STUDIE:

MRO PMS (ClearSightTM Magnetic Resonance Outcome Post Marketing Surveillance)

Studienname	MRO PMS (ClearSightTM Magnetic Resonance Outcome Post Marketing Surveillance)
Synopse	Prospektive, zwei-armige, kontrollierte klinische Beobachtungsstudie zur Reduktion der Nachresektionsrate bei der brusterhaltenden Therapie von Brustkrebs unter Anwendung des ClearSight™ Magnetresonanztomographie Systems
Studientyp (Mehrfachantwort)	Registerstudie
	nicht-interventionell
	prospektiv
	nicht-randomisiert
Leiter der Klinischen Prüfung	Prof. Dr. Marc Thill
	AGAPLESION MARKUS KRANKENHAUS Wilhelm-Epstein-Str. 4, 60431 Frankfurt am Main
	E-Mail: marc.thill@agaplesion.de Tel.: +49 (69) 953 322 28
Sponsor	ClearSight™ System ClearCut Medical Ltd. 10 Plaut St., Rehovot, Israel Tel: +972-8-6326004 Fax: +972-8-6326005, E-Mail: info@clrcut.com
Primäres Studienziel	Intraoperative Schnittrandmessung des entfernten Brustgewebes mittels des ClearSight™ Magnetresonanztomographie Systems. Die bisherigen Studien konnten eine deutliche Senkung der Nachoperationsrate aufzeigen. Ziel dieser Studie ist die Überprüfung der Technik im klinischen Alltag.
Einschlusskriterien	– Women histologically diagnosed with invasive carcinoma of the breast, undergoing primary lumpectomy (partial mastectomy) procedure
	– Age ≥18
	– Patient is willing and capable to provide written Informed Consent Form (ICF)
Ausschlusskriterien	– Prior surgical procedure in the same breast within 12 months prior to the surgery date
	– Recurrent breast cancer surgery
	– Neoadjuvant chemotherapy and/or neoadjuvant hormone therapy
	– Previous radiation therapy in the operated breast
	– Pregnancy
	– Lactation
	– Patient has subglandular breast implants in the operated breast
	– Moribund patient and/or patient with comorbidities, per principle investigator discretion
	– Participating in any other investigational study for either drug or device which might influence collection of valid data under this study
	Intraoperative and postoperative:
	– Specimen undergoing pathological specimen assessment (e.g. by frozen section, imprint cytology or gross assessment by sectioning), resulting in deformation of specimen shape/tissue properties (e.g. Formalin conservation) prior to ClearSight™ imaging
	– Specimen dimension is larger than the ClearPack container volume (150cc)
	– Inability to define aspect color/orientation and/or margin border

	– Injection of Methylene blue dye or other such substances into the breast interfering with the ability to decipher between dye colors.
Geplante Patientenzahl	N = 58
Status	rekrutierend
Datum first-patient-in	23.06.2021 (am Markus Krankenhaus)
Follow-Up	Follow-up visits will be conducted only if the investigator fails to provide adequate patient data or if unexpected adverse effects are reported during the course of the study, or at our discretion.