Welcome to Intrauterine Devices Training

WomanCare GLOBAL academy

WomanCare GLOBAL A COMPANY OF dkt INTERNATIONAL

Introductions

Split into pairs and ask each other:

1. What is your name?
2. Where are you from?
3. What experience do you have with intrauterine devices?
4. What expectations do you have about this training?

Ground Rules

Purpose of training

- Discuss family planning and contraception WHO definition and importance
- Overview intrauterine devices (IUDs)
- Provide information on best practice counselling
- Practice counseling on IUDs
- Introduce our products: Etherena, Silverline, Eloira, Avibela

Pre-Course Knowledge Test

Family Planning & Contraception

World Health Organization

"Family planning allows individuals and couples to **anticipate and attain their desired number of children and the spacing and timing of their births.** It is achieved through use of contraceptive methods and the treatment of involuntary infertility.

A woman's ability to space and limit her pregnancies has a direct impact on her health and well-being as well as on the outcome of each pregnancy."[1]

[1]World Health Organization Department of Sexual and Reproductive Health and Research (WHO/SRH) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge SUCCESS. Family Planning: A Global Handbook for Providers (2022 update). Baltimore and Geneva: CCP and WHO; 2022

Family Planning & Contraception

Contraceptive information and services are fundamental to the health and human rights of all individuals.

According to 2022 estimates, **164 million women** in reproductive age **have an unmet need for contraception.**[2]

Reasons for this include:

- Lack of or limited access to information or to services
- A limited choice of methods
- Fear or experience of side-effects
- Cultural or religious opposition
- Poor quality of available services

[2] United Nations Department of Economic and Social Affairs. World Family Planning 2022. Meeting the changing needs for family planning: Contraceptive use by age and method. Online: file:///C:/Users/Silvia%20Rivas/OneDrive%20-%20DKTWomanCare.org/Bureau/undesa_pd_2022_WFP%20(1).pdf (Accessed May 12, 2023).

Intrauterine Devices

Copper IUD

Copper IUDs: Key facts

- Small, flexible plastic device, with copper sleeves or wrapped with copper wire
- Acts by causing a chemical change which damages sperm before it meets the egg
- Inserted by competent provider, through the cervix
- Lasts for up to 12 years (depending on the brand)
- Immediately reversible

Copper IUDs: Effectiveness

- Less than 1 pregnancy per 100 women using an IUD over the first year (6 per 1,000 women who use the IUD perfectly, and 8 per 1,000 women as commonly used).
  - This means that 992 to 994 of every 1,000 women using IUDs will not become pregnant (WHO, 2022)
- Over 10 years of IUD use:
  - About 2 pregnancies per 100 women
- Follow national guidelines and manufacturers' instructions on when IUD should be removed or replaced

Copper IUDs: Suitable for nearly all women

- Adolescents and peri-menopause
- Even if they have never had children
- Married or unmarried
- Just had a vaginal delivery, caesarean section, miscarriage or abortion (non-septic) (within 48h of delivery or after 1 month)
- Breastfeeding
- Fine for women who have previously had pelvic inflammatory disease (PID), ectopic pregnancy, anaemia, HIV

Copper IUDs: Health Benefits

Health benefits:

- Reduce the risk of pregnancy
- Reduces the risk of ectopic pregnancy

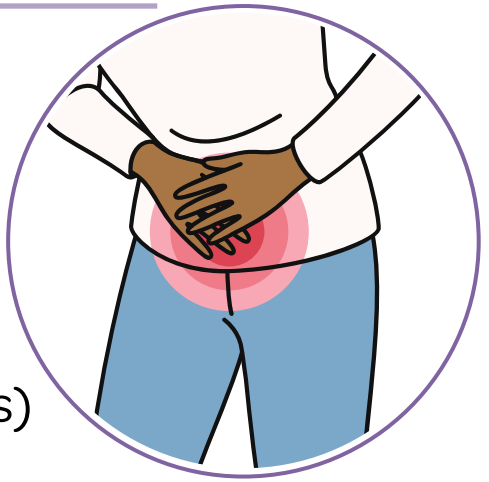
Can protect against:

- Endometrial and cervical cancer

Copper IUDs: Side effects and management

- Bleeding pattern changes
- Heavier, prolonged bleeding which can be more painful
  - Message: changes are not harmful, and do not mean the method is not working
  - Treatment: reassure, common in first 6 months

Copper IUDs: Side effects and management

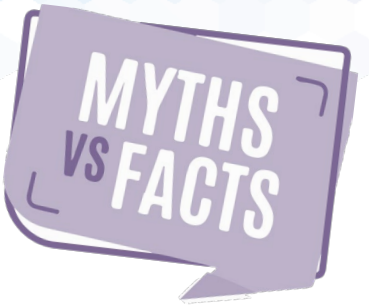


- Heavy bleeding:
  - Tranexamic acid (1,500 mg) 3 times daily for 3 days, then 1,000 mg once daily for 2 days, beginning when heavy bleeding starts.
  - Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (400 mg) or indomethacin (25 mg) 2 time. Do not use aspirin.
- Pain:
  - Suggest aspirin (325–650 mg), ibuprofen (200–400 mg), paracetamol (325–1,000 mg), or other pain reliever.
  - If she also has heavy or prolonged bleeding, aspirin should not be used because it may increase bleeding

Copper IUDs: Health risks

- Anaemia
  - If women already anaemic and side effects of heavy loss
- PID
  - Related to presence of cervical infection at time of insertion
- Risk of perforation on insertion:
  - Rare, heals with conservative management

Copper IUDs: Myth busting



- Rarely lead to PID
- Do not increase the risk of miscarriage when a woman becomes pregnant after the IUD is removed.
- Do not increase the risk of contracting STIs, including HIV.
- Do not increase the risk of miscarriage when a woman becomes pregnant after the IUD is removed.
- Do not make women infertile.
- Do not cause birth defects.
- Do not cause cancer.
- Do not move to the heart or brain.
- Do not cause discomfort or pain for the woman or the man during sex.
- Substantially reduce the risk of ectopic pregnancy.

Copper IUDs: Replace, remove or review

- When the woman wants it removed
- Pregnancy
  - Exclude ectopic pregnancy
  - IUD increased chances of septic miscarriage, pre-term delivery. Advise removal
  - Small increase in chance of miscarriage with removal
  - If IUD remains, be aware of warning signs of infection or miscarriage (vaginal bleeding, cramping, pain, abnormal vaginal discharge, or fever).
- If bleeding or pain are continuous or start at a time later to insertion
  - Consider other causes, consider if IUD has been expelled

Copper IUDs: Severe lower abdominal pain

- Exclude ectopic pregnancy
- Assess for pelvic inflammatory disease (PID)
  - Unusual vaginal discharge
  - Fever or chills
  - Pain during sex or urination
  - Bleeding after sex or between monthly bleeding
  - Nausea and vomiting
  - A tender pelvic mass
  - Pain when the abdomen is gently pressed (direct abdominal tenderness) or when gently pressed and then suddenly released (rebound abdominal tenderness)
  - *Start treatment as soon as possible, according to local protocols*
- No need to remove IUD immediately if antibiotics starts and condition improves

Copper IUDs: Suspected uterine perforation

If puncturing is suspected at the time of insertion or sounding of the uterus, stop the procedure immediately (and remove the IUD if inserted).

Observe the client in the clinic carefully:

- For the first hour, keep the woman at bed rest and check her vital signs (blood pressure, pulse, respiration, and temperature) every 5 to 10 minutes.
- If the woman remains stable after one hour, check for signs of intra-abdominal bleeding, such as low haematocrit or haemoglobin or rebound

Copper IUDs: Management of missing strings

- Exclude pregnancy
- Has the IUD been noticed?
- Advise additional contraceptive precautions
- Probe the cervical canal with forceps
  - Half of missing strings will be found
- Strings not visible?
  - Either in uterus or expelled.
  - Refer for USS or X-ray (pregnancy test)

Copper IUDs: Other indications for use

- Use as emergency contraception method
  - Up to 5 days after unprotected sex

- Postpartum contraception
  - Up to 48 hours or after 4 weeks post vaginal delivery or caesarean section
  - Counselling essential in antenatal period
  - Specific training is required with ring forceps available

Copper IUDs: Initiation

Circumstances	Starting Day	Additional contraceptive protection required (if it is reasonably certain she is not pregnant)
Women having menstrual cycles	Day 1-12 of cycle	No
	After Day 12 of cycle	No
Women who are not having periods	Any time if it is reasonably certain she is not pregnant	No
Postpartum: all women	Any time within 48 hours after giving birth, including by caesarean delivery OR after 4 weeks	No
Post first- or second-trimester abortion (no infection)	On the day of the procedure or up to Day 12	No
Switching from another method	Immediately, if she has been using the method consistently and correctly or if it is otherwise reasonably certain she is not pregnant. If she is switching from an injectable, she can have the IUD inserted when the next injection would have been given.	No

Copper IUDs: Discontinuation

Switching to	Starting Day	Additional contraceptive protection required (if it is reasonably certain she is not pregnant)
Combined oral contraceptives (COCs), progestin-only pills (POPs), progestin-only injectables, monthly injectables, combined patch, combined vaginal ring, or implants	If starting during the first 7 days of monthly bleeding (first 5 days for COCs and POPs), start the hormonal method now and remove the IUD.	No
	If starting after the first 7 days of monthly bleeding (after the first 5 days for COCs and POPs) and she has had sex since her last monthly bleeding, start the hormonal method now.	Leave IUD in place until her next monthly bleeding.
	If starting after the first 7 days of monthly bleeding (after the first 5 days for COCs and POPs) and she has not had sex since her last monthly bleeding.	IUD can stay in place and be removed during her next monthly bleeding, or the IUD can be removed, and she can use a backup method* for the next 7 days (2 days for POPs).
Male or female condoms, spermicides, diaphragms, cervical caps, or withdrawal	The next time she has sex after the IUD is removed.	
Female sterilization	If during the first 7 days of monthly bleeding, remove the IUD and perform the female sterilization procedure.	No
	If after the first 7 days of monthly bleeding, perform the sterilization procedure.	IUD should stay in place until her follow-up visit or her next monthly bleeding.

Intrauterine Devices

Hormonal – LNG-IUD

LNG-IUD: Key facts

- Small, flexible plastic device, releases small amount of levonorgestrel daily (20mcg/24 hours)
- Acts by thickening cervical mucus. Difficult for sperm to reach egg
- Can suppress ovulation
- Thins endometrium
- Inserted by competent provider, through the cervix, sit in uterine cavity
- Lasts for up to 8 years (depending on the brand)
- Immediately reversible

LNG-IUD: Effectiveness

- Less than 1 pregnancy per 100 women using an LNG-IUD over the first year (2 per 1,000 women).
  - This means that 998 of every 1,000 women using LNG-IUDs will not become pregnant.
- A small risk of pregnancy remains beyond the first year of use and continues as long as the woman is using the LNG-IUD.

(WHO 2022)

LNG-IUD: Suitable for nearly all women

- Adolescents and peri-menopause
- Even if they have never had children
- Married or unmarried
- Just had a vaginal delivery, caesarean section, miscarriage or abortion (non-septic)
- Breastfeeding
- Fine for women who have previously had PID, ectopic pregnancy, anaemia, HIV

! But - Not suitable for women who have liver disease, current/previous breast cancer, current DVT/pulmonary embolism, advanced HIV, high individual risk of STI without testing

LNG-IUD: Health benefits vs risk

- Health benefits:
  - Reduce the risk of pregnancy
  - Reduces the risk of ectopic pregnancy
- May protect against:
  - Iron deficiency anaemia
  - Endometrial and cervical cancer
- Health risks:
  - Pelvic infection - related to presence of cervical infection at time of insertion
  - Risk of perforation on insertion: Rare, heals with conservative management
  - Miscarriage, preterm birth or infection if pregnancy occurs

LNG-IUD: Side effects

- Bleeding pattern changes
  - Not harmful, does not mean the method is not working
  - Lighter, less frequent, irregular bleeding
  - Bleeding can completely stop
- Hormonal side effects relate to progestin
  - Acne, headache, breast pain, nausea, weight gain

Treatment: Reassurance that irregular or heavy bleeding will settle after a few months and that no bleeding does not mean she is pregnant

LNG-IUD: Other indications for use

- Highly effective non-surgical treatment for heavy bleeding and for women with heavy bleeding due to fibroids
- Reduce pain related to endometriosis
- Treat endometrial hyperplasia
- As endometrial protection for women on combined hormone replacement treatment (off label)

LNG-IUD: Other indications for use

Postpartum contraception

- Up to 48 hours or after 4 weeks post vaginal delivery or caesarean section
- Counselling essential in antenatal period
- Specific training is required with ring forceps available

Not suitable for use as emergency contraception

LNG-IUD: Similarities with Copper IUDs

- Same management advice as for copper IUD on:
  - Replacement and removal
  - Pregnancy with device *in situ*
  - Lost strings
  - Lower abdominal pain
  - Suspected perforation

LNG-IUD: Initiation I

Circumstances	Starting Day	Additional contraceptive protection required (if it is reasonably certain she is not pregnant)
Women having menstrual cycles	Day 1-7 of cycle	No
	After Day 7 of cycle	Yes for 7 days
Women who are not having periods	Any time if it is reasonably certain she is not pregnant	No
Post first- or second-trimester abortion (no infection)	On the day of the procedure or up to Day 7	No
	After 7 days, insert anytime	Yes for 7 days
Switching from another hormonal method	Immediately, if she has been using the method consistently and correctly or if it is otherwise reasonably certain she is not pregnant.	No
	<7 days after start of her monthly bleeding	No
	>7 days after the start of her monthly bleeding	No
	If she is switching from an injectable, she can have the IUD inserted when the next injection would have been given.	No

LNG-IUD: Initiation II

Circumstances	Starting Day	Additional contraceptive protection required (if it is reasonably certain she is not pregnant)
Postpartum: all women	Any time within 48 hours after giving birth, including by caesarean delivery OR after 4 weeks	No
Breastfeeding: fully <6 months	Monthly bleeding has not returned, any time between 4 weeks and 6 months	No
Breastfeeding: fully >6 months	Monthly bleeding has not returned, insert any time Monthly bleeding has returned, insert any time	Yes, 7 days
Breastfeeding: Partially	Monthly bleeding has not returned, inserted any time Monthly bleeding has returned, insert any time	Yes, 7 days
After taking progestin-only, combined, or ulipristal acetate (UPA) emergency contraceptive pills (ECPs)	Insert when pregnancy is excluded She should not have the LNG-IUD inserted in the first 6 days after taking UPA-ECPs.	

LNG-IUD: Discontinuation

Switching to	Starting Day	Additional contraceptive protection required (if it is reasonably certain she is not pregnant)
Combined oral contraceptives (COCs), progestin-only pills (POPs), progestin-only injectables, monthly injectables, combined patch, combined vaginal ring, or implants	If starting during the first 7 days of monthly bleeding (first 5 days for COCs and POPs), start the hormonal method now and remove the IUD.	No
	If starting after the first 7 days of monthly bleeding (after the first 5 days for COCs and POPs) and she has had sex since her last monthly bleeding, start the hormonal method now.	Leave IUD in place until her next monthly bleeding.
	If starting after the first 7 days of monthly bleeding (after the first 5 days for COCs and POPs) and she has *not* had sex since her last monthly bleeding.	IUD can stay in place and be removed during her next monthly bleeding, or the IUD can be removed and she can use a backup method* for the next 7 days (2 days for POPs).
Male or female condoms, spermicides, diaphragms, cervical caps, or withdrawal	The next time she has sex after the IUD is removed.	
Female sterilization	If during the first 7 days of monthly bleeding, remove the IUD and perform the female sterilization procedure.	No
	If after the first 7 days of monthly bleeding, perform the sterilization procedure.	IUD should stay in place until her follow-up visit or her next monthly bleeding.

Intrauterine Devices

Copper vs. Hormonal

Similarities: Copper IUDs vs. Hormonal IUDs

- Very effective and safe
- Long-acting and reversible
- Return to fertility is not delayed upon removal
- Can be removed anytime the client wants
- Require a trained provider to insert and remove
- Protect against the risks of pregnancy and may protect against endometrial and cervical cancer
- Can be inserted at any time in the cycle if the provider is reasonably sure that the client is not pregnant
- Can be inserted post abortion and postpartum if no evidence of complications

Source: Training Resource Package for Family Planning. Levonorgestrel Intrauterine Devices (LNG-IUD), Session I.

Differences: Copper IUDs vs. Hormonal IUDs

	Copper IUDs	Hormonal IUDs
Appearance	T-shaped plastic device with **copper** sleeves or wire wrapped around them	T-shaped plastic device with the **hormone** reservoir in the stem of the T frame
Duration of use	**Up to 12 years** depending on the brand and national guidelines	**Up to 8 years** depending on the brand and national guidelines
Effectiveness	Very effective; **6 per 1,000** women will become pregnant in the first year	Very effective; **1 per 1,000** women will become pregnant in first year
Hormones	No hormones	Small amounts of the hormone levonorgestrel
Mechanism of action	Causes a chemical change that interferes with sperm motility and prevents sperm and egg from meeting	Thickens cervical mucosa; interferes with movement of the sperm, so the sperm and the egg do not meet
Side effects	Changes in bleeding patterns including prolonged and heavy monthly bleeding, more cramps and pain during monthly bleeding	Changes in bleeding patterns including lighter bleeding, fewer days of bleeding, or no bleeding. Mild systemic side effects such as headaches, breast tenderness
Additional considerations	• May contribute to anemia if woman has low iron stores • May be more easily available and less expensive than hormonal IUDs • Can be used as emergency contraception	• May help protect against iron-deficiency anemia • Reduces heavy monthly bleeding and may reduce menstrual cramps as well as pelvic pain and irregular bleeding from uterine fibroids and endometriosis

Source: Training Resource Package for Family Planning. Levonorgestrel Intrauterine Devices (LNG-IUD), Session I.

Counselling

A Rights Based Approach to care

This session is for all staff to gain new skills and refresh any knowledge you already have:

Counselling as part of a Rights-Based Approach

> "Principles of a rights-based approach to service delivery: service users must not only have access to safe, effective, acceptable care – there should be access, equity and availability."

How can we ensure that the client is getting rights-based care?

1. Ensuring stock and method mix
2. Importance of contraceptive choice
3. Importance of consent

Rights of patients who attend FP services

- Information
- Access
- Choice
- Security
- Privacy
- Confidentiality
- Comfort
- Follow-up
- Opinion

Characteristics of Balanced Counselling

In Family Planning

- Sexual and reproductive rights
- Communication
- Listen
- Inform
- Clarify doubts

What is Good Counselling?

- Principles of good counselling?
- One well known framework is e.g. EngenderHealth REDI
  - R Rapport Building
  - E Exploring
  - D Decision Making
  - I Implementing the Decision

EngenderHealth
for a better life

What is Good Counselling?

Rapport Building

- Greet client with respect
- Make introductions and identify category of the client (i.e., new, satisfied return, or dissatisfied return)
- Assure confidentiality and privacy
- Explain the need to discuss sensitive and personal issues
- Use communication skills effectively (throughout the phases)

What is Good Counselling?

Exploring

- Identify reason for the visit in detail
- New clients: SRH history, does she want spacing or no more children?
- Return clients: satisfaction with current method, confirm it is being used properly. Does she want spacing or no more children? Discuss existing problems, treating them or switching
- All clients: Focus on the method(s) of interest to the client, addressing individual and other key factors and risk of STIs/HIV

What is Good Counselling?

Decision Making

Summarize from the Exploring phase:

- Identify the decisions the client needs to make or confirm
- Identify relevant options for each decision (e.g., pregnancy prevention, STI/HIV risk reduction)
- Confirm medical eligibility for contraceptive methods the client is considering
- Help the client consider the benefits, disadvantages, and consequences of each option (provide information to address any remaining knowledge gaps)
- Confirm that any decision the client makes is informed, well-considered, and voluntary

What is Good Counselling?

Implementing the Decision

- Assist the client in developing a concrete and specific plan for implementing the decision(s)
- Identify barriers that the client may face in implementing the plan
- Develop strategies to overcome the barriers
- Make a follow-up plan and/or provide referrals, as needed

Importance of Informed Consent

Brainstorm:

What are the principles of informed consent?

THE IMPORTANCE OF INFORMED CONSENT IS TO RECORD THE COUNSELLING PROCESS

Informed Consent

Clients right to make decisions about her own health and welfare

Clients must not be coerced, consent must be voluntary

Clients must have capacity to make decisions for herself and understand risks and benefits

Role Play Counselling and Informed Consent

Let's Play ...

Intrauterine Devices

Insertion

Preventing infection at IUD insertion

For all IUDs

- Screen for individual risk of STIs
- No touch technique
  - Cleaning the cervix thoroughly with antiseptic before IUD insertion
  - Being careful not to touch the vaginal wall or speculum blades with the uterine sound or loaded IUD inserter
  - Passing both the uterine sound and the loaded IUD inserter only once each through the cervical canal
- Do not reuse equipment unless high level disinfection
- Routine use of antibiotics is not recommended

IUD insertion: Particular requirements

- Questions to ask women who are having an IUD inserted
- Can be found in the WHO green book
- Replicated in local protocols

1. Is there any type of ulcer on the vulva, vagina, or cervix?

❑ NO ❑ **YES** Possible STI.

2. Does the client feel pain in her lower abdomen when you move the cervix?

❑ NO ❑ **YES** Possible PID.

3. Is there tenderness in the uterus, ovaries, or fallopian tubes (adnexal tenderness)?

❑ NO ❑ **YES** Possible PID.

4. Is there a purulent cervical discharge?

❑ NO ❑ **YES** Possible STI or PID.

5. Does the cervix bleed easily when touched?

❑ NO ❑ **YES** Possible STI or cervical cancer.

6. Is there an anatomical abnormality of the uterine cavity that will prevent correct IUD placement?

❑ NO ❑ **YES** If an anatomical abnormality distorts the uterine cavity, proper IUD placement may not be possible. Help her choose another method.

7. Were you unable to determine the size and/or position of the uterus?

❑ NO ❑ **YES** Determining the size and position of the uterus before IUD insertion is essential to ensure high placement of the IUD and to minimize risk of perforation. If size and position cannot be determined, do not insert an IUD. Help her choose another method.

Remember:

Characteristics of Balanced Counselling In Family Planning

- The Rights Based Approach
- Communication
- Listen
- Inform
- Clarify doubts

Before you Begin

Once the client has chosen an IUD

- Counsel client on what to expect, both during and after insertion including common side effects
- Consider what pain relief will be required. Offer e.g. ibuprofen pre insertion, or consider paracervical block
- Be clear and concise
- Reassure that common side effects are not harmful
- Project professionalism, clinical confidence, and receptivity to questions
- If possible, also provide printed materials

Required Equipment

For Insertion:

- Speculum
- Tenaculum
- Sound
- Scissors
- Forceps
- Narrow forceps (for removal)
- Gallipot with cotton balls
- Antiseptic solution
- Local anaesthetic (for paracervical block if required)

Insertion Procedure

1. Bimanual examination to assess size and position of uterus
2. Insert speculum, clean cervix
3. Use tenaculum to grasp cervix at 12 o' clock position to steady the uterus
   - Consider local anesthetic injection prior to this
4. Insert sound gently into cervical canal and into uterus to measure uterine cavity and its orientation
5. Gently insert IUD into the uterus, without touching
6. Remove the inserter.
7. Cut strings to 3 cm length hanging from cervix
8. Remove tenaculum, check there is no bleeding from site
9. Remove speculum

Post IUD insertion: follow up

- For all IUDs
- Best practice is to review woman 3-6 weeks later
- Ask whether she is satisfied
- Report side effects and support with treatment or information
- Has the IUD fallen out?
  - Routine pelvic examination not required
- Reassess STI risk

Follow-Up

"Come back any time"

Assure every client she is welcome to come back any time, for example, when:

- She has problems, questions, or wants another method,
- She has a major change in health status,
- She thinks she might be pregnant.

Remind her to bring the follow-up card during each visit to the clinic

A routine follow up visit is not necessary

Routine pelvic examination is not required

Management after insertion

- Be open to patient questions
- Practice active listening
- Rule out other causes of any complaints
- Give advice about managing the side effects
- Try medical management before removal first for side effects
- Honor the wishes of the woman
- If removal is chosen, contraceptive and/or pregnancy counseling

Warning Signs

The client should return to the clinic if she has any of the following problems:

- Symptoms of pregnancy
- Symptoms of ectopic pregnancy: missed period, new abnormal bleeding, abdominal pain
- Symptoms of PID: vaginal discharge, fever/chills, abdominal pain
- Symptoms of perforation: feeling a hard object in the vagina or cervix

Time to practice!

4 Stage method

1

Stage 1:
Silent demonstration by the trainer in real time without any comments or explanation

2

Stage 2:
Demonstration by trainer with commentary and explanation

3

Stage 3:
Demonstration by trainer but this time ask a volunteer trainee provide commentary

4

Stage 4:
Trainee to perform the skill and provide their own commentary

- Include what happens after insertion

Intrauterine Devices

Removal

LNG-IUD: Discontinuation

Switching to	Starting Day	Additional contraceptive protection required (if it is reasonably certain she is not pregnant)
Combined oral contraceptives (COCs), progestin-only pills (POPs), progestin-only injectables, monthly injectables, combined patch, combined vaginal ring, or implants	If starting during the first 7 days of monthly bleeding (first 5 days for COCs and POPs), start the hormonal method now and remove the IUD.	No
	If starting after the first 7 days of monthly bleeding (after the first 5 days for COCs and POPs) and she has had sex since her last monthly bleeding, start the hormonal method now.	Leave IUD in place until her next monthly bleeding.
	If starting after the first 7 days of monthly bleeding (after the first 5 days for COCs and POPs) and she has *not* had sex since her last monthly bleeding.	IUD can stay in place and be removed during her next monthly bleeding, or the IUD can be removed and she can use a backup method* for the next 7 days (2 days for POPs).
Male or female condoms, spermicides, diaphragms, cervical caps, or withdrawal	The next time she has sex after the IUD is removed.	
Female sterilization	If during the first 7 days of monthly bleeding, remove the IUD and perform the female sterilization procedure.	No
	If after the first 7 days of monthly bleeding, perform the sterilization procedure.	IUD should stay in place until her follow-up visit or her next monthly bleeding.

Remember:

Characteristics of Balanced Counselling In Family Planning

- The Rights Based Approach
- Communication
- Listen
- Inform
- Clarify doubts

Remember

1. Assist the client to make an informed decision, based on her needs and wishes.
2. Ensure method mix for ongoing contraceptive needs if required!
3. Dual protection!

Before you Begin

- Once the client has decided to remove an IUD
  - Counsel client on what to expect, both during and after removal
  - Be clear and concise
  - Project professionalism, clinical confidence, and receptivity to questions
  - If possible, also provide printed materials

Removal Procedure

1. Insert a speculum to see the cervix and IUD strings
2. Clean the cervix and vagina with an antiseptic solution
3. Ask the woman to take slow, deep breaths and to relax
4. Using narrow forceps, the provider pulls the IUD strings gently until the IUD comes completely out of the cervix.

Diagnosis and Management of Complications

What are we concerned about?

1. Pelvic Inflammatory Disease (PID)
2. Ectopic pregnancy
3. Intrauterine pregnancy
4. Perforation
5. Lost Strings

1 Pelvic Inflammatory Disease (PID)

Does she have fever, vaginal discharge and lower abdominal pain, pain on passing urine with rebound and guarding on abdominal palpation?

Key points:

- Pregnancy test
- Swab for gonorrhoea and chlamydia but do not delay treatment
- Follow local protocols
- No need to remove IUD unless symptoms do not improve or if women wants it removed

2 Ectopic Pregnancy

- Severe lower abdominal pain with or with or without abnormal vaginal bleeding with rebound and guarding on abdominal palpation
- Threat to life if treatment is delayed
- Be aware of the signs of a ruptured ectopic pregnancy which includes shoulder tip pain fainting and light headedness and rigid abdomen and a rising pulse rate. The blood pressure will only fall once the women goes into shock.
- REFER!

3 Intrauterine Pregnancy

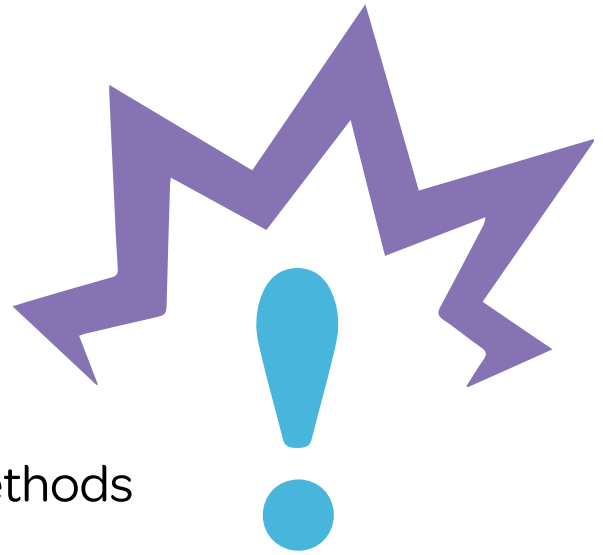
- Exclude ectopic pregnancy
- To remove or not to remove IUD?
  - Counsel woman that any intrauterine device increases the risk of preterm delivery, miscarriage with a risk of sepsis and advise removal
- If left in situ:
  - Counsel on symptoms of sepsis and advise return for clinical assessment

4 Uterine Perforation

- Incidence 2 in 1000 but higher in breast feeding women
- At time of insertion?
  - **STOP!**
    Remove device!
    Monitor vital signs (pulse and blood pressure)
  - BEWARE THE RISING PULSE RATE
  - REFER!

5 Lost Strings

- Does she remember if she has seen the device?
- Could she be pregnant?
- Consider perforation if there is abdominal pain as well as lost strings
  - Ultrasound scan, plain abdominal and pelvic X rays
- Always advise the use of other contraceptive methods while being investigated



Time to practice!

4 Stage method

1

Stage 1:
Silent demonstration by the trainer in real time without any comments or explanation

2

Stage 2:
Demonstration by trainer with commentary and explanation

3

Stage 3:
Demonstration by trainer but this time ask a volunteer trainee provide commentary

4

Stage 4:
Trainee to perform the skill and provide their own commentary

- Include what happens after removal

ETHERENA

Product Information

ETHERENA

Positioning Statement

Etherena is a non-hormonal intrauterine device effective for up to 10 years. Etherena is a highly effective, long-lasting reversible method suitable for women who prefer a non-hormonal method of contraception

1

Patient-centered

- Long-term contraceptive method, can be used up to 10 years.
- Reversible at any time.
- Ease of use and privacy.

2

Effectivess

- One of the most effective contraception methods.
- Over 99% effective at preventing pregnancy over the period of 10 years.

3

Safety

- Minimal side-effects, avoids use of hormones.
- Insertion and removal is done by a HCP.

ETHERENA: Mode of Action (MoA)

- Etherena is a Copper IUD.
- It contains copper, which has 2 contraceptive actions:

1. Damages sperm and reduces their motility → preventing sperm from fertilising the egg

2. Decreases the chances of implantation by acting on the endometrium

ETHERENA: Side Effects

Side Effects	Management	Be Aware
Heavy or prolonged periods	• Trial of tranexamic acid - 1500mg tds for 3 days then 100mg od for 3 days **or** • Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (400 mg) or indomethacin (25 mg) 2 times daily after meals for 5 days • Check haemoglobin if suspect anaemia	• Is this due to another pathology?
Abdominal cramps	• Ibuprofen (200–400 mg), • Paracetamol (325–1000 mg), • or other pain reliever.	• Is this due to PID or ectopic pregnancy? • Is this due to perforation?

ETHERENA: Benefits

Benefits for the provider

Innovative Intra-Uterine Enabler (IUE) technology offers:

- No-touch aseptic procedure
- Easy one-handed loading and insertion
- Perfect fundal placement reduces pain, bleeding and risk of expulsion
- Curvilinear design fits retroverted or anteverted uterus
- Quicker, easier insertion reduces fatigue and shortens procedure time
- Intuitive click sound adjusts per depth of uterus
- In-built uterine scale for operability, convenience and accuracy
- Comes with complementary uterine sound in sterile package

ETHERENA: Benefits

Benefits for the patient

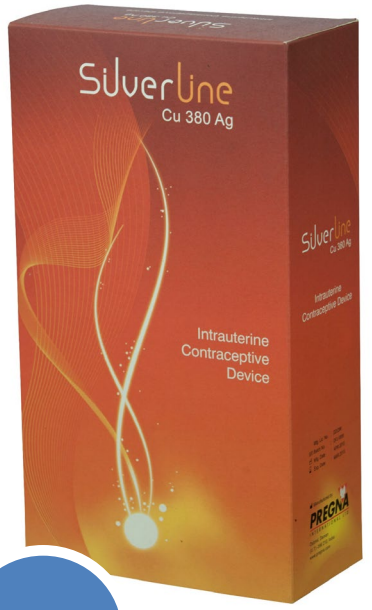
Innovative Intra-Uterine Enabler (IUE) technology offers:

- Over 99% effective at preventing pregnancy over the period of 10 years
- Safe and quick procedure with less waiting time
- Safe for breastfeeding women, can be inserted up to 48 hours after delivery or after 1 month (if medically eligible)
- Immediate return to fertility upon removal
- Can be inserted at any time during menstrual cycle
- No daily attention and does not interfere with sexual activity
- Soft nylon suture is comfortable for both partners
- Can be used as highly effective emergency contraceptive

SILVERLINE

Product Information

SILVERLINE



Positioning Statement

Silverline Cu 380 Ag is a non-hormonal intrauterine device effective for up to 5 years

1

Patient-centered

- Long term contraceptive method, can be used up to 5 years
- Reversible at any time
- Ease of use and privacy

2

Effectivess

- One of the most effective contraception methods.
- Over 99% effective at preventing pregnancy.

3

Safety

- Minimal side-effects as other hormonal-contraceptive methods
- Insertion and removal is done by a HCP.

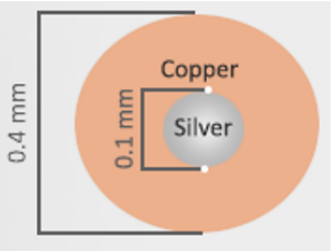
SILVERLINE: Mode of Action (MoA)

- Silverline is a Copper IUD.
- It contains copper, which has 2 contraceptive actions:

1. Damages sperm and reduces their motility → preventing sperm from fertilising the egg
2. Decreases the chances of implantation by acting on the endometrium

Silverline Cu 380 Ag

0.4mm copper diameter with 0.1mm silver core. Offers long-term protection for 5 years.



SILVERLINE: Side Effects

Side Effects	Management	Be Aware
Heavy or prolonged periods	• Trial of tranexamic acid - 1500mg tds for 3 days then 100mg od for 3 days **or** • Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (400 mg) or indomethacin (25 mg) 2 times daily after meals for 5 days • Check haemoglobin if suspect anaemia	• Is this due to another pathology?
Abdominal cramps	• Ibuprofen (200–400 mg), • Paracetamol (325–1000 mg), • or other pain reliever.	• Is this due to PID or ectopic pregnancy? • Is this due to perforation?

SILVERLINE: Benefits

Benefits for the provider

Innovative Intra-Uterine Enabler (IUE) technology offers:

- Soft, flexible Y-frame design offers perfect fundal placement which reduces risk of perforation or expulsion
- Silver core prevents copper wire from fragmenting
- Quicker insertion as requires only 1/3 dilation of Copper T 380A
- Printed insertion tube adds accuracy and convenience
- Packed sterile to prevent infection

SILVERLINE: Benefits

Benefits for the patient

- Over 99% effective at preventing pregnancy
- Quicker, more comfortable insertion requires only 1/3 dilation of standard IUD
- Safe for breastfeeding women, can be inserted up to 48 hours after delivery or after 1 month (if medically eligible)
- Lower copper content better for women with Anemia or excess bleeding condition
- Immediate return to fertility upon removal
- Can be inserted at any time during menstrual cycle
- No daily attention and does not interfere with sexual activity
- Soft nylon suture is comfortable for both partners
- Can be used as highly effective emergency contraceptive

ELOIRA

Product Information

ELOIRA

Positioning Statement

Eloira is a hormonal intrauterine device (IUD) that is effective up to 5 years. Eloira is a highly effective contraceptive method that is also used to treat a range of gynecological conditions.

1

Patient-centered

- Long-term contraceptive method, can be used up to 5 years.
- Reversible at any time.
- Ease of use and privacy.

2

Effectivess

- One of the most effective contraception methods.
- More than a 99%success rate over 5 years.

3

Safety

- Minimal side-effects as other hormonal-contraceptive methods
- Insertion and removal is done by a HCP

ELOIRA: Mode of Action (MoA)

- Eloira contains a hormone called **levonorgestrel** (it does not contain copper).
- Eloira works by releasing a small but steady amount of levonorgestrel over time leading to:

1. Thinning of the endometrium → making it less likely that eggs can implant

2. Increasing the thickness of cervical mucous → making it harder for sperm to reach the uterine cavity

ELOIRA: Side Effects

Side Effects	Management	Be Aware
• Irregular bleeding, spotting • No monthly bleeding • Heavier or prolonged bleeding	• Reassure that these are common with the IUS especially in the first 6 months of use and not harmful	• If bleeding begins after several months of use, consider underlying cause

ELOIRA: Non-Contraceptive Effects

Eloira can be used as a treatment (even when contraception is not required) to:

- Reduce menstrual blood loss in women with menorrhagia
  - heavy or prolonged menstrual period
- Decrease dysmenorrhea
  - painful menstrual cramping
- Decrease pain and bleeding from endometriosis and adenomyosis
  - abnormal growth in the uterine lining, causing pain and bleeding

ELOIRA: Benefits

- More than a 99%success rate over 5 years
- Also effective in treating effects of:
  - **Menorrhagia**: heavy or prolonged menstrual bleeding
  - **Dysmenorrhea**: painful menstrual cramping
  - **Endometriosis**: abnormal growth of endometrial tissue - causes pelvic pain
  - **Adenomyosis**: abnormal growth of uterine lining - causes pain and bleeding
  - **Anemia**: decrease in red blood cells in the bloodstream
  - **Uterine Fibroids**: benign growths of smooth muscle in or on the uterus
- Effective substitute for **hysterectomy**:
  - 64% of women awaiting hysterectomy operation cancelled after 6 months of using the hormonal IUD
  - Provides safe, quick, affordable outpatient alternative to surgery
- Does not interfere with sexual activity

Avibela®

Product Information

AVIBELA: In a nutshell

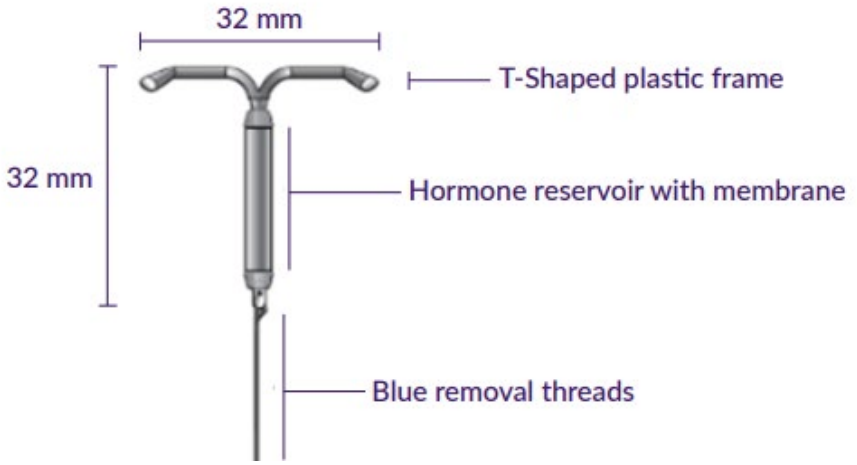
AVIBELA is a reversible 52 mg levonorgestrel-releasing intrauterine system ("hormonal IUD") that is about 99% at **preventing pregnancy** for up to 8 years* and treats **heavy menstrual bleeding** for up to 5 years

*Please refer to the approved product labeling in your country for the approved duration of use

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

AVIBELA: In a nutshell

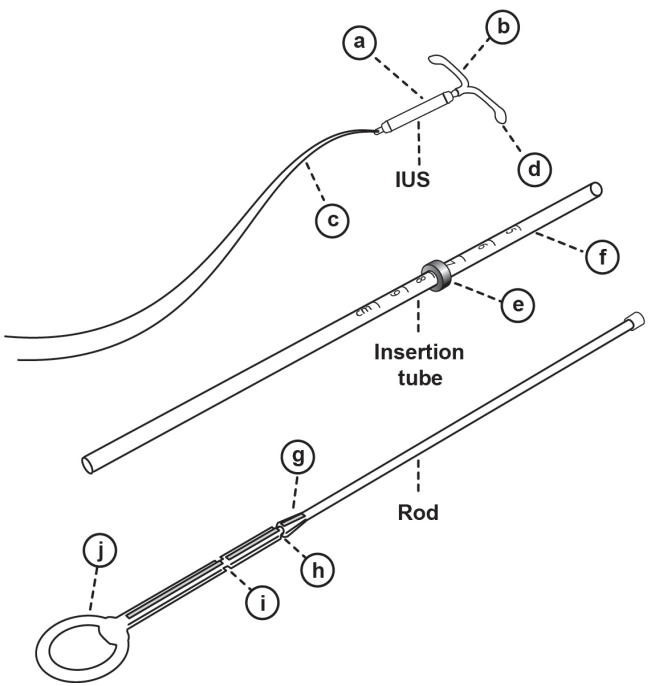
AVIBELA IUD



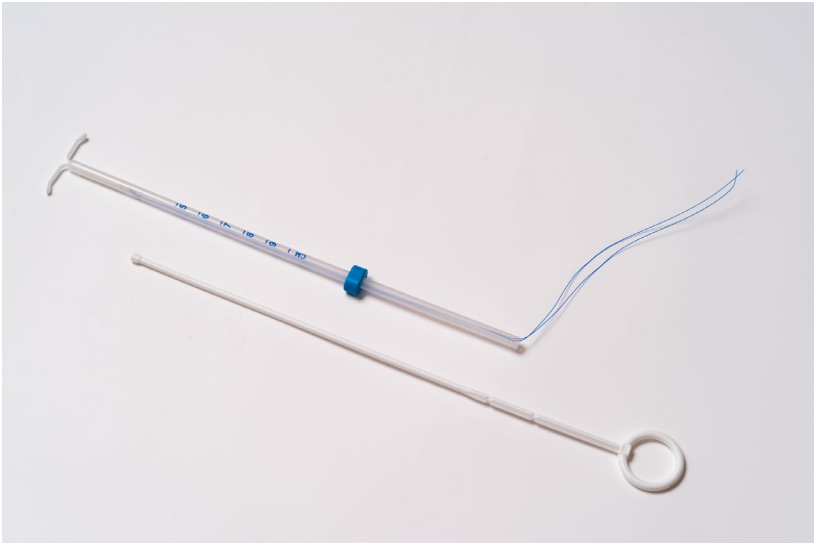
Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

AVIBELA: In a nutshell

AVIBELA IUD with two-handed inserter



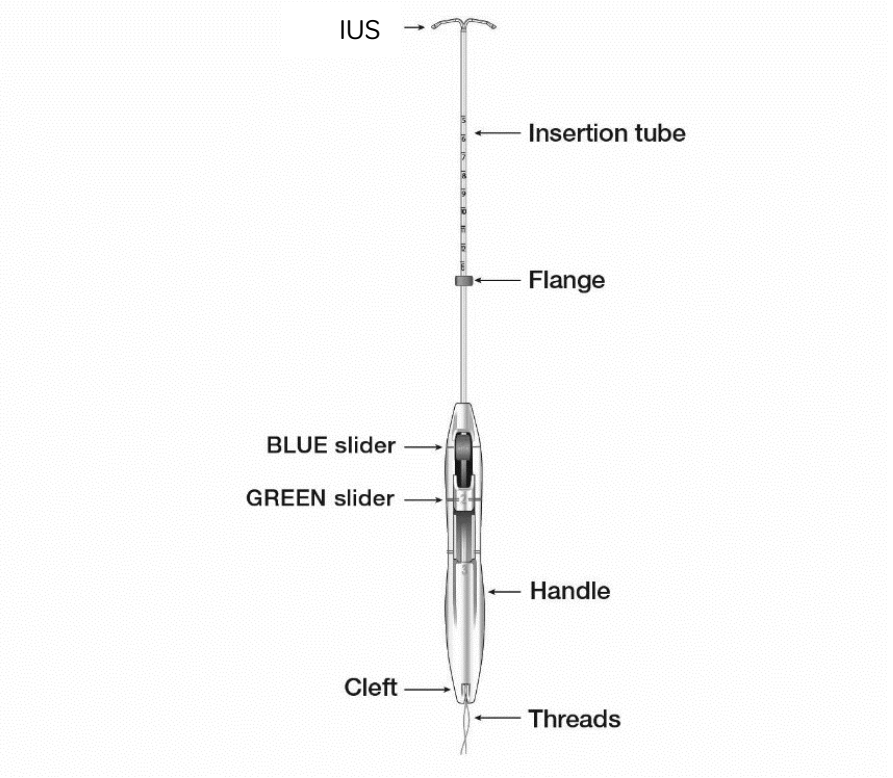
- (a) Levonorgestrel reservoir with membrane
- (b) Lateral arms
- (c) Blue removal threads
- (d) Knobs
- (e) Flange
- (f) Centimeter markings
- (g) Thickened mark
- (h) First indent
- (i) Second indent
- (j) Ring



Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

AVIBELA: In a nutshell

- AVIBELA IUD with single-handed inserter

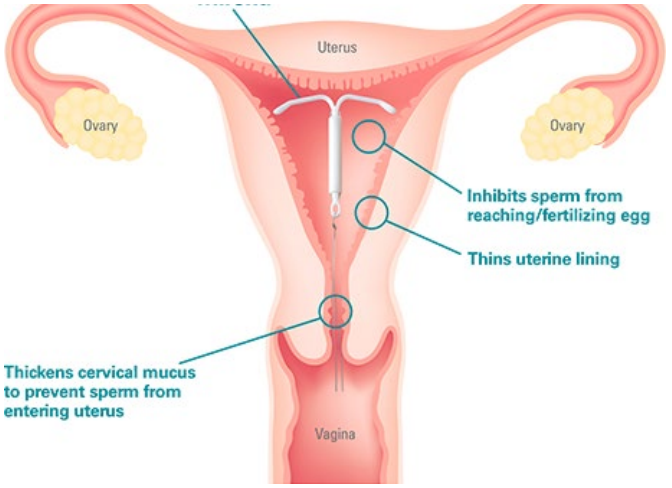


Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

AVIBELA: Mechanism of Action (MoA)

1. The mechanism of action for contraception is thickening of cervical mucus that inhibits sperm passage through the cervix, inhibition of sperm mobility and function, and thinning of the uterine lining

2. The mechanism of action for treatment of heavy menstrual bleeding is thinning of the uterine lining



Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

AVIBELA

Clinical Research

AVIBELA: Contraception indication

AVIBELA contraception efficacy and safety was studied in the phase 3 ACCESS IUS clinical trial

- **29** U.S. study centers
- **1751** generally healthy, sexually active women
- **16 to 45** year-old women
- **1401** women used for 1 year
- **380** used for 8 years

ACCESS IUS: Clinical Trial

1

Primary outcome:

Efficacy of AVIBELA for pregnancy prevention in nulliparous and parous females of childbearing potential

2

Secondary outcomes:

- Safety and bleeding patterns
- Return of menses after discontinuation
- Return to fertility after discontinuation

Source: Eisenberg, D. et al. Three-year efficacy and safety of a new 52 mg levonorgestrel-releasing intrauterine system. *Contraception.* 2015: (92); 10-16.

ACCESS IUS: Clinical Trial

Study Participants

Age	Race/ Ethnicity	BMI	Parity Status
16 to 45 years N = 1751 *Efficacy was evaluated among women aged 16 to 35*	White 78.4% Black 13.3% Asian 3.9% Other 4.4% *14.7% of women indicated Hispanic ethnicity*	Mean: 26.9 kg/m^2 Overall Range: 15.8 to 61.6 kg/m^2 25.1% obese* 5.3% morbidly obese‡	Nulliparous 58% N=1011 Parous 42% N = 740

*BMI ≥ 30 kg/m^2

‡ BMI ≥ 40 kg/m^2

Source: Eisenberg, D. et al. Three-year efficacy and safety of a new 52 mg levonorgestrel-releasing intrauterine system. *Contraception.* 2015: (92); 10-16.

ACCESS IUS: Clinical Trial

1

Primary outcome:
Efficacy of AVIBELA for pregnancy prevention in nulliparous and parous females of childbearing potential: calculated as the Pearl Index

Study results: Primary outcome

99.85%

Efficacy rate during the first year of use

98.63%

Cumulative efficacy rate through 8 years of use

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg [Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

ACCESS IUS: Clinical Trial

Study results: Secondary outcomes

2

Secondary outcomes:

- Return of menses after discontinuation
- Return to fertility after discontinuation

99.8%

of women aged 16-35 at enrollement experienced return to menses after IUD removal

63.1%

of women desiring pregnancy conceived within 6 months of IUD removal

83.2%

of women desiring pregnancy conceived within 12 months of IUD removal

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

ACCESS IUS: Clinical Trial

Study results: Secondary outcomes

Secondary outcomes:

- Safety and bleeding patterns

Most common adverse reactions (occurring in ≥10% of users):

Adverse reaction	% of users who experienced adverse reaction
Nasopharyngitis	23.3%
Vaginitis Bacterial	18.0%
Urinary Tract Infection	17.9%
Vulvovaginal Mycotic Infection	17.4%
Cervical Dysplasia	13.1%
Upper Respiratory Tract Infection	12.3%
Sinusitis	11.1%
Influenza	10.3%

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023

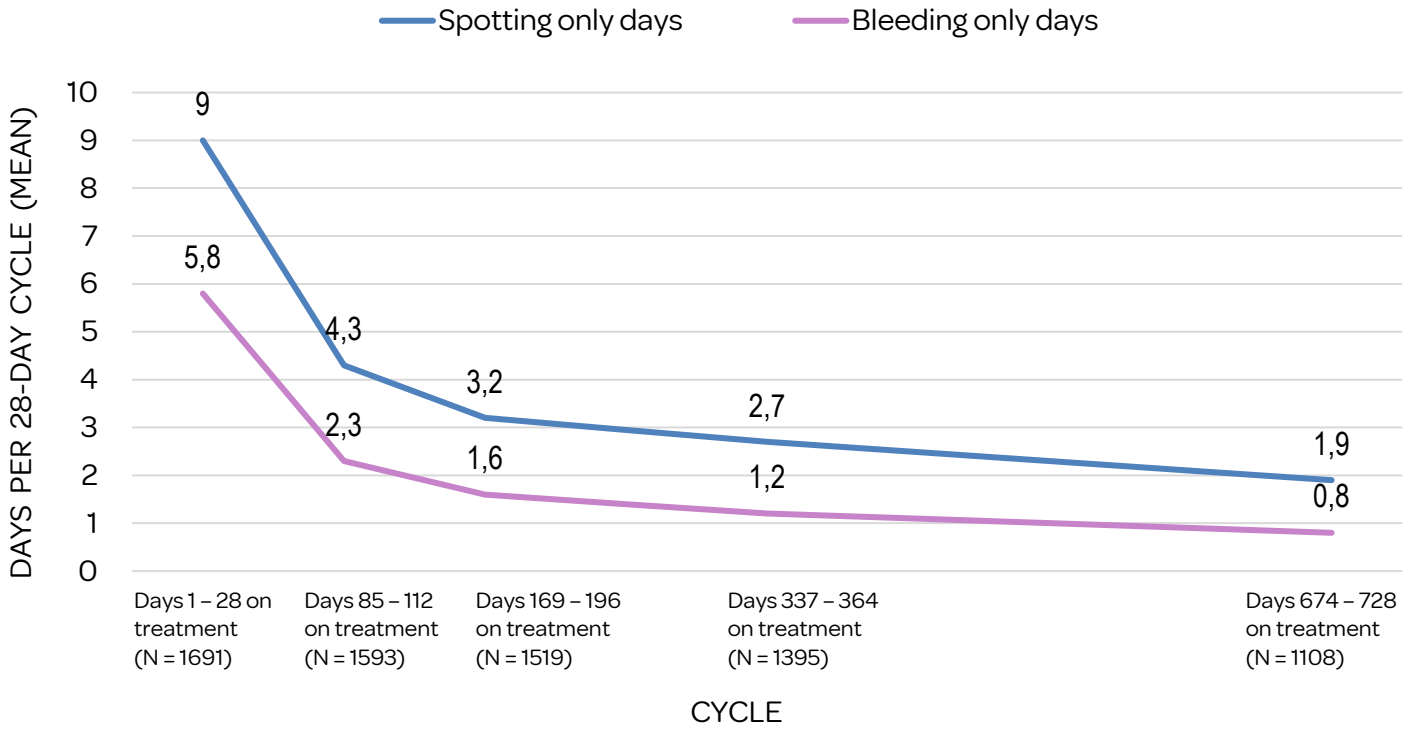
ACCESS IUS: Clinical Trial

Study results: Secondary outcomes

Secondary outcomes:

- Safety and bleeding patterns

- Rates of spotting and bleeding



Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

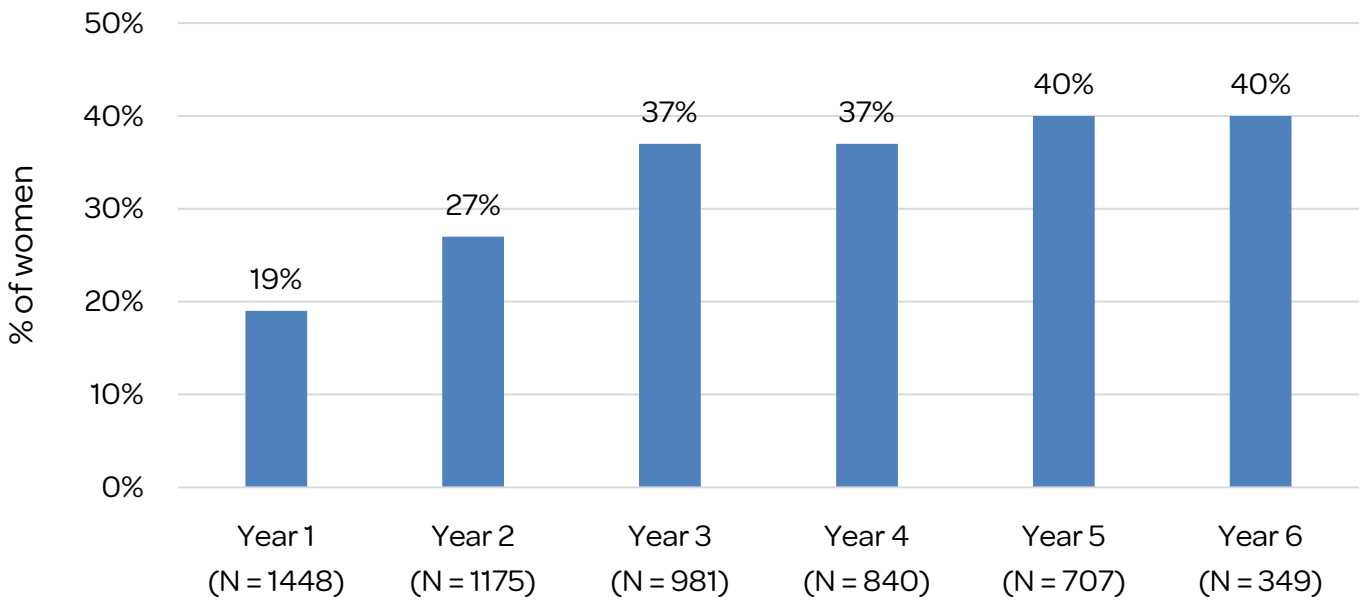
ACCESS IUS: Clinical Trial

Study results: Secondary outcomes

Secondary outcomes:

- Safety and bleeding patterns

Rates of absence of bleeding/spotting in the last 90-day interval of the year



39% of participants had an absence of bleeding/spotting at the end of the eigth year of use

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

AVIBELA: Misconceptions about hormonal IUD

The secondary outcomes evaluated in the ACCESS IUS trial help to dispel some misconceptions about the hormonal IUD

"The hormonal IUD cannot be used in nulliparous or obese women"	• 58% of ACCESS IUS trial participants were nulliparous • 25% of participants were obese
"The hormonal IUD negatively impacts future fertility, especially for nulliparous women"	• Fertility rates within one year after IUD removal are consistent with the general population
"Testing for sexually transmitted disease is required prior to insertion"	• Patients without clinical evidence of infection can have STI screening at the time of IUD placement, if indicated based on standard screening guidelines • IUD users who have a positive STI test after placement can be safely treated with outpatient antibiotics and rarely require IUD removal

Sources: Eisenberg, D. et al. Three-year efficacy and safety of a new 52 mg levonorgestrel-releasing intrauterine system. *Contraception.* 2015: (92); 10-16; Creinin MD, et al. Levonorgestrel 52 mg intrauterine system efficacy and safety through 8 years of use. *Am J Obstet Gynecol.* 2022:S0002-9378(22)00366-0.

AVIBELA: Heavy menstrual bleeding indication

AVIBELA's impact on heavy menstrual bleeding (HMB) was studied in a phase 3 clinical trial conducted in the U.S.

- **29** study centers
- **105** participants with HMB
- **18 to 50** year-old women
- **6-month** study

AVIBELA's HMB indication is also supported by a study conducted in Eastern Europe.

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

U.S. HMB clinical trial

1

Primary outcome:

The proportion of women with successful treatment, defined as (1) an end-of-study MBL volume < 80 mL and (2) ≥50% reduction in MBL from baseline to end-of-study

2

Secondary outcomes:

- The impact of AVIBELA on the absolute change from baseline MBL and the associated percent reduction in MBL from baseline to mid-study (Cycle 3) and to end-of-study (Cycle 6)
- Bleeding pattern changes

Source: Eisenberg, D. et al. Three-year efficacy and safety of a new 52 mg levonorgestrel-releasing intrauterine system. *Contraception.* 2015: (92); 10-16.

U.S. HMB clinical trial

Study results: Primary outcome

1

Primary outcome:
The proportion of women with successful treatment, defined as (1) an end-of-study MBL volume < 80 mL and (2) ≥50% reduction in MBL from baseline to end-of-study

84%

of women with successful treatment after 3 months of use

80%

of women with successful treatment after 6 months of use

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg [Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

U.S. HMB clinical trial

Study results: Secondary outcomes

91%

reduction in menstrual blood loss after 3 months of use

96%

reduction in menstrual blood loss after 6 months of use

2

Secondary outcomes:

- The impact of AVIBELA on the absolute change from baseline MBL and the associated percent reduction in MBL from baseline to mid-study (Cycle 3) and to end-of-study (Cycle 6)
- Bleeding pattern changes

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

U.S. HMB clinical trial

Data from a clinical study conducted in Eastern Europe also showed that this IUD is effective at treating heavy menstrual bleeding

88%

decrease in volume of menstrual bleeding by the end of three months of use

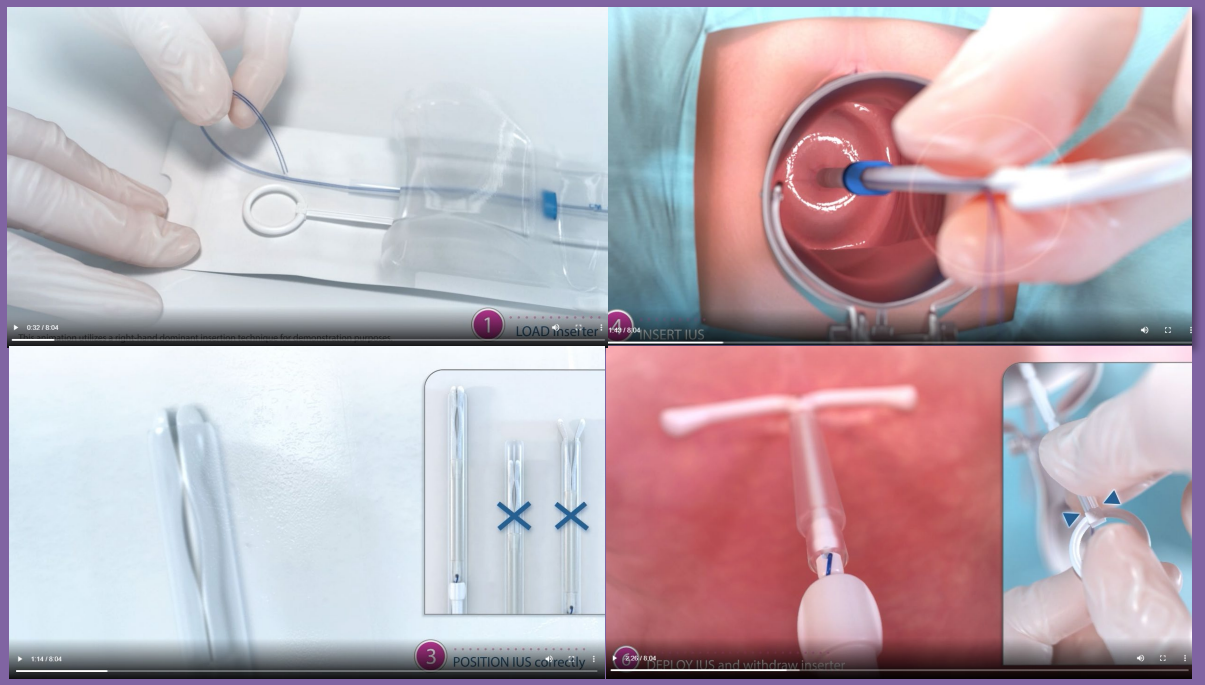
82%

reduction sustained for 12 months (duration of the study)

Source: AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg [Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2023.

AVIBELA

Insertion Videos



https://avibela.com/

AVIBELA: Key Messages

- Highly effective long-acting reversible contraceptive
  - About 99% effective at preventing pregnancy for up to 8 years[1]
- Effective at treating heavy menstrual bleeding
  - Successful treatment of HMB for 80% of women over 6 months, reducing menstrual blood loss by 91% after 3 months of use and by 96% after 6 months
- Does not alter fertility after removal
  - 99.8% of women experience return to menses by three months after IUD removal[1]
  - 83.2% of women desiring pregnancy conceive within 12 months[1]

[1] AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2022.
[2] Eisenberg, D. et al. Three-year efficacy and safety of a new 52 mg levonorgestrel-releasing intrauterine system. Contraception 92 [2015] 10-16

AVIBELA: Key Messages

- Studied in a broad range of women
  - 1751 women ages 16-45[2]
  - 58% nulliparous (having never given births)[2]
  - BMI range 16-62 and average 27[2]
- Same-day insertion is possible
  - Can be inserted at any time (if the provider is reasonably certain the woman is not pregnant)[2]
  - Same-day insertion is possible for patients without clinical evidence of infection, if indicated based on standard screening guidelines

[1] AVIBELA (levonorgestrel-releasing intrauterine system) 52 mg {Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2022.
[2] Eisenberg, D. et al. Three-year efficacy and safety of a new 52 mg levonorgestrel-releasing intrauterine system. Contraception 92 [2015] 10-16

AVIBELA® IMPORTANT SAFETY INFORMATION

Indications

- AVIBELA is a sterile, levonorgestrel-releasing intrauterine system indicated for contraception for up to 8 years; replace after 8 years if continued use is desired.
- AVIBELA is indicated for treatment of heavy menstrual bleeding (HMB) for up to 5 years; replace after 5 years if continued use is desired.
- AVIBELA may be particularly useful in women with HMB requiring (reversible) contraception.

Who is not appropriate for AVIBELA?

- AVIBELA is contraindicated when one or more of the following conditions exist:
  - pregnancy;
  - for use as post-coital contraception (emergency contraception);
  - congenital or acquired uterine anomaly, including leiomyomas, that distorts the uterine cavity and would be incompatible with correct intrauterine system (IUS) placement;
  - acute pelvic inflammatory disease (PID);
  - postpartum endometritis or infected abortion in the past 3 months;
  - known or suspected uterine or cervical malignancy;
  - known or suspected breast cancer or other hormone-sensitive cancer, now or in the past;
  - uterine bleeding of unknown etiology;
  - untreated acute cervicitis or vaginitis, including bacterial vaginosis, known chlamydial or gonococcal cervical infection, or other lower genital tract infections until infection is controlled;
  - acute liver disease or liver tumor (benign or malignant);
  - conditions associated with increased susceptibility to pelvic infections;
  - a previously inserted IUS that has not been removed;
  - a history of hypersensitivity reaction to any component of AVIBELA.

Clinical considerations for use and removal of AVIBELA

- Use AVIBELA with caution after careful assessment if any of the following conditions exist and consider removal of AVIBELA if any of them arise during use:
  - coagulopathy or use of anticoagulants;
  - migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia;
  - exceptionally severe or frequent headache;
  - marked increase of blood pressure;
  - or severe arterial disease such as stroke or myocardial infarction.
- Consider removal of AVIBELA if the any of the following conditions arise during use:
  - uterine or cervical malignancy, or jaundice.
- Because irregular bleeding/spotting is common during the first months of AVIBELA use, exclude endometrial pathology (polyps or cancer) prior to the insertion of AVIBELA in women with persistent or uncharacteristic bleeding.
- If the threads are not visible or are significantly shortened, they may have broken or retracted into the cervical canal or uterus.
- If AVIBELA is displaced (e.g., expulsed or perforated the uterus), remove it.

Pregnancy related risks with AVIBELA

- If pregnancy should occur with AVIBELA in place, attempt to remove AVIBELA because leaving it in place may increase the risk of spontaneous abortion and preterm labor.
- Removal of AVIBELA or probing of the uterus may also result in spontaneous abortion.
- Evaluate for ectopic pregnancy because the likelihood of a pregnancy being ectopic pregnancy is increased.
- Tell people about the signs of ectopic pregnancy and associated risks, including loss of fertility.
- People with a history of ectopic pregnancy, tubal surgery, or pelvic infection have a higher risk of ectopic pregnancy.

Educate about PID or endometritis

- Insertion of AVIBELA is contraindicated in the presence of known or suspected PID or endometritis.
- IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion.
- In the contraception study, one person diagnosed with PID and two people diagnosed with endometritis developed the infection within a week of insertion. One endometritis case was diagnosed at 39 days after insertion. The remaining 11 cases of PID and endometritis were diagnosed more than 6 months after insertion, including one at 30 days after IUS removal.
- In the HMB study, one person was diagnosed with PID about 5 months after insertion.
- Counsel people who use AVIBELA to notify a healthcare provider if they develop lower abdominal or pelvic pain, fever, chills, unusual or malodorous discharge, unexplained bleeding, genital lesions or sores, or dyspareunia.
- PID and endometritis are often associated with sexually transmitted infections (STIs); AVIBELA does not protect against STIs, including HIV.
- PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae.
- Inform people about the possibility of PID or endometritis and that these infections can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death.

Expect changes in bleeding patterns with AVIBELA

- Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months.
- Periods may become shorter and/or lighter thereafter.
- Cycles may remain irregular, become infrequent, or even cease.
- Consider pregnancy, including ectopic pregnancy, if menstruation does not occur within 6 weeks of the onset of previous menstruation.
- If a significant change in bleeding develops during prolonged use, conduct diagnostic tests to assess possible endometrial pathology.

Be aware of other serious complications and most common adverse reactions

- Some serious complications with IUSs like AVIBELA are sepsis, perforation, and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. Aseptic technique during insertion of AVIBELA is essential to minimize serious infections such as GAS.
- Perforation (total or partial, including penetration/embedment of AVIBELA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may also occur at any time during use. Perforation may reduce contraceptive efficacy. If perforation is suspected, locate and remove AVIBELA as soon as possible. Surgery may be required. Delayed detection or removal of AVIBELA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. The risk of perforation is increased if inserted in patients who have fixed retroverted uteri, are postpartum, or are lactating. Delay AVIBELA insertion a minimum of 4 weeks or until uterine involution is complete following a delivery or a second-trimester abortion.

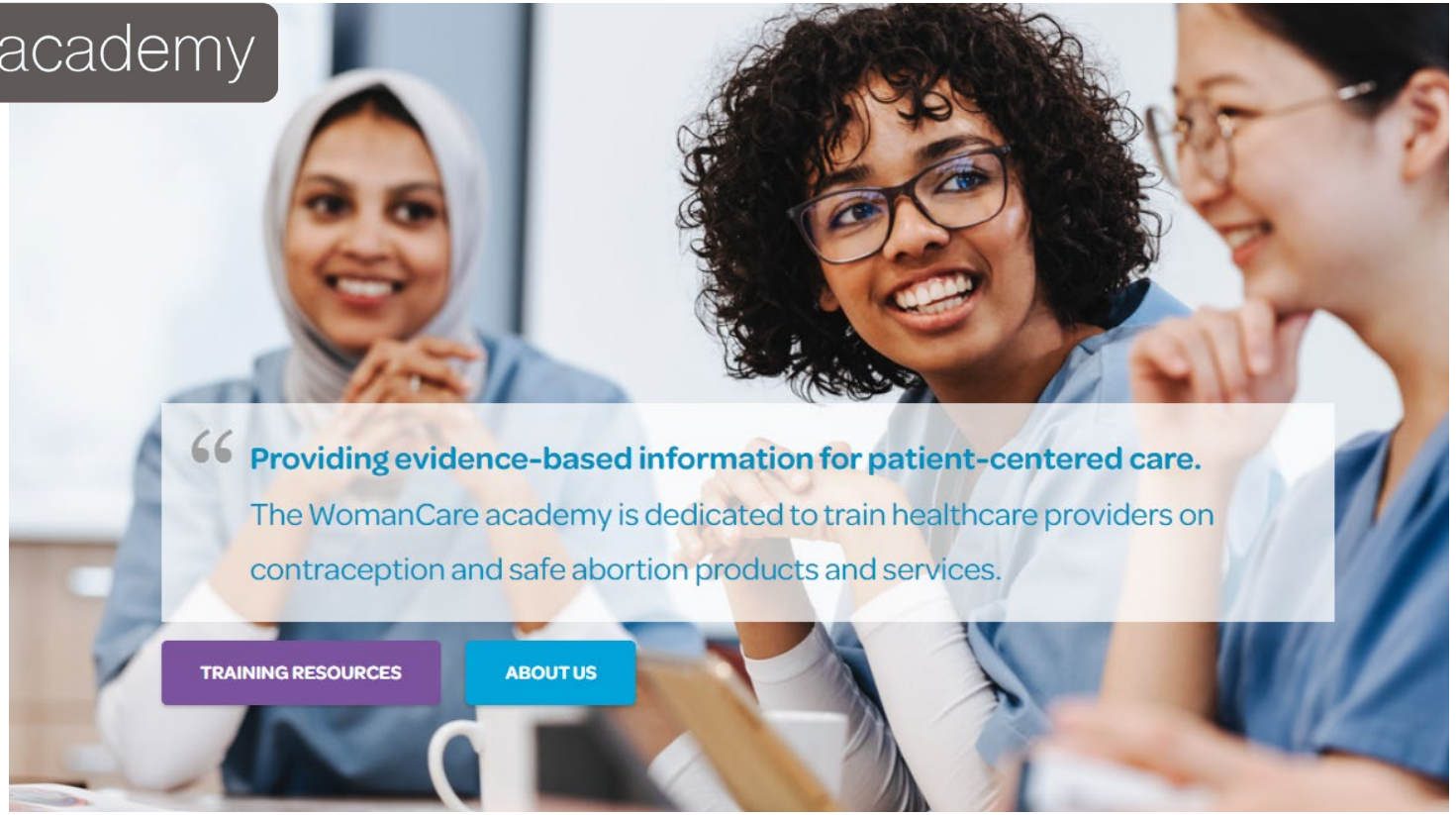
Be aware of other serious complications and most common adverse reactions, continued

- Partial or complete expulsion of AVIBELA may occur, resulting in the loss of contraceptive protection. Expulsion risk is increased when inserted immediately after delivery; it appears to be increased with insertions after second-trimester abortion, based on limited data. Risk of expulsion is increased for people with a history of HMB or greater than normal BMI at the time of insertion. Remove a partially expelled AVIBELA. If expulsion has occurred, a new AVIBELA may be inserted when there is reasonable certainty the person is not pregnant.
- Ovarian cysts may occur and are generally asymptomatic. Cysts may be accompanied by pelvic or abdominal pain or dyspareunia. Evaluate persistent ovarian cysts.
- In the AVIBELA contraception study, the most common adverse reactions (≥10% users) were vulvovaginal mycotic infections, vaginal bacterial infections, acne, nausea or vomiting, abdominal discomfort or pain, and procedural bleeding). In the AVIBELA HMB study, the adverse reaction profile was consistent with the adverse reaction profile in the contraception study.
- Teach people to recognize and immediately report signs or symptoms of the aforementioned conditions. Consider evaluating people 4 to 6 weeks after AVIBELA insertion and during routine care, or more often if clinically indicated. Check threads during each evaluation.

Questions, Comments, Or Concerns?

We want to hear about it ...

Training resources: WomanCare Academy



Training resources: WomanCare Academy

Training resources for healthcare providers

Through the WomanCare Academy, we educate a spectrum of healthcare providers: gynecologists, nurses, midwives and others worldwide, to build their skills in delivering high quality, patient-centered care using our contraceptive and safe abortion products.

womancare-academy.org

Training resources: WomanCare Academy

- Training tools for contraception and safe abortion products
  - Implants
  - Emergency contraception
  - Injectable contraception
  - IUDs
  - Medical abortion
  - Surgical abortion
  - Early pregnancy loss management

womancare-academy.org

WomanCare GLOBAL | A COMPANY OF dkt INTERNATIONAL

Email: contact@dktwomancare.org
www.dktwomancare.org
www.womancare-academy.org