

# Intrauterine Contraception



# State of the ART

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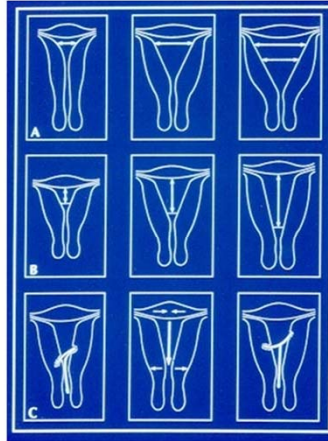
Control Research, Ghent, Belgium

A RESEARCH ORGANIZATION SPECIALIZED IN ADVANCED INTRAUTERINE DRUG  
DELIVERY SYSTEMS FOR CONTRACEPTION AND OTHER HEALTH NEEDS IN WOMEN

This slide series demonstrates the importance of harmony between the intrauterine foreign body and the cavity of the uterus



## Background



The main complaints of IUD are: abnormal, increased and erratic bleeding, cramping pain and expulsion. These are mainly due to dimensional incompatibility between the IUD and the endometrial cavity

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Uterine cavities differ considerably in size and shape in all women. It is therefore unreasonable to expect that one standard sized intrauterine device (IUD) will fit in uterine cavities of every different sizes and volume. IUDs that are much bigger than the uterine cavity can cause problems. If the width of the uterine cavity is too small, side effects and complications are likely to occur. The crossarms of standard T-shaped IUDs are frequently too long for a large number of uterine cavities, as the average width of most uterine cavities is often smaller than the width of the IUD itself.

## Comparison with the human foot

- “Individual variations in size and shape of the human uterus are probably greater than variations in size and shape of the human foot”\*



\*Hasson HM. *Clinical studies of the Wing Sound II metrology device*. In: Zatzuchni GI, Goldsmith A, Sciarra JJ, eds. *Intrauterine contraception: advances and future prospects*. Philadelphia: Harper & Row, 1984: 126-141.

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When we make the comparison with our feet, then it is obvious that we choose the right size so that we are comfortable. Based on measurement studies of the “living” uterine cavity, Prof. Hasson of Chicago concluded that “The individual variations in size and shape of the human uterus are probably greater than variations in size and shape of the human foot”. Because the cavity of the uterus is difficult to measure, providers insert a standard size IUD in the uterus. If the woman is lucky, and the device fits, absence of pain complaints and other side effects are the rule. However, we know that in many women, this is not the case. Side effects lead to removal of the IUD, often forever. Medical science should offer better intrauterine methods to women that cause less side effects and are better tolerated so that they continue the method. High continuation of a birth control method is the best way to reduce the number of unintended pregnancies and induced abortions.



## Frameless copper IUDs : GyneFix®



GyneFix 330

GyneFix 200

FibroPlant-LNG

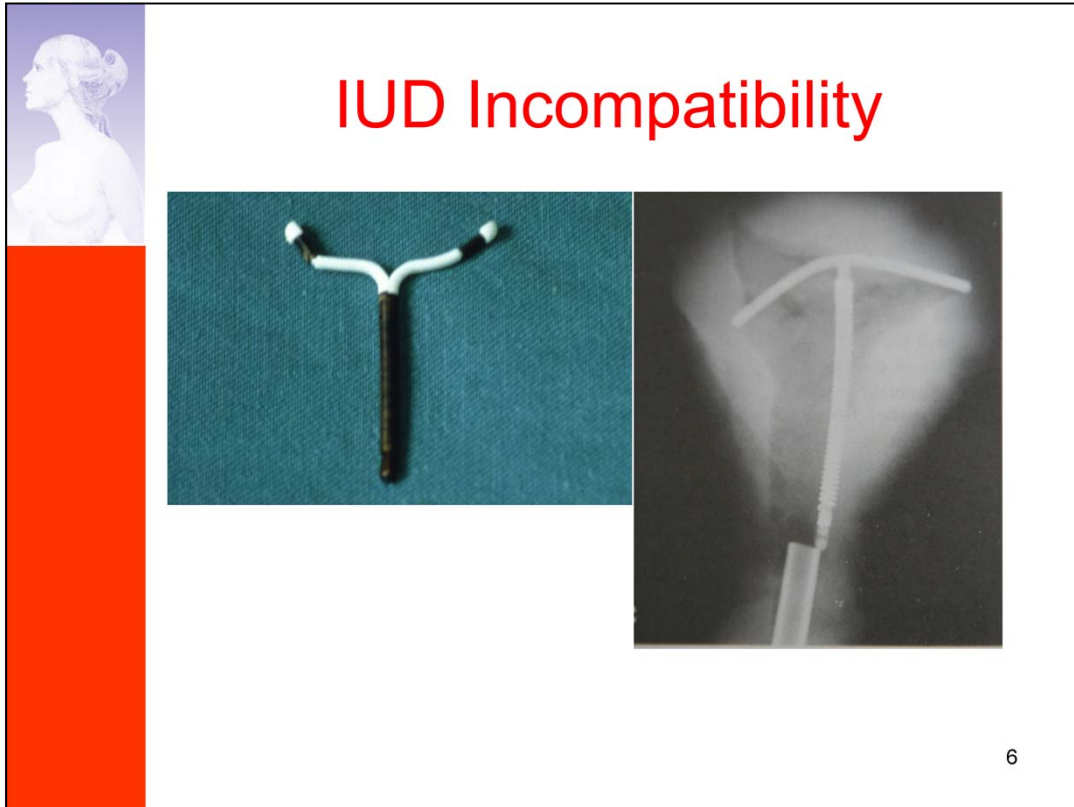
FibroPlant® is not yet on the market

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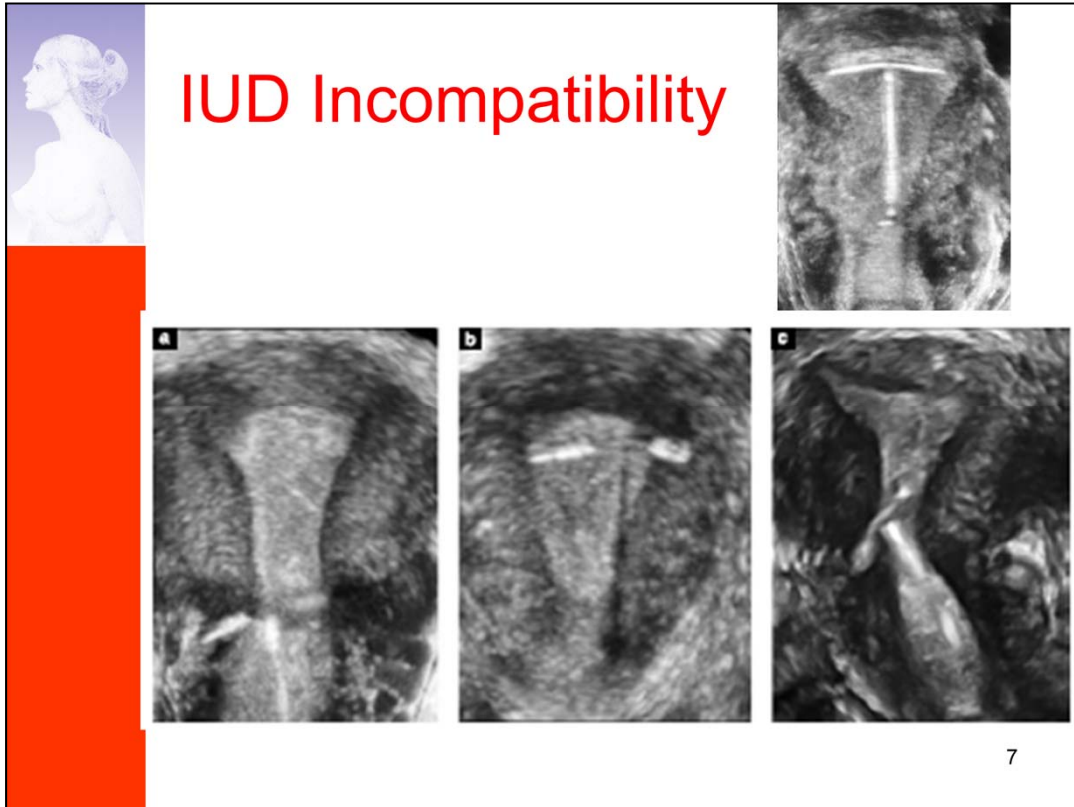
**GyneFix®** is smaller than any other IUD and consists only of a number of copper tubes attached to a string. It is flexible and uni-dimensional and, therefore, it fits in uterine cavities of every size and shape. The size of an IUD is closely related to the side effects it causes such as abnormal bleeding and cramping pain, so that it is better tolerated with less effect on the amount of blood loss. This is an advantage over conventional IUDs that can induce heavy periods. Heavy menstrual bleeding is the most common cause for the removal of an IUD.

**FibroPlant®** is provided with a hormone-releasing fiber instead of copper. The co-axial fiber releases a small amount of hormone which prevents fertilization and strongly reduces menstrual bleeding. FibroPlant is not yet marketed.

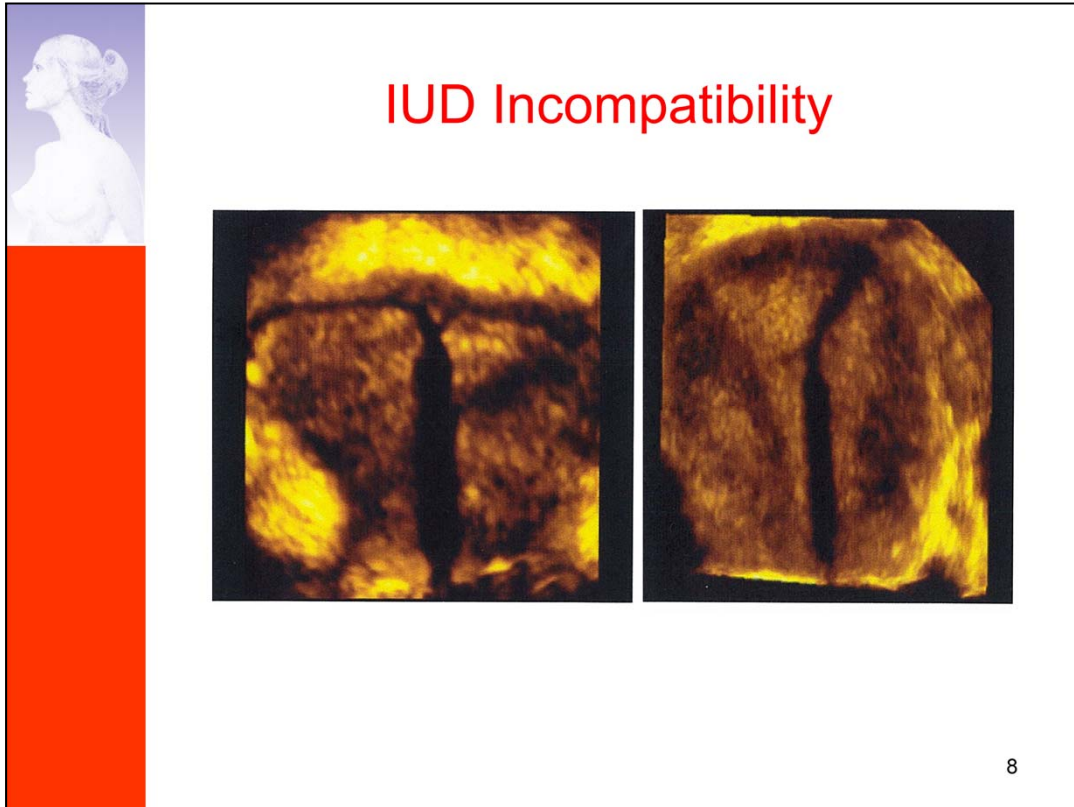
Both GyneFix and FibroPlant are attached to the uterine wall by pushing a surgical knot gently into the myometrium with a specially designed inserter.



Examples of disharmony are shown here: on the left you can see that the crossarms of the IUD have been severely compressed by the small uterus leading to cramping pain and removal. On the right hand side is an X-ray showing the small uterine cavity and the too long crossarms that penetrate the muscular wall on one side and the fallopian tube on the other side (courtesy of Dr. A de Castro and Dr. K-H Kurz).



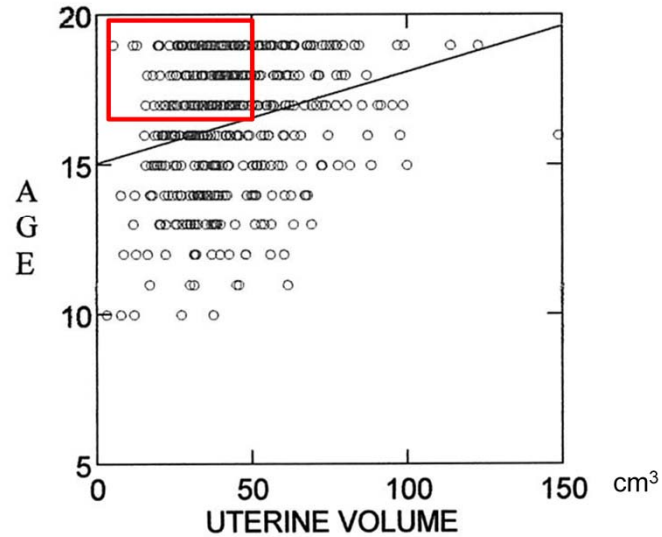
Disharmony between the IUD and the uterus can be best evaluated by 3-D ultrasound. On top is an IUD that fits well in the uterine cavity. The three pictures below, on the other hand, show severe disharmony because the IUD is too big for the small, and, above all, narrow uterine cavity (courtesy of Dr. B. Benacerraf)



Similar pictures illustrating the importance of harmony with the uterine cavity are shown here: On the left side, the hormone-releasing IUS, Mirena is properly positioned in the uterus, with extended arms, as the transverse diameter of the cavity is sufficient. On the right side, however, the uterine cavity is too small; one arm is penetrating the uterine muscle (the other arm is not visualized on the picture) (courtesy of Dr. D. Van Schoubroeck).

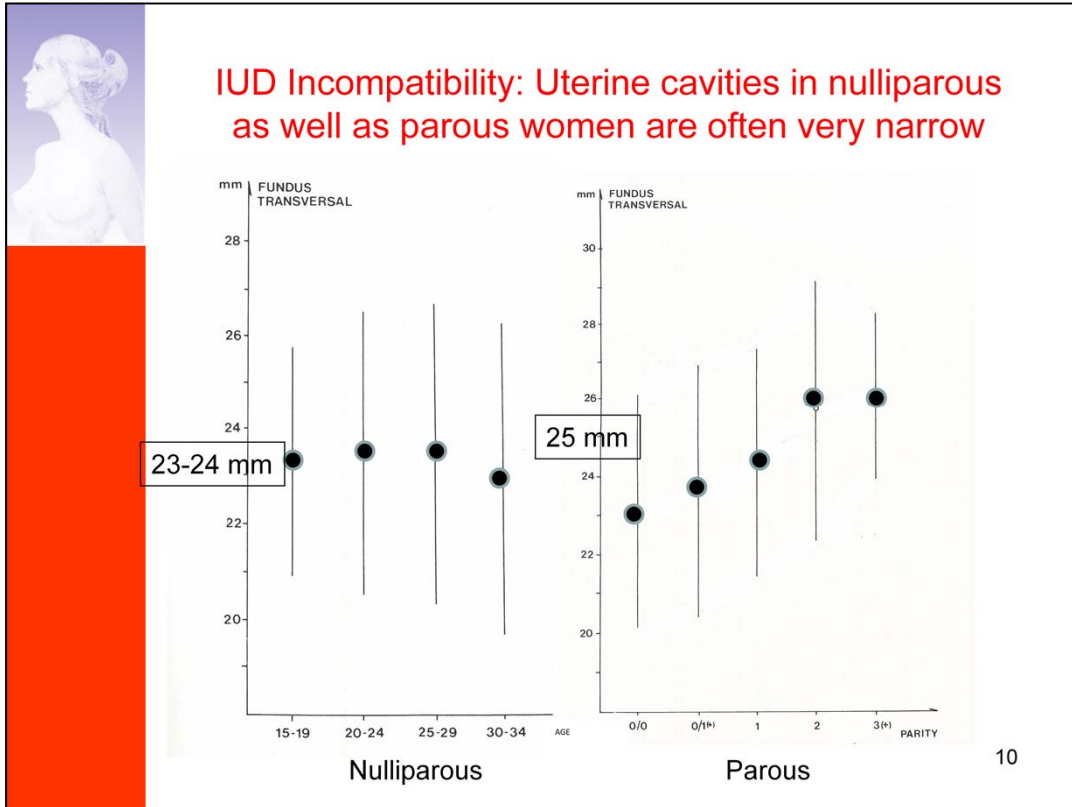


## IUD Incompatibility: many women at this age have very small cavities



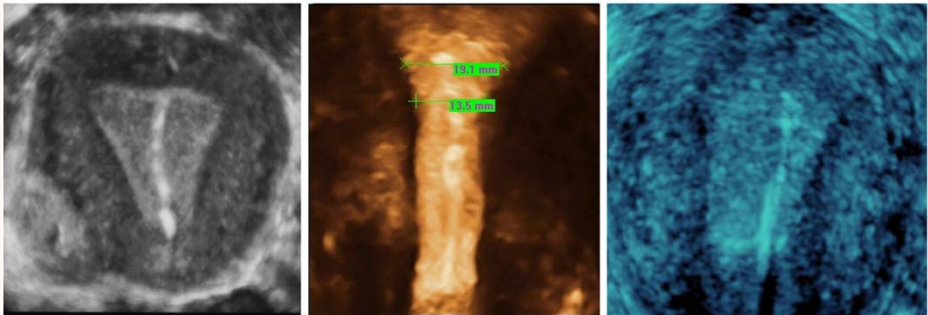
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Many young women have a very small uterus. As many women at this age need contraception, they should use an IUD that fits their uterine cavity if they want to select this form of contraception to avoid pain, abnormal bleeding and expulsion which can lead to an unintended pregnancy.



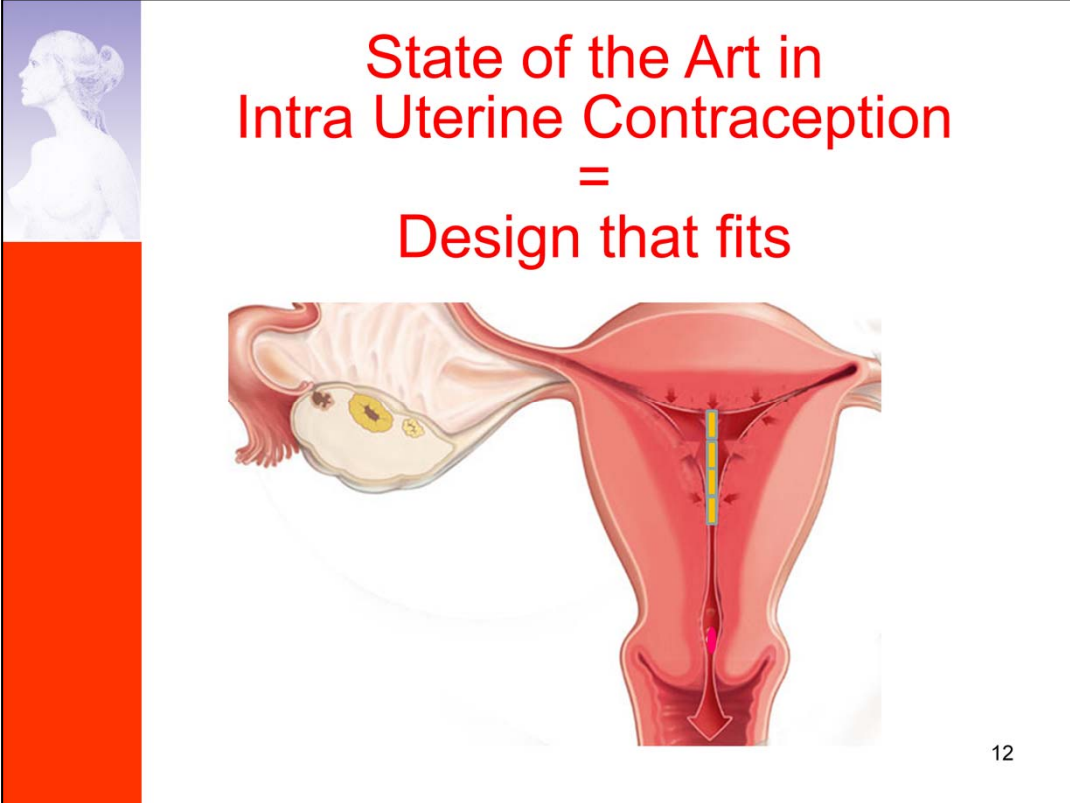
Researchers in Germany and in the US have measured the width of the uterine cavity in the top of the uterus and found that in women who have not given birth (left) as well as in those who have given birth (right) the average width is around 2.5 cm which is significantly less than the length of the crossarms of traditional T-shaped IUDs. These studies show that uterine cavities are often very small.

State of the Art = obtaining perfect harmony due to the frameless design



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The frameless (plastic body free) GyneFix IUD fits in cavities of every size and shape as is shown here: Left: GyneFix in a normal uterus; middle: GyneFix in a very narrow uterus less than 2 cm in width; and right: the FibroPlant hormone-releasing intrauterine system in a small uterus.



State of the Art in  
Intra Uterine Contraception  
=  
Design that fits


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#### “DESIGN THAT FITS”



When considering the insertion of an intrauterine device (IUD), doctors should realize that the uterine cavity may be small or very small and will become even smaller during menstruation.

An IUD that is uni-dimensional and flexible will fit in cavities of every size and shape and this will help to avoid side effects. Moreover, a design that fits will contribute to continuation of use and help prevent an unintended pregnancy.

Patients will greatly appreciate if the doctor attaches importance to this.




## Advantages of the frameless copper IUDs vs. framed IUDs

	GyneFix 	ParaGard 
Efficacy	High	High
Expulsion	Low, if properly inserted	> Low (high in nullips)
Bleeding	No change (GF200)	Increased
Pain during use	Virtually absent	Increased (especially in nullips)
Use in young nulliparous and adolescent women	Ideal because of perfect harmony	IUD too big in many women
Continuation rate	>90% at 5 years	Continuation rate around 50% at 5 years

GyneFix is highly effective. Even the tiny GyneFix, which can be used by all women with a normal uterus, has a very low failure rate. Of course the proper performance of the frameless IUD depends on its proper anchoring in the uterine cavity. If insertion is done by a trained doctors, expulsion of the IUD is rare.

Bleeding/spotting might be more frequent in the beginning after insertion but, the small IUD, in general, does not significantly increase menstrual blood loss. This has been shown in menstrual blood loss studies. Because it is so small, pain complaints are rare; it is usually very well tolerated. This makes it a highly useful contraceptive method for young and even adolescent women. These characteristics result in a high continuation of use. When a woman is happy with her method, she continues to use it, unless she wants to become pregnant. High continuation of use also translates in less unintended pregnancies. Pregnancies should be wanted and unintended pregnancies should be avoided, right?



### Effectiveness of modern contraceptives (US figures 2010)

METHOD	% pregnancies after 1 year		% continuation after 1 year
	Typical	Perfect	
Nuvaring	9	0.3	67
Evra patch	9	0.3	67
PILL	9	0,3	67
IUD	0.2-0.8	0.2-0.6	78-95
Injection	6	0.2	56
Implanon	0.05	0.05	84

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This slide shows that women should use effective methods that can be forgotten once initiated, and be usable 'first-line' by adolescents. Long-acting IUDs and hormone-releasing intrauterine systems are methods which point the way forward. A major advantage of long-acting hormonal methods is that they eliminate the need for specific action at the time of coitus such as putting on a condom, or for daily action, such as the pill. They offer discretion and privacy. Intrauterine devices and intrauterine systems are particularly attractive as they have the advantage of acting locally, avoiding systemic effects. New developments in intrauterine technology are providing smaller frameless devices. They may be ideal for use in younger women because they are small, effective and well tolerated. Unlike the pill, they are genuinely 'fit-and-forget'. In use, they are much more effective than pills in this age group. Moreover they are long acting and reversible. So, the reward is substantial.



## Comments From GyneFix® Users

### Why did you choose GyneFix®?

- "My sister had it already and was happy. So, I also decided to have GyneFix".
- "It is different from the standard IUDs and apparently very safe and efficient".
- "A friend of mine had GyneFix and told me that it might also be a good method for me".
- "I forget to take the pill and am afraid of becoming pregnant".
- "I have tried the pill several times and find taking it cumbersome. GyneFix is easy".
- "An IUD is easy, safe, cheap, healthy. I don't have to remember to take the pill every daY".
- "My mother recommended me the frameless IUD because it can be used by young girls like me".
- "It was recommended by a friend. I had the pill before but I wasn't happy. The pill ruined my sex life".
- "When I was 17, an IUD was fiited into my womb but I had, cramping pain and heavy bleeding".

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### Why did you choose GyneFix?

It appears from studies that the single most important property of a contraceptive is its **effectiveness**. **Long duration of action** is also highly valued by women. For women who don't want to be pregnant again, the longer the method works, the better and most women would select a method that is reversible if they could choose. A "**secret**" **method** is important for many young women, especially adolescents. Women largely dislike methods that cause disturbance of the menstrual pattern. Most women want to have normal menstruations. An increasing number of women are concerned about their **health** when choosing a birth control method.



## Comments From GyneFix® Users

### How did you experience the fitting of your GyneFix®?

- "It is easy, convenient, you just insert it and that's it".
- "The fitting of GyneFix was slightly painful for a few seconds. Afterwards I felt some discomfort but I didn't have to take painkillers".
- "I did not feel the fitting because it was done under local anaesthetic. I wish I had had the device earlier, I could have avoided the abortion".
- "Insertion was very easy and quick. I thought it was much more complicated and would take longer".
- "The fitting was painful but I was very nervous and it lasted only a few seconds".
- "I don't remember the insertion very well. The doctor gave me some local anaesthetic".
- "The fitting hurts a little but it was quickly over. I still felt some discomfort the next day and the day after, just like period pain. But the next day it was over. I had some spotting for about 1 week".

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### How did you experience the fitting of your GyneFix?

Doctors should attach importance to comfort during the insertion of an IUD. There are several ways how to accomplish this:

- Some medication can relax or open the cervix of the uterus so that insertion is easier for the doctor and more comfortable for the patient.
- Intracervical anaesthesia with a dental syringe with very thin needle can also be done.
- Painkillers can often be helpful too.
- If you can't relax by yourself some sedation can be helpful.



## Comments From GyneFix® Users

### How do you like GyneFix®?

- "It is easy and you don't have to think about anything."
- "I have always been well off with GyneFix. My periods were heavier in the beginning after insertion, but they are normal now".
- "I don't want another method. It does not cause mood changes. GyneFix is an easy and safe method. When you are young: you can't afford to forget a pill and to fall pregnant".
- "My periods are somewhat longer than usual but I am not worried and I don't complain about it. I trust the method. It's easy, healthy and safe".
- "My periods are as usual. I have had it now for more than 3 years".
- "When you think about it and compare it with the pill, GyneFix is a healthy method. Taking hormones constantly is not ideal".
- "I have no side effects and no discomfort for the last two years. I have no pain with intercourse and bleeding is less than with my previous IUD. My periods are exactly the same as when I had no IUD".

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### How do you like GyneFix?

Clinical studies have shown that the tiny GyneFix IUD is highly effective and well tolerated, due to its special design characteristics, resulting in a high continuation of use. GyneFix is designed to fit in all uterine cavities, small, very small or larger. The small total surface area of the GyneFix 200 IUD also minimizes the impact on the amount of menstrual bleeding and is an improvement over larger types of conventional IUDs, as indicated by the low removal rate for abnormal bleeding with the small GyneFix.