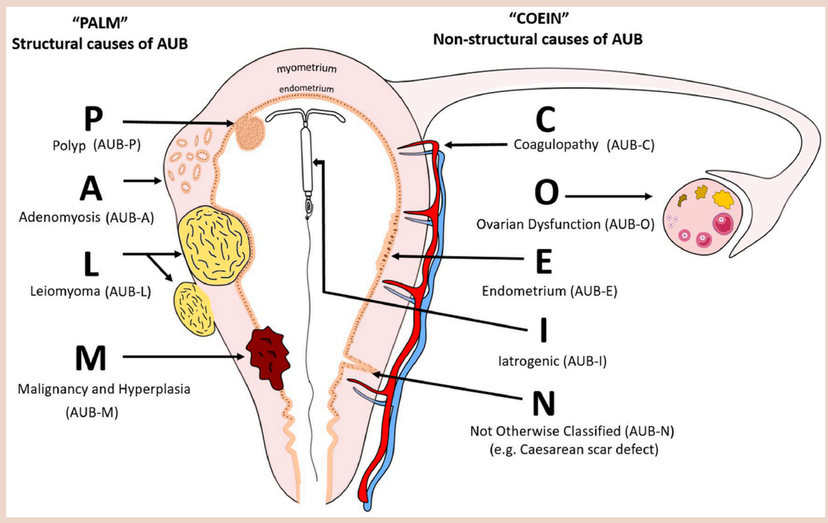
Avana Health

life sciences | women's health | femtech

Addressing a critical unmet need in uterine health that affects 1 in 3 women with a fast-acting drug + device treatment system

Problem: Abnormal Uterine Bleeding / Heavy Menstrual Bleeding (HMB)



- **Definition:** Heavy menstrual bleeding is excessive menstrual blood loss that lasts more than 7 days and/or requires changing protection more than every 1–2 hours, passes quarter-sized clots, or impairs quality of life, and is classified within PALM–COEIN to guide evaluation and treatment.
- Heavy menstrual bleeding is common and impactful, reported by up to 1 in 3 reproductive-age women when directly asked in research, and is a major contributor to iron deficiency and anemia worldwide.
- **Care gap**: Women often endure HMB for years before effective treatment due to recognition and measurement gaps that delay diagnosis and care.

33 Million

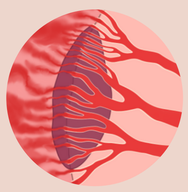
cases per year in the US alone

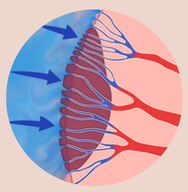
Care pathway: first-line meds (combined oral contraceptives, oral progestins, NSAIDs), levonorgestrel IUD for durable control, then procedures (endometrial ablation, uterine artery embolization, hysterectomy) when indicated based on etiology and patient goals

Equity and Access: Delayed care and higher anemia rates due to stigma, limited diagnostics, product scarcity, and specialist access gap. Disproportionate burden in low-resource settings.

Tsolova AO et al, Pre-clinical models to study abnormal uterine bleeding (AUB). eBioMedicine 2022:84:104283

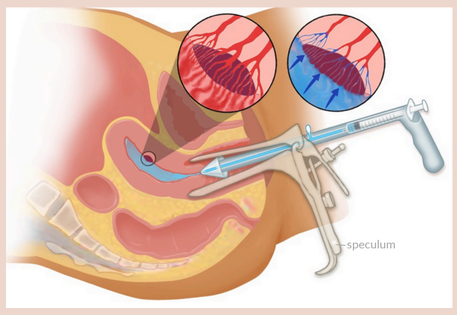
Avana Health's Treatment:
Proposed new indication for marketed hemostatic agent + novel intrauterine delivery





- Representative abnormal uterine bleeding from compromised blood vessels
- Bleeding may arise from nine causes

- **Polidocanol** (drug in blue) induces rapid closure of bleeding vessels and **stops bleeding in 3** minutes based on a well-understood mechanism
- Proposed method is intended to work only on damaged/open vessels (**regardless of AUB cause**) and not to impact healthy, non-bleeding tissue



Polidocanol has not been used previously for intrauterine application as there was not an effective way to deliver it. Until now:

- Polidocanol (blue) quickly collapsing damaged vessels in 3 minutes
- **Proprietary device provides intrauterine delivery at optimal pressure and fluid-tight seal**

Polidocanol is off-patent; Avana has filed patents to protect the drug + device system, plus method of use.

Expanding Access and Addressing Gaps in Care: Acute HMB

- **No regulatory-approved therapy for Acute HMB**; current practice relies on off-label treatment options
- **Target performance goals:** achieve **hemostasis in 3 minutes**, compared to the hours- to-days it takes with current options
- **Single intrauterine administration** under evaluation, in contrast to IV infusions followed by multi-day oral regimens often used today.

Target Advantages:	
Stops bleeding in 3 minutes	Non-hormonal
Single intrauterine dose (vs IV infusion + multi-day oral dose)	**Easy to use for doctors, nurses, and nurse midwives**
Preserves fertility	May prevent surgical interventions (e.g., ablation, hysterectomy)

Key Milestones Reached and Validation of Avana's Strategy

- **Pre-existing Data/ Commercial Use**
- **Demonstrated Preclinical Proof of Concept**
- **Filed Patents**
- **Assembled World Class Advisory Board**
- **Created 5-Year Clinical Dev. Plan**
- **Developed Device Prototype**
- **Phase 1 Clinical Trial Completed**
- **Peer-reviewed Publication ACOG's O&G Open Journal**


Clinical Perspective
Understanding Acute Heavy Menstrual Bleeding: Insights From an Interdisciplinary Panel

Established Clinical Use

Current Human Use

- 50+ years in EU, 12 in US market
- Approved for commercial use in 32+ countries
- Polidocanol Market Approvals to Treat:
  1. Acute esophageal bleeding
  2. Varicose veins
  3. Hemorrhoids

Preclinical and Translational Evidence Driving Innovation

- **Wide safety margin for acute use**
- **Negative genetic toxicity**
- **Reproductive and developmental:** No teratogenicity and no adverse effects on fertility.
- **NHP intrauterine** studies show normal histology and labs, with pregnancies progressing to term.
- **PK profile:** Rapid distribution, no BBB penetration, **T1/2 is 1.5 hours**.
- **Local effects:** targeted MOA to vascular endotheliam
- **Stability:** Stable for for 3 years at RT.

HPLC-MS assay developed to quantify pharmacokinetics
Demonstrated proof of concept- Efficacy of Polidocanol when applied directly to uterine bleeding in sheep

- **Treated sites: profuse bleeding stopped within 3 minutes**
- **Safety: No harm to non-bleeding, healthy tissue**
- **Saline Control: profuse bleeding continued unabated**

Advancing Clinical Pipeline in Women's Health

Preliminary Phase 1 Findings from AUB/HMB Study

Bioavailability: <12% Systemic Circulation. Most Polidocanol is limited to local application
Safety: transcervical delivery of 1% polidocanol is well tolerated
Efficacy: Numerical decrease in PBAC scores with polidocanol treatment compared to placebo

Next steps:

- **Multinational Phase 2** trial in HMB
- **Raising next round** to support these milestones, Lead investor secured
- **Pipeline Indication: Postpartum Hemorrhage**

Connect with us

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