

The MOZART[®] System

Intraoperative Specimen Tomosynthesis



Margin Management
Without All the False Positives

KUBTEC[®]
MEDICAL IMAGING

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Leading Breast Surgeons Agree The MOZART® System Advances Quality of Care



Peter Blumencranz, MD, FACS
Medical Director
The Comprehensive Breast Care
Center of Tampa Bay

"I believe that 3D tomosynthesis specimen X-ray is more accurate. It helps us beyond the other generation of two-dimensional imaging. Good for the patient because if we can be more accurate, of course it reduces the re-excision rate."

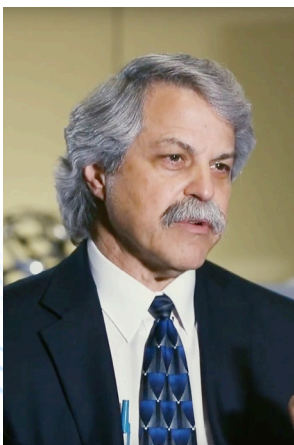
"We want the patient to have the best possible results, a combination of least times having to go back for cancer or re-excision, but taking out the least amount of tissue to preserve the best cosmesis. So I think having 3D specimen X-rays is letting us do both those things."



Andrea Madrigano, MD, FACS
Assistant Professor of Surgery
Rush University Surgeons,
Chicago, IL

"Specimen tomosynthesis allows real time evaluation of the tissue removed from the breast, and this allows us to look not only in two dimensions but three dimensions..."

"This allows us to remove less tissue and, therefore, if it's eccentric in the specimen, to just focus the shave."



Cary Kaufman, MD, FACS
Associate Clinical Professor
of Surgery, Bellingham
Regional Breast Center

"You have a much better view with specimen tomosynthesis of exactly what needs to be removed. I avoid excessive tissue being taken from the patient, and the patient likes it, because the cosmetic result is better."

"Specimen tomosynthesis is a no-brainer. If you're a breast surgeon, and you want to provide the best care, this is it. To identify whether you've done the right operation, you need this."

For the full video on specimen tomosynthesis, please visit:
kubtec.com/mozart



"For my practice, and many breast cancer centers of excellence around the world...
Using 3D specimen tomosynthesis during surgery has helped the best surgeons reduce their re-excision rates even more."

- U.S. News & World Report
 October 30, 2019

Sheldon M. Feldman, MD, FACS

Chief of Breast Surgery and Breast Surgical Oncology and Director of Breast Cancer Services at Montefiore Health System, New York, NY

"3D tomography has radically streamlined breast cancer surgery

by allowing surgeons to better visualize the breast and affected area, even through dense breast tissue, in the operating room."

- ABC 7 Here & Now
 October 14, 2019

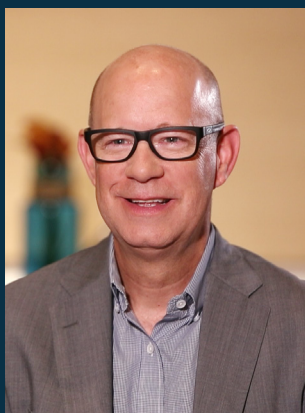


Roshni Rao, MD, FACS

Chief of Breast Surgery Program at New York-Presbyterian/Columbia University Irving Medical Center

"Now with specimen tomosynthesis you can run the slices through the specimen. You can actually see in real time where the target is in relation to all margins, which has been much, much better for us in the operating theater."

"I would tell my fellow surgeons or other people that I know in breast surgery that the Tomosynthesis for specimen radiography is exceptional."



Michael Alvarado, MD, FACS

Professor of Surgery
 Director, Breast Surgery Fellowship
 University of California San Francisco



"It reduces amount of tissue removed at re-excision

(intra-operatively at first surgery or subsequent surgery) to hemi-quadrant (1/8 shave) vs hemisphere or multiple 6 margin random shaves."

Ralph Corsetti, MD, FACS

Edward G. Schlieder Educational Foundation Chair in Surgical Oncology
 Tulane University School of Medicine

"The picture slices it from top to bottom with one-millimeter slices, which allows me to look at each slice individually.

This allows me to identify things more easily and be more precise in patient procedures."

- Hamburg Journal
 September 2019



Andrea Colton, MD, MPH

Breast Surgical Oncologist Lexington Clinic
 Lexington, KY

The MOZART® System is more accurate at identifying positive margins.

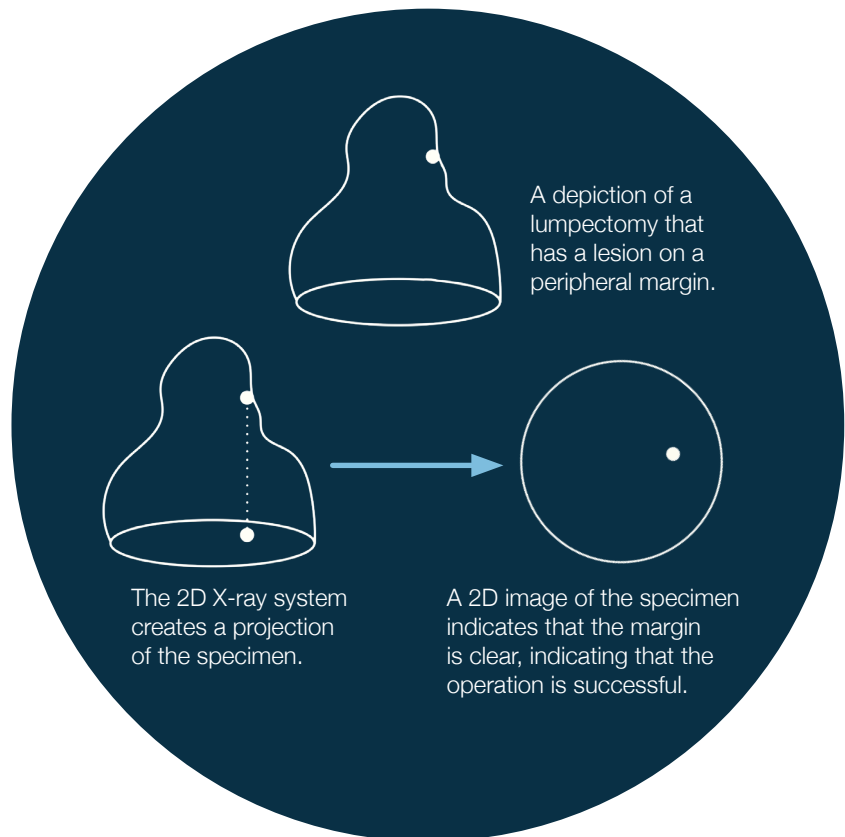
Here's why.

Digital Breast Tomosynthesis is rapidly gaining acceptance as the next gold standard for specimen mammography. Unlike its traditional 2D X-ray counterpart, tomosynthesis allows the physician to see the breast specimen in 3 dimensions which improves accuracy and reduces false positives.

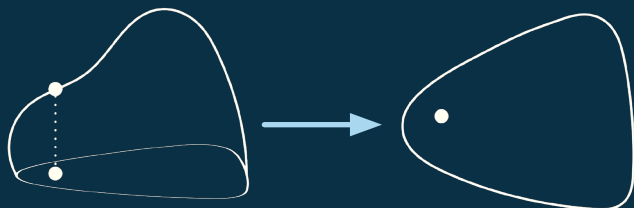
Limitations of 2D X-ray

In a traditional 2D specimen X-ray, the three dimensional anatomy is compressed into a single planar view. All vertical perspective is lost.

In this example the positive margin would be identified during final pathology, and the patient would be scheduled for re-excision.



Orthogonal views are not the same as true 3D.



A lumpectomy turned on it's side. The specimen deforms when repositioned.

A 2D image of the repositioned specimen mistakenly indicates that the margin is still clear.

Note that even when orthogonal views are taken, the same inaccuracies are still encountered with both images.

For the full video on specimen tomosynthesis, please visit: kubtec.com/mozart

Benefits of 3D Tomosynthesis

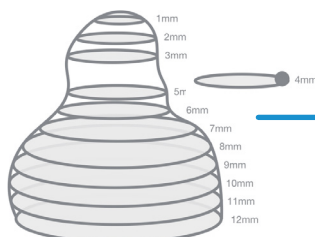
Specimen tomosynthesis enables analysis of the specimen in 1 millimeter digital slices.

Each slice anatomically has its own margin, and can be viewed independently of all the other slices.

The view of each slice is unobscured by dense tissue above or below.



A depiction of a lumpectomy that has a lesion on a peripheral margin.



Specimen tomosynthesis creates 1mm digital slices, each independent of the others.

The peripheral lesion is on the 4mm slice. The surgeon is able to analyze the location and the extent of the lesion, and involvement of the peripheral, anterior and posterior margins.

To try a demo of Specimen Tomosynthesis, please visit: kubtec.com/tomo-slicer-demo

Comparing specimen tomosynthesis and traditional 2D imaging using clinical specimens.

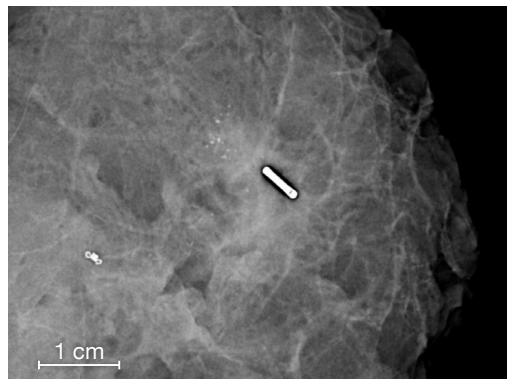


Figure 1: The 2D image shows the seed, clip, and microcalcifications.

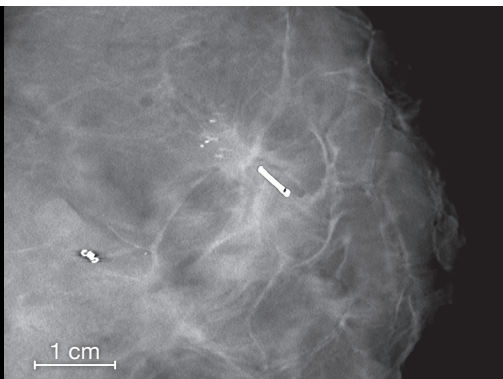


Figure 2: 1mm from the top of the specimen shows microcalcifications.

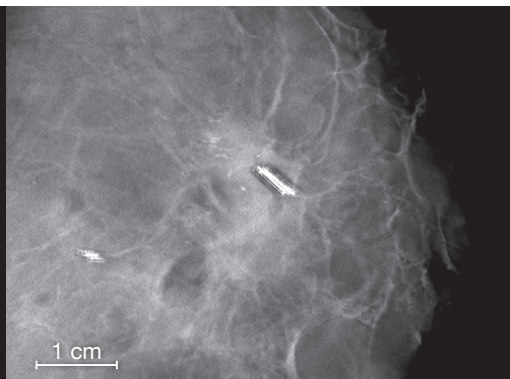


Figure 3: The microcalcifications extend to the 7mm slice.

Traditional 2D imaging shows a marker seed, biopsy clip, and a cluster of microcalcifications in the specimen. But it gives no indication of their true location and proximity to the margin (Fig 1).

Viewing the same specimen using specimen tomosynthesis shows that the microcalcifications extend to less than 1mm (Fig 2) from the anterior margin and extend to 7mm (Fig 3) inside the specimen.

Using specimen tomosynthesis the surgeon would conclude that additional targeted excision is required anteriorly, prior to completing the procedure.

Only the MOZART System from KUBTEC uses specimen tomosynthesis to show your surgical margins as they really are.

Only from Kubtec

The MOZART Specimen Tomosynthesis System

The MOZART® System from KUBTEC uses intraoperative 3D tomosynthesis to enable you to see your surgical margins with unparalleled accuracy in the Operating Room.

DID YOU KNOW?

Specimen Tomosynthesis in the Operating Room has several clinical, patient, and facility benefits.

RE-EXCISION RATES

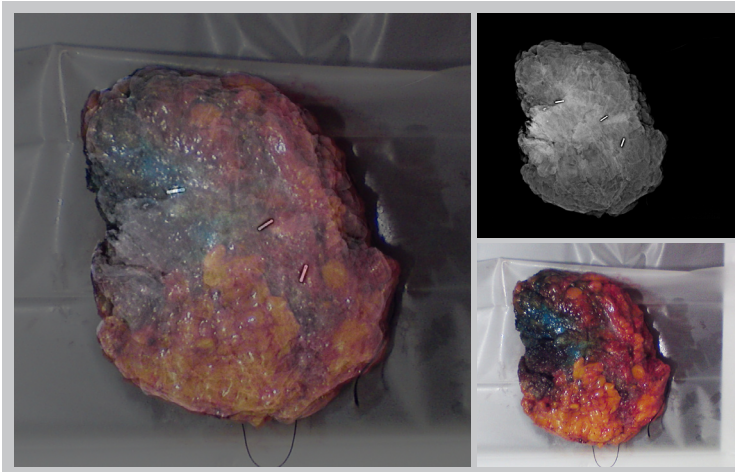
Using 3D tomosynthesis in the Operating Room reduces re-excision rates by more than 50% compared to the traditional 2D imaging systems commonly in use.¹

REDUCTION IN OR TIME & COST

Using 3D Tomosynthesis resulted in an average of 7.6-minute reduction in OR time and a \$284.62 charge savings for wire-localized segmental mastectomies with sentinel node biopsy.²

HEALTHY TISSUE

3D Tomosynthesis is less likely to recommend excising additional healthy tissue unnecessarily³ which can negatively effect cosmetic outcomes.



The Image Blender™

Designed for the OR.
Only from KUBTEC.

The Image Blender allows you to dynamically overlay the X-ray and optical images of your surgical specimen. This enables you to accurately identify the location of lesions and markers directly on the physical specimen itself.

Compare us to the Competition.

	KUBTEC®	COMPETITION
3D Tomosynthesis	✓	✗
The Image Blender™	✓	✗
HD Optical Camera	✓	✗
AutoMagnification	✓	✗
Voice Control	✓	✗
Automatic Specimen Alert	✓	✗

Clinical Studies

Specimen Tomosynthesis is a breakthrough technology for intraoperative quality of care. Clinical research suggests that The MOZART® System can help reduce re-excision rates and improve cosmesis for your patients.

Study: Differences in Re-excisions Rates for Breast Conserving Surgery using Intraoperative 2D vs. 3D Tomosynthesis Specimen Radiograph

Colton A, Calvo C, Mokdad A, Pouns K, Clifford E, Farr D, Huth J, Wooldridge R, Leitch M, Partain N.

Poster presented at: American Society of Breast Surgeons; 2019 May 1-4; Dallas, TX.

- 514 breast conserving operations for cancer were performed from 2016-2018
- 323 cases performed using 2D while 191 cases performed using 3D
- A lower re-excision rate (50% reduction) is independently associated with 3D tomosynthesis
- 3D tomosynthesis may be considered to reduce re-operation rates by allowing surgeons to excise additional margins at the index operation, decreasing reoperations and anxiety/costs for patients

Study: View for View, 3D Specimen Tomosynthesis Provides More Data Than 2D Specimen Mammography

Kaufman C, Zacharias K, Rogers A, Nix S, O'Donnell J, Ness K, Schnell N, Hill L

Poster presented at: American Society of Breast Surgeons; 2017 May 2-5; Las Vegas, NV.

- Over an 18-month period, 200 patients who had image guided lumpectomies using both intraoperative 2D imaging and intraoperative 3D tomosynthesis were compared
- During the 18 months of adoption of the intraoperative 3D tomosynthesis, there was a significant reduction in re-excision rates, from 16% to 9%
- Use of specimen tomosynthesis in the OR has improved the accurate of intraoperative imaging in 43% of cases

Study: Digital Breast Tomosynthesis for Intraoperative Margin Assessment during Breast-Conserving Surgery

Park KU, Kuerer HM, Rauch GM, Leung JWT, Sahin AA, Wei W, Li Y, Black DM.

Ann Surg Oncol 2019;26:1720-28.

- Study was to determine the ability of digital breast tomosynthesis (DBT) to detect positive margins compared with an institution's standard extensive processing (SEP)
- This demonstrated the ability of DBT to accurately identify segmental mastectomy specimens having tumor at ink, with a similar sensitivity and higher specificity compared with our institutional SEP
- DBT can replace labor-intensive processing methods given that its rapid acquisition of high resolution, cross-sectioned images of the intact specimen takes approximately 1 min, and can be read by the surgeon

Study: The temporal and financial benefit of intraoperative breast specimen imaging: A pilot study of the Kubtec MOZART

Kornfeld H, Mulder L, Spivey T, Cortina C, Madrigano A, Kopkash K.

Breast J. 2019;25:766-768.

- A retrospective chart review was conducted of all breast cancer patients from Jan 1, 2015 to December 31, 2016 with non-palpable lesions requiring wire-localization for excision
- On average, OR time was 7.6 minutes shorter when using intraoperative imaging as opposed to sending the specimen to diagnostic radiology. This time reduction translates into estimated OR cost savings of \$284.62 per case
- This three-dimensional intraoperative imaging allows the surgeon to make a more accurate decision regarding targeted shave margins, which may improve more aesthetics and decrease re-excision rate, which would also provide a financial benefit



The MOZART® Supra®
Specimen Tomosynthesis System



The MOZART®
Specimen Tomosynthesis System

3D Specimen Imaging

Call 1.203.364.8544
to set up a demo for
your operating room.

Calculate the Savings for Your Operating Room.

Operating Room Savings Calculator

of surgeries per week
6

OR Cost / minute (\$)
38

Time Savings / surgery (mins)
19

Average Time / surgery (mins)
33

Current OR Costs

Per Procedure	Weekly	Monthly	Annually
\$1,254	\$7,524	\$30,096	\$376,200

Re-Excision Savings Calculator

Total Cost / Procedure
\$15,000

Total Procedures / Month
28

Current Re-excision Rate
20%

Re-Excision Cost
\$84,000

Reduction in Re-Excision Rate w/ MOZART
30%

Cost Savings w/Mozart

Per Procedure	\$722
Weekly	\$4,332
Monthly	\$17,328
Annually	\$216,600

Cost Savings w/ Mozart

Monthly	\$126,000
Annually	\$1,512,000

This is intended to be an example of potential savings for the Operating Room. All figures will be adjusted based on your needs.

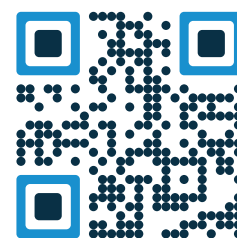
REFERENCES

1. Colton A, Calvo C, Mokdad A, Pouns K, Clifford E, Farr D, Huth J, Wooldridge R, Leitch M, Partain N. Differences in Re-excision Rates for Breast Conserving Surgery Using Intraoperative 2D vs. 3D Tomosynthesis Specimen Radiograph. Poster presented at: American Society of Breast Surgeons; 2019 May 1-4; Dallas, TX.
2. Kornfeld H, Mulder L, Spivey T, Cortina C, Madigrano A, Kopkash K. Breast J. 2019;25:766-768.
3. Park KU, Kuerer HM, Rauch GM, Leung JWT, Sahin AA, Wei W, Li Y, Black DM. Digital Breast Tomosynthesis for Intraoperative Margin Assessment during Breast-Conserving Surgery. Ann Surg Oncol 2019;26:1720-28.

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