Device for Periurethral Treatment of Urinary Incontinence

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Background

- Stress Urinary Incontinence
  - 15M-25M women in US
  - 35% of all women over 65 years of age
  - 50% nursing home residents
  - Bulking agents are used in a minority of patients to treat SUI
  - May be amendable to combination therapy

Bulking agents help suspend the bladder and narrow the urethra
Current Treatments

• Kegel Exercises
• Electrical Stimulation
• Biofeedback
• Timed Voiding

• Medications - anticholergenics
• Pessaries – vaginal devices
• Surgery – slings
  – Option of last resort

• Catheterization

• Absorbent Undergarments

• Bulking Agent Injection

Significant Unmet Medical Need
Opportunity
Disposable Device for Bulking Agent Administration

- Problems placing bulking agent
  - Surgeon skill dependent
  - If not successful in first couple of procedures, will not offer to other patients

- Trans-urethra injection
  - most commonly used procedure for bulking agent placement

- Bladder sling creates additional organ damage
  - 15% treated have severe complications
  - Trans-vaginal placement - invasive
Trans-urethral vs Peri-urethral Agent Administration

**Cons**
- UTIs in up to 30% patients
- Material in urethra
- Inconsistent results
- Multiple injections required

**Pros**
- Minimally invasive
- High reimbursement rates
- Complements pharmacologic treatments
- Up to 90% success rates

**Cons**
- Difficulty with BA placement
- Inconsistent results
- Multiple injections required
Reduce Procedure Variability

Goal: Uniformly placed masses of bulking agent
Approved Bulking Agents

- Contigen – Bard Medical
  - Bovine collagen

- Durasphere – Carbon Medical Tech.
  - Carbon coated beads

- Zuidex – Q-Med
  - Dextranomer/hyaluronic acid copolymer

- Coaptite – Boston Scientific
  - Calcium hydroxylapatite ceramic microsphere

- Macroplastique – Uroplasty
  - Polyvinylpyrrolidone/cross-linked polydimethylsiloxane
Intellectual Property Status and Development Plan

• Provisional patent application filed
• Evaluated multiple device prototyping companies
  – Cost estimate $10,000

• Create prototype(s)
• Test assumptions in animal and/or cadaver tissue
• Repeat prototyping as needed with continued IP development
Summary

• SUI bulking agents are widely accepted by the medical community

• Consistent placement of bulking agent is dependent on the skill of the physician

• Disposable guide for bulking agent placement is needed for increased acceptance

• Accepted reimbursement procedures

• Increased market potential for guide/bulking agents with more consistent medical outcomes