Marketing Toolkit

SoftVue™

Media Resources

- Media Messaging & Talking points
- Press Release Templates

Delphinus Medical Technologies

SoftVue™ Media Messaging

SoftVue was created to address a clearly unmet clinical need

- Women with dense breasts, BIRADS C & D density, have a 4x increased risk for developing breast cancer, but mammography misses roughly half of the cancers in women with dense breasts, as both cancer and dense tissue appear white on x-ray.
- 40% of women in the US have dense breast tissue, so the increased risk combined with decreased sensitivity creates a dense breast screening challenge.

SoftVue is THE SOLUTION for dense breast patients

- SoftVue was developed to address the unmet clinical need for dense breast screening. The Triple Acoustic Detection technology, or TRIAD technology, embedded in the SoftVue system increases sensitivity by 20% and specificity by 8%, which means SoftVue is proven to identify more cancers in women with dense breasts and decreases the number of unnecessary call-backs or biopsies of benign masses.
- The TriAD™ technology captures not only reflected echoes, but the acoustic properties of sound speed and attenuation that is transmitted through the breast tissue. These three foundational image data sets formulate the image sequences presented to the radiologist for interpretation: Wafer, Reflection, Sound Speed, and Stiffness Fusion.
- SoftVue delivers a consistent and uniform exam without reliance on operator skill or technique. The entire breast is imaged in one scan, through a consistent, reproducible acquisition, unlike any other automated or mechanized breast ultrasound system.

SoftVue delivers a better patient experience

- The unique design of SoftVue offers a streamlined breast imaging experience for women and does not use compression or radiation during the scan. The SoftVue exam can be performed on the same day as screening mammography and provides a comfort unavailable in other imaging modalities without the risks of imaging agents or radiation. The SoftVue scan takes 3-5 minutes on average per breast, so it supports efficient integration into clinical practice.
- Each scan begins with the patient positioning herself on her stomach on the comfort padded table-top. The patient will then lower the first breast into the imaging chamber, which is filled with fresh, warm water as the coupling agent.
- When the breast descends into the water, with the assistance of a gentle suction, the nipple will engage with the Sequr breast interface that rests on the telescope platform inside the imaging chamber. Sequr is an acoustically transparent, anatomically shaped gel pad that provides stability and extension during the exam.
- Once in position, the unique ring transducer then moves from the nipple to the chest wall capturing image data in 2mm increments. SoftVue's ring transducer images the entire breast in a continuous 360° scan sequence, creating a cross-sectional image map. No mechanical rotation occurs around the breast, providing for close contact with the chest wall.
- SoftVue features an aesthetic profile with curved contours and subtle lighting that delivers unparalleled breast imaging capability and patient comfort.

Delphinus Medical Technologies

Delphinus Q & A for New SoftVue Sites

ıt Delphinus

What is Delphinus?

Delphinus Medical Technologies, Inc. is a privately held medical technology company dedicated to revolutionizing the detection of breast cancer in women with dense breasts. SoftVue, is transforming the way dense breast tissue is imaged with its ring ultrasound transducer, designed to deliver increased specificity (fewer false positives) with improved sensitivity (find more cancers) in women with dense breasts.

How was Delphinus started? Who were the founders?

While working as colleagues at the Barbara Ann Karmanos Cancer Institute and Wayne State University in Detroit, Mich., Peter Littrup, M.D., and Neb Duric, Ph.D., recognized the healthcare gap for women with dense breasts as 50% of cancers are missed in women with dense breast tissue using mammography alone. Together, they created SoftVue, the world's first three-dimensional, whole-breast ultrasound tomography system that is capable of mapping the entire breast, including the chest wall, in one scan per breast.

Karmanos Cancer Institute served as the primary investigational site for the system, including case collection and clinical studies. In 2010, Delphinus Medical Technologies, Inc., was formed as a spin-off from Karmanos Cancer Institute to commercialize SoftVue.

Are Peter Littrup and Neb Duric still involved in Delphinus?

Yes, Peter Littrup is our chief medical officer and Neb Duric is our chief technology officer.

ıt SoftVue

What is the advantage of SoftVue?

SoftVue is the world's first three-dimensional, whole-breast ultrasound tomography system utilizing Delphinus' proprietary TriAD (triple acoustic detection) technology, which is designed to provide physicians with an unparalleled understanding of the tissue within the breast through a non-invasive imaging platform. The breast cancer screening and diagnostic device is developed to provide detailed images of the breast tissue and chest wall without the radiation or compression associated with other methods.

Unlike standard ultrasound technology, which is only able to capture reflection echoes during imaging, SoftVue uses a proprietary 360-degree ring transducer that is able to simultaneously capture echoes reflecting back from breast tissue, as well as signals passing through the breast. By recording sound speed and attenuation which measure the speed and direction of

phinus Medical Technologies

ne to receive innovative, FDA-approved SoftVue™ Breast Imaging System

-kind technology designed to improve outcomes for women with dense breast tissue

h.—Site Name, is proud to announce they are adding SoftVue™ 3D Whole Breast omography System (SoftVue™) to the breast center, following its approval by the Food inistration. Developed by Novi-based Delphinus Medical Technologies, the new and hnology was designed to be the screening solution for women with dense breast

tissue is common, affecting 40 percent of women and making them four times more op breast cancer. Compounding the increased risk, dense breast tissue typically solid white area on a mammogram, making it difficult to distinguish from masses and abnormalities, missing roughly half of new cancer cases.

with a screening mammogram, SoftVue™ has been shown to identify up to 20 percent while also reducing false positives and decreasing unnecessary call-backs and

nitted to providing our patients with superior screening technology and the of SoftVue™, in partnership with Delphinus Medical Technologies, will further ır fight against breast cancer that accounts for one in three new cancer diagnoses in year," said Site Leader/Doctor. "The key to breast cancer survival is early detection screening device will be lifesaving for so many women in our community."

ed as an adjunct to mammography, allows women with dense breast tissue to have creenings during a single appointment. Taking approximately eight to 10 minutes, a mmogram uses warm water and ultrasound technology to create a 3D image of the to detect the presence of cancer in its earliest stages — including masses in dense often missed by mammography alone — while avoiding radiation exposure and allowing the radiologist to make a more accurate diagnosis.

n graduate it, I am excited that this community is at the forefront of dense ning innovation and has an opportunity to lead a transformation in imaging e hundreds of thousands of lives." Mark J. Forchette, President & CEO, Delphinus nologies, Inc.

System will be available to patients at site name in launch date. To learn more hnology, its benefits and request an appointment, visit website address

###

750-00202 Rev 0.01

TO OFFER SOFTVUE SYSTEM FOR DENSE BREAST SCREENING

ind 20 Percent More Cancers in Women with Dense Breasts, no Radiation or Compression

[MONTH] [DATE], 2022 – [NAME OF FACILITY] is first in [AREA] D whole breast ultrasound tomography system FDA approved kam to digital mammography for screening asymptomatic e SoftVue exam requires no compression or radiation and can ent as screening mammograms. Clinical studies have shown cers in women with dense breasts compared to

OLUTION FOR WOMEN WITH DENSE BREASTS," said [NAME OTE ABOUT HOW SOFTVUE WILL ALLOW FACILITY TO BREASTS AND POTENTIALLY SAVE LIVES."

ave dense breast tissue, and they have a four-to-six-time er. Mammography alone misses about half the cancers in tissue and cancer both appear white on mammogram ldress this unmet clinical need and provides a new annual / underserved population.

N DENSE BREAST SCREENING TECHNOLOGY THAT SOFTVUE Y SPOKESPERSON 2]. "QUOTE ABOUT DISTINCT PATIENT

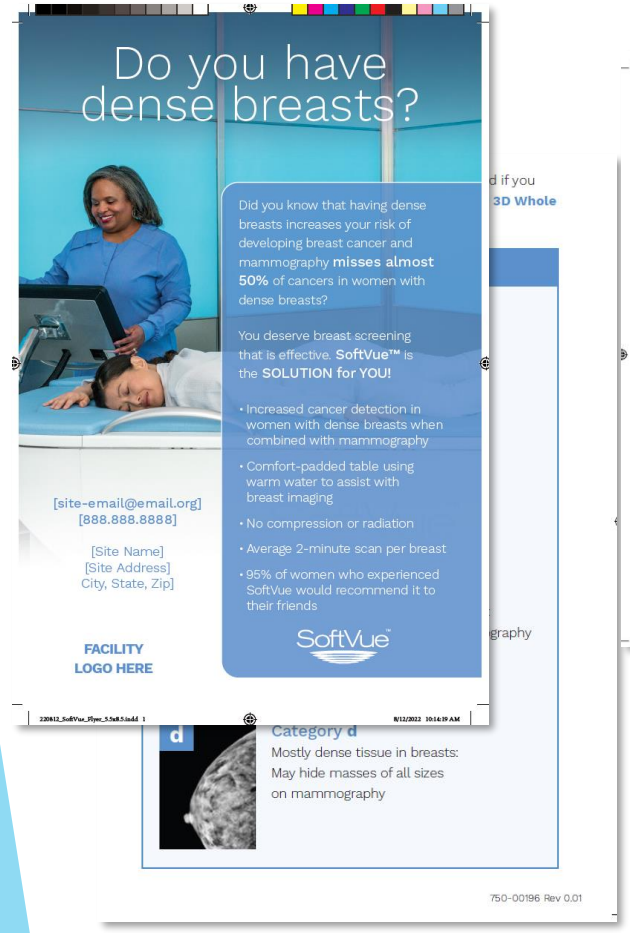
cancers, with potentially fewer callbacks, using a proprietary chnology that effectively characterizes tissue by capturing nd waves moving through breast tissue, unlike traditional on.

on her stomach with her breast submerged in a warm water lized and centered with a disposable Sequr™ Breast Interface proprietary 360-degree ring transducer, scanning each breast ge of three minutes, capturing new images every two then analyzed using sophisticated algorithms that provide lume of breast tissue. After both breasts have been scanned, ages alongside the patient's mammography images to xamination.

xams for dense breast screening at [LOCATION].To learn more ease contact [FACILITY'S CALL CENTER OR WEBSITE].

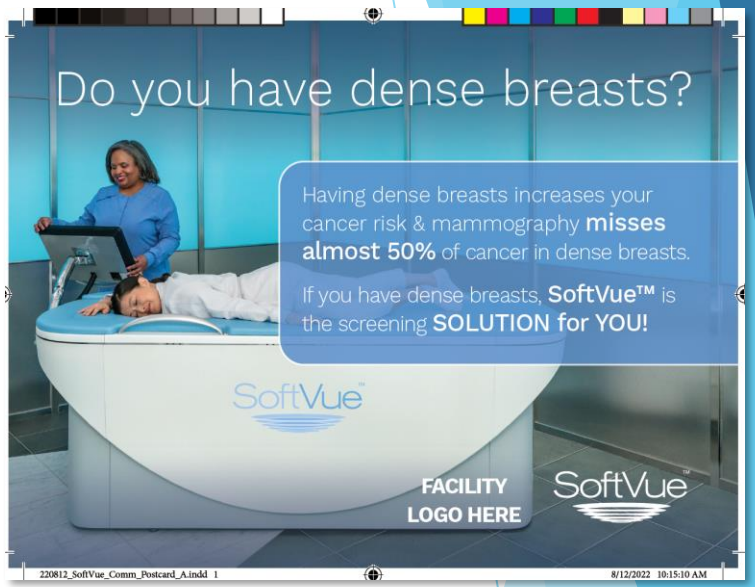
Patient Marketing Collateral

- Flyers



- Brochures

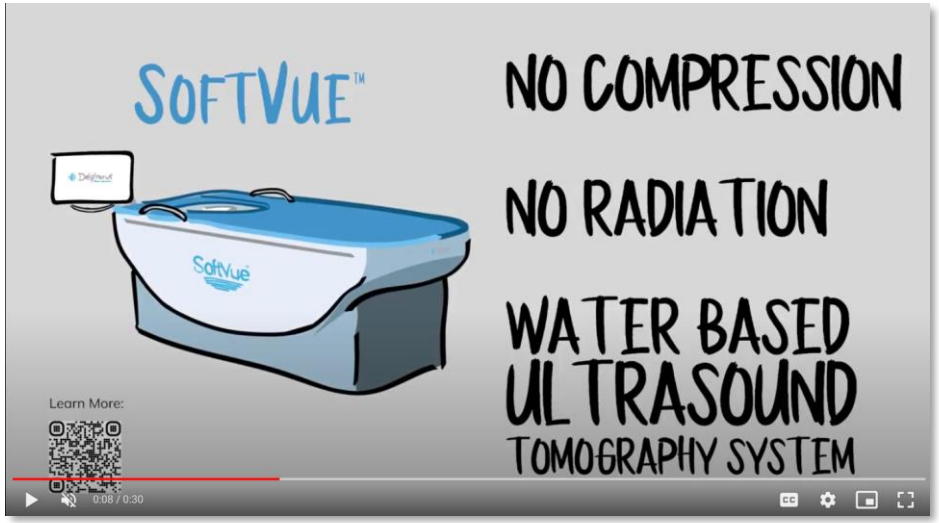
- Postcards



- Posters

Supplemental Marketing Resources

- CO-branded 30 Second Commercial



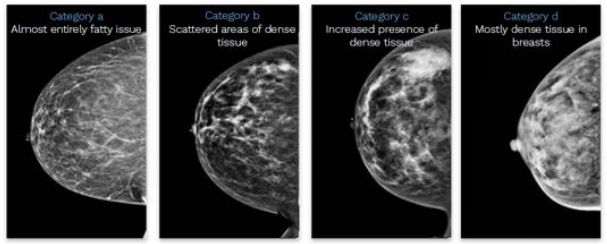
- Website Text

Delphinus

SoftVue™ offers a SOLUTION for DENSE BREAST SCREENING

What does it mean to have dense breasts?
There are 4 categories used to determine breast density. Breast density is determined by mammography and having dense breasts is normal as around 50% of women over the age of 40 have dense breasts.

BREAST DENSITY CATEGORIES



However, having dense breasts, defined as falling into **categories c or d**,

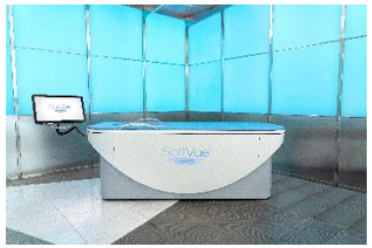
- Increases the risk of developing breast cancer and is a greater risk factor than having two first degree relatives with breast cancer
- Mammography misses almost 50% of cancers in women with dense breasts.

which makes it difficult to detect cancer in women with dense breasts using mammography.

- Newsletter Text

Delphinus

SoftVue 3D Whole Breast Ultrasound Tomography
The Solution to Dense Breast Screening is Here



It is no secret that there is an unmet need for screening women with dense breasts as cancer can hide within dense tissue on mammography. However, the healthcare team at (site name) realized that there were few effective and efficient supplemental imaging options available for screening dense breasts. Until now!

Delphinus Medical Technologies, Inc. received U.S. Food and Drug Administration (FDA) premarket approval (PMA) of its SoftVue™ 3D Whole Breast Ultrasound Tomography System (SoftVue™) for use as an adjunct to digital mammography in the screening of asymptomatic women with dense breast tissue.

"Quote from physician leadership....SoftVue plus mammography finds more cancers when screening women with dense breasts. We are excited to be one of the first healthcare organizations in the nation to offer our patients this new cutting-edge technology that not only detects more cancers, but does so with fewer biopsies," said Dr. XX, title.

Clinical evidence has demonstrated that SoftVue enhances dense breast screening by identifying up to 20% more cancers with greater accuracy and increasing specificity by 8%, resulting in fewer biopsies than with full field digital mammography (FFDM) alone.

"With the approval of SoftVue, we now have a critically needed new tool for screening women with dense breasts to enable the earliest possible detection of cancer," said Dr. Mary Yamashita, lead investigator of the SoftVue PCC clinical trial and Clinical Associate Professor of Radiology at Keck School of Medicine, University of Southern California, Los Angeles.

The SoftVue system is able to identify more cancers, with fewer callbacks, using a proprietary TriAD™ (Triple Acoustic Detection) technology that effectively characterizes tissue by recording reflection, speed and attenuation of sound waves moving through breast tissue, unlike traditional ultrasound which utilizes only reflection.

During the exam, the patient relaxes on her stomach with her breast submerged in a warm water bath. The breast is comfortably stabilized and centered with a disposable Sequr™ Breast Interface gel pad. Imaging is performed with a proprietary 360-degree ring transducer, scanning each breast from the nipple to the chest wall, without making contact with the patient, in an average of three minutes, capturing new images every two millimeters.

The captured reflection, sound speed and attenuation signals are reconstructed using sophisticated algorithms providing four full-volume, coronal-plane image sequences of each breast for interpretation in conjunction with mammography. These four image sequences are designed to optimize SoftVue's tissue specific imaging allowing for a decrease in unnecessary callbacks or

Implementation Resources

- Patient Mammography Reminder Letter Text & Informational Insert

Patient Reminder Letter Text – add to the bottom c
template.

If you have been notified that you have dense breasts, you
SoftVue™ 3D Whole Breast Ultrasound Tomography exam i
mammogram. SoftVue™ can be performed on the same da
performed in combination with mammography increases c
women with dense breasts. If you have dense breasts, ask
schedule your annual mammogram appointment. If you al
mammogram scheduled, call us to add a SoftVue™ exam t
appointment.

750-00212

DID YOU KNOW...

- Having dense breasts increases the risk of developing breast cancer
- Mammography misses almost 50% of cancers in women with dense breasts

Breasts are made up of different types of tissue, and fat. When there is more tissue than fat in the breasts, the breasts are considered dense. Both dense tissue and cancer appear white on mammography which makes detecting cancer difficult in dense breasts with mammography alone.

If you have been notified that you have **dense breasts**, talk to your (insert site name) healthcare team to **schedule your SoftVue™ exam** with your next mammogram.

THE SOFTVUE™ SOLUTION

- **No Compression, No Radiation**
- **Detects 20% more cancers in dense breasts when combined with mammography**
- **2-3 minute scan per breast**
- **95% of women would recommend SoftVue to other women**

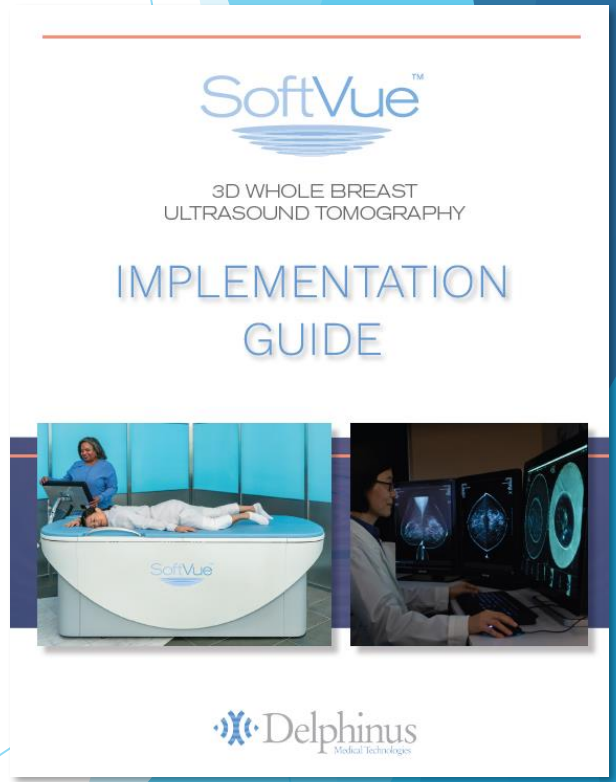
SV Site Logo

Phone # • website

- SoftVue Brand Kit including logos, font files and brand guidelines

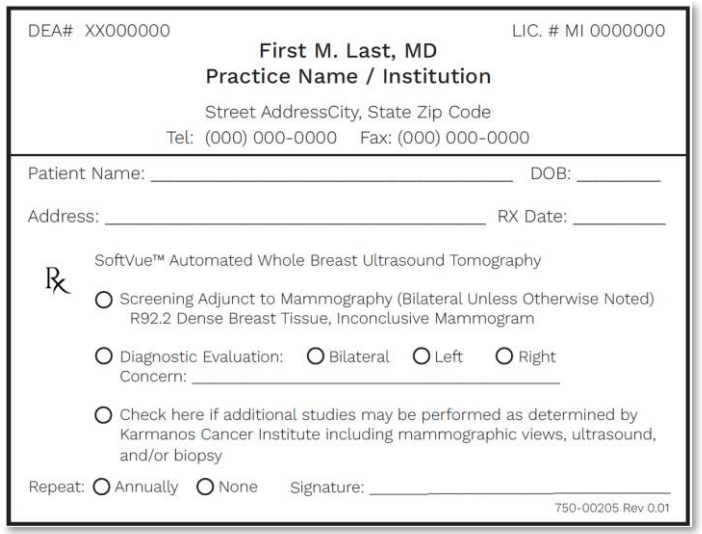
SoftVue™

- Implementation brochure



Referring Physician Resources

- Customizable Prescription Pad



DEA# XX000000 LIC. # MI 0000000

First M. Last, MD
Practice Name / Institution

Street AddressCity, State Zip Code
Tel: (000) 000-0000 Fax: (000) 000-0000

Patient Name: _____ DOB: _____

Address: _____ RX Date: _____

℞ SoftVue™ Automated Whole Breast Ultrasound Tomography

- ○ Screening Adjunct to Mammography (Bilateral Unless Otherwise Noted) R92.2 Dense Breast Tissue, Inconclusive Mammogram
- ○ Diagnostic Evaluation: ○ Bilateral ○ Left ○ Right Concern: _____
- ○ Check here if additional studies may be performed as determined by Karmanos Cancer Institute including mammographic views, ultrasound, and/or biopsy

Repeat: ○ Annually ○ None Signature: _____

750-00205 Rev 0.01

- Educational Presentation & Letter

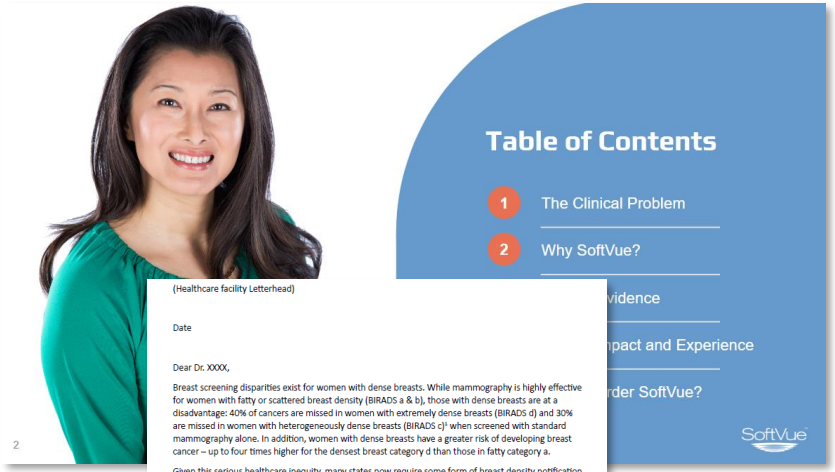


Table of Contents

1. The Clinical Problem
2. Why SoftVue?

...idence

...pact and Experience

...der SoftVue?

SoftVue

2

(Healthcare facility Letterhead)

Date

Dear Dr. XXXX,

Breast screening disparities exist for women with dense breasts. While mammography is highly effective for women with fatty or scattered breast density (BIRADS a & b), those with dense breasts are at a disadvantage: 40% of cancers are missed in women with extremely dense breasts (BIRADS d) and 30% are missed in women with heterogeneously dense breasts (BIRADS c)[1] when screened with standard mammography alone. In addition, women with dense breasts have a greater risk of developing breast cancer – up to four times higher for the densest breast category d than those in fatty category a.

Given this serious healthcare inequity, many states now require some form of breast density notification following a patient's mammogram and women are turning to physicians, like yourself, for guidance and answers about what supplemental breast imaging options are available to them.

The team at (greater healthcare facility) wanted to make you aware of a new efficient and effective screening solution available at (breast center name) for your patients with dense breasts. SoftVue™ 3D Whole Breast Ultrasound Tomography is the first and only FDA Approved supplemental dense breast screening modality that not only increases cancer detection by 20% but also increases specificity by 8% when combined with standard mammography[2]. This means more cancer detection with fewer unnecessary call backs and biopsies for your patients. The best part is that SoftVue is indicated to be performed on the same day as a patient's screening mammogram, so an additional visit to the (breast center) is not necessary to take advantage of SoftVue™ benefits.

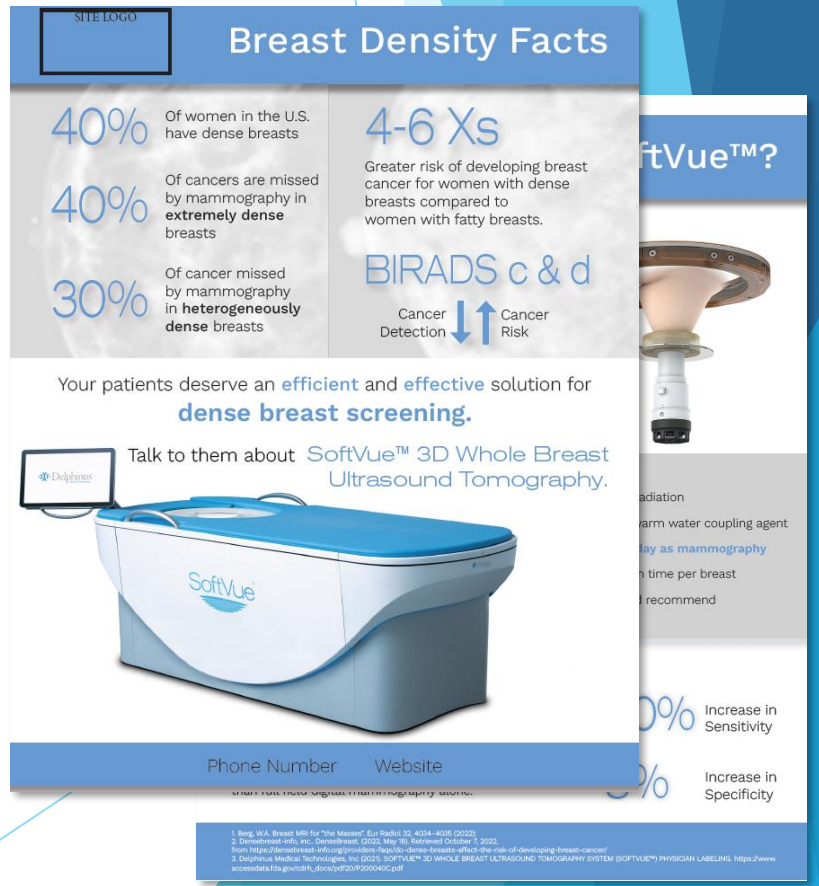
I would like to discuss with you what this transformative technology could mean for your dense breast patients. You are personally invited to visit (healthcare facility) where I will show you first-hand how this solution works and answer any questions you may have about patient workflow. If a visit to my center is not convenient at this time, perhaps we can meet virtually where I can show you a video of the patient scan and answer any questions about SoftVue's benefits for patients.

I look forward to speaking with you soon and will plan to reach out within the next two weeks to schedule a meeting. Meanwhile, if you or your patients have questions regarding SoftVue, please contact my office for prompt attention.

Sincerely,

1. Berg, W.A. Breast MRI for "the Masses". Eur Radiol 32, 4034–4035 (2022)
2. Delphinus Medical Technologies (2022). *Clinical Research*. Delphinusmt.com. https://delphinusmt.com/professionals/clinical-research/

- Informational Flyer



SITE LOGO

Breast Density Facts

40% Of women in the U.S. have dense breasts

40% Of cancers are missed by mammography in **extremely dense** breasts

30% Of cancer missed by mammography in **heterogeneously dense** breasts

4-6 Xs Greater risk of developing breast cancer for women with dense breasts compared to women with fatty breasts.

BIRADS c & d

Cancer Detection ↓ ↑ Cancer Risk

Your patients deserve an efficient and effective solution for **dense breast screening.**

Talk to them about SoftVue™ 3D Whole Breast Ultrasound Tomography.

Delphinus

SoftVue

Phone Number Website

...ftVue™?

...adiation

...arm water coupling agent

...day as mammography

...time per breast

...recommend

...% Increase in Sensitivity

...% Increase in Specificity

1. Berg, W.A. Breast MRI for "the Masses". Eur Radiol 32, 4034–4035 (2022);
2. Densebreast-info, inc.. Densebreast. (2022, May 18). Retrieved October 7, 2022, from https://densebreast-info.org/providers-faqs/dc-dense-breasts-affect-the-risk-of-developing-breast-cancer/
3. Delphinus Medical Technologies, Inc (2021). SOFTVUE™ 3D WHOLE BREAST ULTRASOUND TOMOGRAPHY SYSTEM (SOFTVUE™) PHYSICIAN LABELING. https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200040C.pdf