancy is excluded, Nova T 380 may be inserted at any time of the cycle. The small diameter of the insertion tube, which is easy to introduce, makes dilatation usually unnecessary. It can be replaced by a new device at any time in the cycle.

Nova T 380 can also be inserted immediately after first trimester abortion. Postpartum insertions should be postponed until the uterus is fully involuted, however not earlier than six weeks after delivery. If involution is substantially delayed, consider waiting until 12 weeks postpartum. In case of a difficult insertion and/or exceptional pain or bleeding during or after insertion, physical examination and ultrasound should be performed immediately to exclude perforation.

It is recommended that Nova T 380 should only be inserted by medical practitioners/ healthcare professionals who are experienced in Nova T 380 insertions and/ or have undergone sufficient training for Nova T 380 insertion.

Nova T 380 is removed by gently pulling on the threads with forceps. If the threads are not visible and the device is in the uterine cavity, removal should be postponed until after the next menstrual bleeding since the threads usually become visible immediately after menstruation. If they are still not

visible, the device may be removed using a narrow tenaculum. This may require dilatation of the cervical canal.

Nova T 380 should be removed after five years. If the woman wishes to continue using the method, a new device can be inserted at the same time.
If pregnancy is not desired, the removal should be carried out during menstruation. If the device is removed mid-cycle and the woman has had intercourse within a week, she is at risk of pregnancy unless a new device is inserted immediately following removal.
Insertion and removal may be associated with some pain and bleeding. The procedure may precipitate fainting as a vasovagal reaction, and a seizure in an epileptic patient.

Instructions for use
NOVA T 380 IS SUPPLIED STERILE, STERILISED BY IRRADIATION. IT IS FOR SINGLE USE ONLY. DO NOT RE-STERILISE. DO NOT RE-PROCESS. RE-USE, REPROCESSING OR RE-STERILISATION MAY COMPROMISE THE STRUCTURAL INTEGRITY OF THE DEVICE AND/OR LEAD TO DEVICE FAILURE.
Do not use if the pouch is damaged or open. Insert the device before the expiry date shown on the pouch label. Each device should be handled with aseptic precautions. Special instructions for insertion are in the package. The device should be removed five years after insertion at the latest. After removal, Nova T 380 should be disposed of in accordance with the local guidelines for the handling of biohazardous waste.

SIDE EFFECTS:

Increased menstrual bleeding; spotting; dysmenorrhoea; lower abdominal or back pain; anaemia.
Pregnancy in the case of the method failure may be ectopic.
Pelvic inflammatory disease may occur during the use of Nova T 380.
The Nova T 380 or parts of it may perforate or penetrate the uterine wall. Risk of perforation is increased in breastfeeding women and women with an insertion up to 36 weeks after delivery (see “Warnings and Special Precautions”).
Allergic skin reactions may occur.
Cases of sepsis (including group A streptococcal sepsis) have been reported following insertion (see “Warnings and Special precautions”).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Not applicable

IDENTIFICATION:
A white plastic body – shaped as a modified T, with silver-cored copper wire wound around the vertical arm and removal threads tied to the loop of the vertical arm.

PRESENTATION:
The device with accessories is packed in a heat-sealed sterilisation pouch of polyester/ polyethylene/polyamide.

STORAGE INSTRUCTIONS:
Store at or below 30 °C.
Keep the product in carton until required for use.
Protect from direct sunlight and moisture. Keep out of reach of children.

REGISTRATION NUMBER:

34/34/0132

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
ISANDO
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DATE OF PUBLICATION OF THE PACKAGE INSERT:

02 June 2017