CIRREF UAE FIBROID Registry

Site number: ___ ___ ___ ___ Case number: ___ ___ ___

ADMISSION CRITERIA

INCLUSION CRITERIA: *All answers must be marked YES for the patient to be eligible for participation.*

	Yes	No
1.The patient chooses to participate and has signed a written informed consent. . .	❑	❑
2. The patient has uterine leiomyomata confirmed by ultrasound or MRI.	❑	❑
3. The patient is a female, 21 years of age or older.	❑	❑
4. The patient is willing to complete follow-up (for core sites)	❑	❑

PATIENT INTAKE DATA

1. Date of Birth: ___ ___ ___ / ___ ___ ___ ___
month year

2. Race *(check only one):* ❑ American Indian or Alaska Native ❑ Asian ❑ Black or African American ❑ Native Hawaiian or other Pacific Islander ❑ White

Ethnicity: ❑ Hispanic or Latino

BASELINE DATA

MENSTRUAL STATUS:

1. Date of last menstrual period: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day month year

2. Regularity of menstrual cycle: *(check only one)* ❑ Regular ❑ Irregular

3. Length of time between periods: *(check only one)* ❑ 0- 21 days ❑ 22 - 35 days ❑ over 35 days

4 . Bleeding between periods: ❑ No ❑ Yes

REPRODUCTIVE STATUS:

1.*(Enter a number for each)*
Gravida: _____ Para: _____ Spontaneous Abortion: _____ Induced Abortion: _____ Ectopic: _____

2.Number of pregnancies delivered prior to 37 weeks gestational age: _____

Number of cesarean sections: _____

3.Heterosexually active: ❑ No ❑ Yes ➜ If Yes, check all contraceptive methods that apply:
- ❑ None ❑ Oral contraceptive ❑ Intrauterine device
- ❑ Diaphragm ❑ Injectable/Implantable ❑ Condoms
- ❑ Surgically sterile➜ If Yes, (check only one): ❑ Tubal ligation ❑ Oophorectomy ❑ Partner vasectomy

4. Postmenopausal: ❑ No ❑ Yes

5. Suspected infertile: ❑ No ❑ Yes ➞ If Yes, (check all that apply):
- ❑ Previous treatment for infertility
- ❑ No pregnancies within past 1 year while engaging in unprotected intercourse
- ❑ 3 or more consecutive miscarriages

CIRREF UAE FIBROID Registry

Site number: ___ ___ ___ ___ Case number: ___ ___ ___

BASELINE DATA (continued)

REPRODUCTIVE STATUS (continued):

6. Plans for future pregnancy? ❑Yes, likely within the next 2 years ❑ Would like to keep as an option ❑ No

OTHER POTENTIAL GYNECOLOGICAL CAUSES OF PAIN/INFERTILITY:

1. Prior history of gynecological disease: ❑ No ❑ Yes→If yes, (check all that apply):

❑ Endometriosis ❑ Pelvic adhesions ❑ Pelvic Inflammatory Disease ❑ Adenomyoses ❑Other

SYMPTOMS:

1. Primary presenting symptoms: *(Please specify)*
   - ☐Yes ☐ No Heavy menstrual bleeding
   - ☐Yes ☐ No Intermenstrual or menstrual pelvic pain
   - ☐Yes ☐ No Bulk related symptoms (urinary pressure/pelvic pressure, backaches, urinary frequency, nocturia: >2X/night, bloating, constipation)
   - ☐Yes ☐ No Other
2. Predominant /primary presenting symptom (*check only one*):

☐ Heavy menstrual bleeding ☐ Intermenstrual or menstrual pelvic pain

☐ Bulk related symptoms ☐ Other

PRIOR TREATMENT FOR SYMPTOMS:

1. Therapy within 3 months prior to procedure:(check all that apply)

- ❑ **None**
- ❑ **Nonsteroidal Antiinflammatory**
- ❑ **Oral Contraceptive Pill**
- ❑ **Depro Provera**
- ❑ **Oral Progesterones**
- ❑ **GnRH agonist (Lupron®) →Duration of Administration: _____ months**

  Date of Last Dose: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
  day month year
- ❑ **Narcotics**
- ❑ **Other**

2. Invasive procedures:(Check all that apply)

- ❑ **None**
- ❑ **Myomectomy → Total number of procedures: _____**
- ❑ **Previous UAE → Total number of procedures: _____**
- ❑ **Hysteroscopy → Total number of procedures: _____**
- ❑ **Myolysis → Total number of procedures: _____**
- ❑ **D & C → Total number of procedures: _____**
- ❑ **Endometrial ablation → Total number of procedures: _____**
- ❑ **Other**

CIRREF UAE FIBROID Registry

Site number: ___ ___ ___ ___ Case number: ___ ___ ___

BASELINE DATA (continued)

PREVIOUS ABDOMINAL INVASIVE PROCEDURES:

1. Other Uterine, GYN, or abdominal procedures? ❑ No ❑ Yes ➜ If Yes, check all that apply
   ❑ Laproscopic procedure ❑ Open procedure

HISTORY:

1. Smoking history: ❑ Never ❑ Previous ❑ Current

2. Chronic diseases: ❑ Diabetes Mellitus ❑ Hypertension (HTN) ❑ Thyroid ❑ Other

3. Height: ___ ___ ___ ❑ cm or ❑ inches **4. Weight: ___ ___ ___ . ___ ❑ kg or ❑ lbs**

LABORATORY DATA:

1. Hemoglobin:_____ . ____ g/dl

2. FSH:_____ mIU/ml

QUALITY OF LIFE:

1. Symptom Score: _____

2. Quality of Life Score: _____

MEASUREMENTS AND LOCATIONS

1. Date of Imaging:___ ___ / ___ ___ ___ / ___ ___ ___ ___
   day month year

Imaging Modality Use:*(check all that apply)* ❑ MRI ❑ Ultrasound Transabdominal ❑ Ultrasound Transvaginal

2. Overall Uterine Dimensions: Sagittal:_____ cm Transverse:_____ cm AP:_____ cm

3. Number of Demonstrable Fibroids:*(check only one)* ❑ One ❑ Two ❑ Three ❑ Four ❑ Five or more

Evidence of adenomyosis: ❑ No ❑ Yes

MEASUREMENTS AND LOCATIONS (continued)

4. Dominant Fibroid Measurements and Location:

	Largest Fibroid	**Fibroid causing Symptoms** ❑ **N/A** If different from first column
Location	(Check only one) ❑ Fundal ❑ Body-lateral ❑ Body-anterior ❑ Body-posterior ❑ Lower Uterine segment/cervix ❑ Interligamentous	(Check only one) ❑ Fundal ❑ Body-lateral ❑ Body-anterior ❑ Body-posterior ❑ Lower Uterine segment/cervix ❑ Interligamentous
Morphology	(Check only one) ❑ Cervical ❑ Subserosal ❑ Transmural ❑ Intramural ❑ Submucosal ❑ Pendunculated Subserosal ❑ Pendunculated Submucosal	(Check only one) ❑ Cervical ❑ Subserosal ❑ Transmural ❑ Intramural ❑ Submucosal ❑ Pendunculated Subserosal ❑ Pendunculated Submucosal
Measurements	Sagittal: _____ cm Transverse:_____ cm AP: _____cm	Sagittal: _____ cm Transverse:_____ cm AP: _____cm

PROCEDURE

1. Date of Procedure: ___ ___ **/** ___ ___ ___ **/** ___ ___ ___ ___
day month year

2. Total Procedure Time:

Time patient entered room: ___ ___ : ___ ___
(00:00 to 23:59)

Time procedure started: (anesthesia of puncture site) ___ ___ : ___ ___
(00:00 to 23:59)

Time procedure end: (catheter removed) ___ ___ : ___ ___
(00:00 to 23:59)

Time patient left room: ___ ___ : ___ ___
(00:00 to 23:59)

CIRREF UAE FIBROID Registry

Site number: ___ ___ ___ ___ Case number: ___ ___ ___

MEDICATIONS

1. Prophylactic antibiotics: ❑ No
❑ Yes→ If Yes, (check only one) ❑ Pre-procedure
❑ Post-procedure
❑ Both pre-procedure and post-procedure

2. DVT prophylaxis: ❑ No ❑ Yes →If Yes (check one): ❑ Low molecular Heparin
❑ Coumadin
❑ Automated venous compression device

3. Peri-procedure pain management: (check all that apply)
❑ Conscious sedation ❑ Narcotics non-PCA ❑ PCA narcotics (IV) ❑ Acetaminophen
❑ NSAIDs ❑ Epidural pain control ❑ Spinal pain control

TECHNIQUE

1. Vessels Embolized: (Check only one)
❑ UA bilateral
❑ UA single → If Yes, check only one: ❑ Right ❑ Left
→ If Yes,specify reason: ❑ Only one uterine artery present
❑ Technical failure
❑ None → Specify reason: ❑ Couldn't catheterize ❑ Equipment failure ❑ Complication
❑ Other, (specify): _____

Anomalous Vessels: ❑ No ❑ Yes → If Yes, specify: ❑ Ovarian
❑ Other abnormal supply
→ If Yes, Embolized?: ❑ No ❑ Yes
→ If Yes, ❑ Single (check only one) → ❑ Right ❑ Left
❑ Bilateral

2. Primary Embolic Agent: (indicate the total amount of agent used for each product by indicating size range and milliliters used)

Manufacturer:	Medi-Tech/ BSCI/Target (Contour) *Indicate # of mls*	Biosphere Medical (Embosphere) *Indicate # of mls*	Cook Inc (Biodyne) *Indicate # of mls*	Cordis (Trufill) *Indicate # of mls*	Ivalon *Indicate # of mls*	Gelatin Sponge (e.g., gel-foam)
Total mls & Size Range	____ 45-150µ ____ 150-250µ ____ 250-355µ ____ 355-500µ ____ 500-710µ ____ 710-1000µ ____1000-1180µ	____ 40-120µ ____ 100-300µ ____ 300-500µ ____ 500-700µ ____ 700-900µ ____ 900-1200µ	____ 50-100µ ____ 100-200µ ____ 200-300µ ____ 300-500µ ____ 500-700µ ____ 700-1000µ ____1000-1500µ ____1500-2000µ ____2000-2800µ	____ 150-250µ ____ 250-355µ ____ 355-500µ ____ 500-710µ ____ 710-1000µ ____1000-1400µ ____1400-2000µ	____ 45-150µ ____ 150-25µ ____ 250-355µ ____ 355-500µ ____ 500-710µ ____ 710-1000µ ____1000-1180µ	❑ Yes ❑ No

3. Supplemental Embolic: ❑ No ❑ Yes →If yes, specify below:
Gelatin Sponge (check one): ❑ Right ❑ Left ❑ Both ❑ Neither
Coil (check one): ❑ Right ❑ Left ❑ Both ❑ Neither
Other (check one): ❑ Right ❑ Left ❑ Both ❑ Neither *(specify)*: _____

CIRREF UAE FIBROID Registry

Site number: ___ ___ ___ ___ Case number: ___ ___ ___

TECHNIQUE (continued)

4. Microcatheters: ❑ No ❑ Yes ➞If yes, (check only one): ❑ Right ❑ Left ❑ Both; Number used: _____

5. Number of Standard arteriographic catheters used: _____

6. Flouro Time: (specify in minutes) _____

7.Number of angiographic images: _____

IN HOSPTIAL EVENTS

1. Adverse Events: ❑ No ❑ Yes ➞If yes, (check all that apply and enter numeric SCVIR complication classification):

	SCVIR Classification		SCVIR Classification
❑ Groin hematoma		❑ Vessel injury	
❑ Symptomatic non-target embolization		❑ Contrast Reaction	
❑ Adverse Drug Reaction		❑ Thromboembolic event	
❑ Pain requiring prolonged hospitalization > 48 hrs		❑ Fever >100.4°requiring prolonged hospitalization > 48 hrs	
❑ Nausea/vomiting requiring prolonged hospitalization > 48 hrs		❑ Urinary retention	
❑ Device Related, name device: _____			
❑ Other complications (specify): _____			

URL link to FDA Adverse Reaction Reports: http://www.fda.gov/medwatch/report/hcp.htm

SCVIR Complication Classification codes:
A- No Therapy, no consequence
B - Nominal Therapy, observation, no consequence
C - Required Therapy, minor hospitalization (<48°)
D- Major Therapy, unplanned increase level of care, prolonged hospitalization (48°)
E - Permanent adverse sequelae
F - Death

DISCHARGE

1. Date of Discharge : ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day month year

2. Post-procedure pain management:
Patient's **rating** of maximum level of pain experienced prior to discharge: _____(0 to 10 scale)
0 = No pain, 10 = worst imaginable

CIRREF UAE FIBROID Registry

Site number: ___ ___ ___ ___ Case number: ___ ___ ___

30-DAY FOLLOW-UP

1. Recovery Time:

Total days missed from work, including procedure: _____ days

Total days until back to normal activity from procedure date: _____ days

2. Re-interventions: (check all that apply)

- ❑ None
- ❑ Myomectomy
- ❑ Embolization
- ❑ Hysteroscopy with resection
- ❑ Hysteroscopy without resection
- ❑ D & C
- ❑ Hysterectomy
- ❑ Endometrial Ablation
- ❑ Other

3. Adverse Events/Unanticipated consequences:

	Event **(check all that apply)**	**If Yes, indicate** Associated Service Utilization: (check all that apply)	**If Yes**, specify Outcome:
❑No ❑ Yes	None		
❑No ❑ Yes	Recurrent Pain	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown ❑ Death
❑No ❑ Yes	Sloughing of Submucosal Fibroid/Fibroid Passage	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown ❑ Death
❑No ❑ Yes	New Hot Flashes/Night Sweats	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown ❑ Death
❑No ❑ Yes	Radiation Skin Burn	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown ❑ Death
❑No ❑ Yes	Infection or Possible Infection	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown ❑ Death

CIRREF UAE FIBROID Registry

Site number: ___ ___ ___ ___ Case number: ___ ___ ___

		Event (check all that apply)	If Yes, indicate Associated Service Utilization: (check all that apply)	If Yes, specify Outcome:
❑No	❑ Yes	Thromboembolism	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown Death
❑No	❑ Yes	Spinal headache	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown Death
❑No	❑ Yes	Persistent bleeding, hemorrhage following embolization	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown Death
❑No	❑ Yes	Other; _____ _____ _____	❑Unanticipated Office Visit Date: ____/_____/_____ ❑Unanticipated Emergency Room Visit Date: ____/_____/_____ ❑Unanticipated Hospitalization Date of Admission:____/_____/_____ Date of Discharge: ____/_____/_____	❑ Resolved ❑ Resolved with sequelae ❑ Unresolved ❑ Unknown Death