

MIUDELLA[®] Hormone-Free Copper Intrauterine System (IUS) Phase 3 Data Publication in *Contraception* Honored with Daniel Mishell, Jr. MD Outstanding Article Award at Society of Family Planning Annual Meeting

Study Investigators David K. Turok, MD, MPH and Mitchell Creinin, MD Honored at the Society for Family Planning Annual Meeting In Pittsburgh

ROSWELL, GA, October 27, 2025 – Sebela Women’s Health Inc., a part of Sebela Pharmaceuticals, today announced that the journal *Contraception* has awarded the publication of Phase 3 data of MIUDELLA[®] (copper intrauterine system) one of the Daniel Mishell Jr., MD Outstanding Article Awards for 2025.¹ The data publication and the award were presented at the annual meeting of the Society of Family Planning in Pittsburgh.

The Daniel Mishell Jr., MD Outstanding Article award is given yearly in recognition of “remarkable peer-reviewed research” by the Editors and Editorial Board of *Contraception*, saluting works having a unique and important impact in the field of family planning.² Daniel Mishell Jr., MD founded *Contraception* and was the editor for more than 43 years, and his pioneering work in contraception research has favorably influenced family planning care globally.³

“Sebela Women’s Health is honored that the MIUDELLA publication is being recognized by *Contraception* as an important contribution to the contraceptive literature, and we extend our thanks to Phase 3 Study Principal Investigator David K. Turok, MD, MPH, and the article’s lead author Mitchell Creinin, MD -- as well as to the entire Copper 175mm² IUD Phase 3 Clinical Investigator Group -- and the women nationwide who were involved in the study,” said Kelly Culwell, MD, Head of Research and Development, Sebela Women’s Health.

Culwell continued: “Sebela is particularly thrilled, as MIUDELLA was also recently named by TIME editors and correspondents worldwide to TIME’s List of the Best Inventions 2025.”

David K. Turok, MD, MPH is Professor and Director of the ASCENT Center for Reproductive Health, Department of Obstetrics and Gynecology, University of Utah, School of Medicine, Salt Lake City, UT; and Mitchell Creinin, MD, is a Distinguished Professor, Director, Complex Family Planning Fellowship, Department of Obstetrics and Gynecology, University of California Davis Health, Sacramento, CA.

“I’m delighted to have been part of making the first hormone-free IUD in the U.S. in over 40 years a reality,” said Dr. Turok . “Providing a safe and effective long-term, low-dose copper birth control option that utilizes a flexible nitinol frame is a step forward for women, particularly considering the low rates of expulsion and discontinuation for bleeding and pain-related symptoms seen in the study.”

¹ Creinin MD, Gawron LM, Roe AH, et al.: Copper 175mm² IUD Phase 3 Clinical Investigator Group. Three-year efficacy, safety, and tolerability outcomes from a phase 3 study of a low-dose copper intrauterine device. *Contraception*. 2024 Nov 22:110771. doi: 10.1016/j.contraception.2024.110771.

² *Contraception*, accessed on Oct. 9, 2025, <https://www.contraceptionjournal.org/content/outstanding-article-award>,

³ Jenny M. Jaque, David A. Groneberg, Doris Klingelhöfer, Dörthe Brüggmann: Five decades of contraception research – The legacy of Daniel R Mishell Jr. *Women’s Studies International Forum*, Volume 77, 2019: 102293. ISSN 0277-5395, <https://doi.org/10.1016/j.wsif.2019.102293>.



In addition to Dr. Turok accepting the outstanding article award on behalf of the authors, Dr. Creinin was also awarded the Society of Family Planning Lifetime Achievement Award at the meeting, recognizing those who have dedicated their careers to the science of contraception, and have supported others in achieving their own success.⁴

“Sebela Women’s Health would also like to congratulate Dr. Creinin on this well-earned recognition, and we are grateful for his encouragement of and ongoing commitment to research,” said Dr. Culwell. “We’re fortunate that these esteemed researchers played such a significant role in bringing MIUDELLA to market.”

MIUDELLA was approved on February 24, 2025, by the U.S. Food and Drug Administration for the prevention of pregnancy in females of reproductive potential for up to three years. MIUDELLA is expected to be available to patients through trained healthcare providers in the U.S. in the first half of 2026.

Guidelines from the American College of Obstetrics and Gynecology state that long-acting reversible contraceptive (LARC) methods, including intrauterine devices and contraceptive implants, are the most effective contraceptive methods, have few contraindications, and are appropriate for almost all patients.⁵ While there are a variety of contraceptive methods available to women, 41.6 percent of pregnancies in the U.S. are unintended.⁶

INDICATION FOR MIUDELLA®

MIUDELLA® is a copper-containing intrauterine system (IUS) indicated for prevention of pregnancy in females of reproductive potential for up to 3 years.

IMPORTANT SAFETY INFORMATION

- **WARNING: Improper insertion of intrauterine systems, including MIUDELLA®, increases the risk of complications.**
- **Proper training prior to first use of MIUDELLA® can minimize the risk of improper insertion.**
- **MIUDELLA® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MIUDELLA® REMS program to ensure healthcare providers are trained on the proper insertion of MIUDELLA® prior to first use. Further information is available at miudellarems.com and 1-855-337-0772.**
- **Contraindications:** Don’t use MIUDELLA® if you are or may be pregnant, have a uterine anomaly that may affect correct placement, acute pelvic inflammatory disease, postpartum endometritis or postabortal endometritis in past 3 months, known or suspected uterine or cervical malignancy, for use as post-coital contraception (emergency contraception), unexplained bleeding, untreated acute

⁴ Society of Family Planning website, accessed Oct. 9, 2025: <https://societyfp.org/community/awards/>

⁵ ACOG, Clinical Practice Bulletin #186, Nov. 2017 reaffirmed 2021; Committee Statement #5, April 2023. Accessed Oct. 24, 2025: <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/11/long-acting-reversible-contraception-implants-and-intrauterine-devices> and <https://www.acog.org/clinical/clinical-guidance/committee-statement/articles/2023/03/increasing-access-to-intrauterine-devices-and-contraceptive-implants>

⁶ Centers for Disease Control and Prevention. Accessed Feb. 18, 2025. <https://www.cdc.gov/reproductive-health/hcp/unintended-pregnancy/index.html#:~:text=Overview,2010%20to%2035.7%20in%202019>



cervicitis or vaginitis or other lower genital tract infection, conditions associated with increased susceptibility to pelvic infections, Wilson's disease, a previously placed IUS that has not been removed and/or hypersensitivity to any component of MIUDELLA[®] including copper, nitinol or any trace elements present in the copper components of MIUDELLA[®].

- Pregnancy with MIUDELLA[®] is rare but can be life threatening and cause infertility or loss of pregnancy.
- MIUDELLA[®] may attach to or go through the uterus and cause other problems.
- Tell your healthcare provider (HCP) if you develop severe pain or fever shortly after placement, miss a period, have abdominal pain, or if MIUDELLA[®] comes out. If it comes out, use backup birth control.
- At first, periods may be altered and result in heavier and longer bleeding with spotting in between.
- Tell your HCP you have MIUDELLA[®] before having an MRI or a medical procedure using heat therapy.
- Additional common side effects include painful periods, pelvic discomfort/pain, procedural pain, post procedural bleeding, and pain during sex.
- **MIUDELLA[®] does not protect against HIV or STDs.**

Only you and your HCP can decide if MIUDELLA[®] is right for you. Available by prescription only.

For additional information or to report suspected adverse reactions, please contact Sebela Women's Health Inc. at 1-866-246-2133.

You are encouraged to report negative side effects of prescription drugs to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Click [here](#) for the Full Prescribing Information for MIUDELLA[®].

About Sebela Pharmaceuticals[®]

Sebela Pharmaceuticals is a US pharmaceutical company with a market leading position in gastroenterology and a focus on innovation in women's health. In addition to the newly approved MIUDELLA, Sebela Women's Health has another next-generation hormonal IUD for contraception in late-stage clinical development. Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals, is the market leader in colonoscopy screening preparations for over 35 years, having invented, developed and commercialized a broad portfolio of innovative prescription colonoscopy preparations and multiple gastroenterology products. Braintree also has several gastroenterology programs in late-stage clinical development including Tegoprazan which is in phase 3 trials for gastro-esophageal reflux disease (GERD), specifically, erosive esophagitis (EE) and non-erosive reflux disease (NERD).

Sebela Pharmaceuticals has offices/operations in Roswell, GA; Braintree, MA; and Dublin, Ireland. Please visit sebelapharma.com for more information or call 844-732-3521.

MIUDELLA is a registered trademark of Sebela Women's Health Inc.

Forward Looking Statements



This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sebela Women's Health Inc. under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, as amended, and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the development, launch, introduction and commercial potential of IUDs as described herein; growth and opportunity, including peak sales and the potential demand for these IUDs, as well as their potential impact on applicable markets; market size; substantial competition; our ability to continue as a growing concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third-party payer reimbursement; dependence upon third parties supply and manufacturing uncertainties; our financial performance and results, including the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical trials discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, are based on current expectations, and Sebela Women's Health Inc. does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

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