

Scott & White Hospital & Clinics Clinical Research at Scott & White

Please complete this form for each of your studies that are currently enrolling subjects. This information will be used to create a web page available for viewing by the general public. Please use lay terminology as in the consent form. The information should be complete and accurately describe your studies.

Study Title: POST-APPROVAL STUDY OF COAPTITE® IN THE TREATMENT OF FEMALE URINARY INCONTINENCE

Project ID#: 81555

Department: Urology

Sponsor: BIOFORM MEDICAL, INC.

1. Provide a brief synopsis of the study (purpose of the study from abstract, consent form, or protocol using lay terminology):

Condition(s):	Treatment(s):
Female Stress Urinary Incontinence (SU)	Coaptite® (FDA approved)

2. Who is eligible to participate in the study (basic qualifications such as age, gender, etc.)?***

Age: 18 years and older

Gender: Female

- Has female urinary stress incontinence
- Understands and accepts the obligation and is able to present for all scheduled study visits
- Signs written informed consent
- Cannot have had a previous treatment for urinary incontinence with a urethral bulking agent other than Coaptite or collagen
- Cannot have nocturnal enuresis (*bed wetting*)
- Cannot have a significant history of urinary tract infections without resolution
- Cannot be pregnant or lactating

**Other criteria apply to eligibility as well. Discuss qualifications with the study coordinator.

3. What may be involved/required for subject participation (visits, tests, and/or logs, etc.)?

Once you have signed this consent form, the following information will be collected: your demographic data including date of birth, height, weight, race, duration of incontinence, number of prior surgeries for incontinence, incontinence medical history, and quality of life status. You will be provided with a "24 hour Pad Weight Test" and "4 Day Voiding Diary." This will include a set of dry pads and two Ziploc bags (one for dry unused pads and one for used wet pads). You will be asked to complete the pad weight test and 4 day voiding diary within 30 days. You will be asked to mail the pad and voiding diary back to the study team.

Within 60 days of the baseline pad weight confirmation, you will receive your first Coaptite injection.

Following the first injection, you will receive several in-person/office follow-up visits. You will be asked to return for a minimum of 8 study visits (*enrollment/first injection, 1 Month post first injection, 6, 12, 18, 24, 30 and 36 Months*) during the three-year follow-up.

A cystoscopy and physical exam will be performed 1 month after your initial injection. If you receive a 2nd injection within 6 months of your first injection, you will be asked to undergo a second cystoscopy and physical exam.

You will be sent a "4 Day Voiding Diary" with instructions prior to each follow up visit. You will be asked to complete these diaries prior to each of your scheduled follow up visits and bring them with you to each. At each follow-up visit, a local periurethral exam (*the area surrounding the urethra*) will be done and the following information will be collected: quality of life, adverse events, incontinence medications, and alternative treatment information.

You will be paid \$100 for each visit you complete during the 3 year study (*including the enrollment/initial injection, 1 Month post first injection, 6, 12, 18, 24, 30, and 36 month follow-up visits, and for any additional injection/follow-up visits if the study doctor thinks you need them*).

4. Contact Information:

Coordinator: Nancy Bowman, RN

Title: Clinical Research Coordinator

Telephone Number: (254) 724-6294

E-mail Address: NBOWMAN@swmail.sw.org