



Intraoperative Testing for Clean Surgical Margins

Prof. Donald Engelman
Inventor, Founder and SAB Chairman

CleanMargin, Inc.

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Subsidiary of pHLIP, Inc.

Our Product: MarginVue

Proprietary Fluorescence Imaging Drug

Focus: Intraoperative imaging to guide Cancer removal

Mission: Enable surgeons to achieve "clean" negative margins during surgery

Value: Reduce secondary surgeries, healthcare cost and improve women's health

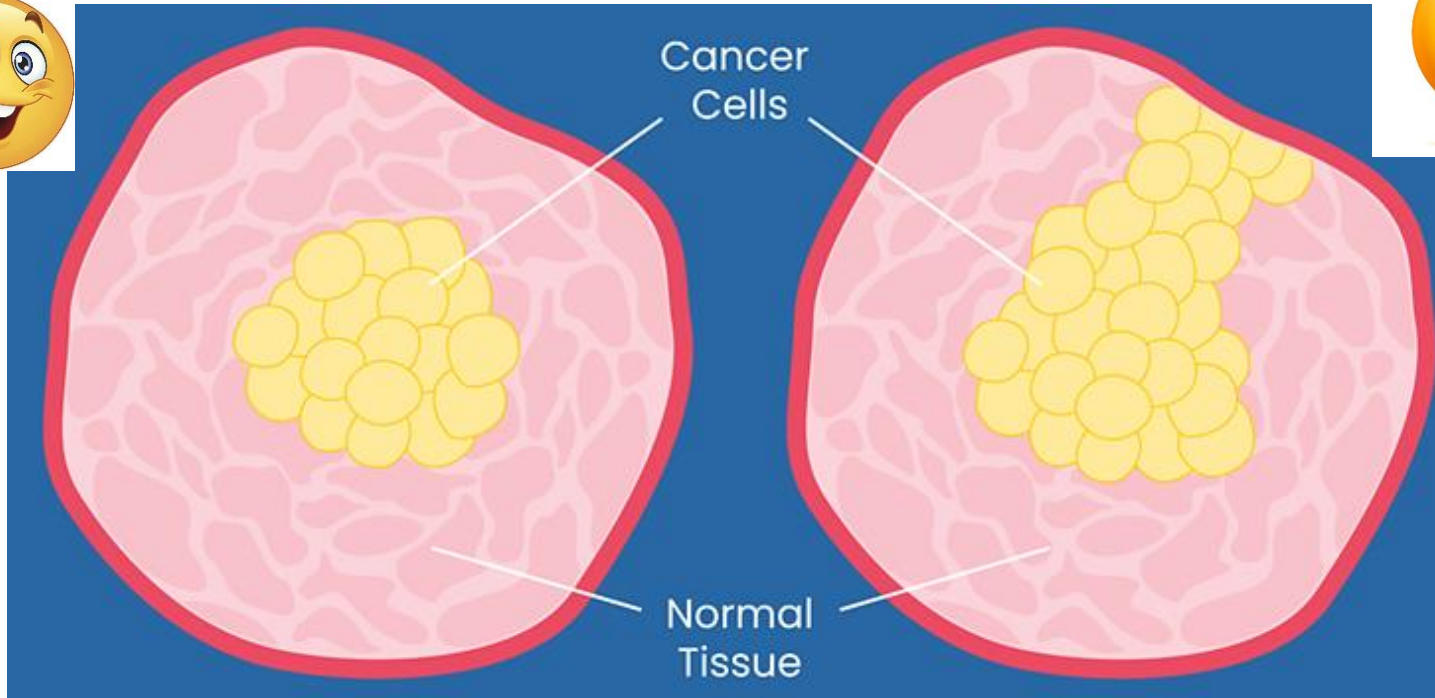
Market: **Breast Cancer with Stryker SPY clinical imaging device**

Problem: Positive Margins in Breast Cancer Surgery

Breast conserving surgery (BCS) success is determined by post-surgical margin assessment

Negative (Clean) Margin

Positive Margin: more surgery



>60%

women with Stage 0-II BC undergo BCS as initial treatment

250K

BCS performed in US annually

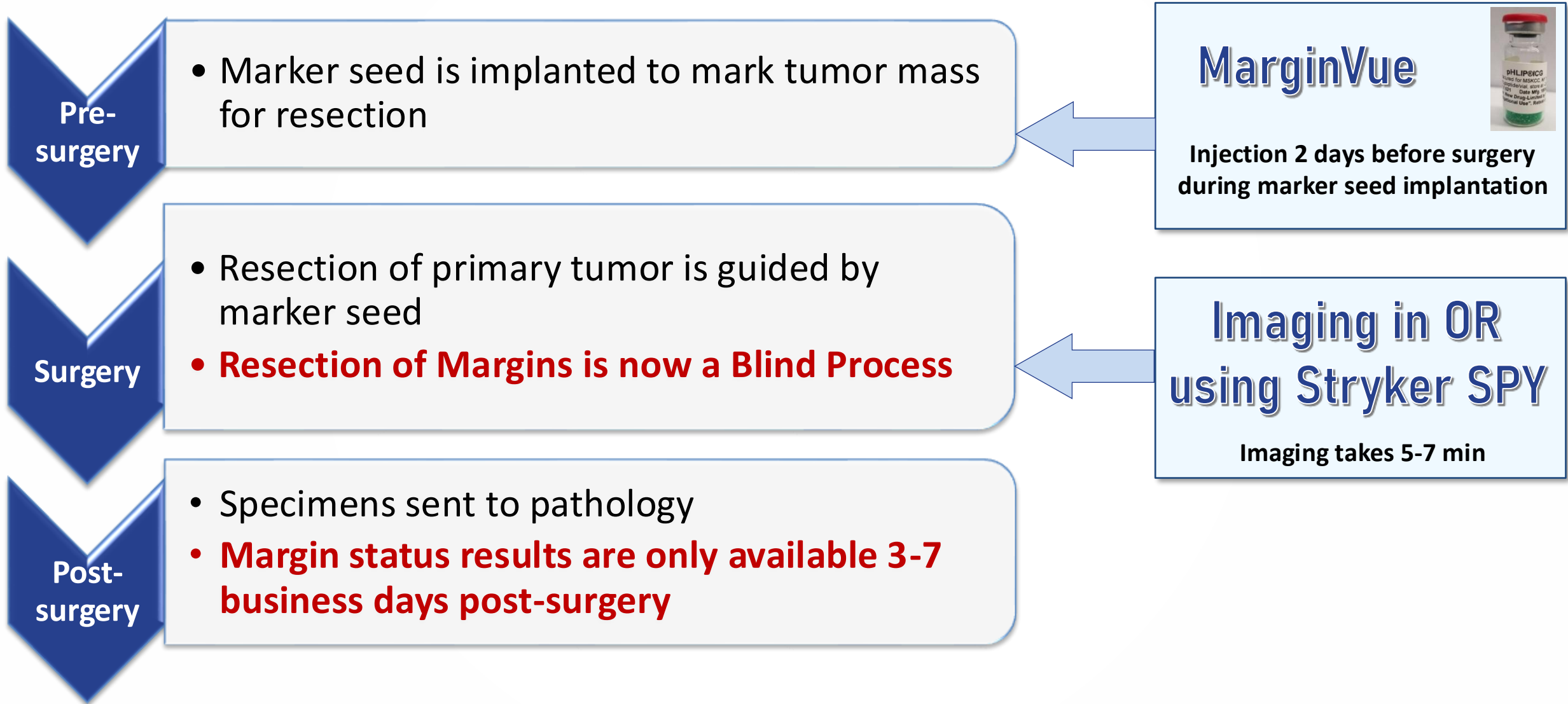
up to 39%

patients require secondary surgery due to positive margins

\$0.5B

annual US healthcare cost for 2nd surgeries due to positive margins

BCS Practice and Our Way to Improve Outcomes



MarginVue is in Phase II clinical trials at MSKCC

CleanMargin

Clinical Trial (NCT05130801): Phase I/IIa study of peri-operative multiparametric MRI and pHLIP® ICG intra-operative fluorescence imaging of primary breast cancer



Memorial Sloan Kettering
Cancer Center



- ✓ Phase I: established safety and pharmacokinetics
- ✓ Part 1 of Phase II: established dose/timing and introduced quantitative imaging protocol using Stryker SPY
- **Part 2 of Phase II (dose expansion) is in progress**

Primary tumor (invasive lobular cancer)

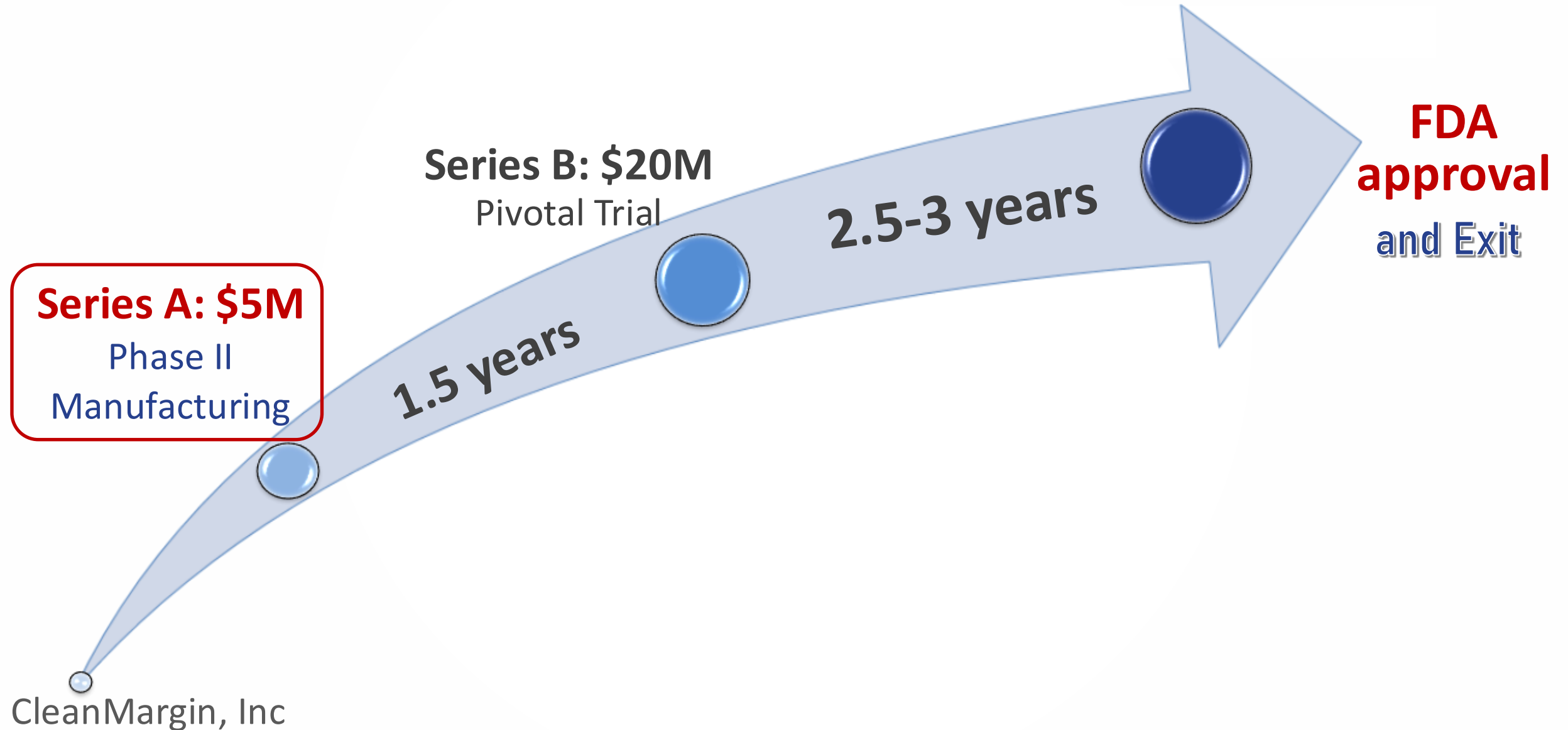


Approach	MarginVue + Stryker SPY	LUMISIGHT + Lumicell DVS	MarginProbe Device	Clarix Device	Claire Device
Sensitivity	100%	49%	75%	92%	PSM confirmed by pathology was detected in 40% of patients
Specificity	95%	85%	46%	83%	
Major Limitations	None	Imaging of cavity only Safety warnings	Problematic with dense (fibrotic) tissue		Lobular carcinoma was excluded

MarginVue does NOT miss cancer

MarginVue does NOT target fibrotic tissue

Path for FDA Approval and Exit



Management Team

CleanMargin



Yana Reshetnyak, PhD
CEO & CSO

Inventor and Founder, expert in fluorescence imaging, experience leading preclinical and IND-enabling studies, GMP manufacturing, clinical translation studies, IP development & sublicensing



Steven Wilcox, JD
EXVP BD & GC

Ropes & Gray partner for > 30 years; founder and former chair of its Life Sci. Practice Group, Extensive experience in corporate financings, M&A and licensing & collaborations



Sonia Sequeira, PhD
CTO & CRO

>15 years of experience at MSKCC and companies in regulatory strategy, preclinical, CMC & early clinical development, >75 INDs for theranostics & companion diagnostics

Consulting CFO: A seasoned financial professional in the life sciences industry

Clinical Team



Memorial Sloan Kettering
Cancer Center



Grant PI
Monica Morrow, MD
Anne Burnett Windfohr Chair
of Clinical Oncology
Chief Breast Service



Trial PI
Giacomo Montagna,
MD MPH FSSO
Assistant Attending Breast Surgery,
Co-director Rare Breast Cancer Program

Device Partner:

stryker®

Manufacturing:

CORDENPHARMA

Total Annual Addressable US Market: \$1B

Total Annual Serviceable US Market: \$350M

Clinical Adoption

- Robust clinical performance
- Quantitative imaging
- Tier 1 Key Opinion Leaders

Reimbursement

- Buy-and-bill model
- Separate reimbursement code without surgery package bundling

Market Penetration

- Co-marketing with Stryker
- >10 years of proprietary position after projected FDA approval

**We expect to raise the standard of care in cancer surgeries
using**

MarginVue

Surgeons can say to patients immediately after surgery:

“We got it ALL”

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