

Rejoni Receives FDA Approval of the Juveena® Hydrogel System to Reduce Intrauterine Adhesions Following Hysteroscopic Adhesiolysis

Approval supported by a multicenter, randomized, subject- and evaluator-blinded pivotal study

BEDFORD, Mass.--([BUSINESS WIRE](#))--Rejoni, Inc., a commercial-stage women's health company focused on uterine health, today announced that the U.S. Food and Drug Administration (FDA) has granted Premarket Approval (PMA P250051) for the Juveena Hydrogel System. The Juveena Hydrogel System is indicated for use in adult women to reduce the incidence and severity of intrauterine adhesion formation following hysteroscopic adhesiolysis for symptomatic moderate to severe intrauterine adhesions.

Intrauterine adhesions (IUA) can form inside the uterus following trauma to the endometrium and may lead to menstrual disruption, infertility, recurrent pregnancy loss, and serious obstetric complications. Recurrence after surgical removal of IUAs is common, and women with severe disease often face repeated procedures. Juveena is designed to protect the uterine cavity during the healing period after adhesiolysis to reduce the incidence and severity of IUAs.

The Juveena hydrogel is delivered through a proprietary transcervical catheter at the end of the hysteroscopic procedure. Once placed, the hydrogel forms in situ, conforms to the uterine cavity, and separates uterine walls. Within approximately 14 to 21 days, the hydrogel softens, liquefies, and is naturally discharged through the cervix and vagina.

Pivotal Trial Results

FDA approval is supported by the Juveena Pivotal Study, a multicenter, randomized, subject- and evaluator-blinded controlled study conducted at 15 U.S. centers. Women were randomized 2:1 to Juveena or surgery alone, with randomization stratified by procedure type, and underwent second-look hysteroscopy approximately eight weeks after surgery. The primary endpoint, adhesion-free rate, was adjudicated by a blinded Central Review Committee using paired video review. The study met its primary endpoint, the percentage of patients free of adhesions at week 8, in the overall study population. Results for women treated after hysteroscopic adhesiolysis for symptomatic moderate to severe IUAs, the population for which Juveena is approved, as reported in the FDA-approved labeling:

- **Adhesion-free rate after adhesiolysis (descriptive subgroup analysis):** 61.5% of Juveena-treated women were free of intrauterine adhesions at week 8, compared with 38.2% of controls.
- **Lower adhesion severity (prespecified secondary endpoint):** Adhesion severity at week 8 was significantly lower with the Juveena Hydrogel System than

with control ($p=0.001$). Severe adhesions were seen in 6.1% of Juveena patients vs. 28.6% of controls.

- **Safety:** In the overall safety population, adverse events attributed to the device occurred in 8% of Juveena patients: uterine spasm, pelvic discomfort, pelvic pain, dysmenorrhea, and one device expulsion. All were non-serious; most were mild or moderate, and all resolved with no intervention or conservative medical management.

“Recurrence of IUAs after adhesiolysis has been a persistent problem with few good options,” said John Nealon, President and Chief Executive Officer of Rejoni, Inc. “This approval gives surgeons a tool backed by rigorous scientific evidence. We are excited to bring this innovation to physicians and their patients very soon.”

"For women with moderate to severe intrauterine adhesions, protecting the uterine cavity after surgery is critical," said Pietro Bortoletto, M.D., reproductive endocrinologist and co-founder of Terra Fertility in Dedham, Mass. "As an investigator in the Juveena pivotal study, I saw its impact on my patients firsthand, and I'm excited to now offer it as part of my standard of care."

Launch and Availability

Rejoni will initiate a limited market release of Juveena at select U.S. centers specializing in hysteroscopic surgery and reproductive medicine, followed by a broader commercial rollout. The company has established a patient access program to support coverage and reimbursement. Juveena procedures may be reported using CPT Category III code 0990T.

About the Juveena Hydrogel System

The Juveena Hydrogel System is an in situ-forming hydrogel designed to help reduce the incidence and severity of intrauterine adhesions following hysteroscopic adhesiolysis. Delivered transcervically as a liquid, it forms a temporary hydrogel spacer that conforms to the uterine cavity and keeps the uterine walls apart while they heal.

Important Safety Information

The Juveena Hydrogel System is indicated for use in adult women to reduce the incidence and severity of intrauterine adhesion formation following hysteroscopic adhesiolysis for symptomatic moderate to severe intrauterine adhesions. The Juveena Hydrogel System should not be used in patients with hemorrhage, active pelvic infection, sexually transmitted disease, or pregnancy, or in patients with known hypersensitivity or allergy to polyethylene glycol (PEG) or FD&C Blue #1 dye. Safety and effectiveness have not been established following hysteroscopic procedures other than adhesiolysis of moderate to severe intrauterine adhesions, or in patients undergoing thermal endometrial ablation. Patients should avoid pregnancy during the first

complete menstrual cycle after treatment. Potential adverse reactions include discomfort, pain/cramping, infection, local inflammatory reaction, and allergic reaction. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner. For complete information, see the Instructions for Use.

About Rejoni, Inc.

Rejoni, Inc. is a privately held, commercial-stage company based in Bedford, Massachusetts, that is developing and commercializing gynecological products based on its proprietary biomaterials, including the Juveena® Hydrogel System. Founded in 2020, Rejoni is the latest company started by serial entrepreneur Amar Sawhney, who also founded Confluent Surgical, Ocular Therapeutix, and Augmenix. More information is available at www.rejoni.com.

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