

## Statement of Work

Equipment being ordered: Electrosurgical Generator

Transaction number: \_\_\_\_\_

Please provide the following information clearly and precisely.

1. Description of what the equipment being requested is: Used during implant to minimize the risk of tissue damage and neuromuscular stimulation and provide coagulation.
2. Description of how the equipment being requested operates: the generator adjust automatically, responding to tissue changes, maintaining power delivery and minimizing drag.
3. Where will the equipment being requested be used: 4123B cardio Cath/Lab
4. Who will be using the equipment being requested: Cath/Lab attending and Cardio Fellows.
5. Other: The C A requirements do not apply, and that a security accreditation package is not required.

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## Statement of Work

**Equipment being ordered: Electrosurgical Generator**

**Transaction number:** [REDACTED]

**Please provide the following information clearly and precisely:**

- 1. Description of what the equipment being requested is:** an isolated output electrosurgical generator that provides power for cutting, desiccating (removing moisture) and fulgurating tissue (destruction of small growths or areas of tissue during diathermy) during bipolar and monopolar surgery. Diathermy is a medical and surgical technique involving the production of heat in a part of the body by high-frequency electric currents, to stimulate the circulation, relieve pain, destroy unhealthy tissue, or cause bleeding vessels to clot.
- 2. Description of how the equipment being requested operates:** The generator automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density. This adjustment is based on the selected mode (bipolar or cut modes only), the power setting and the level of tissue resistance. The maximum output is controlled to reduce capacitive coupling and video interference and to minimize sparking. Bipolar modes are able to be chosen to provide a high degree of precision and fine control over amount of desiccation (precise – low), standard for most bipolar applications and macro for bipolar cutting or rapid coagulation. Three monopolar modes are used for a cut with little or no sparking (low), when a clean precise cut in any tissue with little or no hemostasis (pure) and where slower cutting and additional hemostasis is desired (blend). Three coagulation modes for dehydrating and destroying tissue without sparking or cutting (desiccate), coagulating tissue by sparking from the active electrode, through air, to patient tissue and affording optimum fulguration (spray) as penetration is less deep and the tissue area is larger than with the fulgurate mode.
- 3. Where will the equipment being requested be used:** 4123B Cardiac Cath/Lab
- 4. Who will be using the equipment being requested:** Cath/Lab attending and Cardiac Fellows.
- 5. Justification:** To be used during implant surgery to minimize the risk of tissue damage, neuromuscular stimulation and provide coagulation.

"In accordance with Appendix A, Handbook 6500.6 Checklist block 6, the C&A requirements do not apply to this requirement, and Security Accreditation Package is not required.

In accordance with Appendix A, Handbook 6500.6 Checklist block 7, Due to the non-technical nature of this requirement there is no information to be protected.”

This product does not capture or produce PII/PHI. There is no storage mechanism in the equipment or software requested.