HITLAB

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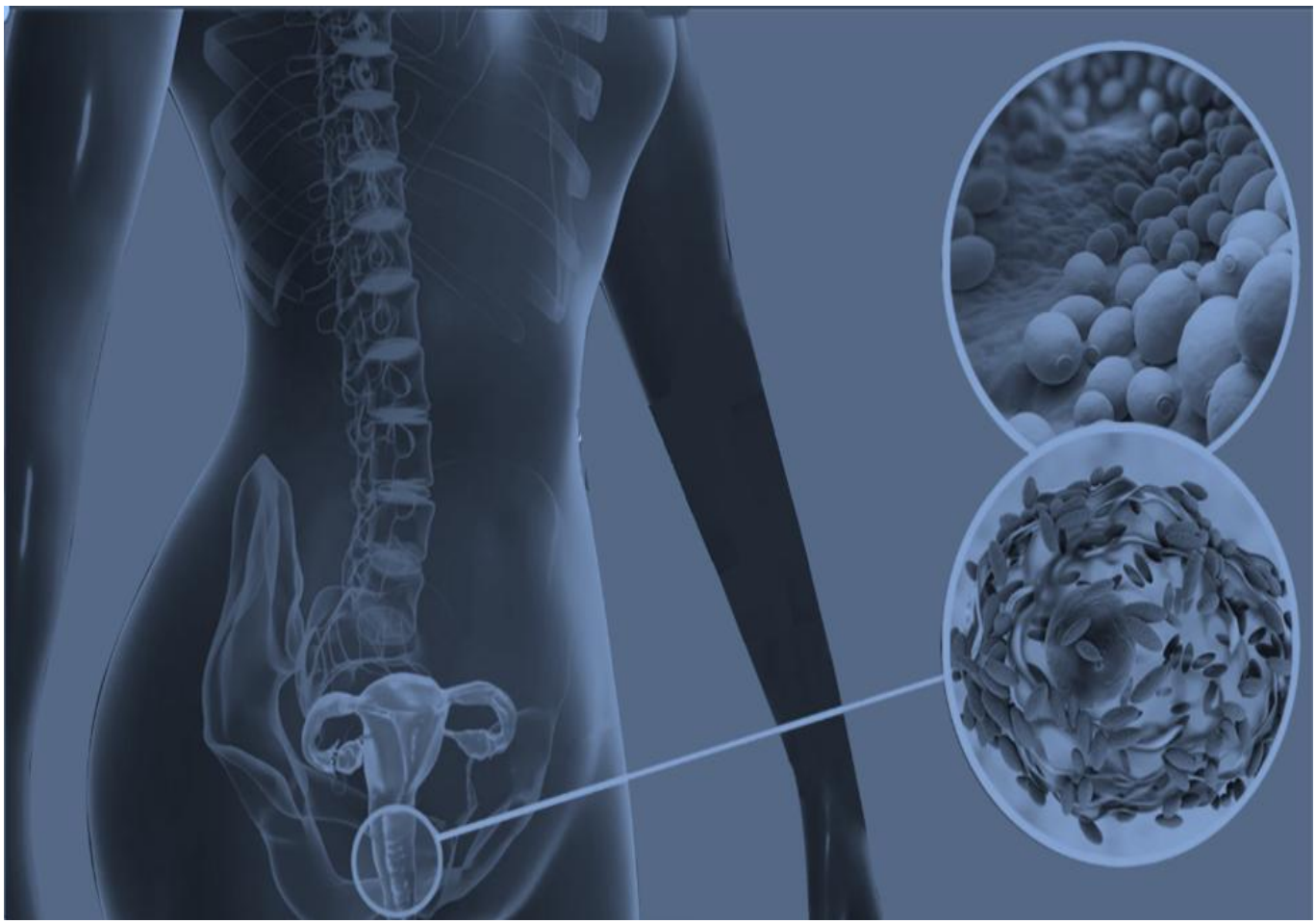
Rethinking Vaginitis Management: Cern Corporation's Non-Drug Innovation in the Treatment of Yeast & Bacterial GYN Infection



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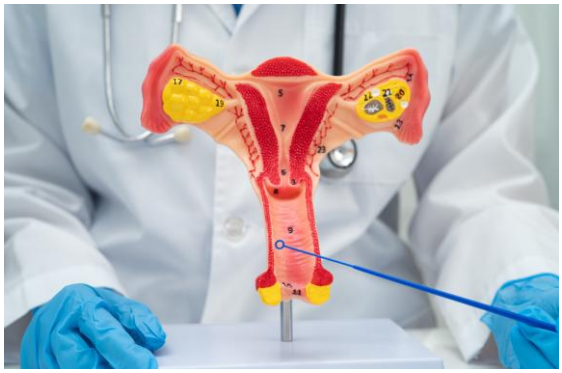
Executive Summary

This white paper, curated and reviewed by HITLAB, is an independent, evidence-based report of the CERN Device™, which is an emerging therapeutic innovation in women's health. With HITLAB's expertise in digital health innovation, usability research, medical devices value proposition, and clinical validation, this paper assesses the device's safety, mechanism of action, and potential clinical value in the management of recurrent bacterial vaginosis (BV) and vulvovaginal candidiasis (VVC) based on the evidence studies conducted.

The paper talks about the challenges that the CERN Device™ addresses within the broader landscape of vaginitis care, by highlighting persistent gaps related to antimicrobial resistance, biofilm-driven recurrence, microbiome disruption, and patient quality of life. It further demonstrates how the CERN Device™ proposes a non-drug, microbiome-preserving, home-use therapeutic model that aligns with modern, patient-centered care pathways. It validates clinical promise, may complement or, in select cases, reduce reliance on traditional antibiotics and antifungals.

Importantly, HITLAB identifies the device's user-friendly care at home potential to support safer long-term management, improve adherence, and telehealth integration. This contributes to more sustainable healthcare delivery, positioning the CERN Device™ as a forward-looking solution in an area of substantial unmet clinical need.



CERN Device highlights a dual value proposition: improving women's quality of life while reducing long-term healthcare burden associated with recurrent infections, repeated prescriptions, and downstream complications. As women's health moves toward precision, prevention, and personalization, the CERN Device™ stands as a compelling example of how thoughtful, evidence-based innovation can reshape the future of gynecologic care.

KEY TAKEAWAY

HITLAB affirms that the CERN Device™ exemplifies its evidence-based innovation, transforming gynecologic care, by pioneering microbiome-friendly solution to alleviate unmet needs in vaginitis management. The device delivers safer, sustainable outcomes for women for recurrent infections and reduces antibiotic overuse.

1 The Persistent Burden of BV and VVC

Vaginal infections are among the most common gynecologic conditions affecting women of reproductive age, contributing substantially to morbidity and healthcare utilization globally. Bacterial vaginosis (BV) and vulvovaginal candidiasis (VVC) are the two most prevalent causes of vaginitis, accounting for the majority of clinical cases.

In the United States, more than 10 million outpatient visits are made annually for vaginitis.[1] Out of which, BV accounts for 50%, while VVC contributes 20%–25% of the cases, and 20–25% other forms.[1] Almost 29% of U.S. women aged 14–49 years are estimated to have BV once or more times,[2] with more than 50% experiencing recurrence within 6–12 months after standard antibiotic therapy.[3] Similarly, about 53% of U.S. women report a lifetime diagnosis of VVC,[4] with an annual incidence of approximately 5.2% for clinically diagnosed cases.[4]

BV is characterized by disruption of the vaginal microbiome, with depletion of Lactobacillus species and overgrowth of anaerobic bacteria. It is associated with adverse reproductive outcomes, including preterm birth and increased susceptibility to sexually transmitted infections, including HIV.[5]

It is associated with adverse reproductive outcomes, including preterm birth and increased susceptibility to sexually transmitted infections, including HIV.

VVC, most commonly caused by Candida albicans, is similarly widespread. Globally, recurrent VVC affects an estimated 138 million women annually, with approximately 372 million affected over their lifetime.[6]. Prevalence is highest among women aged 25–34 years (approximately 9%),[6] and the annual global burden is projected to rise to nearly 158 million cases by 2030.[6]

Collectively, BV and VVC represent a major source of gynecologic morbidity. Their high prevalence, frequent recurrence, and substantial economic and quality-of-life impacts highlight the need for improved prevention, diagnosis, and long-term management strategies.

2 Disease Pathophysiology and Therapeutic Limitations

Bacterial vaginosis (BV) and vulvovaginal candidiasis (VVC) are among the most common vaginal health infections affecting women of reproductive age, accounting for the majority of vaginitis-related clinical visits. Despite their high prevalence, effective long-term management remains limited, particularly for women with recurrent or treatment-resistant disease.

BV and VVC are increasingly understood as a disruption of protective Lactobacillus-dominant flora depletes (<5% dominance), allowing pathogenic bacteria or Candida species to proliferate (Gardnerella 40-72%, Prevotella, Atopobium), which produce foul discharge, disrupting the mucosa. It forms biofilms, contributing to treatment failure and recurrence. [7], [8],

VVC is mainly caused by *Candida albicans* (85-95% cases) hyperproliferation triggered by antibiotics, estrogen, and diabetes, forming biofilms resistant to antifungals.

The standard antibiotic and antifungal therapies for these infections provide short-term symptom relief but may further disrupt microbial balance, contributing to high recurrence rates and growing antimicrobial resistance [9], [10],.

This calls for an urgent need for non-antibiotic, microbiome-preserving therapies to manage vaginitis and its recurrence that address the underlying drivers of vaginitis.

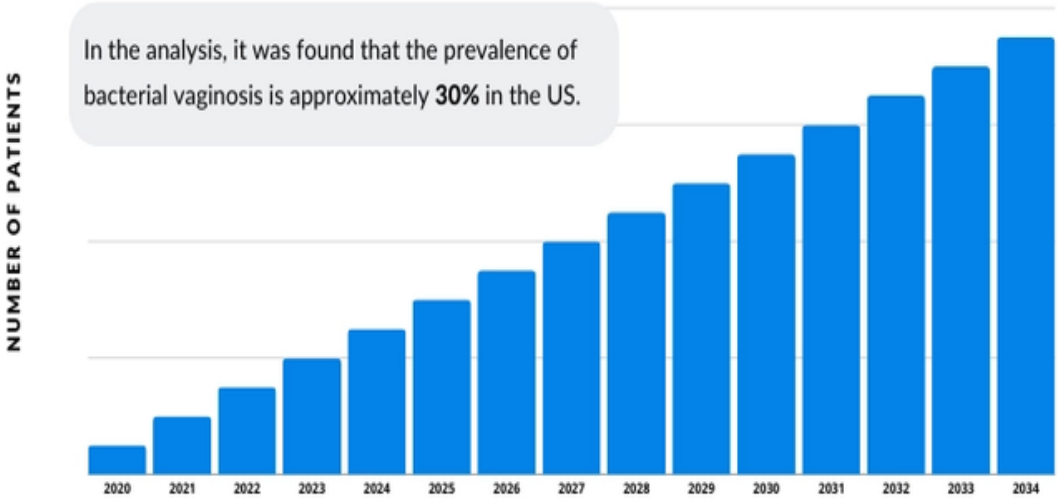


Figure 1: Bacterial Vaginosis Epidemiology Source: Delveinsight Bacterial vaginosis insight report

3 High Recurrence Driving Significant Economic Burden

Globally, BV affects approximately 23%–29% of women, with an estimated annual treatment cost of USD 4.8 billion; in the United States, this burden nearly triples when BV-associated preterm births and HIV infections are included[11].

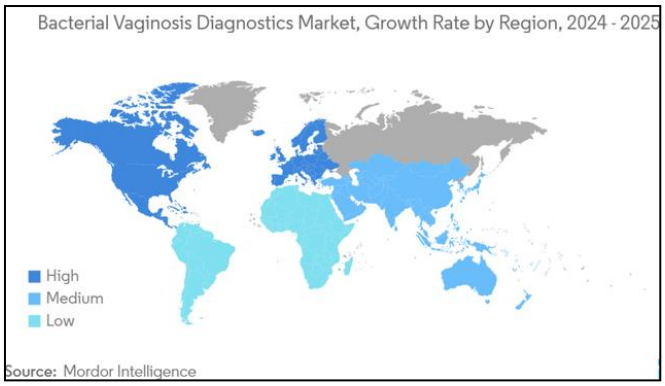


Figure 2: Bacterial Vaginosis Epidemiology Diagnostic market Growth rate: Global Comparison

RECURRENCE AMPLIFIES ECONOMIC IMPACT

Recurrence rates of 50–60% within 12 months for BV and 5–8% for recurrent VVC increase per-patient costs, with annual healthcare expenditures of approximately ~USD 8,900 per patient in women with recurrent BV [9, 11, 12].

DIRECT HEALTHCARE EXPENDITURES

The estimated annual direct medical cost of BV exceeds USD 1.3 billion, driven by diagnostic testing, repeated clinical visits, and antimicrobial prescriptions[12]. VVC treatment costs contribute an additional USD 368 million per year in direct healthcare spending [13].

STRAIN ON MEDICAID AND PUBLIC PAYERS

BV prevalence is higher among women of lower socioeconomic status, leading to disproportionate utilization of Medicaid-funded services, including OPDs, diagnostics, and pharmacy claims [14].

OVERALL IMPACT

Indirect costs from lost productivity, work absenteeism, and reduced quality of life—particularly in recurrent VVC—further increase the economic burden and place downstream pressure on Medicare and Medicaid budgets due to complications, comorbidities, and long-term care needs [12,15].

4 Challenges in Current Management

High Prevalence of Recurrence

- BV and VVC have shown high recurrence rates, despite standard antimicrobial therapy.
- Around 50–70% of women experience BV recurrence within 6–12 months following treatment with metronidazole or clindamycin [16, 17].
- Recurrent vulvovaginal candidiasis (RVVC), defined as ≥4 episodes per year, affects ~9% women, with increased recurrence risk over time [18, 19].
- The prolonged maintenance therapy can suppress symptoms, with 40–50% relapse after discontinuation, highlighting persistent treatment limitations and concerns around resistance, cost, and adherence[20, 21].

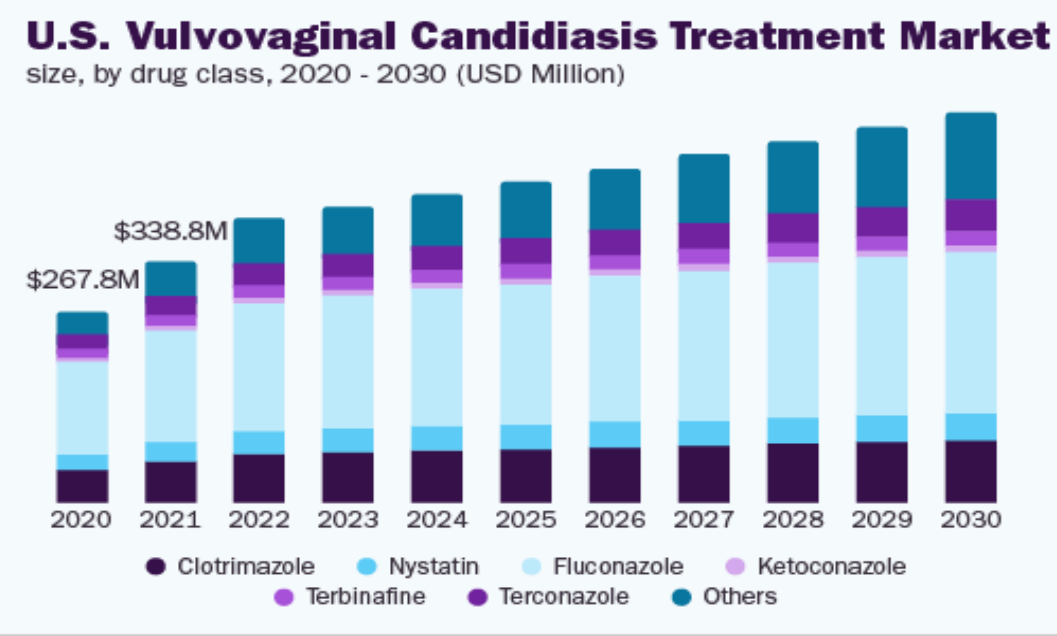


Figure 3: US VVC treatment Market (2020-2030) in USD Million

Biofilm Formation and Persistence

- Biofilm formation is a central driver of treatment resistance and recurrence in both BV and VVC.
- BV-associated bacteria, particularly Gardnerella vaginalis, form dense polymicrobial biofilms on the vaginal epithelium that resist antibiotic penetration and immune clearance, enabling persistence despite apparent clinical resolution[7,22].
- Similarly, Candida species form structured biofilms with reduced antifungal susceptibility, which may sometimes need up to 1000-fold higher drug concentrations for eradication compared to planktonic cells [8,23].

Challenges in Current Management

Antimicrobial Resistance and Complex Pathogens

In VVC, antimicrobial resistance is increasingly observed among non-albicans *Candida* species, particularly *C. glabrata*, demonstrating reduced susceptibility to first-line azole therapies[24]. In women exposed to repeated or prolonged antifungal treatment, Fluconazole resistance in *C. albicans* has also been reported[25]. The antibiotic resistance is not yet a dominant clinical challenge in BV; concerns persist regarding repeated antimicrobial exposure. The global emergence of multidrug-resistant *Candida auris*, although primarily healthcare-associated, underscores the broader risk of escalating antifungal resistance[26].

Constraints in VVC Treatment

Management of VVC relies predominantly on azole antifungal therapies, with limited effective alternatives for azole-resistant or non-albicans *Candida* species[27]. Treatment failure is common in recurrent cases. Long-term suppressive regimens are often required, increasing concerns around resistance, adherence, and cost[12]. Therapeutic options are constrained during pregnancy, as oral azoles are contraindicated, leaving extended topical therapies with reduced efficacy[25]. The lack of therapeutic and resistance-aware strategies represents an unmet clinical need.

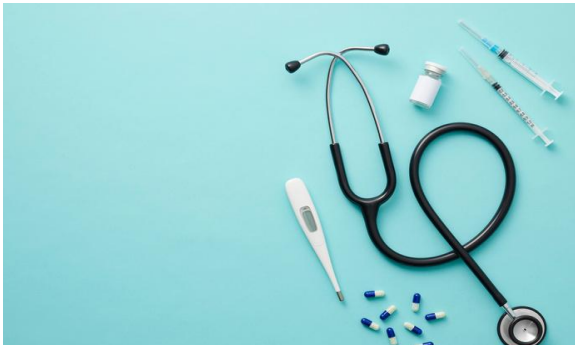
Limitations of Current BV Therapies

Standard antibiotic regimens for BV had cure rates of 70–90%, yet recurrence remains high, and treatment options are largely limited to metronidazole and clindamycin[9]. These antibiotics disrupt the vaginal microbiome by reducing protective *Lactobacillus* species, impairing restoration of healthy flora, and perpetuating dysbiosis[10]. Systemic side effects, particularly with oral metronidazole, further limit adherence and tolerability [28]. Yet no approved therapies directly target BV-biofilms to restore vaginal ecology.

Challenges in Current Management

Absence of Microbiome-Restorative Approaches

BV is recognised as a dysbiotic condition; evidence-based microbiome-restoration therapies are not widely available. Probiotics show inconsistent benefit due to heterogeneity in strains, dosing, and study design[29, 30], limiting clinical adoption[31]. Experimental approaches such as vaginal microbiome transplantation remain investigational[32]. For VVC, probiotic evidence is even weaker, contributing to persistent recurrence[33].

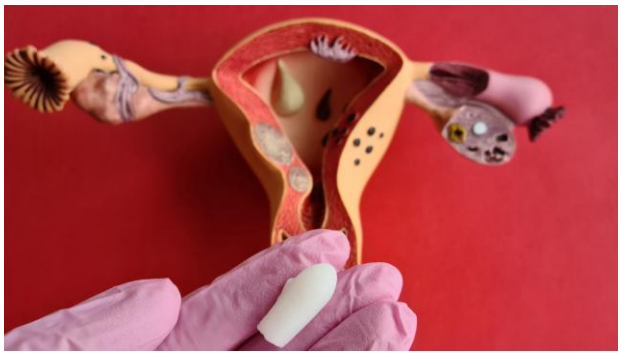


Diagnostic Gaps and Misclassification

Current BV diagnostics (Amsel criteria, Nugent scoring) are not universally accessible, and molecular testing may not correlate with symptoms, leading to overtreatment or missed diagnoses[35, 36]. VVC is frequently self-diagnosed, with accuracy rates of 50–60%, resulting in inappropriate antifungal use and delayed diagnosis [37, 38].

Constraints in VVC Treatment

Recurrent or untreated BV is associated with increased susceptibility to STIs, including HIV, and serious reproductive complications such as preterm birth and pelvic inflammatory disease [34, 35]. While VVC is less likely to cause systemic complications, recurrent disease significantly impairs quality of life and sexual health[12].



Psychosocial Burden and Quality-of-Life Impact

BV and RVVC impose a significant psychosocial burden, including anxiety, depression, sexual dysfunction, and reduced quality of life, which are often overlooked in clinical care [39, 40]. Women with BV frequently report stigma, shame, and avoidance of intimacy, while those with RVVC describe frustration, helplessness, and fear of recurrence, adversely affecting mental health, self-esteem, and daily functioning, thereby affecting the overall quality of life[39,41].

5 Persistent Unmet Needs in Vaginitis Care

Microbiome disruption and recurrence

Conventional and standard antibiotic and antifungal therapies disrupt protective Lactobacillus species, contributing to >50% recurrence of bacterial vaginosis within 12 months[42, 43].

Limited non-drug alternatives

Despite >10 million vaginitis-related cases annually in the U.S., validated non-pharmaceutical treatment options remain limited[44].

Biofilm-driven persistence

Pathogen biofilms significantly reduce treatment effectiveness and are a major contributor to persistent and recurrent infections, yet targeted biofilm-disruptive therapies are lacking[45].

Lack of patient-friendly, home-based care

Recurrent vulvovaginal candidiasis affects ~138 million women globally each year, highlighting the need for safe, effective at-home treatment solutions[46].

Inadequate personalized diagnostics

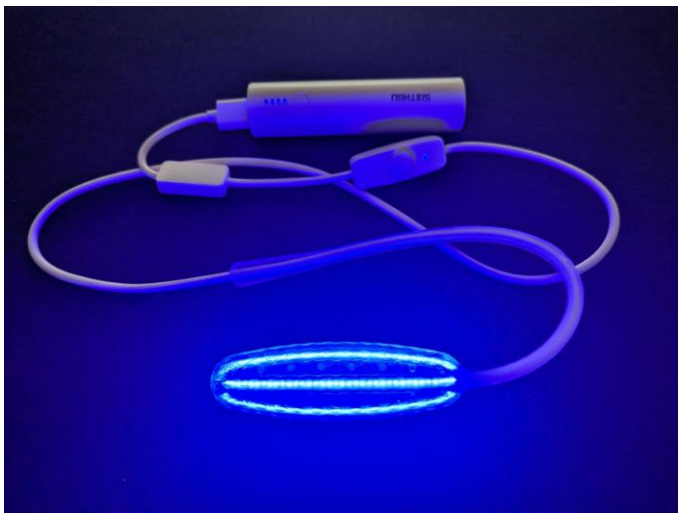
Up to 50% of vaginitis cases are misdiagnosed due to symptom-based assessment, underscoring the need for microbiome-informed diagnostics [43].

Recurrence Prevention

Long-term Treatment or therapy to prevent relapse of BV and VVC has been a persistent need for management.

6 CERN Device: Purpose-Built Innovation for High-Impact Clinical Needs

- Cern Corporation, Inc. is a medical technology company based in Southern California, developing a non-drug therapeutic solution for vaginal infections like fungal vaginitis and bacterial vaginosis.
- Their core innovation, The CERN Device™, is designed as a science-based, non-pharmaceutical alternative to standard drug therapies.
- The device represents an ergonomically designed intravaginal light-delivery deviceinnovative, home-based, non-pharmaceutical approach, a home-based, non-drug, intravaginal medical device for managing vaginitis, including bacterial vaginosis (BV) and yeast/fungal vaginitis (i.e., vulvovaginal candidiasis).
- It leverages low-level microbicidal visible light technology combined with a natural photosensitizer gel to address persistent vaginal infections while minimizing disruption to the protective vaginal microbiome.



DEVICE PARTS

- Single-use hygienic Packaging of natural photosensitizer gel (which is a combination of water-soluble formulation, including natural photodynamic agent and lubricant and carrier is provided in individual-use foil packs
- Power and Control Unit, which regulates light intensity, wavelength, and treatment duration

Figure 4: The images above show the CERN Device™ with a charging case and the gel in a tube

7 Mechanism of Action and Therapeutic Rationale

Low-Level Microbicidal Visible Light

- Operates in the safe visible light spectrum
- Delivers low-level effective light that is effective yet tissue-friendly

Reactive Oxygen Species (ROS) Generation

A natural photosensitizing gel enhances light energy to interact with pathogen cell membranes, generating reactive oxygen species (ROS) that disrupt DNA and cellular replication, leading to cell death.

Selective Pathogen Control

- Effective against key pathogens associated with vaginitis, including *Candida* species (yeast) and *Gardnerella vaginalis* (bacterial vaginosis)
- Reduces pathogenic dominance without sterilizing the environment

Microbiome Preservation

- Designed to minimize impact on beneficial *Lactobacillus* species
- Supports maintenance of healthy vaginal flora

Restoring Balance: Dysbiosis → Symbiosis

- Addresses dysbiosis, where yeast or bacteria overgrow and cause infection
- Promotes a return to symbiosis, where naturally occurring bacteria and yeast coexist at healthy levels

8 The Expertise Driving CERN's Breakthrough

THE TEAM

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Reimbursement Advisor

Backed by 220+ years of combined expertise, our leadership team bridges patient care, breakthrough science, and scalable medical device commercialization

- Urogynecology, Infectious disease (GYN bacterial & fungal pathology)
- Genetics, cell biology & biotech R&D
- OB/GYN surgical leadership
- FDA & regulatory strategy for medical devices
- Medical device engineering & product development
- Microbiology & fungal pathogenesis

9 CERN's Differentiators: Where Science Meets Commercial Impact

- **Microbiome-Conscious Design** to selectively reduce pathogenic bacteria and fungi while preserving beneficial Lactobacillus species, supporting restoration of healthy vaginal balance.
- **Non-Drug, Localized Therapy:** Provides localized treatment without systemic drug exposure, reducing risks associated with antibiotics and antifungals, such as side effects and microbiome disruption.
- **Safe Visible-Light Mechanism:** Uses Low Level, Visible Spectrum, Microbicidal Bluelight— not UV, providing microbicidal activity with a strong safety profile for mucosal tissue.
- **Designed for Home Use with Clinical Oversight:** Prescription-based system enables at-home treatment while supporting telehealth monitoring and clinician supervision, improving access and adherence.
- **Controlled & Consistent Treatment Delivery:** Precisely calibrated LED output and exposure time ensure repeatable, predictable dosing across treatment sessions
- **Biocompatible, Medical-Grade Materials:** constructed from validated biocompatible materials designed for intravaginal use, comfort, and repeated cleaning without degradation.
- **Evidence-based Development:** Supported by in vitro, ex vivo, and in vivo (animal) studies, demonstrating safety, selectivity, and effectiveness, including against drug-resistant pathogens.

Table 1: Comparison of Therapeutic Approaches with CERN Medical Device

Differentiator Categories	Antibiotics	Probiotics	CERN
Drug-free	No	Yes	Yes
Biofilm Addressing	No	No	Yes
Microbiome-safe	No	Inconsistent	Yes
Home-use	Sometimes	Yes	Yes
Resistance risk	High	Low	None

10 Evidence from Preclinical Studies

- The CERN Device™ has generated robust evidence through evidence synthesis research, encompassing in vitro, ex vivo, and in vivo studies. These studies were designed to evaluate the device's:
  - antimicrobial efficacy,
  - microbiome selectivity,
  - tissue safety, and
  - Overall biological compatibility.

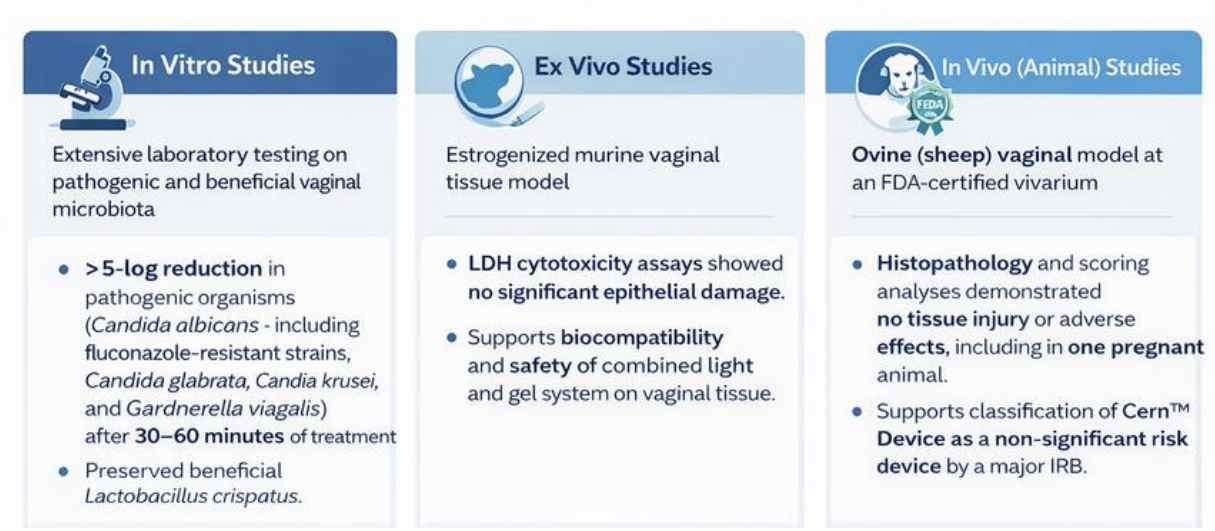


Figure: Evidence Synthesiss studies conducted for CERN Device™

In-Vitro Study

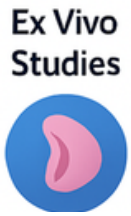
In vitro testing encompassed a broad range of pathogenic and beneficial vaginal microorganisms, including *Candida albicans* (with fluconazole-resistant strains), *Candida glabrata, Candida krusei,* and *Gardnerella vaginalis*.

Treatment resulted in a >5-log reduction of pathogenic species within 30–60 minutes, while preserving the integrity of beneficial *Lactobacillus crispatus*.

The findings demonstrate the device’s selective, broad-spectrum antimicrobial efficacy, including activity against drug-resistant organisms, while maintaining microbiome balance.

Evidence from Preclinical Studies

The EX-Vivo Study



Objective: To evaluate the potential cytotoxic effects of low-level visible blue light used with a natural photosensitizer on estrogenized murine vaginal tissue.

The assessment aimed to confirm tissue safety of the photodynamic treatment under worst-case exposure conditions, and a range of natural photosensitizer concentrations . Cytotoxicity was measured using a lactate dehydrogenase (LDH) release assay, with *Candida albicans*–infected tissue serving as a positive damage.

The study demonstrated no measurable cytotoxicity across all tested conditions. Vaginal tissues exposed to a natural photosensitizer with LED light activation showed LDH levels comparable to untreated controls and significantly lower than *Candida albicans*–infected tissues.

In-Vivo Study

Objective: To evaluate the effects of the Cern™ intravaginal device, which emits low-level visible blue light in combination with a natural photosensitizer-based photosensitizing lubricant, on vaginal mucosal tissue.

Four adult ewes, including one pregnant animal, were treated daily for five consecutive days with one hour of exposure, reflecting intended clinical-use conditions.

The study demonstrated that repeated intravaginal exposure to the CERN Device™ and its photosensitizing lubricant is well tolerated by vaginal mucosal tissue under clinically relevant conditions. The absence of tissue injury, inflammation, or behavioral distress supports the device's favorable safety profile and its classification as a non-significant risk device.

11 Evidence from Active Human Clinical Trials

The trial is registered on ClinicalTrials.gov as NCT06933420, titled “Phototherapy Device for the Treatment of Bacterial Vaginosis and Vaginitis.”

Objective

Primary Objective:
Establish the safety of the Cern™ Medical Device in premenopausal women with symptomatic vaginitis.

Secondary Objective:
Evaluate the clinical effectiveness of the device in treating symptomatic vaginitis, including yeast infections and bacterial vaginosis

Study Design

- First-in-human, single-arm study in premenopausal women with vaginitis (yeast/BV).
- Up to 60 participants; same-day screening to treatment.
- CERN Device™ treatment as per instructions for 5 days (60 min/session).
- 45-day follow-up with testing and weekly calls.

Preliminary Findings

- 76% showed clinically meaningful improvement.
- Symptom relief seen as early as 1 session, commonly by day 3.
- No significant adverse events; mild warmth reported, often soothing.
- Supports safety & efficacy of CERN Device™ for BV and fungal vaginitis.

Future Vision: Connected, Accessible Care

CERN Device™ aims to advance this therapy into a telemedicine-enabled platform by integrating sensors and Bluetooth connectivity to transmit real-time data to users’ smartphones and healthcare providers for remote monitoring and consultation. The goal is to bridge critical healthcare gaps, improving access to timely care for underserved populations.

12 Conclusion

The Worldwide healthcare systems confront rising antimicrobial resistance, high recurrence rates of vaginitis, and growing dissatisfaction with drug-dependent care; innovations like the CERN Device™ are increasingly essential.

The CERN Device™ offers a promising alternative by bridging the gap between antimicrobial efficacy and microbiome preservation. It introduces a non-pharmacologic mechanism that targets pathogenic organisms by combining low-level visible blue light with a photosensitizer and biofilms, while sparing beneficial bacteria.

The early clinical experience suggests not only symptom improvement and high patient acceptance, but also the potential to reduce recurrence, minimize systemic side effects, and preserve vaginal ecological balance. With further controlled clinical trials and real-world validation, the CERN Device™ highlights a dual value proposition: improving women's quality of life while reducing long-term healthcare burden.

Importantly, the HITLAB-led evaluation reinforces the credibility, highlighting CERN's usability, safety profile, and alignment with emerging priorities in women's health innovation toward precision, prevention, and thoughtful, evidence-based innovation can reshape the future of gynecologic care.

> *"CERN device represents a shift in how we think about treating vaginitis—moving from repeated drug exposure toward targeted, localized, microbiome-aware therapy. Its approach aligns with modern science and patient-centered care."*
>
> ***— Stan Kachnowski, Chair, HITLAB***

13 Abbreviations Used

S.No	Full-Form	Abbreviation
1	Bacterial Vaginosis	**BV**
2	Carboxymethyl cellulose	**CMC**
3	Human Immunodeficiency Virus.	**HIV**
4	Lactate dehydrogenase	**LDH**
5	Light Emitting Diode	**LED**
6	Outpatient Departments.	**OPDs**
7	Reactive oxygen species	**ROS**
8	Recurrent vulvovaginal candidiasis	**RVVC**
9	Sexually Transmitted Infection	**STI**
10	United Stated Dollar	**USD**
11	United States	**U.S.**
12	Ultra-violet	**UV**
13.	Vulvovaginal candidiasis	**VVC**

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