# Clinical Development History

**Selene Pivotal Clinical Trial**
A multi-center clinical trial designed to measure the effectiveness of Perimeter's WF-OCT medical device with AI technology in addressing positive margins in breast conservation surgery. (2021)

**Intraoperative use of the OTIS™ (OCT Imaging System) to Guide Additional Margin Cavity Shaves in Breast-Conserving Surgery**
Study to measure the effectiveness of Perimeter's OTIS™ (OCT Imaging System) medical device in addressing positive margins in breast conservation surgery. (2021)

**Wide-field Optical Coherence Tomography Imaging of Excised Breast Tissue for Evaluation of the Computer-Aided Detection Tool ImgAssist™**
A multi-center data collection study designed to collect OTIS™ imaging data of excised breast tissue margins with corresponding margin status from histopathology to train and validate the ImgAssist™ system. (2020)

**Optical Microscopy of Excised Normal and Neoplastic Human Tissue**
The 1st study to examine data of multiple tissue types. This study also contributed to the early development support of ImgAssist™. (2018)

**Intraoperative use of the OTIS™ in Surgically Excised Lumpectomy Breast Tissue**
Study to validate that the intraoperative workflow of the OTIS™ system does not interfere with the current surgical standard of care procedure. This data will also be used to contribute to the OTIS™ image library. (2018)

**Intraoperative Use of the OTIS [Optical Tissue Imaging System] in Oral Cavity and Oropharyngeal Tissue**
A data collection study designed to collect OTIS™ imaging data of excised tonsil, tongue, and buccal tissue microstructures and compare it with corresponding histopathology and abnormalities visualized in permanent sections of aerodigestive tract tissue. (2018)

**Intraoperative Use of OTIS™ in Surgically Excised Lumpectomy Breast Tissue**
The objective of this study was to validate that the OTIS™ system can be integrated into the surgical workflow in the operating room for ex vivo imaging of breast tissue microstructure without affecting the existing standard of care procedure and to contribute to the OTIS™ image library of training data sets. (2018)

**Evaluation of Surgically Excised Breast Tissue Microstructure using Wide-Field Optical Coherence Tomography**
The objective of this two-phase study, with breast specimens imaged in the pathology suite and specimens imaged in the operating room, was to 1) contribute to the OTIS™ image library of training data sets and 2) validate that the OTIS™ system can be integrated into the surgical workflow in the operating room for ex vivo imaging of tissue microstructure without affecting existing standard of care procedure. Wide-Field optical coherence tomography demonstrated concordance with histology at tissue margins, supporting its potential for use as a real-time adjunct intraoperative imaging tool for margin assessment. (2017)

**Tissue Microstructure of Surgical Specimens Depicted with Optical Coherence Tomography**
Summary: The purpose of this study was to collect data to provide visualization of tissue microstructure in formalin-fixed breast, kidney, and colon tissue samples and to correlate the OCT images to permanent section histology for training and algorithm development. (2015)

**Tissue Microstructure of Surgical Specimens Depicted with Wide-Field Optical Coherence Tomography – Data Collection Study – Part 2**
In this feasibility study, fresh breast tissue specimens were imaged on an OTIS™ 1.0 device following excision. The study's objective was to assess whether different breast cancer subspecialty physicians could be trained to distinguish non-suspicious areas of post-lumpectomy specimen margin in patients with breast cancer using OCT images with final histology as the reference standard. (2015)

**Tissue Microstructure of Surgical Specimens Depicted with Wide-Field Optical Coherence Tomography – Data Collection Study – Part 1**
The study intended to develop methods to correlate WF-OCT to digitized permanent section histology using the OTIS 1.0 system to image fresh samples of thyroid, colon, ovary, uterus, cervix, and skin immediately following excision. A "tissue atlas" of WF-OCT images correlated to permanent section histology was developed to serve as a standard library for image interpretation training. (2015)

**Evaluation of Breast Cancer Surgical Margin Assessment with Optical Coherence Tomography (Study 2)**
This feasibility study with the first generation WF-OCT system assessed specimen scanning and evaluated imaging time. (2014)

**Evaluation of Breast Cancer Surgical Margin Assessment with Optical Coherence Tomography (Study 1)**
This feasibility study was conducted with a prototype device in the pathology lab to collect data and assess specimen scanning with Optical Coherence Tomography. (2012)