Leica Microsystems Sponsored Study to Collect and Confirm Clinical Data on the Performance of the GLOW800 Device When Used in Accordance With Its Intended Use.

NCT07164040

Status	RECRUITING
Sponsor	Leica Microsystems (Schweiz) AG
Enrollment	29 participants

Key Eligibility Criteria

Inclusion (4)

- Participants must be 18 years of age or older at the time of signing the informed consent.
- Participants must have a condition requiring surgical intervention in the cerebral vascular area as well as during plastic and reconstructive surgery.
- The Indocyanine Green (ICG) cyanine dye is administered as a contrast agent per instructions for use.
- The participant or their legal representative must understand the study and have voluntarily signed and dated the Informed Consent Form, which has been approved by the Sponsor and the Ethics Committee for this study

Exclusion (4)

- Known allergy to Indocyanine Green (ICG) cyanine dye.
- Any uncontrolled systemic condition that may adversely affect the surgical outcome.
- Patients holding United States citizenship.
- Severe iodine-induced reactions to macromolecular iodine-containing compounds (e.g., iodinated contrast media, iodine-based antiseptics, or drugs like amiodarone), especially if the reaction involved anaphylaxis or respiratory compromise.

Locations (3 total)

Unidade Local de Saúde de São João, Porto, Portugal
Hospital Germans Trias I Pujol, Barcelona, Spain
University Hospital Basel, Basel, Switzerland