Intrauterine Device

NOVA-T®

Model Cu 200 Ag

COMPOSITION

NOVA-T is an intrauterine device made of plastic (polyethylene), approximately in the shape of a T. Polyethylene threads are attached to the lower portion. The horizontal and vertical arms of the T are 32 mm in length and 1.2 mm in diameter; a loop 2.6 mm wide is found at the tip of the vertical arm; and a thin copper wire (107–141 mg Cu, surface area of 200 mm²) stabilized with a silver core (11–29 mg Ag) is coiled onto the vertical portion of the T. The silver core prevents fragmentation of the wire and prolongs the lifespan of the device. The polyethylene removal threads are pigmented with iron oxide.

INDICATION

NOVA-T is indicated for intrauterine contraception in gynecologically normal women of childbearing age. The pregnancy rate with **NOVA-T** is 1.26 per 100 woman-years. After removal of **NOVA-T**, fertility is promptly restored. Duration of use: **NOVA-T** can be left inserted for a maximum of 30 months. If continued contraception is desired by the patient, a new **NOVA-T** should be inserted at once. 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 after removal.
Copper IUDs prevent pregnancy by preventing fertilization. This is based on the inhibition of sperm and egg transport and/or the capacity of sperm to fertilize eggs. This happens through cytotoxic and phagocytic effects before the egg reaches the uterine cavity.

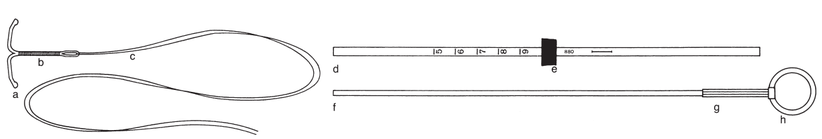
CONTRAINDICATIONS

NOVA-T should not be used in the presence or suspicion of: pregnancy; lower genital tract infection; postpartum endometritis; infected abortion during the past three months; cervicitis; cervical dysplasia; malignant tumor in the genital area; acute, subacute and chronic pelvic inflammatory disease; profuse menstrual bleeding; congenital or acquired anatomical changes of the uterus or cervix including fibroids; endometriosis; hypoplasia or extreme positional anomalies of the uterus; genital bleeding of unknown origin; clotting disorders; severe anemia; conditions associated with a weakened immune defense; Wilson's disease; copper allergy; a history of ectopic pregnancy.

WARNINGS

1. The risk/benefit ratio of inserting an intrauterine device must be carefully weighed following surgery on the uterine body or in the pelvic and abdominal cavity - and particularly on the fallopian tubes - since there have been isolated reports of an increased risk of ectopic pregnancy and uterine perforation.
2. The rate of expulsion may be increased when insertions are made before the normal uterine involution occurs following delivery or abortion. It is recommended that **NOVA-T** be inserted not earlier than 6 weeks post-partum or post-abortion. If involution is substantially delayed, consider waiting 12 weeks to insert **NOVA-T**. 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. Current data indicate that slightly higher expulsion and pregnancy rates may be anticipated with earlier insertion.
3. In young and nulliparous women the risk/benefit ratio must be carefully appraised because of reports of higher failure rates and complications. Some epidemiological surveys suggest that nulliparous patients using an intrauterine device may be at a greater risk of pelvic inflammatory disease and subsequent infertility and increased risk of ectopic pregnancy. Women with multiple sexual partners or who have frequent intercourse also seem to be more affected in this respect.
4. The insertion tube protects **NOVA-T** from contamination with micro-organisms during insertion. In users of copper IUDs, the highest rate of pelvic infections occurs during the first month of insertion and decreases later.
5. As with other gynecological or surgical procedures, severe infection or sepsis (including group A streptococcal sepsis) can occur following IUD insertion, although this is extremely rare.
6. Patients should be examined for the presence of pelvic inflammatory disease before inserting **NOVA-T**. In cases of infection (e.g. subsequent to a septic abortion or a sexually transmitted disease) appropriate treatment should be given before inserting the IUD. If a patient woman experiences recurrent endometritis or pelvic infections, or if an acute infection does not respond to treatment within a few days, **NOVA-T** must be removed.
7. **NOVA-T**, as other intrauterine devices, is not effective in preventing ectopic pregnancies. When a patient becomes pregnant with **NOVA-T** in situ, the relative likelihood of ectopic pregnancy is increased. Women with a previous history of ectopic pregnancy, pelvic surgery or pelvic infection carry a higher risk of ectopic pregnancy.

Figure 1



a) arms
b) copper wire
c) threads
d) insertion tube
e) yellow ring
f) plunger
g) ribbed part
h) backstop

8. Perforation or penetration of the uterine corpus or cervix by the IUD may occur most often during insertion. The risk of perforation is increased in women who are breastfeeding at the time of insertion and when insertion takes place up to 36 weeks after giving birth. The risk of perforation may be increased in women with abnormal uterine anatomy or fixed, retroverted uteri.

Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until sometime later. If perforation occurs, pregnancy may result. NOVA-T must be located and removed. Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of the adjacent viscera.

9. **NOVA-T** should be removed for the following reasons:
   a) Perforation of the uterus which places the device outside the uterine cavity (usually occurs during insertion).
   b) Excessive and persistent bleeding, cramping, and inflammation in the region of the uterus or pelvis minor, to prevent worsening of these symptoms or possible infertility.
   Note: In patients with inflammation or mild symptoms indicative of inflammatory changes (e.g. discharge), bacteriological examinations and antibiotic therapy, where applicable, are indicated. If actinomycetes are found in cytological smears, consideration must be given to removing the intrauterine device as a precaution – particularly after it has been in situ for a long time - even in asymptomatic patients and to giving appropriate treatment.
   c) Partial or total downward displacement of **NOVA-T** within the cervical canal (in some cases the tip of the "T" device can be palpated).
   Note: NOVA-T should be removed by gentle traction on the threads or on the tip of the "T". When **NOVA-T** is in the cervical canal, protection against pregnancy may be reduced or absent.
   d) Pregnancy occurring with **NOVA-T** in situ.
   Note: NOVA-T should be removed by pulling on the threads to reduce the increased risk of secondary symptoms (e.g. abortion, general bacterial infection, preterm labour). Removal or probing of the uterus may result in spontaneous abortion therefore if **NOVA-T** cannot be withdrawn gently, termination of pregnancy should be considered. If the patient wishes to continue the pregnancy and the device cannot be withdrawn, she should be informed of the risks and the possibility of premature birth. Ectopic pregnancy should be excluded. The woman should be followed closely and advised to report any abnormal symptoms, such as fever, cramping, and abdominal pain. To date there is no evidence of birth defects in cases where pregnancy continues to term with an IUD in place.

Important: If there is any suspicion that **NOVA-T** is incorrectly positioned, it must be removed and replaced by another sterile **NOVA-T**.

PRECAUTIONS

1. Prior to inserting **NOVA-T**, the physical examination should include a complete pelvic examination and a Papanicolaou smear. Pregnancy must be ruled out.
2. **NOVA-T** should be used with caution in women with congenital or valvular heart disease who are at risk of infective endocarditis. Antibiotic prophylaxis should be administered to such patients when inserting or removing **NOVA-T**.
3. It is advisable to insert **NOVA-T** at the end of the menstrual period since at this time the patient is unlikely to be pregnant and the cervical canal is still dilated.
4. **NOVA-T** must be placed as high as possible within the uterine cavity, to help avoid downward displacement, expulsion or accidental pregnancy.
5. As a general principle, **NOVA-T** should be inserted under aseptic conditions.
6. The patient should be informed that she may have some spotting, light bleeding or cramps during the first few days after insertion. If these events continue or are severe, they should be reported to the physician.
7. If the patient or her partner can feel the device during intercourse, or if there is complaint of pain or discomfort during intercourse, the patient should not have intercourse until she can see her physician. The possibility of displacement or cervical perforation should be ruled out.
8. Should the patient become aware that **NOVA-T** has been expelled, she should contact her physician because she is no longer protected from pregnancy. Symptoms of partial or complete expulsion may include bleeding or pain.
9. The patient should contact her physician immediately if she misses a menstrual period or thinks she may be pregnant.
10. After insertion, the threads should remain outside the cervical canal, in the vagina. At weekly intervals or at least after each menstrual period, the patient should be instructed to verify with a finger whether the threads of NOVA-T can be felt in the vagina. If the patient cannot feel the threads or senses the device, she should see her physician and in the meantime use a method of barrier contraception. If the threads are not visible, pregnancy must be excluded. The threads may have been drawn up into the uterus or cervical canal or NOVA-T may have perforated the uterus or been expelled unnoticed. In exceptional cases NOVA-T may be lying outside the uterus as a result of perforation. An X-ray examination should be performed to assess the situation. The plastic component of NOVA-T contains barium sulfate and therefore gives good contrast. The position of NOVA-T can also be ascertained by ultrasound.
    Normally, **NOVA-T** can be removed by simply pulling on the threads. If **NOVA-T** is inside the uterus and pregnancy has been excluded, the device or the threads can be gripped through the cervical canal by a slender, slightly convex forcep. This may require dilatation of the cervical canal. If the position of the device is extrauterine, surgical removal is essential, using laparoscopy if possible.
11. Patients should be followed up at 1, 3, 6 and 12 months after insertion, and thereafter at approximately yearly intervals. A Papanicolaou smear should be done at least once a year.
12. Ectopic pregnancy must be considered in the presence of vague lower abdominal complaints associated with irregular cycles (especially amenorrhea after persistent bleeding).
13. Women who are taking anticoagulants should inform their physician because of the increased tendency to hemorrhage.
14. Reports have been published indicating that the contraceptive effect of intrauterine devices appears to be diminished in patients receiving chronic treatment with non-steroidal anti-inflammatory drugs (particularly acetylsalicylic acid) and with corticoids; however, experience has shown that contraceptive protection is not reduced during short-term treatment of dysmenorrhea with nonsteroidal anti-inflammatory drugs.
15. Caution should be exercised when performing diathermy (short-wave or microwave) of the sacral or abdominal region since heating of the copper can subsequently damage **NOVA-T**.
16. For copper IUDs, safety has been demonstrated in magnetic resonance imaging (MRI) systems operating with up to 3 Tesla.

ADVERSE EFFECTS

In extremely rare cases, a brief loss of consciousness or decelerated pulse rate, or a seizure in an epileptic patient may occur during insertion or removal of intrauterine devices. Perforation of the uterus or the cervix may occur. The risk of perforation is increased in women who are breastfeeding at the time of insertion and when insertion takes place up to 36 weeks after giving birth. Initially, NOVA-T can cause persistent pain in the lower abdomen or sacral area, but this usually subsides.
Menstrual bleeding is sometimes stronger and of longer duration than normal, or is more painful. Iron deficiency anemia may then occur in individual cases. Slight intermenstrual bleeding, often in the form of spotting, may occur but it usually subsides spontaneously (the physician should be informed if intermenstrual bleeding persists). Lower abdominal infections, with the risk of subsequent infertility, occur more frequently in patients using an intrauterine device than in other women.
Cases of sepsis (including group A streptococcal sepsis) have been reported in association with the insertion of intrauterine contraceptives (see **WARNINGS**).
Isolated cases of skin reactions have been described in the literature which may be attributable to copper allergy, since they disappeared when the copper device was removed.
The preclinical safety of intrauterine copper is well-established. No teratogenicity was found in animal studies. The studies did not indicate any particular risk for human use.

AVAILABILITY

NOVA-T is packaged in individual sterile package units, with an insertion tube imprinted with a centimetre scale, and a plunger. It is sterilized by irradiation. For single use only. Do not re-use, resterilize or re-process as this may compromise the structural integrity of the device or lead to device failure. Used **NOVA-T** systems should be considered biohazardous waste and disposed of accordingly.

NOVA-T INSERTION TECHNIQUE

Prior to Insertion:
Prior to the insertion of **NOVA-T** the patient should be given a thorough gynecological examination. The size and position of the uterus should be established and pregnancy or other contraindications should be ruled out (see "Contraindications"). **NOVA-T** does not interfere with lactation.

Insertion:
NOVA-T can be inserted on any day of the cycle; however, the last days of menses are recommended, since at this time the patient is unlikely to be pregnant and the cervical canal is still dilated, thus facilitating insertion. Given its small diameter, the insertion tube is easy to introduce and usually does not call for further dilation.
As a general principle, **NOVA-T** should be inserted under aseptic conditions using sterile gloves. It is recommended that **NOVA-T** should only be inserted by health care professionals who are experienced in **NOVA-T** insertions or have undergone sufficient training. The following steps should be followed when inserting **NOVA-T**:

1. Insert a speculum to visualize the external os uteri and disinfect the vagina and cervix.
2. Use a tenaculum forcep to stretch the neck of the uterus. The forceps should be left in position until **NOVA-T** has been inserted.
3. Utilize a sound to determine the position and length of the uterine lumen.
4. Prepare **NOVA-T** (Fig. 2-7)

Fig. 1 **NOVA-T**
Fig. 2 Open the plastic covering far enough to expose the lower end of the insertion tube; however, **NOVA-T** and the insertion tube are not to be withdrawn. While holding the tube firmly with one hand, expose the threads and draw the device into the insertion tube not more than five minutes prior to insertion.
Fig. 3 Steadying the yellow ring with one hand, move the insertion tube until the yellow ring's lower rim indicates the previously sounded length on the scale. Holding the threads slightly stretched with one hand, place the plunger into the tube with the free hand. This will ensure that the threads are lying straight in the tube and are not disarranged by the plunger. If necessary, the insertion tube can be bent so that it is better adapted to the position of the uterus.
Fig. 4 Remove **NOVA-T** from the plastic covering. Gently insert **NOVA-T** into the cervical canal and advance it until the yellow ring touches the cervix. The broad sides of the yellow ring must be horizontal to ensure subsequent correct unfolding of the arms.
Fig. 5 Hold the plunger firmly with one hand and draw the tube back until it reaches the ribbed part of the plunger, thereby removing the yellow ring from the cervix (distance approximately 1.5 cm). The arms of **NOVA-T** are now unfolded.
Fig. 6 Advance the insertion tube until the yellow ring touches the cervix again. **NOVA-T** is then in contact with the fundus uteri.
Fig. 7 To release **NOVA-T** entirely from the insertion tube, hold the plunger firmly and draw the tube back as far as the backstop. To avoid entangling the threads between the tube and the plunger, carefully remove the plunger first and then the insertion tube. Cut the threads about 3 cm from the cervix.

Storage Conditions:
NOVA-T should be stored at 15°C - 30°C protected from direct sunlight and moisture.

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Figure 2

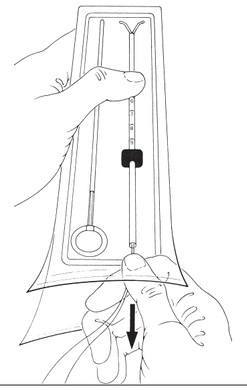

Figure 3

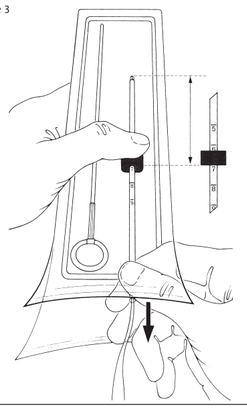

Figure 4

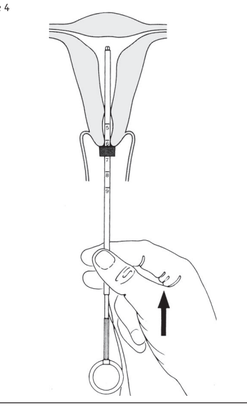

Figure 5

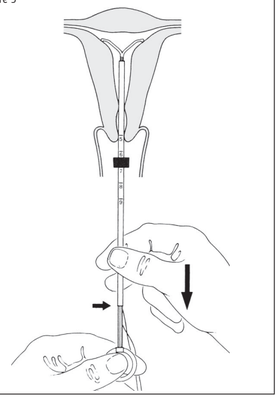

Figure 6

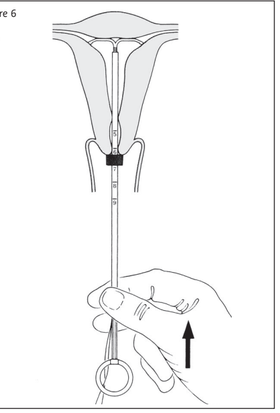

Figure 7