

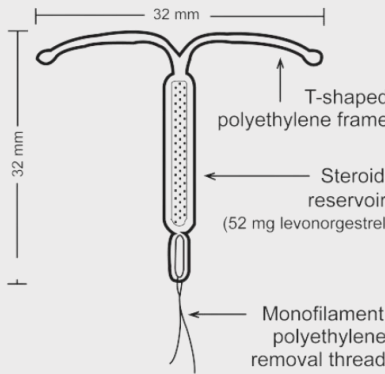
Developing a Resilient Product Introduction Ecosystem: Lessons Learned from the Global Scale-Up of the Hormonal IUD

20 October 2023

**Moderator: Andrée Sosler, Technical Director
FHI 360**

What is the hormonal IUD?

A highly effective long-acting reversible contraceptive (LARC)
with non-contraceptive benefits²

Looks Like:	Works By:	Provides:
 <p>Plastic T-frame with 52 mg* of levonorgestrel</p>	<ul style="list-style-type: none">• Thickening cervical mucus• Inhibiting sperm movement & survival	<ul style="list-style-type: none">• 99% contraceptive efficacy• Potential treatment for heavy menstrual bleeding

Possible side effects include:

Changes in Periods

Cramping During &
Right After Insertion

and less commonly

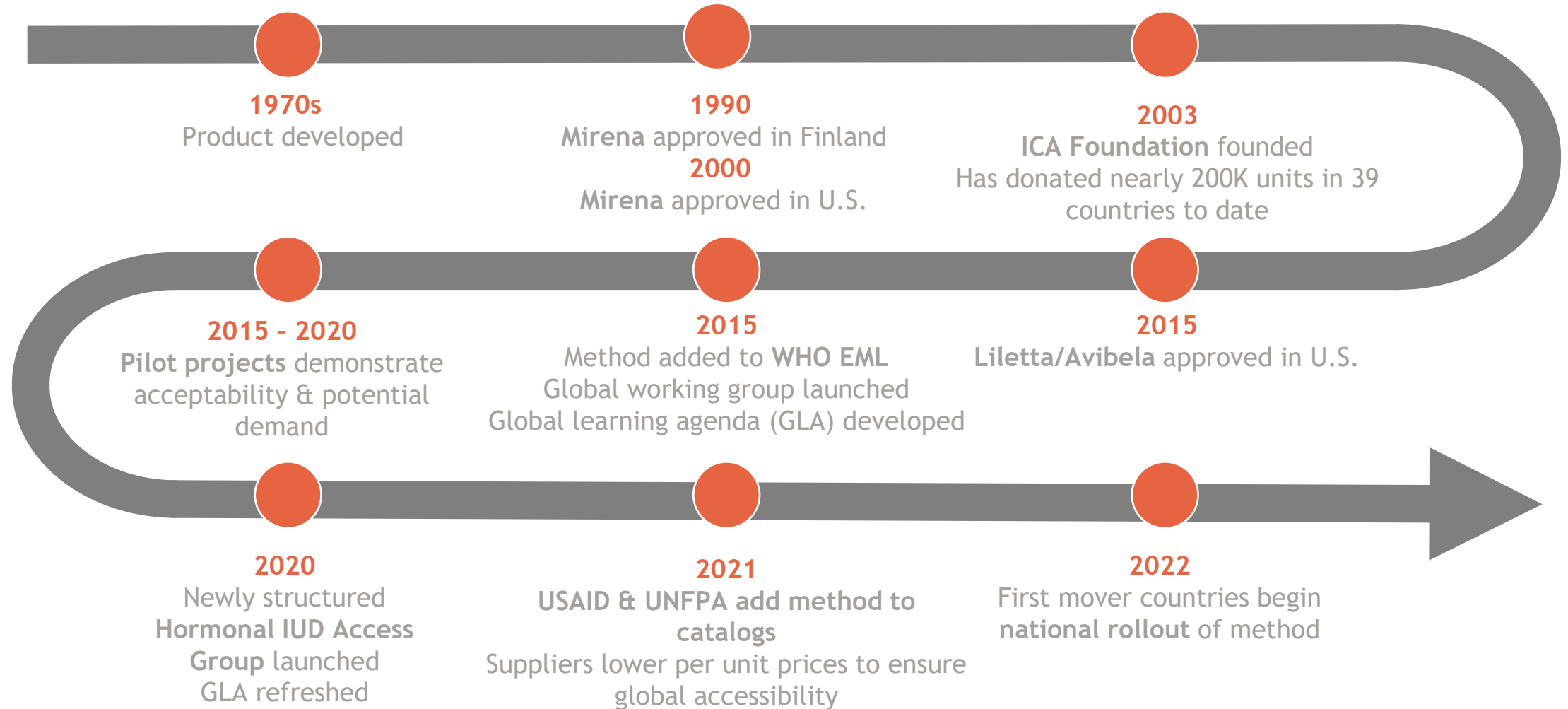
Headaches

Breast Tenderness

Acne

**13.5 mg and 19.5 mg IUDs available in limited contexts*

There has been a 30+ year gap between initial approval of the hormonal IUD and widespread availability in LMICs



Hormonal IUD Access Group Structure & Goals

Launched: 2015

Restructured: 2020

Steering Committee

Purpose: Develop, monitor and implement global strategy to expand access to hormonal IUD and strengthen hormonal IUD market; identify and mitigate risks in market health; maintain relationships with suppliers; review demand forecasts.

Operations Group

Purpose: Forum that supports monitoring of market health, development of communications, identifying and tracking country needs.

Partners Exchange

Purpose: Technical working group to discuss/share lessons learned related to rollout; address country rollout issues; share information to support steering committee

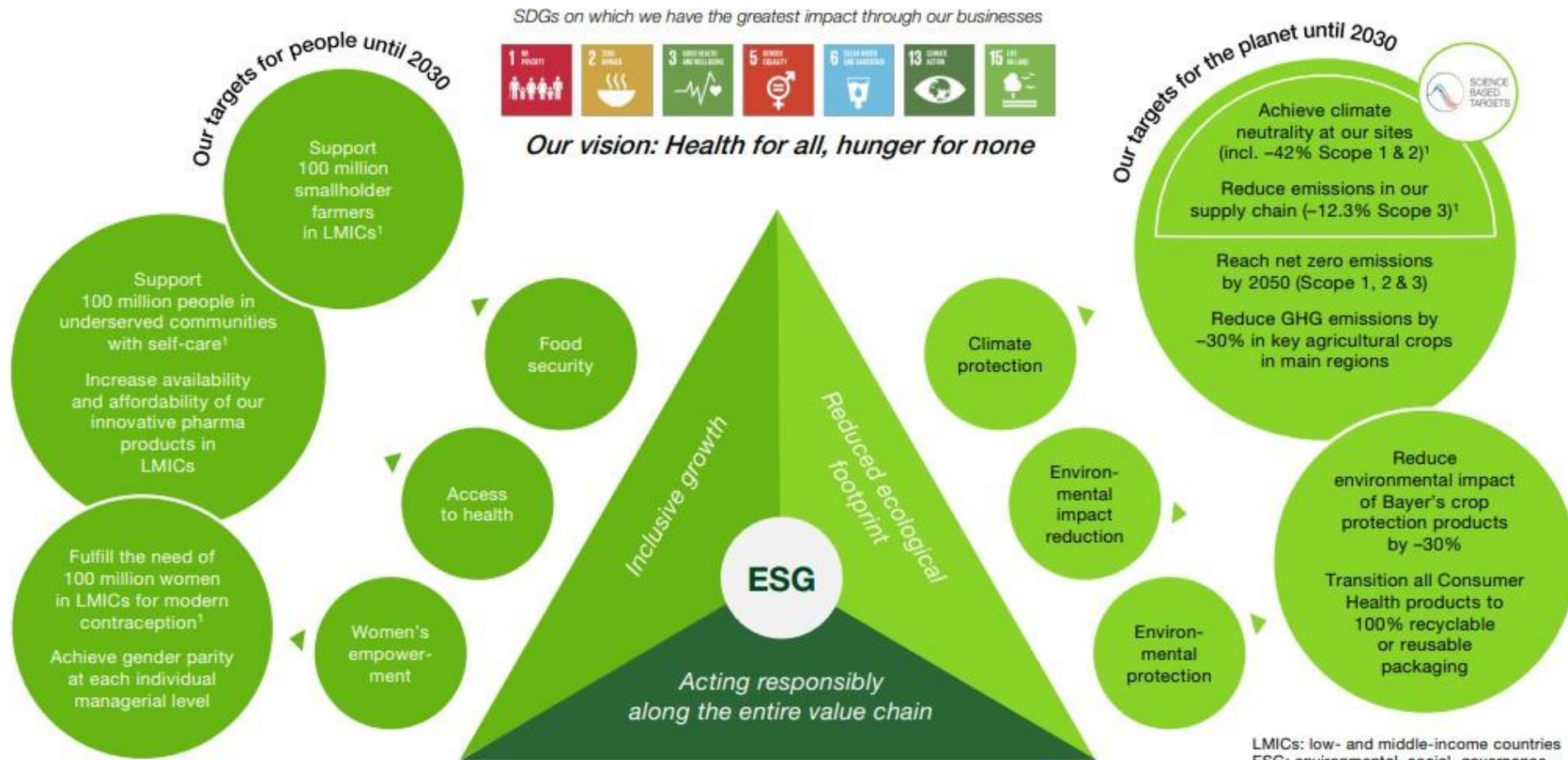
Governments
Donors
Researchers
Suppliers
Procurers
Implementers

**Kai Risse, Global Head - Institutional Supply Partnerships
Bayer AG**



Bayer's Sustainability Strategy: Strategic Elements, Impacts and 2030 Targets

Target for Pharma: We aim to provide 100m Women in LMIC with access to modern contraception annually by 2030



¹ These targets are accounted for in the long-term variable compensation (LTI) of our Board of Management and our LTI-entitled managerial employees.



Family Planning with modern Contraceptives

Securing Essential Contraceptive Supplies

Bayer has been supporting Family Planning Programs for more than 50 Years

Bayer offers a broad range of high-quality, hormonal contraceptives



Implants



Injectables



Oral Contraceptives



Hormonal IUDs

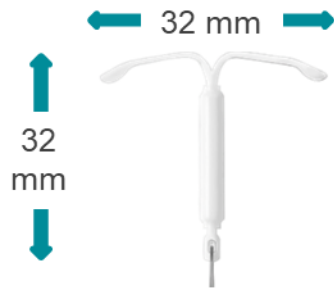




Facts about Mirena®

- was first launched in **1990**
- is available worldwide with marketing authorization in over **120** countries¹
- has over **218** million women-years of experience¹
- more than **6000** publications related to levonorgestrel-releasing intrauterine systems or levonorgestrel in over **20** different languages

Mirena® can offer a number of benefits making it a suitable choice at different stages of a woman’s reproductive life

Properties of Mirena®	
Maximum duration of use (years)	up to 8 years
Efficacy (Pearl Index)	0.35 in Year 6
Average <i>in vivo</i> LNG release rate over the first year	20 µg/24 hours
Total LNG content (mg)	52
T-frame dimensions (mm)	32 x 32
Insertion tube diameter (mm)	4.4
Silver ring/ MR compatibility	No Silver Ring/ MR Compatible
Color of the monofilament threads	Brown



Mirena[®] has 4 approved indications

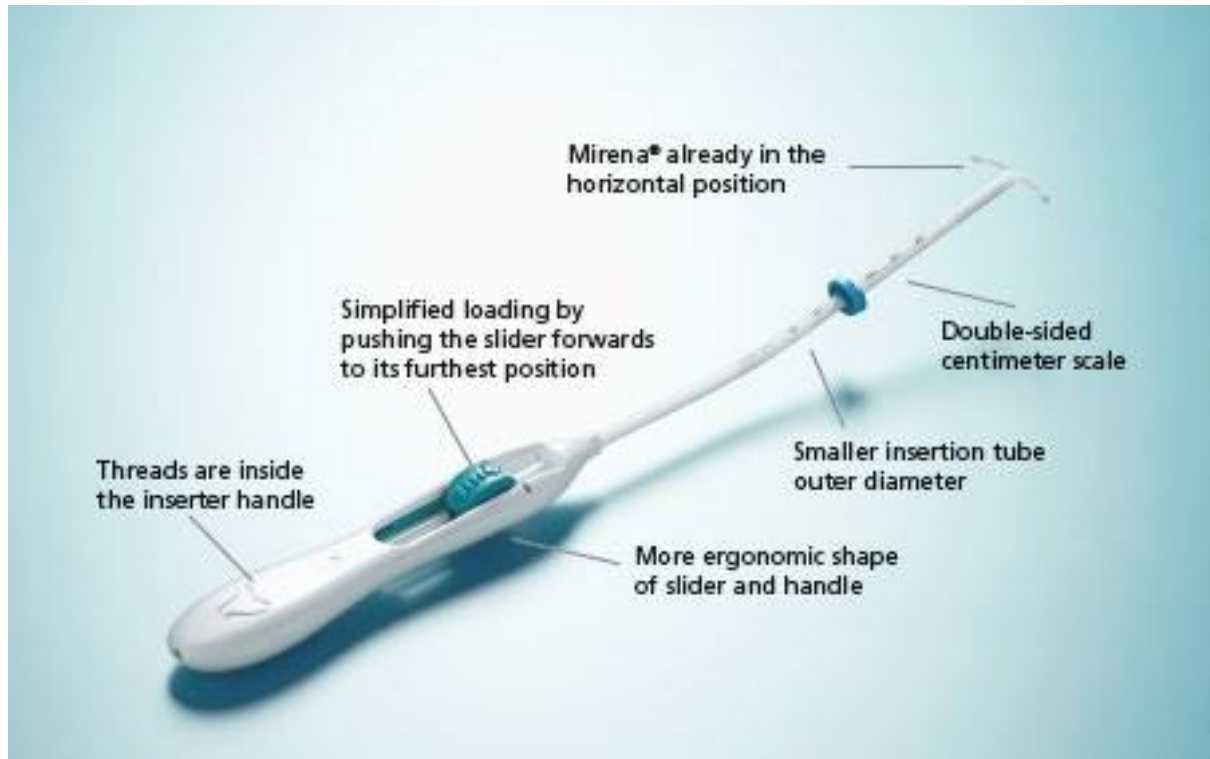
(not all indications are approved in all countries)

- // Contraception (up to 8 years);
- // Treatment of idiopathic menorrhagia (heavy menstrual bleeding without structural cause);
- // Protection from endometrial hyperplasia during estrogen replacement therapy (ERT);
- // Treatment of dysmenorrhea.





Mirena[®] - The EvoInserter[®]



EvoInserter[®]

- // was assessed to have a user-friendly design
- // is associated with a high placement success rate, ease of placement
- // may remove some concerns among HCPs about difficult placement of LNG-IUSs, thereby encouraging increased uptake of an effective contraceptive method



Training Resources: Slide Deck

Intended to provide a basis for effective training Mirena[®], covering important topics such as clinical data, counseling, placement procedure and FAQ

When Mirena is found to be low within the uterine cavity, is efficacy compromised?

Summary of evidence

- Fundal positioning of Mirena is important in order to reduce the risk of expulsion. However, there is no evidence defining the allowable distance from the fundus to ensure maximum safety and efficacy for Mirena.¹
- In one study, over half of the women who had become pregnant while using an IUC had malpositioned device (n=42).²
- In another study of women with malpositioned IUC (n=182), no pregnancies occurred with the device *in situ*.³
- The position of Mirena did not influence pain scores or bleeding patterns (n=413) suggesting these symptoms are not reliable predictors of malpositioning.⁴
- The efficacy of Mirena may be less affected by its position in the uterine cavity than is a Cu-IUD, because of the local release of progestogen. Placement of Mirena in the cervical canal did not increase risk of pregnancy relative to placement in the uterine cavity.⁵

Fundal positioning of Mirena is important to reduce risk of expulsion. Evidence for the efficacy of malpositioned devices is conflicting and minimal

Step 5: Deploy the side arms

Open the arms
While holding down to the
Wait 10 seconds completely!

How to approach counseling on IUS

Mechanism of action

LNG-IUS releases
Due to the low, mean
Studies of
have suggested
prevent pregnancy
- The
- Inf
- Su

1. Mirena Product Monograph, Bayer Inc., Mississauga, Ontario, June 14, 2019; 2. Moschos E, Twickler DM. *Am J Obstet Gynecol*. 2011;204:427.e1-427.e.6; 3. Braaten KP, et al. *Obstet Gynecol*. 2011;118(5):1014-1020; 4. Van Schoubroeck D, et al. *Eur J Obstet Gynecol Reprod Biol*. 2013;171(1):154-6; 5. Pakarinen P, Luukkainen T. *Contraception*. 2005;72(5):342-5.



Training Resources: Virtual Training Module

Provision of licences to access the online training platform

BAYER

BAYER

1 Place the tenaculum
Click "Place tenaculum" to grasp the appropriate tip of the cervix with a tenaculum forceps.
If the uterus is anteverted, the upper tip should be grasped.
For retroverted, it might be more appropriate to grasp the lower tip of the cervix.

2

3

4

5

6

7

1. Task description
2. Task list with next and back buttons to skip the steps
3. Change view of the uterus or device
4. Show or hide the interior of the uterus
5. End the simulation and get feedback report
6. Action buttons for the current task
7. Change the language

View
Lateral
Top
Oblique

Place tenaculum

End simulation

POWERED BY
VIRTAMED

BAYER

View the procedure from different perspectives

POWERED BY
VIRTAMED

BAYER

Increase understanding of key steps, including applying traction

Traction scale

POWERED BY
VIRTAMED

BAYER

Compare techniques for anteverted and retroverted uteri

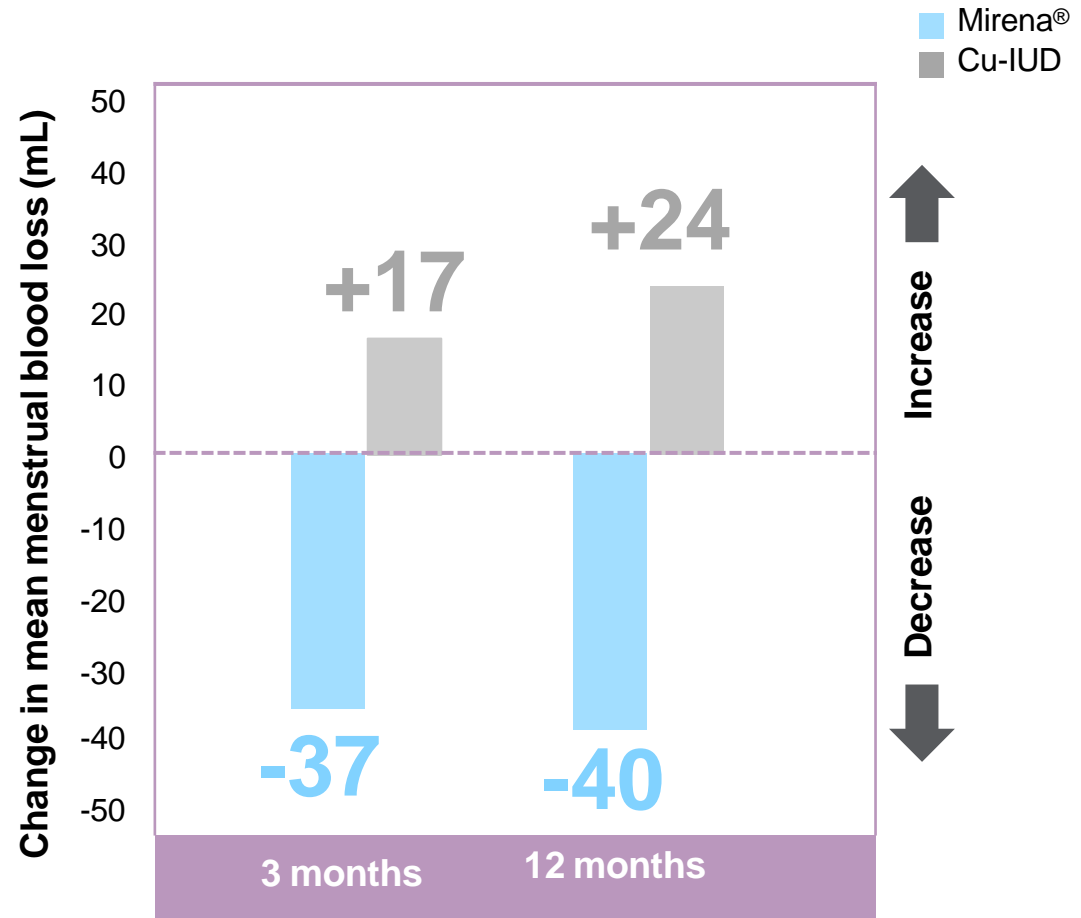
Traction scale

POWERED BY
VIRTAMED



Mirena® has a favorable bleeding profile

Menstrual blood loss progressively declines with Mirena® use, resulting in lighter periods



Scholten PC. Thesis. The Levonorgestrel IUD: clinical performance and impact on menstruation. University Hospital, Utrecht, 1989

Medicines360 and Avibela™

*Jill Keesbury, Sr. Director, Global Access, Medicines360
MDAWG and Manufacturers Group*

#RHSUPPLIES2023

Medicines®
360 ♀

Medicines360 is a nonprofit pharmaceutical organization with a mission to catalyze equitable access to medicines and devices through product development, policy advocacy, and collaboration with global and U.S. partners



AVIBELA is a hormonal IUD indicated for contraception and treatment of heavy menstrual bleeding

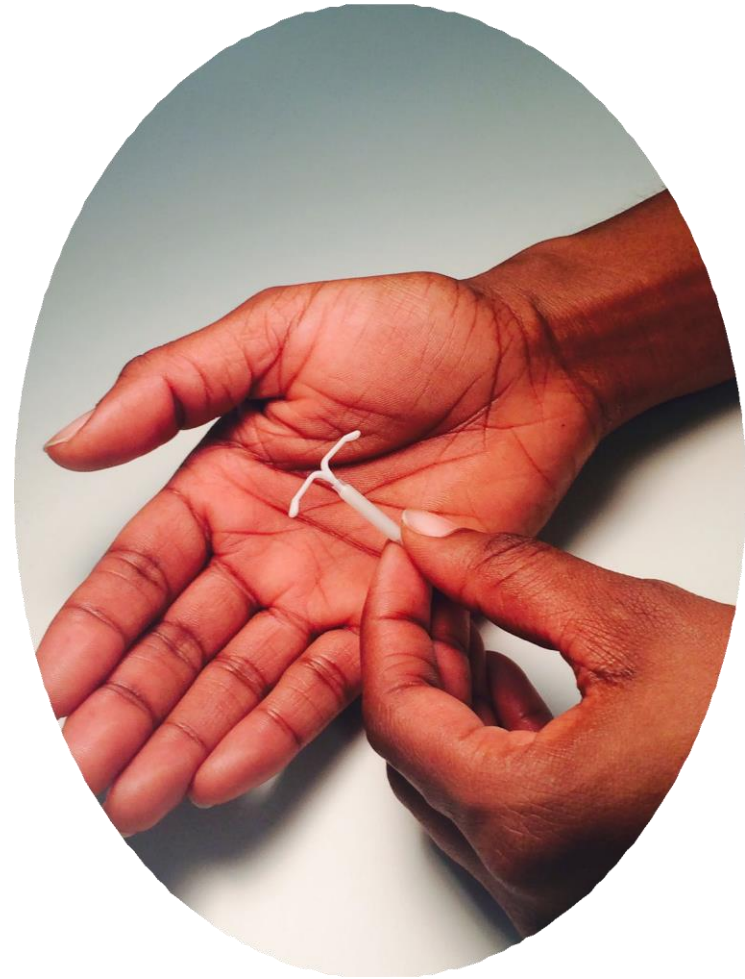


- Our IUD is approved by the U.S. FDA and 25+ other stringent regulatory authorities
- AVIBELA was one of 2 hormonal IUDs added to the global procurement catalogs in 2021
- AVIBELA can be made available in 88 countries in Africa, Central America and the Caribbean, and South and Southeast Asia
- AVIBELA is registered in 7 countries in Africa with 9 more registrations pending approval

- Duration of use: 6 years (extension to 8 years in process)
- Shelf-life: 5 years

Medicines360's goal is to build sustainable markets for the hormonal IUD

- AVIBELA's arrival on the global market in 2015 at an affordable price made the hormonal IUD a viable contraceptive option for women in LMICs
- We supply AVIBELA using a total market approach
 - Access pricing for the public sector
 - Affordable and competitive prices for the social marketing and private sectors



Medicines360 helps strengthen global and country capacity to provide hormonal IUDs

In-country research

- Introduction pilots in Madagascar, Zambia, and Tanzania (ongoing)
- FHI 360's anemia study in Kenya

Regulatory capacity-building

- Registered AVIBELA via EAC-MRH and published experience
- Developed harmonized labeling strategy; shared via RHSC webinar

Awareness generation

- Presented at HIUD Access Group webinars
- Provided informational webinars in Spanish for RHSC's ForoLAC

Training resources

- Training deck and video (EN, FR, SP)
- Nigeria-based expert clinical trainer



What's next for Medicines360 and AVIBELA?

Expanding equitable access

New AVIBELA registrations

Extending AVIBELA's duration of use from 6 to 8 years

Keeping AVIBELA affordable

Enabling affordable access through the global procurement catalogs

Reducing the cost of manufacturing to keep prices low

Prioritizing partnerships

Continued participation in HIUD Access Group to support country introduction and scale-up

Forming new global partnerships to expand AVIBELA's reach

Ashley Smith

Senior Public Health Advisor with USAID in the Office of Population and Reproductive Health, Commodity Security and Logistics Division

USAID's support for product introduction

- Availability is part of choice
- Global supply coordination
- Technical support locally



GLOBAL COMMODITY
PROCUREMENT AND
LOGISTICS



COUNTRY SUPPLY
CHAIN SYSTEMS
STRENGTHENING



GLOBAL
COLLABORATION

Procurement support to countries

- Countries and missions indicate interest
- Local introduction plan developed
- Mission places order in catalog
- GHSC-PSM procures with supplier and ships to country
- Shipment information shared in VAN
- Introduction efforts supported by technical assistance and USAID partners
- Coordination with Hormonal IUD Access Group



Introduction of long-acting family planning method to USAID Product Catalog

Home > Global Health > Health Areas > Family Planning and Reproductive Health > News and Updates > [Introduction of long-acting family planning method to USAID Product Catalog](#)

DATE: April 2021

In April 2021, the levonorgestrel-releasing intrauterine device (IUD) also known as the hormonal IUD or hormonal intrauterine system (IUS) was added to the [U.S. Agency for International Development \(USAID\)'s Product Catalog](#)¹ for the first time. This milestone was made possible thanks to support from the [Global Health Supply Chain Program: Procurement and Supply Management \(GHSC-PSM\) project](#)², working on behalf of USAID's Bureau for Global Health Office of Population and Reproductive Health Commodities Security & Logistics Division (GH/PRH/CSL), USAID's Bureau for Global Health Office of Population and Reproductive Health Research, Technology and Utilization Division (GH/PRH/RTU) and the [Hormonal IUD Access Group](#)³.

The products being introduced are MirenaTM, which is supplied by [Bayer AG](#)⁴, and AvibelTM, which is supplied by [Impact RH360](#)⁵. Both products are quality-assured by stringent regulatory authorities. With a goal of facilitating procurement and distribution in low- and middle-income countries (LMICs), USAID's [family planning priority countries](#) are eligible to procure the product through GHSC-PSM.

The hormonal IUD is a highly effective, long-acting, reversible contraceptive with important non-contraceptive health benefits. The method was first introduced in Europe in 1990 and in the United States in 2000, and it has been popular in these settings. Despite its advantages, the method has not been widely available in LMICs to date.

Globally, introduction of the [hormonal IUD](#)⁶ is being supported by the Hormonal IUD Access Group - a consortium of governments, donors, manufacturers, procurement agencies, researchers, and service delivery groups. The Hormonal IUD Access Group, which was formalized in 2020, takes a comprehensive approach to introduction and scale-up by 1) ensuring availability of affordable, quality-assured products to facilitate sustainable markets; and 2) supporting countries that are ready and willing to introduce and scale-up the method through a phased approach.



Addressing introduction challenges

- Demand creation
- Quantification for new products
- Ensuring global supply during scale up
- Provider training and system readiness
- Ensuring supply chain integrity
- Integration into data systems
- Tracking changes in method mix and new users

**Lawrence Anyanwu, Director - Reproductive Health
Nigeria Federal Ministry of Health**

Q&A

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