Recommendations for training by Dr. Dirk Wildemeersch, MD, PhD

How to insert (and remove) the frameless GyneFix® IUD properly and how to check the position of the visual marker after insertion

Dirk Wildemeersch, MD, PhD, Tel. : +32 50 600 900. Fax: +32 9 234 29 26.
Email: dirk.wildemeersch@contrel.be – www.wildemeersch.com

Dear Colleague,

A tiny stainless steel element, is added on the anchoring thread immediately below the anchoring knot (Figure 1). The medical grade stainless steel element (AISI 316L/1.4404) is biocompatible.

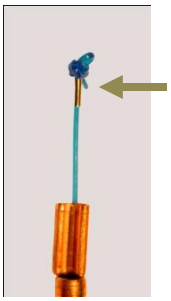


Figure 1 - Anchor with visualization element (magnification x 1.5): Tiny metal piece (2 mm long and 0.5 mm in diameter).

We conducted and studied over 300 insertions, mostly nulliparous women and found that the SA-distances from the serosa of the uterus to the metal element at insertion and at follow-up was 5.0 mm at insertion (range 2.0–8.0 mm) and the mean SA-distance at follow-up was 5.0 mm (range 2.0–9.0 mm). The visualized anchor was highly visible on ultrasound in all cases as shown in Figures 2, 3 and 4.

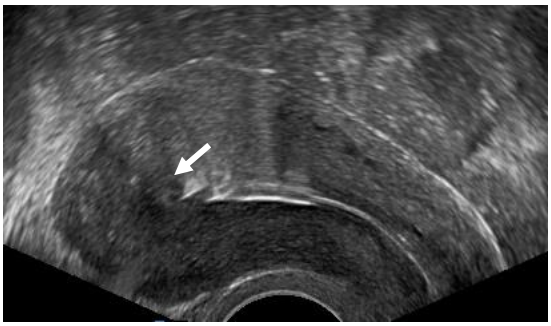


Figure 2 - 2-D ultrasound of non-visualized anchor.

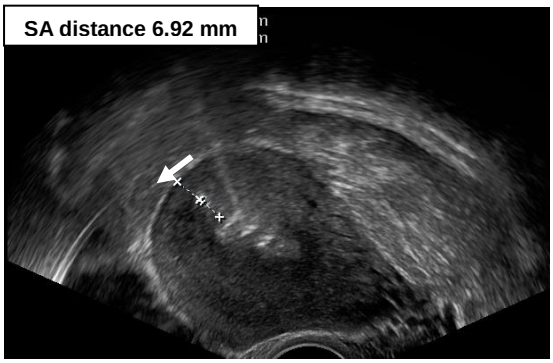


Figure 3 - 2-D ultrasound of visualized anchor located at 6.92 mm (SA-distance) from the serosa of the uterus.

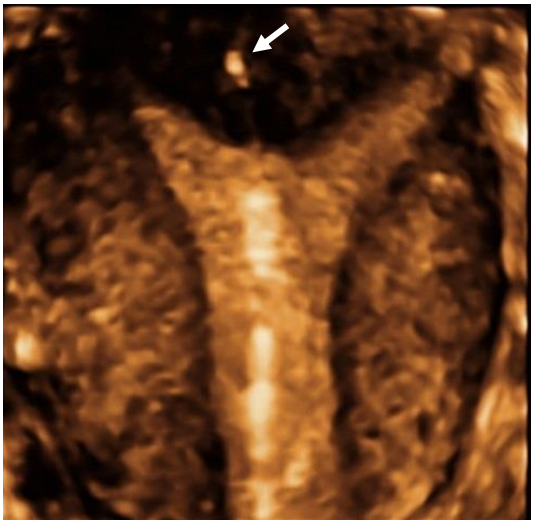


Figure 4 - 3-D ultrasound of visualized anchor.

IMPORTANT MESSAGE AND RECOMMENDATIONS

Visualization of the anchor is considered an important safeguard allowing assessment of the proper position of the anchor in the muscle of the uterine fundus following insertion and at follow-up. It is expected that the possibility to visualize the anchor of the frameless IUD will keep the number of failed insertions and early expulsions low, provide the provider confidence during insertion and follow-up, and last but not least reduce the incidence of perforation or malposition.

However, as the frameless technology is new for many providers, it is also important to become familiar with the insertion procedure which may be acquired only after a number of insertions have been completed, depending on the skill of the provider. Experience has shown that insertion failures and expulsions, in parous as well as nulliparous women, can be minimized to very low rates if providers become familiar by practicing after training by a certified trainer in an appropriate "home" uterine model (see below) before starting insertions in their patients.

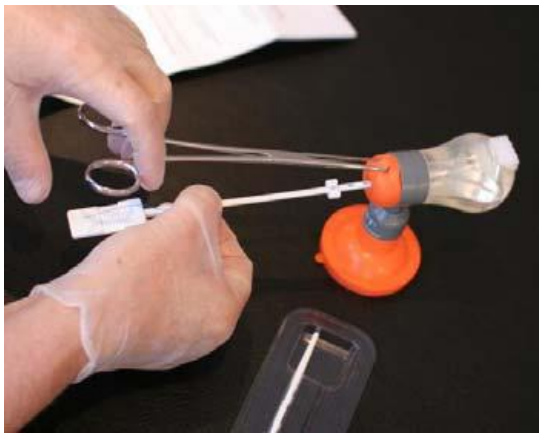


Figure 5 - Home Uterine Model

Best regards and good luck,

Dirk Wildemeersch, MD, PhD (OB/GYN)

HOW TO AVOID FAILED INSERTION-EXPULSION-PERFORATION

Failed insertion/expulsion is usually the consequence of improper insertion of the anchor in the myometrium of the uterine fundus. It could also be the result of tangential insertion in the anterior or the posterior wall of the uterus. In addition, failure to anchor the IUD in the fundus could also be the consequence of a congenital uterus anomaly (polyp, fibroid, septum etc.)

Supervised training in a model (HUT), the home uterine trainer, is important to become familiar with the anchoring technique of insertion of the frameless GyneFix after training by a certified trainer.

If you position your hand on the short tenaculum (18 or 19 cm) as shown on figure 5, and move the handle gently and controlled forward with your thumb of your left hand + your right hand, you will have perfect insertion control while you are aligning the uterus. This will help minimizing failed insertion as you go straight to the middle of the fundus which is the thickest part. Feeling the anchor penetrating the fundal tissue will provide you additional confidence.

Recommendations

1. Measure the **thickness of the fundus** before insertion.
2. **Follow the insertion instructions** as demonstrated below.
3. **Use a short speculum** to allow easy reach of the fundus.
4. After insertion, conduct a **sonographic examination** to determine the position of the anchor related to the serosa (figure 9).
5. A **3-D examination** can provide good information about the size and shape of the uterine cavity.

Remember

1. Uterine cavities differ greatly in size and shape (figure 6)
2. The shape of the uterus differs from woman to woman.
3. Congenital or acquired abnormalities of the uterine cavity can be present (figure 8)

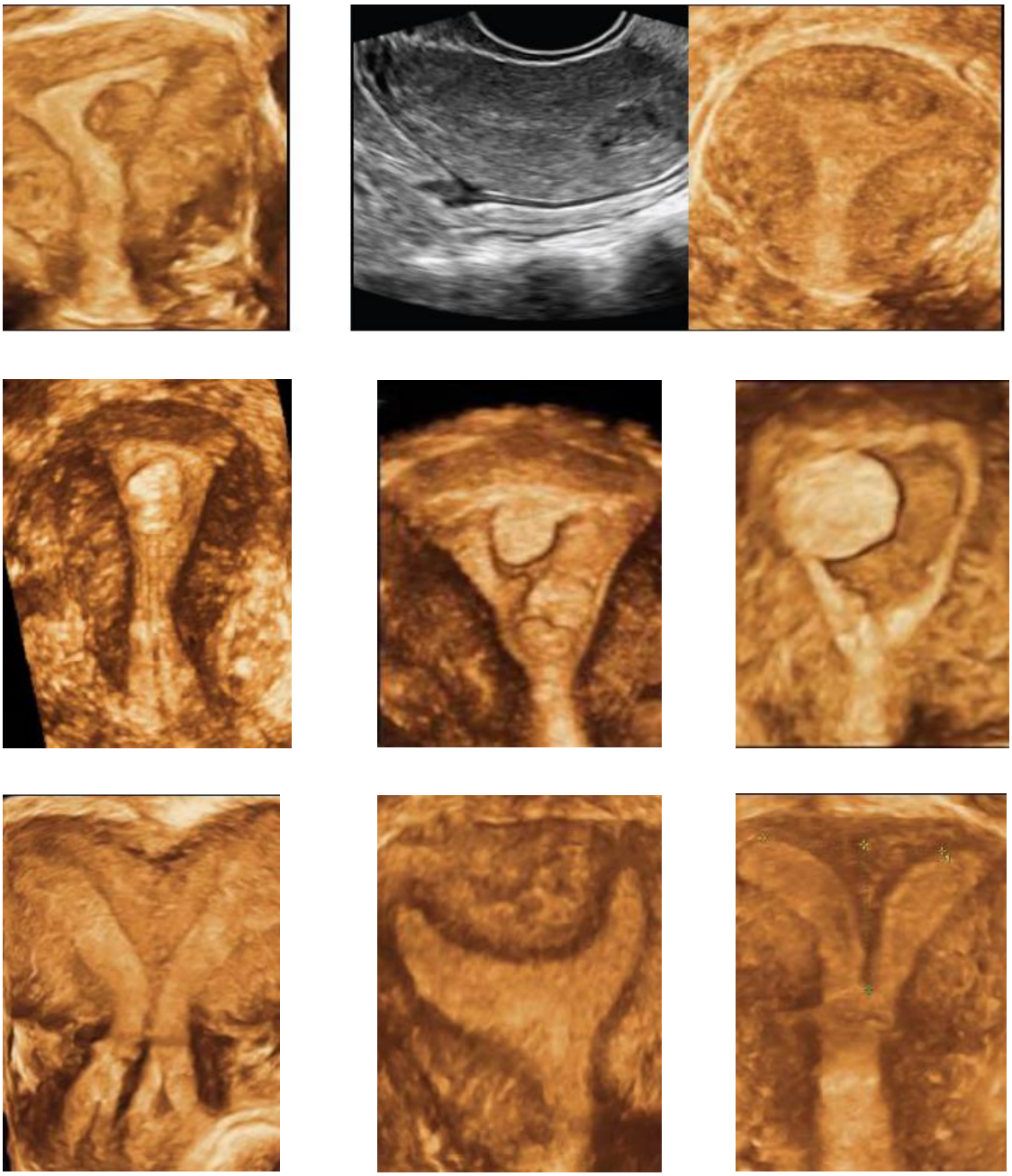


Figure 8 - These anomalies can also be present

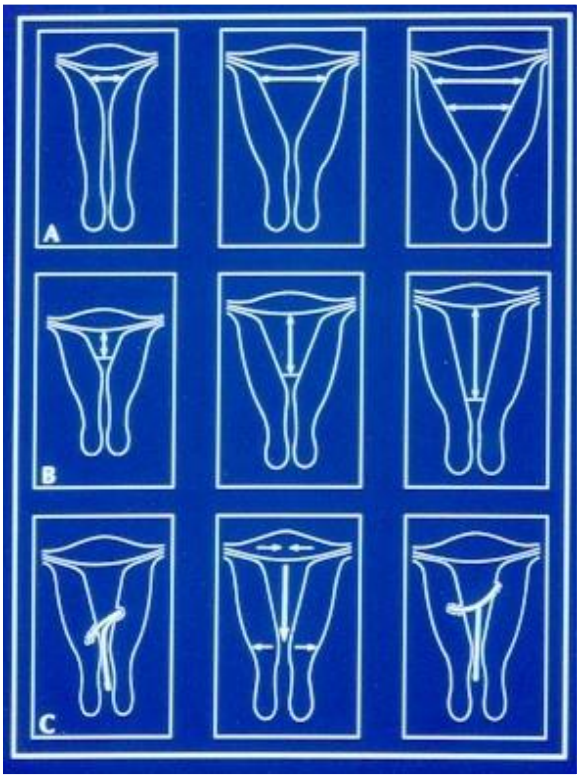


Figure 6 - Not all uteruses are alike

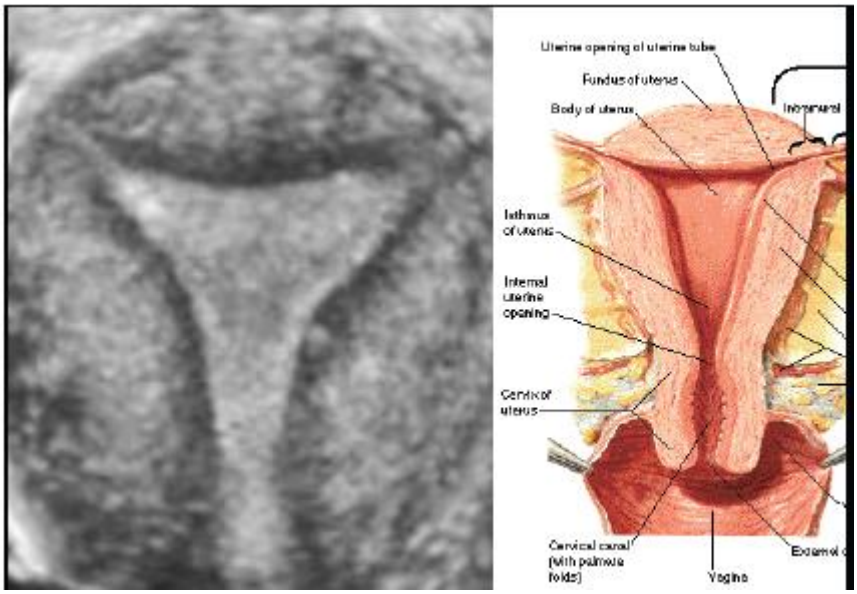


Figure 7 - Normal cavity

Before viewing the insertion procedure, read this, it will help you to perform a proper insertion:

"If you position your hand (see picture STEP 8 recommended insertion procedure below) on the short tenaculum (18 or 19 cm), and you move the inner part of the inserter forward with your thumb of your left hand + your right hand, you have perfect insertion control while you are aligning the uterus. This will help reduce the perforation rate as you go straight to the middle of the fundus which is the thickest part. The current perforation rate is 1-2/1000 and can be reduced by visualizing the anchor and measuring its distance from the serosa.."

Below are a number of sonograms of insertions with SA distance. VIZ is always visible on ultrasound but sometimes you have to search for it**. In the rare occasion that the visualized anchor is not visible in the fundal muscle, and has perforated the uterus, remove the IUD immediately!!**

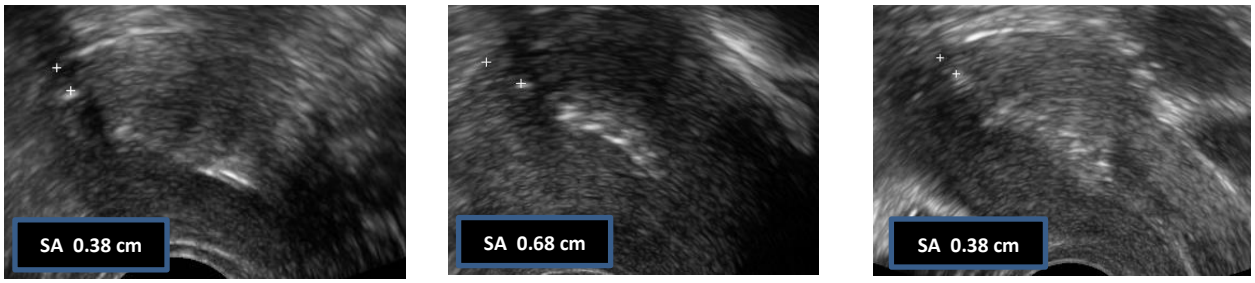


Figure 9 - Examples of SA-distances

GyneFix® Insertion Instructions

Please take into account the following recommendation before inserting GyneFix®:

GyneFix ® is a frameless, flexible IUD, which is fixed at the fundus of the uterus. The following are pertinent recommendations:

- The thickness of the fundus should be at least 10 mm. Usually the fundus is thicker. The use of a forceps with 18 or 19 cm in length, Allis or Pozzi forceps, is recommended as this facilitates insertion.

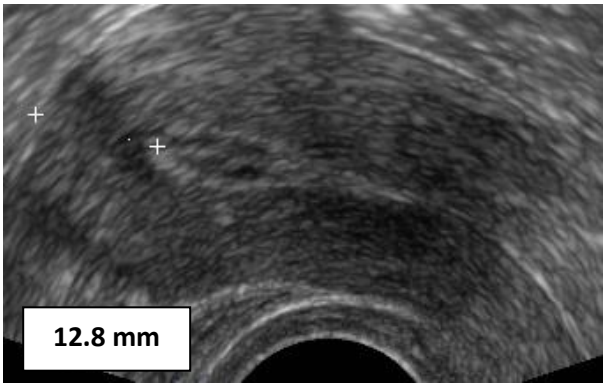


Figure 10

- **Use a short speculum** to have close access to the cervix of the uterus.
- **Use a scalpel** to trim the thread as you fingers may be slippery..
- **Attention to comfort** during insertion is very important. If necessary, perform cervical priming by, for example, Cytotec ®: 2 tablets of 200mg orally, 3 hours before the insertion. In addition, you can also use intra-cervical anesthesia, preferably with a dental syringe.
- **Following delivery**, especially in breast-feeding mothers, the insertion should be postponed until three months after birth.
- **Women using the 3-monthly injectable** should not use GyneFix® because of atrophy of the uterus. These women can only use GyneFix® when the uterus has regained a normal size.
- **Exert traction on the cervix throughout the insertion procedure** to align the utero-cervical axis (figure 5).
- **After the insertion,** the patient should not have intercourse and not use tampons nor Mooncup within 7 days.

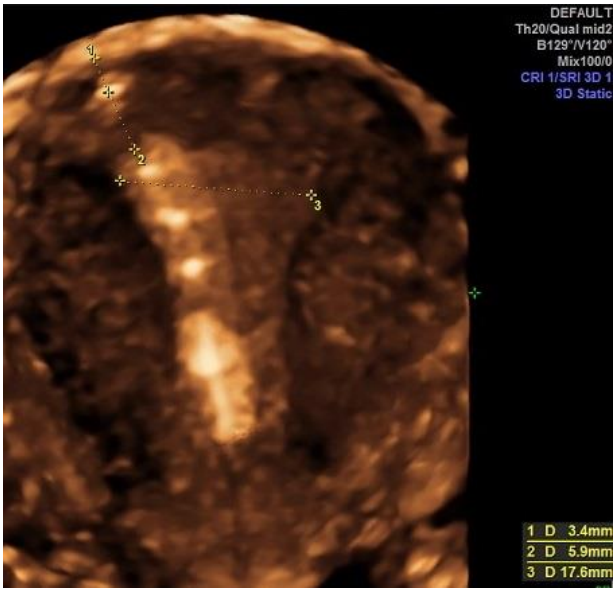


Figure 11

Traction throughout the procedure will avoid oblique insertion which could be a reason for perforation as the fundus can be thinner at the level of utero-tubal junction (see arrow below).

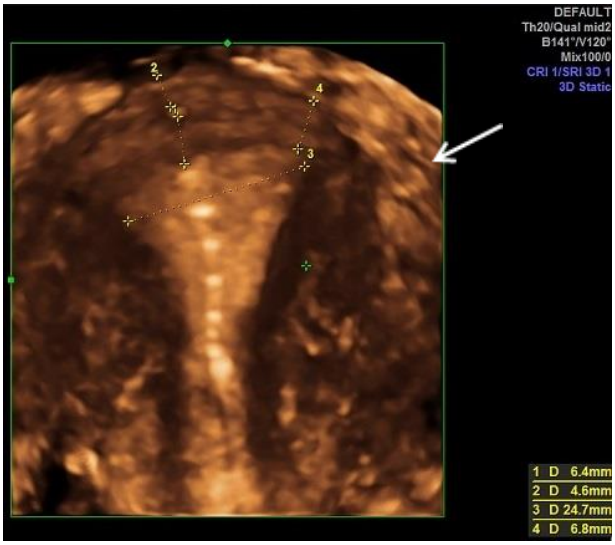


Figure 12

Recommended procedure and HUT® Training:

If properly inserted, GyneFix® has several important advantages when compared to traditional IUDs. It is therefore essential that doctors become familiar with this insertion technique. This leaflet explains how proficiency can be acquired in a minimum of time.

Remark:

- Never insert GyneFix® without proper training.
- After you have participated in a training course, use the HUT® (the "Home Uterine Trainer") to practice at home before you start inserting GyneFix® in your patients. The instructions below concern the insertion procedure in HUT® which is identical with the actual insertion in your patients.

Note: The most important instructions during the insertion procedure are in BOLD.

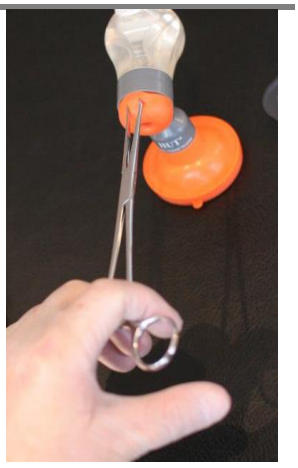
It is very important to measure the fundal thickness by ultrasound before insertion. The thickness should be at least 10mm.

Step 1:

Place Allis or Pozzi forceps (18 or 19cm) on the cervix (horizontally or vertically as you prefer).

Step 2:

Put your hand on the forceps between the first and second finger as shown on the figure. **Make sure your thumb is free.**



Step 3:

Sound the uterus now with the sound: it is very important to know depth and direction of the uterine cavity. Successful sounding of the uterus also provides confidence: if you can make contact with the fundus with the sound, you will also be able to make contact with the GyneFix® applicator.

Step 4:

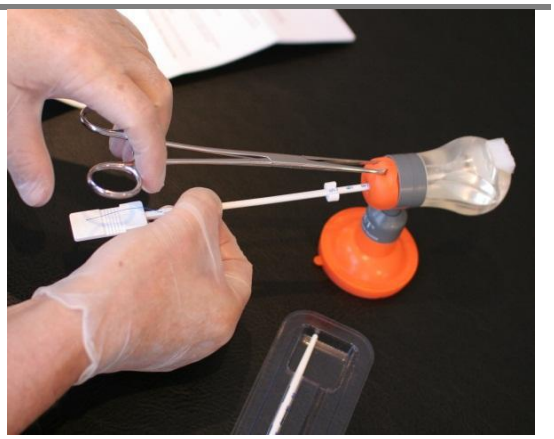
Grasp the applicator as shown on the figure.

Take the applicator with the other hand than the one you are holding the Allis Forceps. Take the applicator between your thumb and index finger out of the package. You can hold the applicator correctly, make sure the needle is at the same level of the insertion.

Maintain this grip until you have reached the fundus (See step 7)

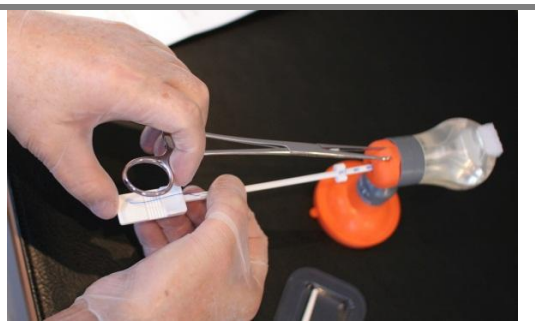
Step 5:

Insert the applicator in the uterus **until it touches the fundal wall** of the uterus. The depth should be identical as the sound length. Do not change the adjustment ring on the application tube; it only serves to fix the applicator in the package, and remains at 10 cm.



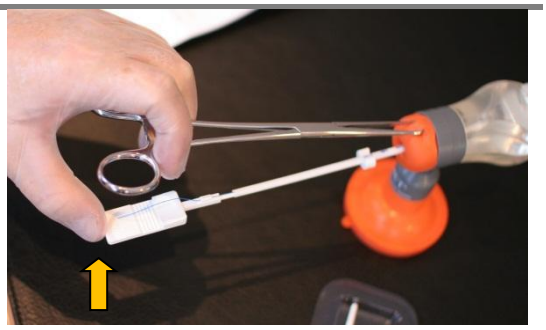
Step 6:

Immediately following contact with the fundus, **put your thumb of the hand holding the forceps at the end of the handle** (see figure) and keep contact with the fundus before anchoring until step 9.



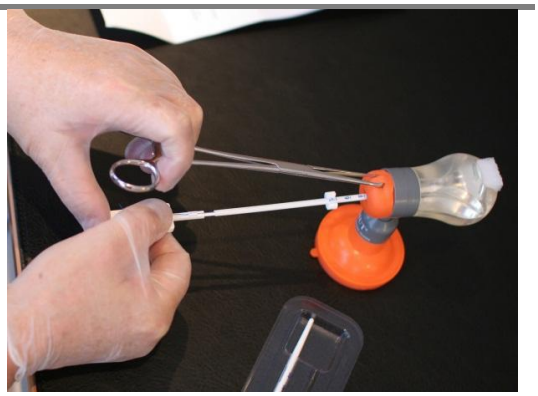
Step 7:

Remove your (other) hand from the applicator now.



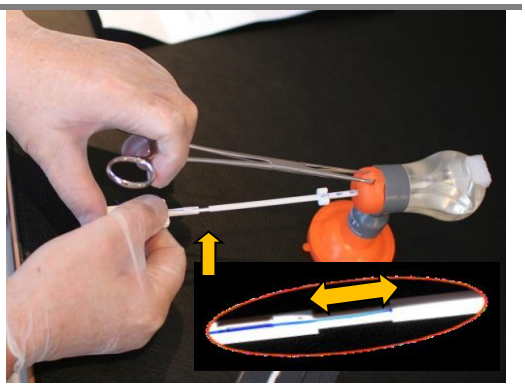
Step 8:

Position your thumb and index finger on the handle as shown.



Step 9:

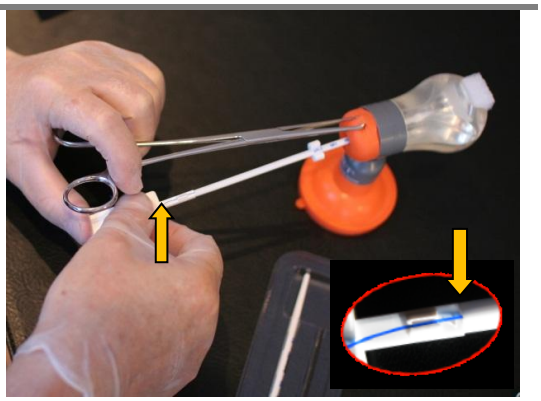
Focus now on the distance between the handle and the end of the insertion tube (see figure).



Step 10:

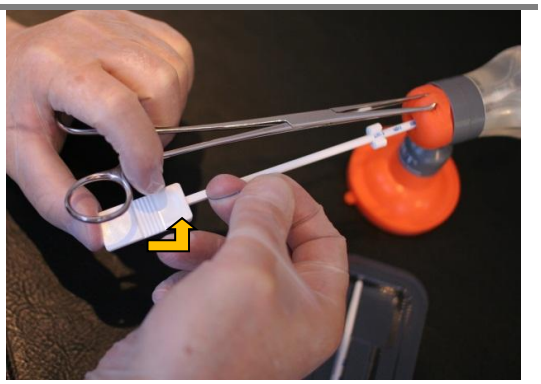
Move the handle forward, feeling the anchoring knot penetrating the fundus. Full penetration is obtained when the handle touches the tube. **It is not necessary to push hard or to push a second time.**

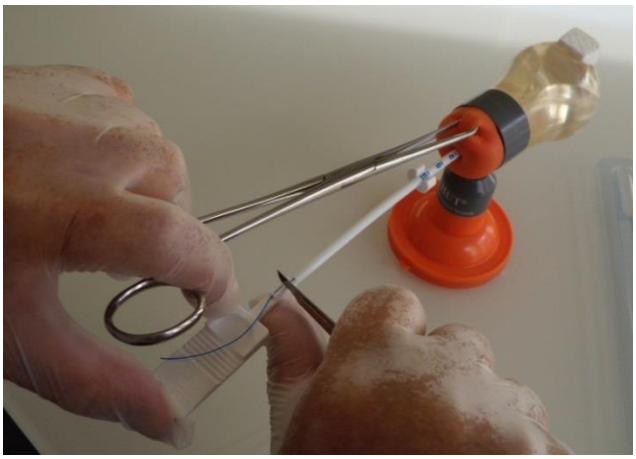
Ask the patient to take a deep breath during insertion.



Step 11 (**ONLY FOR PRACTICE IN HUT®**):

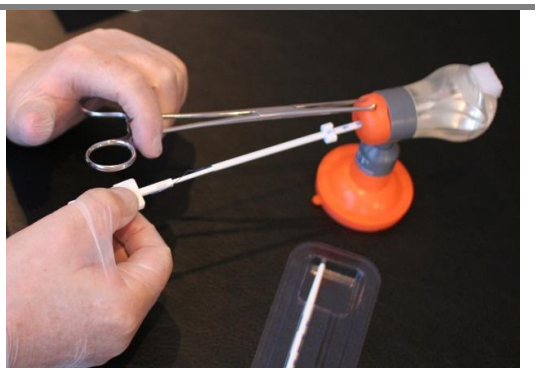
When practising on HUT®, remove the tail which is fixed in the slot on the handle as shown (note: cut the tail with a scalpel when you insert GyneFix® in your patients). **Make sure that your thumb is still positioned at the end of the handle to avoid traction on the anchor.**





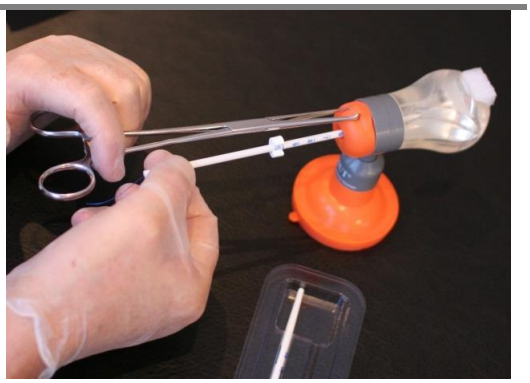
Step 12:

Remove your thumb now and withdraw the handle from the insertion tube.



Step 13:

Withdraw the tube slowly while rotating it. There can be mucus/blood in the tube.



Step 14:

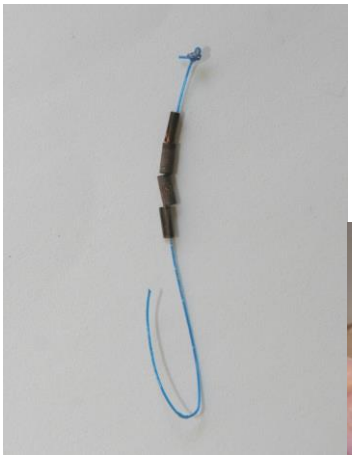
Do not pull the tail immediately after procedure. Cut the tail until 3 cm.

The presence of the tiny metal tube allows visualization on ultrasound. This examination provides important information on the proper placement of the anchor. After insertion, look for the visualization marker and measure the distance to the serosa to check if the insertion was done correctly.

Step 15:

Loop the tail in the cervical canal with a long pincet.

If the partner has complaints about the tail, you can **thermoform the end using an electrocautery**.



REMOVAL OF GYNEFIX®

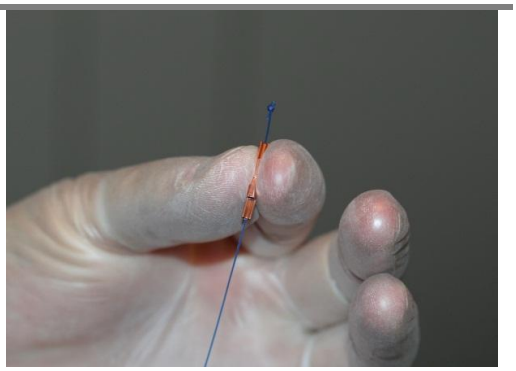
GyneFix® is simply removed by a **short strong pull** at the tail. Experience has shown that if you ask the **patient to cough** at the very moment of **"quick"** removal of the device, painful sensations are usually minimal.

How to reassemble GyneFix®?

(only for training)

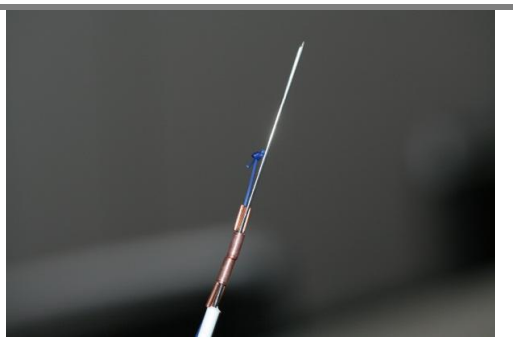
Step 1:

Take the device in your left hand as shown.



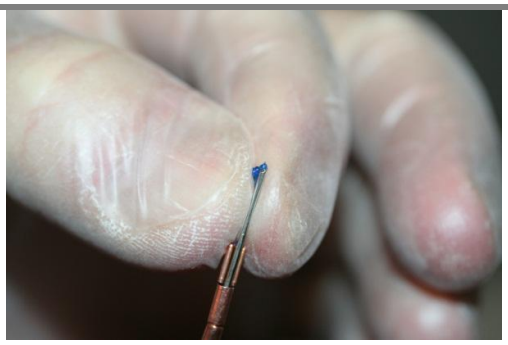
Step 2:

Insert the stylet through the hollow tubes (on the concave side of the crimped tubes)



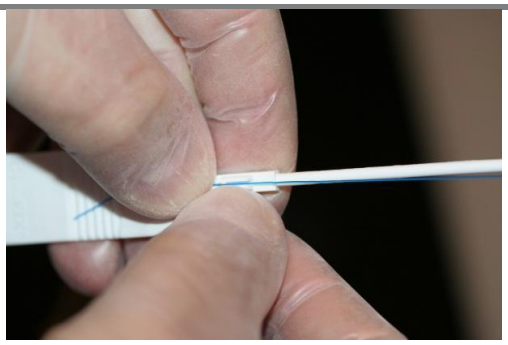
Step 3:

Put the noose of the anchoring knot on the tip of the stylet.



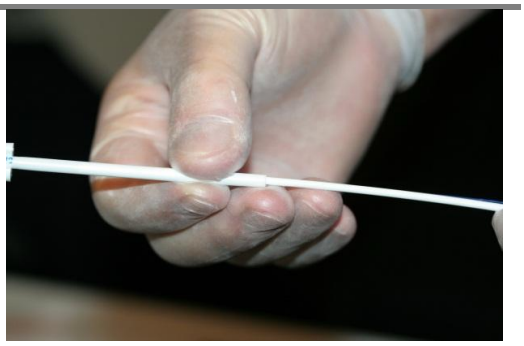
Step 4:

Keep traction on the tail and fix the tail in the slot at the handle.



Step 5:

Slide the tube partly over the needle-handle unit.



Step 6:

Put the applicator in the blister pack. The cervical stop should be positioned at 10 cm from the tip of the tube.