

STUDIE:**APPeaR (A Post Market Prospective Study of FORTIVA® 1mm Porcine Dermis in Breast Reconstruction (APPeaR))**

Studienname	APPeaR (A Post Market Prospective Study of FORTIVA® 1mm Porcine Dermis in Breast Reconstruction (APPeaR))
Synopse	Prospektive Anwendungsbeobachtungsstudie des Einsatzes der porcinen Fortiva® 1.0 Dermis bei Brustrekonstruktionen
Studientyp (Mehrfachantwort)	Registerstudie
	nicht-interventionell
	prospektiv
	nicht-randomisiert
Leiter der Klinischen Prüfung	Prof. Dr. Marc Thill
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Sponsor	RTI Surgical 5600 Rowland Rd Suite 200 Minnetonka, MN 55343 952-698-9942
Primäres Studienziel	Untersuchung der Sicherheit der Fortiva® TissueMatrix
Einschlusskriterien	– Female 18 years or older
	– A candidate for immediate breast reconstruction during post-skin sparing or nipple-sparing mastectomy (unilateral or bilateral)
	– Estimated life expectancy > 2 years
	– Able and willing to return for all scheduled and required study visits
	– Able to provide written informed consent for study participation
	– Able to read, understand, and complete study questionnaires
Ausschlusskriterien	– Any of the conditions listed in the approved labeling as contraindicated
	– Currently enrolled or plan to enroll in another clinical study that would affect the validity of the study
	– Any patient that per the physician's judgement is not a good candidate for this study
Geplante Patientenzahl	N = 100 (insgesamt)
Status	rekrutierend
Datum first-patient-in	11.06.2019 (am Markus Krankenhaus)
Follow-Up	24 Monate