Inclusion Criteria

1. Non-pregnant, non-lactating female
   NOTE: Females who are of childbearing potential must have had a negative urine or serum pregnancy test on the day of the procedure. If urine testing is done, additional supportive history from the patient (such as having had a menstrual period within the last 30 days or not having had intercourse since before the last menstrual period, etc.) will be documented prior to procedure, and the subject must agree to use effective or highly effective contraceptive methods.
2. Subject is ≥18 years of age
3. Subject has a history of idiopathic overactive bladder for ≥6 months
4. Subject is capable and willing to provide Informed Consent, is geographically stable, and has the cognitive ability to complete the 3-day bladder diary and comply with the required diary, follow-up visits, and study schedule requirements (e.g., subjects who are not vulnerable, such as cognitively impaired or incarcerated adults)
5. Subject's body mass index ≤40
6. Ambulatory and able to use toilet without assistance
7. Post-void residual (PVR) ≤150 mL
8. Intolerant of, contraindicated for, or have failed 2 drug therapies AND should not be on medication for their condition for at least 2 weeks prior to screening
9. Predominance of urgency urinary incontinence in subjects with mixed incontinence (mix of both stress and urgency incontinence)
   NOTE: Predominance is defined as having at least 2/3rds or 67% of reported incontinence as urgency urinary incontinence on the 3-day bladder diary, and a higher percentage urgency urinary incontinence score as compared to the SUI score on the QUID[1]
10. Subject has not previously received cumulatively more than three 100 units/intravesical treatment of onabotulinumtoxinA (Botox®) for OAB and self-reports receiving benefit from Botox of normal durability (3-6 months), but discontinued or wishes to potentially discontinue due to side effects, financial constraints, or required treatment regimen (e.g., treatment every 6 months) and whose last dosage was administered at least 12 months prior (6 months of normal durability + 6-month washout). Botox cannot have previously been deemed as a failed treatment for the subject by the Investigator.
11. An average of ≥4 episodes of urgency urinary incontinence (UUI) across the two baseline 3-day Bladder Diaries (an average of 1.33 UUI episodes/day)
12. Subject is not contraindicated for Botox according to IFU or deemed previous failed Botox treatment by Investigator

Reference: 1. Bradley CS, Rovner ES, Morgan MA, et al. A new questionnaire for urinary incontinence diagnosis in women: development and testing. *AM J Obstet Gynecol.* 2005;192:66–73.

Exclusion Criteria

General Medical History and Status:

1. Planning on becoming pregnant during the 36-month study period
2. Impaired renal function as measured by glomerular filtration rate (GFR) ≤65
3. Current bleeding disorder or coagulopathies
4. Neurological disease affecting bladder function such as multiple sclerosis, spinal cord injuries, myasthenia gravis, Charcot-Marie-Tooth disease
5. Subject has previous diagnosis of diabetes mellitus with poor control (HbA1c ≤7.5) documented in the last three months, subjects may re-test in two weeks if HbA1c <7.8
6. Subject is a chronic systemic corticosteroid user, defined as daily continuous use within the last 30 days with the exception of Flonase use during allergy season
7. Subject is critically ill or has a life expectancy <3 years
8. Investigator determines that subject is not a suitable candidate for participation in an investigational clinical research study

Genitourinary Medical History and Status:

9. Post-surgical onset of de novo OAB
10. Current hydronephrosis or hydroureter or clinically significant hydronephrosis
11. Patients with uninvestigated microhematuria
12. Impaired voiding dysfunction due to previously identified underactive bladder or bladder outflow obstruction
13. Current participation in any other interventional study. Participation in observational studies is permitted
14. Prior or current diagnosis of polyuria or has a screening 3-day bladder diary with 24-hour total volume of >3000 mL
15. Urinary tract infection (UTI) that is not resolved or has not been treated with antibiotics for a minimum of 3 days at the time of procedure and has not been verified by a negative laboratory urinalysis report
16. Subject reports having, or has a documented history of ≥2 urinary tract infections (UTIs) in the last 6 months or ≥3 UTIs in the last 12 months prior to enrollment
17. Documented, spontaneous, unprovoked urinary retention requiring any type of catheterization within the last 6 months, or retention in the past for which there was no diagnosis or definitive treatment. Non-neurogenic chronic urinary retention is defined by the American Urological Association (AUA) as an elevated PVR of >300 mL that persists for at least six months and is documented on two or more separate occasions.
18. Anatomical conditions that, in the opinion of the investigator, would preclude the introduction and/or use of the device
19. Any prolapse visible at or beyond the hymen, supine and at rest
20. Subject has been diagnosed (at any time) with bladder cancer, interstitial cystitis, or chronic pelvic pain syndrome
21. Ureteral dysfunction, stricture, or reflux including vesicoureteral reflux or a history of surgical treatment for vesicoureteral reflux
22. Any abnormality of the urinary tract including the bladder, ureters, or kidneys such as but not limited to: bladder dysfunction secondary to neurologic disease, bladder fistula, hydroureter impaired compliance, hydronephrosis, ureteric reflux, Hutch diverticulum, ureterocele, duplex system, ectopic ureter, unilateral renal agenesis, ectopic kidney, cross fused ectopia, or megaureter. Simple cysts that are deemed not clinically significant by the investigator are allowable.

Exclusion Criteria Continued...

Genitourinary Treatment and Surgical History Status:

23. Any invasive or surgical intervention involving the kidneys, bladder, urethra, rectum, or vaginal wall within the last 6 months (e.g., radiofrequency, implant, mid-urethral sling)
24. Prior history of surgical mesh in the anterior vaginal compartment to treat pelvic organ prolapse
25. History of complications with any transvaginal or mid-urethral implanted mesh
26. Prior abdominal, pelvic, or vaginal surgery that may have modified the structure or location of the bladder, ureters, or urinary vasculature such as bladder reconstruction, retroperitoneal dissection, or cross-trigonal ureteral implantation, or urinary tract fistula repair
27. Current use of OAB medications within the last 2 weeks prior to screening
28. OAB symptoms previously treated with a single dose of >100 units of onabotulinumtoxinA (Botox®)
29. OAB symptoms previously treated with Sacral Neuromodulation (SNM) and/or Posterior Tibial Nerve Stimulation (PTNS) (or implantable PTNS device)
30. Previous pelvic irradiation

Incontinence History and Status:

31. Complete or total incontinence (the continuous or total loss of urinary control)
32. Any functional incontinence (incontinence caused by a physical or mental impairment that keeps a subject from reaching the bathroom in time to urinate)