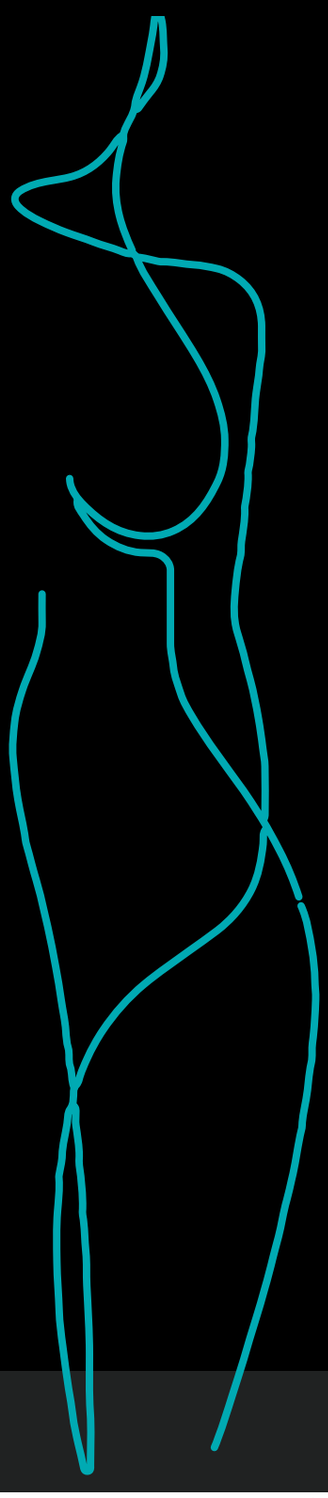
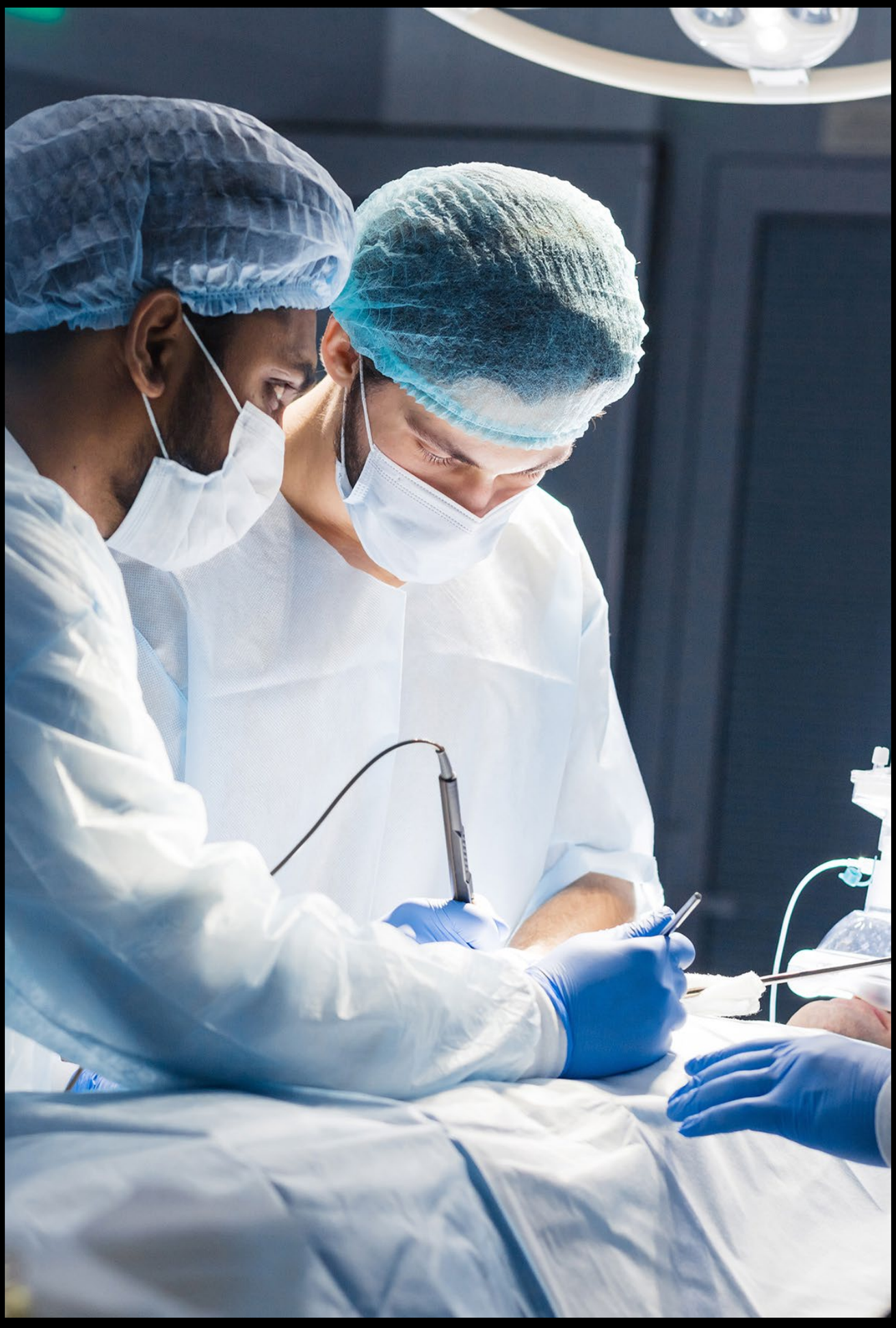
SamanTree
Medical SA

Histolog® Scanner

Cancer cells at your fingertips



BCS brochure - August 2024



The Clinical Need

During Breast Conserving Surgery (BCS), the challenge for the surgeon is to remove all the cancerous tissue while preserving as much healthy surrounding tissue as possible. Intraoperative margin assessment (IOMA) constitutes a crucial part in the decision-making process of surgeons.

Today, there is no consensual IOMA technique for BCS. All current methods present particular benefits and disadvantages, mostly regarding accuracy and time required. Overall, approximately 15-40% of the patients need to undergo an additional surgery[1-3].

Unmet medical need :

- Quick & Accurate IOMA
- Minimal tissue removal
- Avoid re-operations

[1]R. Jeevan et al., "Reoperation rates after breast conserving surgery for breast cancer among women in England: Retrospective study of hospital episode statistics," BMJ, vol. 345, no. 7869, 2012, doi: 10.1136/bmj.e4505

[2]C. Baliski, L. Hughes, and B. Bakos, "Lowering Re-excision Rates After Breast-Conserving Surgery: Unraveling the Intersection Between Surgeon Case Volumes and Techniques," Ann. Surg. Oncol., vol. 28, no. 2, pp. 894–901, 2021, doi: 10.1245/s10434-020-08731-z.

[3]Sandor, M. F., Schwalbach, B., Hofmann, V., Istrate, S. E., Schuller, Z., Ionescu, E., Heimann, S., Ragazzi, M., & Lux, M. P. (2022). Imaging of lumpectomy surface with large field-of-view confocal laser scanning microscope for intraoperative margin assessment - POLARHIS study. Breast, 66(June), 118–125. https://doi.org/10.1016/j.breast.2022.10.003

Our mission

Saman Tree Medical aims to be a game changer in the era of clinical workflow digitalization. We are committed to improving the journey of patients suffering from cancer by enabling fresh tissue analysis in real time to drastically reduce delays in establishing and executing the treatment plan.

	1	2
	REDUCE RE-OPERATION RATE	**SAVE PRECIOUS TIME AND RESOURCES**
	Current standard-of-care for IOMA, such as specimen radiography or ultrasound, lack accuracy to detect microscopic lesions, resulting in a re-operation rate of 15-40%[1-3].	Intraoperative margin assessment often requires resources from different departments, leading to a complex logistic and lengthy procedures.[5]
PROBLEM	Absence of relevant tools providing high accuracy in the OR to detect positive margins.	Current tools not adapted to OR pace and require multiple resources.
SOLUTION	Tissue morphology is the gold standard information. With the Histolog Scanner, the clinician sees the cellular achitecture of the tissue and can immediately visualize cancer lesions (DCIS, IDC, ILC).[3-4]	Whole specimen imaging in minutes. The Histolog Scanner enables fresh tissue assessment, with minimal preparation and 50s imaging time per surface. This technique is non-destructive and allows further processing by pathology.

3

ENABLE CLINICAL WORKFLOW DIGITALIZATION

Specimens are often sent to other departments for intraoperative assessment, or specialists have to come to the operating room. The need for collaboration with specialists from faraway health centers is quite common.

Specimens or specialists required to travel between departments/ hospitals.

An easy-to-use approach providing digital information. With the Histolog Scanner, images travel, not specimens or specialists.

[1]R. Jeevan et al., 2012 (p.3)

[2]Baliski C. et al., 2021 (p. 3)

[3]Sandor, M. et al., 2022 (p.3)

[4]Togawa, R., Hederer, J., Ragazzi, M., Bruckner, T., Fastner, S., Gomez, C., Hennigs, A., Nees, J., Pfob, A., Riedel, F., Schäfgen, B., Stieber, A., Lux, M. P., Heil, J., & Golatta, M. (2023). Imaging of lumpectomy surface with large field-of-view confocal laser scanning microscopy 'Histolog® scanner' for breast margin assessment in comparison with conventional specimen radiography. Breast, 68(February), 194–200. https://doi.org/10.1016/j.breast.2023.02.010

[5]Maloney, Benjamin W et al. "Review of methods for intraoperative margin detection for breast conserving surgery." Journal of biomedical optics vol. 23,10 (2018): 1-19. doi:10.1117/1.JBO.23.10.100901

The Histolog® Scanner

Global mapping of the breast immediately during surgery

The Histolog® Scanner is a breakthrough medical imaging modality based on a novel ultra-fast confocal microscopy technology invented in Switzerland.

Its innovative design brings the visualization of cancerous cells within immediate reach during surgery, enabling clinicians to assess surgical specimens with just a touch on the screen.

In BCS, a recent prospective study revealed the potential of the Histolog Scanner, with up to 75% re-operation rate reduction. The device was easily inserted in the clinical workflow and surgeons with no prior experience on morphology information could detect Ductal Carcinoma in situ (DCIS) lesions. More experienced users detected also invasive lobular carcinoma (ILC).[3]

[3]Sandor, M. F. et al., 2022 (p. 5)

A cost-efficient technique that provides real time morphology information

Easy-to-use platform: Plug and play device with quick learning, usable by clinicians or OR staff

Digital images enabling remote workflows

Result in minutes : 15s for specimen preparation (10s fluorescent dye + rinsing in saline solution) and ~50s for full-resolution image (large field of view 4.8cm x 3.6cm)

A dedicated team and network to support you in the implementation

Intuitive and user-friendly touch screen

Large imaging window of 17cm²

Easy to handle

The Histolog® Scanner is a CE marked product commercialized in EU and not available for sale in the United States.
CAUTION – Investigational device. Limited by U.S. law to investigational use.

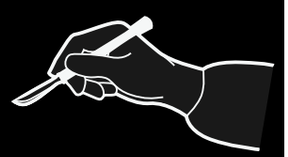
QUICK & CLEAN

4-steps procedure for accurate margin assessment immediately in the OR

Watch how

1 Excision

Excise the tumor from the patient.



4 Evaluation

Assess the images on the device or remotely

Specimen is preserved and the routine histopathological assessment can be performed.

Touchscreen interface

Instant access to special features such as reporting & annotation tools

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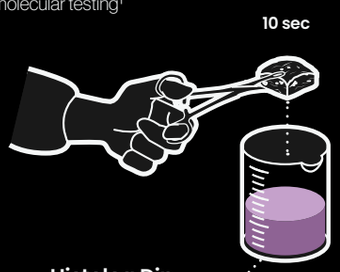
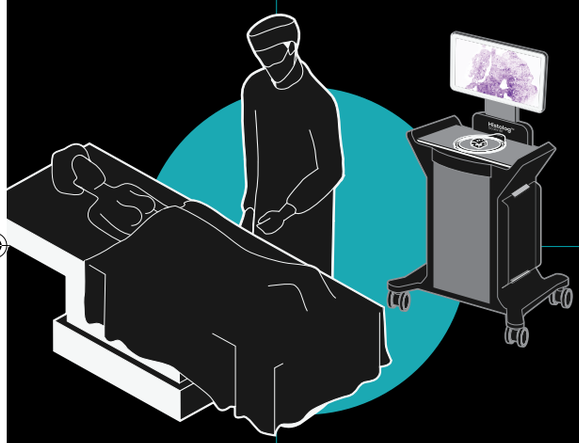
2 Preparation

Immerse the specimen in Histolog Dip and rinse it in saline solution.

The Histolog Dip is compatible with downstream histopathology assessment and molecular testing[1]



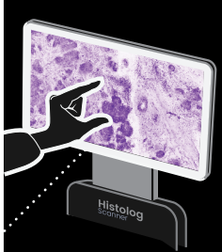
Histolog Dip
Histological stain

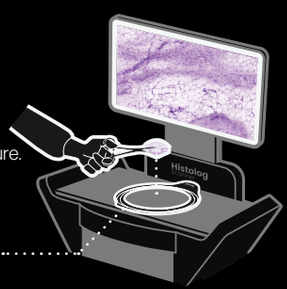


3 Imaging

Map the whole specimen surface in minutes.

Specimen remains visible and accessible during the entire imaging procedure.



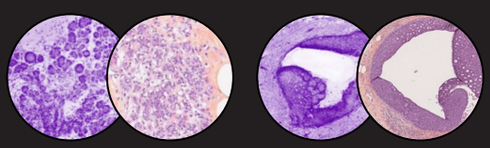


Histolog Dish
Single use optical-grade receptacle

[1]AH Nguyen et al. 2023
DOI: 10.55920/IJCIMR.2023.04.001150

Our partners

Multiple studies conducted in Europe, involving more than 500 patients, have resulted in the creation of an extensive atlas containing over 300 images of breast tissues and carcinomas. These studies showcased the capabilities of the Histolog Scanner for intraoperative assessment of lumpectomies. The study demonstrated that key morphological criteria—such as tissue architecture and cellular characteristics—traditionally defined in histopathology, can be applied to describe Histolog Images content.



Built on these promising results, multiple studies were launched to evaluate the performance of the Histolog Scanner for its intraoperative usage. The studies showed a seamless integration in multiple clinical workflows with potential reduction of re-operation rate up to 75%.

Reference centers

Fribourg Cantonal Hospital, Switzerland
Dr. Benedetta Guani

Valais Cantonal Hospital, Switzerland
Dr. Colin Simonson


Distributed by SamanTree
Distributors network
Imperial College Hospital
Aalst Hospital
St. Vincenz Hospital
University College London Hospital
Fribourg Cantonal Hospital
Institut Cancer de Lorraine
Valais Cantonal Hospital
Reggio Emilia Hospital

Clinical evidence

Imaging of lumpectomy surface with large field-of-view confocal laser microscope for intraoperative margin assessment - POLARHIS study

The Breast, 2022
M.-F. Sandor, B. Schwalbach, V. Hofmann, S.-E. Istrate, Z. Schuller, E. Ionescu, S. Heimann, M. Ragazzi, M. P. Lux - St. Vincenz-Krankenhaus, Paderborn, Germany

Evaluation of the Histolog Scanner for the margin assessment of 40 lumpectomy specimens

- Potential re-operation reduction of 75%
- Detection of invasive cancer & DCIS in lumpectomy margins
- Histolog Scanner easily inserted into surgical workflow

Imaging of lumpectomy surface with large field-of-view confocal laser scanning microscopy 'Histolog® scanner' for breast margin assessment in comparison with conventional specimen radiography

The Breast, 2023
Togawa R, Hederer J, Ragazzi M, Bruckner T, Fastner S, Gomez C, Hennigs A, Nees J, Pfob A, Riedel F, Schäfgen B, Stieber A, Lux MP, Heil J, Golatta M - Heidelberg University Hospital, Germany

Intraoperative margin assessment performed with the Histolog Scanner and assessed by unexperienced clinicians versus specimen radiography in 50 patients

- Similar performance to current practice without any experience or training on morphology images
- Perspective of significantly higher performance with adequate training and education
- Detection of DCIS, ILC, and IDC

Learn to use Histolog images in no-time

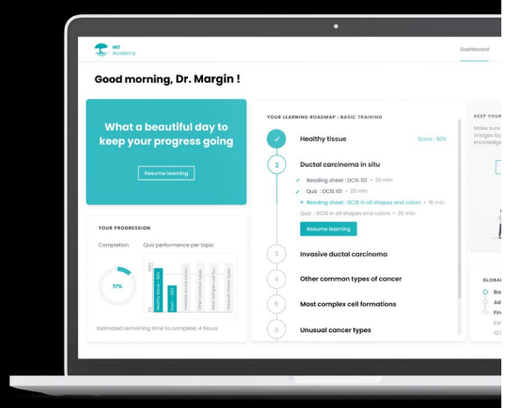
Histolog Image Training program (HIT)

Short. Flexible. Simple.

A learning program designed for clinicians.

The Histolog Image Training (HIT) was developed with our community of pathologists and experts to provide a simple and efficient way of getting familiar with Histolog image. Designed for both beginners and experienced morphology content readers, the HIT is accessible to all and allows for flexible learning. In and out of the operating theatre, you set the pace and we keep it.

hit.samantree.com



Histolog images : morphology in the OR

Examples of images in breast conserving surgery

Tissue with Normal Lobules

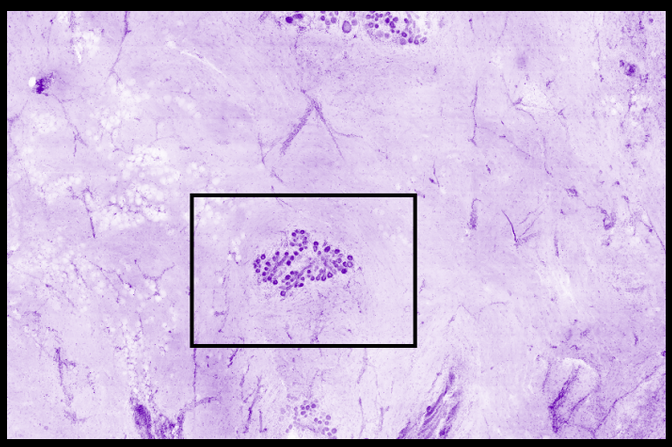
Full Field of View of Histolog Scanner (5% zoom level)

The present tissue is notably composed of a large part of connective tissue and normal lobules. Lobules are usually presenting a strong purple coloration. A typical normal lobule is seen inside the selected black frame.

Tissue with Ductal Carcinoma In-Situ - DCIS

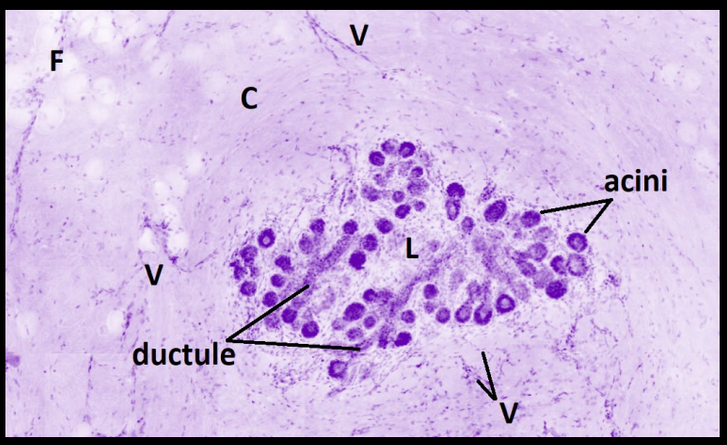
A lumpectomy section with a suspicious area at the bottom right is seen. The present lumpectomy is mainly composed of lobules, fatty and connective tissue.

25% Zoom level of the Histolog Scanner

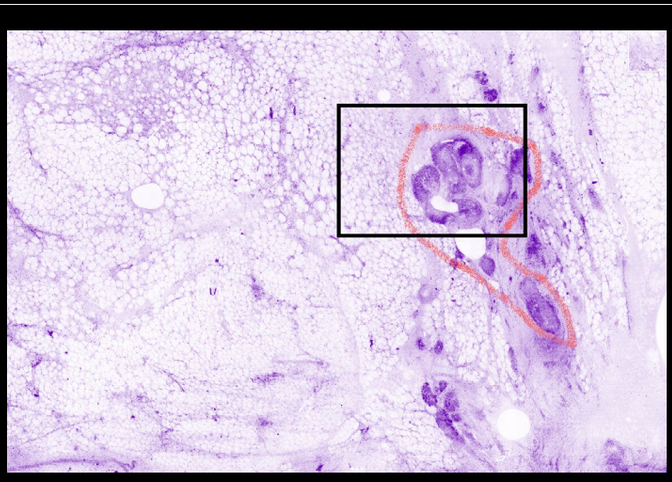


Normal lobules can be recognized with their shape recalling a bunch of grapes. This structures are usually more colored than connective tissue or fatty tissue. In the black frame, a normal lobule can be seen in the center surrounded by normal connective tissue.

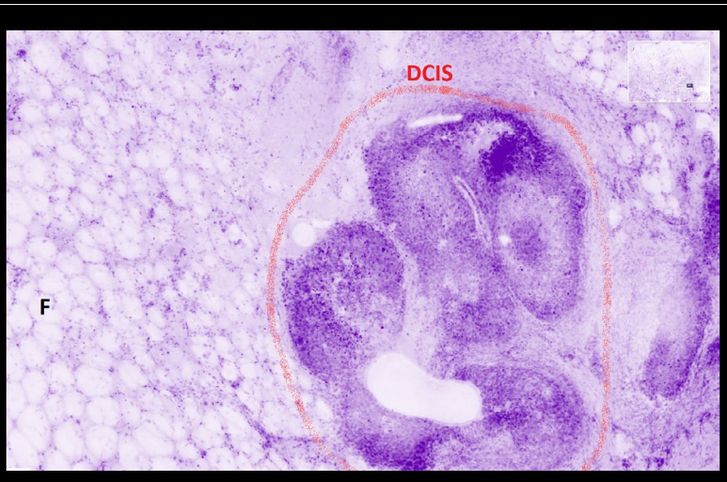
100% Zoom level of the Histolog Scanner



Lobules are composed of circular structures that may appear empty with purple circular walls. They are the Acini from which the milk is secreted. These beads are organized like a bunch of grapes. All the beads of a lobule are connected together with a branching structure of small pipes called ductules (smaller ducts). Acini (lobules) and ducts are composed of epithelial cells that have generally a strong purple color. The present lobule is surrounded by normal connective tissue (C) with few fatty cells (F). The lobule is closely surrounded with thin linear structures, tiny vessels (V).



Within the black frame is seen a roundish pattern that is typical of DCIS. At this magnification, sections of these ducts invaded by DCIS are seen as circular patterns presenting a well-defined border and containing high density of cells strongly colored.



One large DCIS lesion is seen. It presents a roundish pattern with a well-defined border and a content composed of cancer cells. Here the invaded duct can be figured out as a convoluted duct filled with cancer cells. Some inflammatory cells can also be seen in the DCIS as tiny dots strongly colored. This DCIS is surrounded by fatty tissue (F) that also contains few inflammatory cells.

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