Aspivix Announces MHRA Approval for Carevix[™] and Peterborough City Hospital becoming the first Ambassador offering a painless contraceptive care in the United Kingdom

Epalinges, Switzerland — August 29, 2024 - In a significant stride towards transforming women's healthcare, Aspivix, a leading innovator in gynecological solutions, is thrilled to announce that its pioneering device, Carevix™, has received approval from the Medicines & Healthcare products Regulatory Agency (MHRA) for use in the United Kingdom. This milestone marks a pivotal moment for the company and underscores its commitment to modernizing gynecology under its mission, "Gynecology. Now Modern."

The MHRA approval signifies a major leap forward in the availability of advanced, pain-relieving solutions for millions of women, propelling Aspivix into the forefront of women's healthcare innovation.

Carevix[™] is designed to redefine the standards of care in gynecology, offering a more comfortable and empowering experience for patients and healthcare providers alike for transcervical procedures in gynecology, oncology and fertility, including IUD/coil insertions.

"Receiving MHRA approval is not just an achievement for Aspivix but a victory for women's healthcare globally," said Mathieu Horras, CEO & Co-Founder of Aspivix. "This endorsement allows us to bring Carevix™ to the UK market, further expanding our reach and impact on women's health. With existing FDA approval for the US and CE Mark for Europe, we are poised to make significant advancements in gynecological care."

As Aspivix continues to expand its presence in the UK market, the approval of CarevixTM by the MHRA is a testament to Aspivix's dedication to excellence and innovation in healthcare. By focusing on minimally invasive, patient-centric solutions, Aspivix aims to ensure a positive experience for all women by alleviating the pain and bleeding associated with gynecological transcervical procedures such as coil fitting, hysteroscopies, endometrial biopsies.

1st hospital in the United Kingdom adopting Carevix™

Women are offered the opportunity to benefit from Carevix[™], patient-centric experience, at the Peterborough City Hospital - North West Anglia NHS Foundation Trust.

"Carevix™ looks like an excellent product and our team at Peterborough City Hospital is very happy to join the program. I'm sure the patients would love it." shares Dr. Lukasz Polanski, an esteemed member of the Royal College of Obstetricians and Gunaecologists.

Peterborough City Hospital becomes the 17th center of excellence joining the Carevix[™] Ambassador Program which allows OB-GYNs, midwives and nurses worldwide (US, Brazil, France, Sweden, Switzerland, Germany, Italy) using Carevix[™] in routine gynecological procedures to provide a better experience for women.

Over 600 patients have benefitted from the use of the Carevix™ worldwide oas part of our Ambassador Program using Carevix™ in routine, providing women a better experience in gynecology. Now, Aspivix is excited about expanding the access to Carevix™ the healthcare professionals to improve patient outcomes by redefining together the standard of care in clinical practice.

For more information about Aspivix and Carevix™, please visit <u>aspivix.com</u>.

About Dr Polanski

Dr Lukasz Polanski hascompleted his medical degree at the Medical Academy of Prof Feliks Skubiszewski, Poland in 2007 followed by his training in reproductive medicine and surgery at some of the UK's foremost medical institutions. Dr Polanski is a Member of the Royal College of Obstetricians and Gynaecologists and completed his PhD focusing on predictors of success in IVF treatments. Dr Polanski's commitment to education is a hallmark of his career. He has dedicated considerable effort to enhancing scanning practices in gynaecology, successfully establishing courses and contributing extensively to related publications.

About Peterborough City Hospital

Peterborough City Hospital is part of the North West Anglia NHS Foundation Trust a statutory, not-for-profit, public benefit corporation, that runs three acute hospital sites — Peterborough City, Hinchingbrooke and Stamford and Rutland Hospitals.

Peterborough City Hospital at Bretton Gate, Peterborough, is a state-of-the-art, purpose-built facility which opened to its first patients in November 2010. The hospital has over 700 inpatient beds and patients are cared for on modern wards and amongst multiple specialties, has a dedicated Women's and Children's unit.



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



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 $Carevix^{TM}$, 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 multisite 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.