Efficacy and Safety Associated with the Use of the Surfacer® Inside-Out® Access Catheter System: Results from a prospective, multicenter FDA IDE study

Supplementary Materials

Table S1. Inclusion/Exclusion Criteria

| Inclusion Criteria                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------|
| ▪ Subjects are between 18-80 years of age.                                                                                           |
| ▪ Subjects have been referred for placement of central venous access catheter.                                                        |
| ▪ Subjects have limited or diminishing upper body venous access or pathology impeding standard access methods.                      |
| ▪ Subjects are willing and able to give written informed consent.                                                                        |

| Exclusion Criteria                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------|
| ▪ Subjects were contraindicated for if one of the following were found                                                               |
|   - Occlusion of the right femoral vein;                                                                                            |
|   - Occlusion of the iliac vein;                                                                                                    |
|   - Occlusion of the inferior vena cava.                                                                                             |
| ▪ Subjects were contraindicated for central venous access based upon the treating physician’s opinion and institutional standard of care.|
| ▪ Subject with acute thrombosis within any vessel (SVC, jugular, inferior vena cava (IVC), brachiocephalic and subclavian) planned to be crossed by the device.|
| ▪ Subjects with tortuous anatomy which precludes a straight line from femoral venous entry to subclavian exit.                        |
| ▪ Subject diagnosed with pericarditis or endocarditis.                                                                               |
| ▪ Subject has a known or suspected pericardial effusion.                                                                             |
| ▪ Subject has a known or suspected aneurysm or ectasia of ascending aorta, innominate artery, or subclavian artery.                   |
| ▪ Subjects who are pregnant or of childbearing potential not taking adequate contraceptive measures or nursing during the study.      |
Table S2. Schedule for study assessments and the data collected for each assessment period

| Assessments/Interval                                      | Screening | Baseline | Intra-Procedural | Hospital Discharge | 7 Days (+7) Post Procedure |
|----------------------------------------------------------|-----------|----------|-------------------|--------------------|---------------------------|
| Informed Consent                                        | X         |          |                   |                    |                           |
| Study Eligibility                                        | X         |          |                   |                    |                           |
| Medical History/Demographics                             | X         |          |                   |                    |                           |
| Physical Exam including Vital Signs                      | X         | X        |                   |                    | X                         |
| TCVO Lesion Type Classification                          |           |          |                   |                    |                           |
| Procedural Complication Assessment                       |           |          | X                 | X                  | X                         |
| Study Device                                             |           |          |                   |                    |                           |
| Medications (Antithrombotic & Cardiovascular)            | X         |          |                   |                    | X                         |
| Clinical Laboratory Tests                                |           |          |                   |                    |                           |
| Pregnancy Test                                           | X         |          |                   |                    |                           |
| Creatinine                                               |           |          |                   |                    |                           |
| Coagulation Profile (APTT/PT/INR)                        | X         |          |                   |                    |                           |
| CRP                                                      | X         |          |                   |                    |                           |
| LDH/ASAT/ALAT                                            | X         |          |                   |                    |                           |
| Fibrinogen/D-dimer                                       | X         |          |                   |                    |                           |
| Exams and Tests                                          |           |          |                   |                    |                           |
| AP and LAT Chest X-Ray or cine-fluoroscopy               | X         | X        |                   |                    | X                         |
| Ultrasound or Venous Duplex Venography                   |           |          |                   |                    |                           |
| ECG 12-lead                                              |           |          |                   |                    |                           |
| TTE                                                      |           |          |                   |                    |                           |
| Contrast Angiography                                     |           |          |                   |                    | If Cardiac Events         |
| Fluoroscopy                                              |           |          |                   |                    | If Cardiac Events         |
| Cone Beam CT/cardiac echo/advanced imaging modalities    |           | X        |                   |                    |                           |
| Adverse Events                                           | X         | X        |                   |                    | X                         |
| Protocol Deviations                                      | X         | X        |                   |                    | X                         |
Table S3. Additional baseline characteristics and medical histories for patients enrolled in SAVEUS study (ITT population)

| Characteristic                                           | Number of patients (%) |
|----------------------------------------------------------|------------------------|
| Respiratory disease                                      | 14 (46.7%)             |
| Asthma                                                   | 7 (23.3%)              |
| Chronic obstructive pulmonary disease (COPD)             | 6 (20.0%)              |
| Pulmonary hypertension                                   | 2 (6.7%)               |
| Angina                                                   | 3 (10.0%)              |
| Bleeding diatheses or coagulopathy                       | 1 (3.3%)               |
| Carotid Stenosis                                         | 4 (13.3%)              |
| Previous CAD interventional procedures                   | 6 (20.0%)              |
| Previous Stroke                                          | 6 (20.0%)              |
| Previous Transient Ischemic Attack (TIA)                 | 5 (16.7%)              |
| Dyslipidemia                                             | 6 (20.0%)              |
| Hyperlipidemia                                           | 15 (50.0%)             |
| Previous Myocardial Infarction                           | 5 (16.7%)              |
| Chronic Kidney Disease (CKD)                             | 28 (93.3%)             |
| Renal Dysfunction                                        | 24 (80.0%)             |
| Smoker                                                   | 11 (36.7%)             |