The first successful IUD and transcervical procedures performed with the non-traumatic Carevix™ in Indiana, U.S., enhancing Women's Care in gynecology

Epalinges, Switzerland – May 6, 2024 - We are thrilled to announce a groundbreaking achievement in the United States with the first patients benefiting from successful IUD placement and transcervical procedures using the non-traumatic, FDA-approved, cervical stabilizer Carevix™ designed to minimize pain and bleeding and aiming to replace the traditional cervical tenaculum.

The 1st patients in the United States with successful procedures
The first gentle procedures were successfully performed by Alissa M. Conklin, MD. an Assistant Professor of Clinical Obstetrics and Gynecology at Indiana University School of Medicine.

Dr. Conklin said the procedures were conducted with ease and provided excellent suction and traction, allowing adequate access without difficulties. The patient reported significantly less pain and no bleeding compared to previous procedures involving traditional tenaculum use.

"*The suction was perfectly adequate and easy to use, even in a non-traditional position! Carevix™ allowed us to easily place the IUD when I otherwise could not without cervical traction.*" said Dr. Conklin. "*When suction was released, there was no bleeding, so we were able to immediately trim the strings and remove the speculum which makes the procedure shorter. The patient had an IUD before and said this device made her experience so much better than it was the last time*!"

"*It was preferable to prior IUD placement because there was essentially no pain!*" shared the first patient satisfied by the procedure that felt more comfortable. "*I'm glad research to lessen women's pain is being conducted!*". Another patient shared "*Dr. Conklin also explained that the common tool has been around for a while, so knowing this design of the old tool vs the newer one made me feel like I made the right choice.*"

They all felt reassured when presented the device by the healthcare professional.

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The Carevix™ Ambassador Program allows OB-GYNs, midwives and nurses across 12 centers of excellence worldwide (US, France, Sweden, Switzerland, Germany), including Indiana to use Carevix™ in routine gynecological procedures to provide a better experience for women.

"*This program showcases our commitment to innovation, fostering collaboration, and improving patient outcomes by refining our products in clinical practice.*" said Ikram Guerd, Managing Director US of Aspivix.

New clinical study in the United States to improve women's health

In addition to the Ambassador Program, researchers at IU School of Medicine have consented the first patient in the nation for a clinical study focused on "*Suction Cervical Stabilizer Compared to Standard Tenaculum for Intrauterine Procedures*".

The purpose of this clinical study is to evaluate patient-reported pain, bleeding, and device efficiency along with provider satisfaction and ease of use between intrauterine procedures employing the Carevix™ or a single-tooth tenaculum.

This US clinical study complements the Swiss ADVANCE Women study, a single-blinded and randomized study, conducted in the University Hospitals of Geneva that compared the use of Carevix™ to the standard cervical tenaculum in 100 women undergoing Intrauterine Device (IUD) placement. The positive results published in Contraception show a significant reduction in pain by up to 73% and in bleeding occurrence by 78% with the Carevix™ compared to the single-tooth tenaculum for intrauterine contraceptive device insertion (1).

This new clinical trial lead by IU School of Medicine broadens the scope of procedures among all intrauterine procedures, not only IUD insertion, including hysteroscopies, sonohysterography and endometrial biopsies.

Reference:
1. Michal Yaron, Hélène Legardeur, Bastien Barcellini, Farida Akhoundova, Patrice Mathevet, Safety and efficacy of a suction cervical stabilizer for IUD insertion: results from a randomized, controlled study, Contraception, 2023, 110004, ISSN 0010-7824, Contraception link

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About Dr. Alissa M. Conklin, MD

Dr. Alissa Conklin is certified by the American Board of Obstetrics and Gynecology, and has dedicated her life to delivering quality and compassionate care to her patients. She is a passionate advocate for patient-centered care with shared decision-making, and she is recognized for her commitment to trauma-informed care. Graduating from Indiana University School of Medicine Department of OB-GYN in 2012, she has been practicing general obstetrics and gynecology, forming lifelong bonds with her patients. Dr. Conklin believes in empowering individuals through education in the decision making process for their treatment options and to improve their lives, as well as she values a team approach in healthcare.

About IU School of Medicine

IU School of Medicine is the largest medical school in the U.S. and is annually ranked among the top medical schools in the nation by U.S. News & World Report. The school offers high-quality medical education, access to leading medical research and rich campus life in nine Indiana cities, including rural and urban locations consistently recognized for livability. According to the Blue ridge Institute for Medical Research, IU School of Medicine ranks No. 13 in 2023 National Institutes of Health funding among all public medical schools in the country.

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About Aspivix

Aspivix is a pioneering leader in women's health, dedicated to modernizing healthcare solutions for women around the world. With a focus on innovation, Aspivix is committed to developing cutting-edge medical devices, such as Carevix™, which aim to transform the gynecological experience by offering safer and less painful solutions that enhance the quality of care and empower women to take control of their health.

About Carevix™

Carevix™ is an innovative, soft-suction cervical device designed as a modern and gentler alternative to a cervical tenaculum when stabilization of the cervix is needed, aiming to significantly reduce trauma associated with pain and bleeding. Carevix™ has received FDA-clearance and CE-Mark approval in 2023 is available for commercialization in Switzerland, other countries will be available very soon.

Carevix™ has been clinically proven to be atraumatic during transcervical procedures with compelling results from the ADVANCE Women (Atraumatic Device using Vacuum Technology for Cervical Procedures in WOMEN), a randomized controlled trial of Carevix™, used In IUD Procedures against the cervical tenaculum has been published in “Contraception”, the International Reproductive Health Journal in 2023.

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