Research Study Protocol

Study Title: Evaluation of Clinical Outcomes and Patient Satisfaction Following Lumpectomy Using the Photon Blade 3 Illuminated Electrosurgical Device with Integrated Smoke Evacuation

Principal Investigator: Lauren Kopicky, DO

Sponsor: Stryker Instruments

A. BACKGROUND AND SIGNIFICANCE

The PhotonBlade 3 Smoke Evacuation device is a monopolar RF device coupled with illumination that is FDA approved and indicated for cutting and coagulation of soft tissue during surgical procedures and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The device includes a coated electrode at the distal end of a rotatable and extendable shaft (telescope) which delivers monopolar radiofrequency energy for cutting and coagulation of tissue. These devices enable the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit (ESU) to the operative site for the desired surgical effect. The integrated LED-based illumination allows the user to turn on or off the illumination. The integrated smoke evacuation tubing enables the user to evacuate smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

The Photon Blade 3 integrates localized surgical field illumination, simultaneous electrosurgical dissection, and active smoke evacuation. By improving visualization at the point of dissection and reducing smoke plume accumulation, surgeons perform more precise tissue dissection and hemostasis. The Photon Blade 3 device is FDA approved and being used in standard clinical care at Cleveland Clinic per its intended use. Utilization of the Photon Blade 3 expands feasibility of hidden scar lumpectomy approaches without compromising tissue handling. Cosmetic outcome after lumpectomy significantly influences patient satisfaction, body image, and quality of life. Reduced tissue trauma, optimized hemostasis, and improved control of the resection cavity translate into preservation of native breast contour, potentially leading to lower incidence of fat necrosis with less thermal injury, and more discrete scar placement.

B. SPECIFIC AIMS

The overall goal of this study is to assess the clinical performance and safety of the Photon Blade 3 illuminated electrosurgical device with integrated smoke evacuation, including patient reported outcomes, incorporation of oncoplastic techniques, and surgical field optimization. This study allows for the collection of data from cases where the device is already being used in standard clinical care in accordance with its FDA approved indication.

Primary Objective

1. *Clinical performance and safety*
    - *Target lesion excised (operation success rate)*
    - *Intraoperative and postoperative complication rates*
        - *Seroma, hematoma, infection, wound dehiscence*

Secondary Objectives

2. *Patient-Reported Outcomes*
    a. *Cosmetic satisfaction (questionnaire)*
    b. *Overall procedural satisfaction*
3. *Oncoplastic Technique*
    a. *Scar location*
    b. *Distance from incision to the target lesion*
4. *Surgical field optimization*
    a. *Surgeon and assistant reported visibility of operative field*
    b. *Perceived reduction in surgical smoke interference (need to track tissue density)*
    c. *Device usability and ergonomics*

C. **STUDY DESIGN**

This is a prospective observational study with collection of questionnaires and clinical data from 50 participants to assess the performance and safety of the PhotonBlade 3 as the electrosurgical device used in standard of care lumpectomy. There is no intervention. This is not an investigational device.

Subject Population

Inclusion Criteria

- Any adult patient (18 years of age or older) undergoing lumpectomy for benign or atypical disease with PI as surgeon at Avon or Fairview Hospital
- Any age

Exclusion Criteria

- Malignancy

Study Procedures

Patient-reported outcomes (PROs), including cosmetic satisfaction and overall procedural satisfaction, will be collected using validated questionnaires administered at predefined time points (e.g., preoperative, post-op day 3, 2 weeks, 45 days, 90 days). All surveys take approximately 5 minutes or less and may be administered electronically via a secure institutional platform or in paper form during clinic visits.

Patient photos preop and at 90 days will be taken through Haiku and directly stored within the patient electronic health record (Epic).

Schedule of Events

Procedure	Screening	Baseline	Surgery	POD3	2 week	45 day	90 day
Informed consent		X					
Inclusion/Exclusion Criteria	X						
Demographics	X						
Medical History	X						
Physical Exam	X						
Surgery			X				
AE Assessment				X	X	X	X
Photos	X						X
PRO Questionnaire		X					X

Pain questionnaire				X		X	
Aesthetic outcome (surgeon)							X
Blinded surgeon Evaluation aesthetic outcome							X

Recruitment and Consent

Potential participants will be identified from PI's clinic. The PI will introduce the study during the subject's preoperative clinic visit, ensuring confidentiality and privacy. The PI or trained research team members will conduct the consent interview, explaining the study's purpose, procedures, risks, benefits, and the voluntary nature of participation. The subject will be given ample time to review the consent and ask any questions they may have. The consent will be signed before any research related activities take place.

If conducted remotely, consent discussions may also occur via secure MyChart messaging or telephone calls, followed by electronic or written documentation. For electronic remote consent via DocuSign, institutional guidelines for digital documentation and verification will be followed.

D. **DATA ANALYSIS PLAN**

Data will be collected prospectively for enrolled participants undergoing lumpectomy using the Photon Blade 3 device. Clinical and operative data will be abstracted from the electronic medical record (EMR) and operative reports.

Collected variables will include:
- Demographics and baseline clinical characteristics
- Target lesion characteristics (size, and histology)
- Operative details
- Margin status and re-excision rates
- Intraoperative and 30-day postoperative complications
- Pathologic outcomes

Sample size of 50 participants was determined as the anticipated number of eligible participants from PI's clinical schedule for study duration. Descriptive statistics will summarize baseline characteristics and outcomes. Continuous variables will be reported as means with standard deviations or medians with interquartile ranges, as appropriate. Categorical variables will be reported as frequencies and percentages.

E. **ALTERNATIVES**

The only alternative is to not participate. Regardless of the study, the Photon Blade 3 is being used in standard of care lumpectomies at the Cleveland Clinic.

F. **RISKS**

There is a potential risk of loss of confidentiality. This will be minimized by entering into and storing data at the secure website Redcap and limiting access to the data to study team (e.g. PI, Co-PIs, and study coordinators).

G. **BENEFITS**

There are no direct benefits of this study to the participants. However, the study provides valuable insight into the clinical performance and safety of the Photon Blade 3 as the standard electrosurgical device used in lumpectomy.

H. **COSTS**

There are no research related costs to the participants for participating in this research study. Participants will remain accountable for costs of their standard of care procedure and follow up care.

I. **COMPENSATION**

There is no compensation for participation in this trial.

J. **PRIVACY AND CONFIDENTIALITY**

The study's de-identified dataset will be stored in REDCAP database – this is a secure, password-protected institutional servers compliant with HIPAA regulations. Each participant's MRN will be replaced with a unique study identification number. The key with direct identifiers will be stored separately from analytic datasets in a limited-access file stored in institute's shared network drive. Only trained study team members will have access to the study data in RedCap and the file with the key for patient identifiers as necessary for EMR data abstraction. The key file will be destroyed at study completion, and the de-identified data set will remain in RedCap to be stored for a minimum of 6 years after study completion. Data transmission (if applicable) will occur only through encrypted institutional systems. No identifiable patient information will be shared outside the study team.

K. **DATA/SAMPLE SHARING**

De-identified data from this research study may be shared within the Cleveland Clinic with other Cleveland Clinic researchers and/or sent outside of the Cleveland Clinic for data analysis. Investigator will provide Stryker with quarterly status reports during study duration and a final report of de-identified study results within 90 days of study conclusion. No identifiable patient information will be shared outside the study team.

L. **ADVERSE EVENTS AND DATA MONITORING COMMITTEE (DMC)**

Per the data dictionary, this study aims to collect adverse events that may be expected of the standard of care lumpectomy with the PhotonBlade 3. These adverse events include:

- Seroma (with or without intervention)
- Hematoma (with or without intervention)
- Wound dehiscence
- Surgical site infection (requiring antibiotics)

Only additional, unanticipated AE's related to the procedure that are reported during the 90-day post-operative study period for a participant will be reported. AE reporting will follow Cleveland Clinic IRB standards and procedures.