VAPOR 3 Protocol Synopsis

Title:	Vanquish® Water Vapor Ablation for Grade Group 3 PrOstate CanceR: A Multicenter Single Arm Study (VAPOR 3)
Objective and Purpose:	The purpose of this study is to evaluate the safety and effectiveness of prostate tissue ablation with the Vanquish Water Vapor Ablation System ("Vanquish") in participants with Grade Group 3 (GG3) intermediate-risk prostate cancer.
Study Design:	Participants eligible for the study will receive therapy with the Vanquish System. The primary endpoint analyses will occur after the last participant completes 6-month follow-up from the procedure. Participants will be eligible to roll into a post-market real world Registry on Vanquish after exiting at any point.
Sites:	VAPOR 3 will activate up to 10 sites in the United States.
Enrollment:	Up to 120 participants to be consented (enrolled) to identify up to 75 eligible participants for Vanquish Therapy.
Follow Up:	7-days, 6-weeks, 6-months, 12-months, 18-months, and 24-months.
Device/Therapy:	Vanquish Water Vapor Ablation System
Indication:	The Vanquish Water Vapor Ablation System is indicated for the thermal ablation of targeted prostate tissue via a transurethral approach.
Inclusion Criteria:	1. Participant has been diagnosed with Grade Group 3 (GG3) intermediate-risk prostate cancer. 2. ≤20 ng/ml prostate specific antigen (PSA). 3. Prostate volume of 20-80cc per Central Imaging read. 4. ≥50 years of age; with life expectancy of ≥10 years. 5. Clinical cancer stage less than or equal to T2c (tumor may involve both sides of the prostate but without evidence that tumor extends outside of the prostate and with no cancer cells found in nearby lymph nodes) evaluated by prostate specific membrane antigen positron emission tomography (PSMA-PET) scan. 6. Within 6 months prior to signing consent have had a multiparametric MRI (mpMRI). a. mpMRI results must show localized disease meaning a single MRI region of suspicion (PI-RADS lesion volume ≤2.25cc with a maximum lesion diameter <17mm as measured by diffusion weighted imaging (DWI) determined by Central Imaging). 7. Within 6 months prior to signing consent, have undergone a multiparametric MRI software guided fusion biopsy of the prostate (transrectal or transperineal). b. Minimum of 2 targeted cores from a single ROI identified by Central Imaging review, and at least one core confirming GG3

	disease on biopsy (lesion may cross the midline); Gleason Grade Group determined by highest Gleason score of the targeted core. c. GG1 cores from anywhere in the prostate are acceptable. d. Less than 50% of systematic biopsy cores are positive for GG1 disease. For the <50% calculation, all positive cores located in the target, are counted as "one core." e. All positive GG2 or GG3 cores must be located in the lesion, or immediately adjacent to the lesion, as determined by the fusion system's tracking, mapping and imaging documentation features. f. Additional MRI regions of suspicion that are Central Imaging confirmed PI-RADS ≤3 that are negative on biopsy or GG1 are acceptable. 8. Within 6 months prior to signing consent have had a PSMA-PET scan. a. PSMA-PET scan results show no suspicion of metastasis as determined by site read. b. Per Central Imaging, PSMA-PET scan prostate results are concordant with mpMRI results c. If PSMA-PET scan indicates an additional area of suspicion from the planned treatment area, a targeted repeat biopsy is required to rule out ≥ GG2. 9. Participant is willing and able to adhere to specific protocol visits and required testing, including completion of all questionnaires, throughout study. 10. Participant is geographically stable and near the site or able and willing to travel back to site for follow-up visits. 11. Participant is able and willing to provide written consent to participate in the study.
Exclusion Criteria:	1. MRI evidence of extracapsular extension of cancer (MRI read as capsular invasion, bulge, or frank ECE) as determined by Central Imaging. 2. Any additional Central Imaging confirmed PI-RADS 4 or 5 suspicious lesions. 3. Participants with ≥GG4 cores anywhere in the prostate. 4. Participants with GG2 or GG3 cores outside the region of interest. 5. Contraindications per the Vanquish Instructions for Use. 6. Any previous treatment for prostate cancer or any prior surgery, intervention, or minimally invasive therapy (MIST) for the prostate or bladder neck, including but not limited to Vanquish therapy, TUIP,

	TURP, Aquablation, Green Light, Rezūm, Prostatic Urethral Lift, iTind, Prostatic Arterial Embolization, or microwave therapy. 7. Currently taking medications that have hormonal effects on the prostate or PSA, such as: • 5 alpha reductase inhibitors, if on for < 6 months (6-month washout required if participant is able and willing to stop medication), • Androgen blockers, • Luteinizing hormone-releasing hormone agonists or antagonists within the past 12 months, • or Testosterone supplementation, if on for < 3 months (3-month washout required if participant is able and willing to stop medication) A participant on benign prostatic hyperplasia medication which does not affect the PSA can be included. 8. Treated within the past 5 years for a lower and/or upper urinary tract malignancy. 9. Any cognitive or psychiatric condition that interferes with or precludes direct and accurate communication with the study Investigator regarding the study or affects the ability to complete the study quality of life (QOL) questionnaires. 10. Participant currently participating in other prostate tissue and/or cancer study unless approved by Sponsor in writing. 11. Participant is considered vulnerable, such as incarcerated or cognitively impaired.
Primary Effectiveness Endpoint:	Ablative efficacy indicating <GG2 cancer in the region of the prostate targeted for Vanquish therapy and evaluated at 6 months post-ablation.
Primary Safety Endpoint:	Rate of serious adverse events through 6-months classified per Clavien-Dindo and assessed as related to the Vanquish procedure and/or device.
Secondary Effectiveness Endpoint:	Ablative efficacy indicating <GG2 cancer in the region(s) of the prostate targeted for therapy evaluated 24 months post initial ablation.
Secondary Safety Endpoint:	Rate of serious adverse events through 24-months classified per Clavien-Dindo and assessed as related to the Vanquish procedure and/or device.
Secondary Outcomes:	The following outcomes will be analyzed based on data collected per follow-up schedules outlined in protocol. • Out of field ≥ GG2 PCa • Rate of repeat and/or supplementary water vapor ablation • Rate of GG4/GG5 recurrence in targeted region of prostate • Negative biopsy in targeted region of prostate • Rate of ongoing adverse events classified per Clavien-Dindo grades III-V and attributable to the Vanquish procedure and/or device

	• Change in patient reported outcome scores • Change in prostate volume based on MRI • Relationship of lesion location to biopsy outcomes • Change in PSA • Change in Pain Score • Duration of OR time • Duration of entire procedure • Duration of first vapor ablation to last vapor ablation • Duration in recovery room • Duration of facility stay • Days to catheter removal after procedure
Additional Ablative Sessions	Subject may undergo repeat ablation of previous ablated tissue or supplementary ablation of newly identified GG2 or GG3 disease.
Study Monitors:	Francis Medical and/or Designee Francis Medical Inc 7351 Kirkwood Lane N., Suite 130 Maple Grove, MN 55369
Sponsor and Data Management:	Francis Medical Inc 7351 Kirkwood Lane N., Suite 130 Maple Grove, MN 55369