

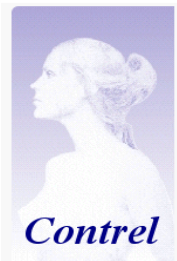
GYN-CS[®]

CAESAREAN SECTION

Developed by Dr. Dirk Wildemeersch

Patient Information

MANUFACTURER



*Controlled Release
for the Enhancement
of Quality of Life
of Women*

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CE 1639

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Whilst this information leaflet is intended to be helpful, we stress that this is not intended to and should not, replace the advice of a qualified medical professional.

www.gyn-cs.com

1. What is GYN-CS®?

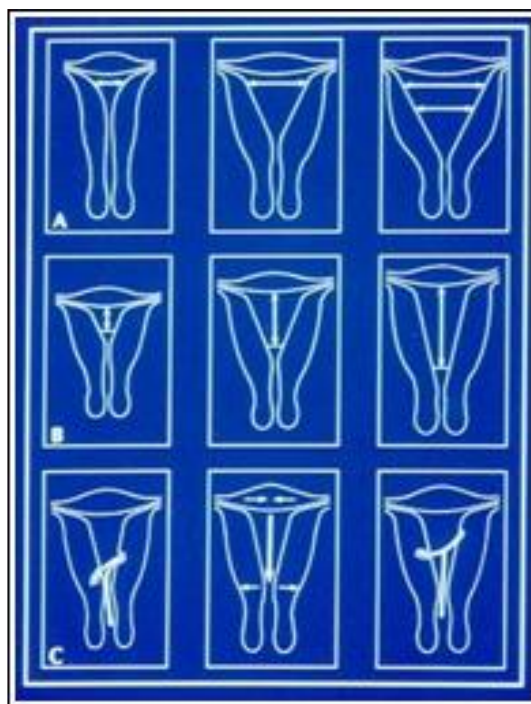
Conventional IUDs have always been one of the most reliable forms of contraception. However, because of their design issues, they were not universally favoured by women, many of whom complained of pain, discomfort, heavy bleeding, displacement, and/or expulsion.

GYN-CS® is a unique, small, flexible, “frameless”, and long-acting copper intrauterine contraceptive device which is approved for use immediately following caesarean section delivery. The insertion is quick and done under direct vision and is, therefore, very safe. GYN-CS® has been specifically designed to be virtually trouble free whilst maintaining superior levels of reliability, ease of use and spontaneity in relationships.

The dimensions and the shape of the uterine cavity is unique for each woman. Conventional IUDs are less flexible and often too large or too small relative to each woman’s uterine cavity. These can likely elicit uterine cramps, pain, and abnormal menstrual bleeding. GYN-CS® differs from conventional T-shaped IUDs by its small size and because it is frameless (which makes it completely flexible). In other words, it takes less space in the uterine cavity and its flexibility allows a perfect adaptation to all uterine cavities. These properties, include it being affixed directly to the uterine wall, makes discomfort and expulsion very rare.

GYN-CS® consists of either 4 or 6 copper tubes which that are threaded on a length of surgical suture. GYN-CS® is anchored in the fundus of the uterus. A tiny knot at the upper end of the thread keeps the device in place, preventing expulsion.

To assure retention in the immediate post-partum period prior to full uterine involution, the knot is secured in place with an external suture consisting of a rapid degrading resorbable material (Vicryl 3-0 or similar).



2. GYN-CS® duration of action

GYN-CS® 3: **3 years**

GYN-CS® 10: **10 years**

3. Why was GYN-CS® developed?

The World Health Organization recommends contraception for at least 18 months after caesarean section, because of the risk of complications (such as partial or total rupture of the uterus during the next pregnancy, which is a life-threatening situation).

4. How does GYN-CS® prevent pregnancy?

Copper leads to decreased sperm and egg viability. In the unlikely event that fertilization does occur, the same inflammatory actions are directed against the blastocyst, and the endometrium is transformed into a hostile site for implantation. With copper IUD, copper levels increase in the mucus of users and lower sperm motility and viability (Williams Obstetrics, 2010).

5. Advantages of GYN-CS®

- Easy to insert
- Easy to remove (starting from 4 weeks post-insertion)
- High efficacy
- Immediately active
- Immediate return to fertility after removal
- Limited impact on menstrual bleeding
- Long effectiveness (3 or 10 years)
- No impact on breastfeeding
- No impact on libido
- No weight gains
- Non-hormonal and, therefore, no disturbance of the hormonal cycle
- Small, flexible, and therefore very comfortable
- Well tolerated and almost no side effects

6. How effective is GYN-CS®?

The effectiveness of GYN-CS® 10 is superior to conventional copper IUDs, has a similar effectiveness as tubal sterilization and is more effective than the pill (0.1 to 0.2 % pregnancies with GYN-CS® 10 against 5% or more with typical use of the pill after one year).

GYN-CS® 3 (4 copper tubes) is slightly less effective (0.1 to 0.5% pregnancies).

7. What if I become pregnant while using GYN-CS®?

Although pregnancy has been rarely observed, you should **consult a doctor immediately** at the first signs of pregnancy (late period, abnormal spotting or bleeding, stomach pain, painful sex, offensive discharge, and/or fever).

8. Contraindications

- AIDS or any other sexually transmitted infection(s).
- Anaemia (low red blood cell count).
- Condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumours.
- Copper and/or polypropylene allergy (very rare).
- Multiple sexual partners or suspect that your partner has multiple sexual partners.
- Pelvic infection called pelvic inflammatory disease (PID).
- Problems with your immune system and susceptibility to infections.
- Suspect you might have cancer of the uterus or cervix.
- Use or abuse of intravenous drugs.
- Wilson's disease.

9. Side effects

Slight bleeding can occur after GYN-CS® insertion but as bleeding (named “lochia”) are normal after a delivery, patients will not notice any increased bleeding due to GYN-CS® insertion.

This is not a complete list. If you have questions, please ask your healthcare provider.

10. Will GYN-CS® interfere with sexual intercourse?

You and your partner should not feel GYN-CS® during intercourse. In case needed, ask the doctor to shorten the thread.

11. Magnetic Resonance Image (MRI) with GYN-CS®?

MRI conditional.

12. Additional information

- **GYN-CS® shall only be inserted by a GYN-CS® insertion trained doctor.**
- You should know when your device needs to be replaced. Therefore, ask your doctor for your **GYN-CS® Pass.**

Follow-up appointments		
Day	Date	Time

Name

To preserve carefully

Gyn-CS® Pass

Intrauterine Contraceptive Device

VER.0201 08/2017

When reporting an event, a copy, scan, or picture of your GYN-CS® Pass is required to process your complaint adequately

- If you get pregnant, your doctor should advise you to remove the device or not.
- **GYN-CS® offers no protection against sexual transmitted diseases** (HIV, hepatitis B, others).
- If you do not have a long-term single partner sexual relationship, you should use additional protection, such as condoms.
- Cardiac conditions: consult your cardiologist.
- In case using immunosuppressant drugs or antibiotics, another barrier such as condoms must be used.
- A follow-up examination is required 4 to 8 weeks following insertion and thereafter yearly.
- Do not have sexual intercourse in the first 14 days following insertion.
- Please do not use tampons or menstrual cups in the first 2 months following insertion.
- Check your pads for possible loss of the GYN-CS® (rare event).
- Removal of GYN-CS® is not possible in the first 4 weeks after insertion.

In case using tampons or menstrual cups, please, change in time according to the manufacturer's instructions

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Nothing in this leaflet should be construed as giving advice or making a recommendation, and it should not be relied on as the basis for any decision or action. It is important that you rely only on the advice of a healthcare professional to advise you on your specific situation and/or possible risks.

CE marking

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Sterilized using ethylene oxide



Do not reuse



Do not resterilize



Manufacturer



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Consult electronic instructions for use

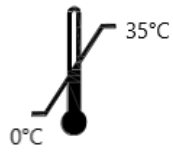


eIFU indicator: www.gyn-cs.com, www.wildemeersch.com

Do not use if package is damaged



Store at room temperature (0-35°C)



Lot number



Caution

Do not insert unless properly trained!



Expiry date



MR conditional

