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Diagnostic Devices
ClearCoast™ MRI System

Manufactured by

ClearCut

Diffusion-weighted MRI for intraoperative
assessment of the surgical margin
during breast-conserving surgery.

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The innovative, diffusion-weighted **ClearCoast™ MRI System** enables precise intraoperative analysis of the excised tumour as part of breast-conserving surgery. Positive margins can already be identified during the procedure and a necessary additional resection can already be performed immediately during the initial operation. This means that re-excisions can be reduced by up to 80%.¹

View

ClearCoast™ MRI System



ClearCoast™ Tissue Container

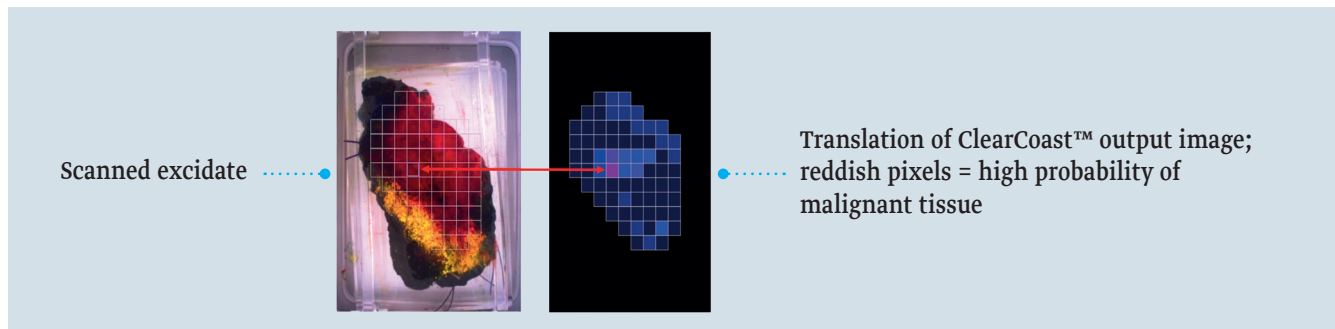
Front and back



Benefits

Easy operation and simple interpretation

The intuitive and easy operation together with the simple interpretation of the colour-coded results eliminate the need for the user to have detailed technical, histopathological or radiological expertise. Trained, non-medical staff, can operate the ClearCoast™ MRI System.



Fewer follow-up operations

The ClearCoast™ MRI System offers surgeons increased confidence in detecting positive margins (R1 situations) during the initial breast-conserving surgery. As a result, the number of repeated surgeries can be reduced by up to 80%.¹

Improved quality of life

A reduction of repeated surgeries can be a significant relief for the patients - both physically and psychologically. General surgical risks as well as worries and fear can be reduced accordingly.² The necessary adjuvant therapies can be introduced without delay.³

Cost savings

In 15% to 35% of breast-conserving surgery cases a re-excision is required.³ Every follow-up operation that is saved reduces costs and freed-up operating theatre capacity can be put to use elsewhere.

Clear vision

Vacuum technology removes air from the ClearCoast™ Tissue Container. This puts the tissue in direct contact with the MRI scanning surface. Blind spots caused by air bubbles are reduced. Aids to fix the tissue are redundant.

Better aesthetic outcome

The aesthetic outcome can be one of the most important aspects of breast-conserving surgery for many patients.⁴ An accurate intraoperative assessment of the margin can allow the surgeon to make the excision with as little safety distance from the tumour as possible. Every follow-up intervention saved also has a positive influence on the result in itself.

Knowledge

Method of operation

The ClearCoast™ MRI System is an in vitro diagnostic device that allows surgeons to make a quick and precise intraoperative assessment of the surgical margin. This allows them to remove the tumour while preserving as much of the healthy tissue as possible.

The ClearCoast™ MRI System enables precise analysis of the excised tissue. Positive margins can thus still be identified during the operations. Translating the scan results into a colour code makes it easy to interpret a 2D colour map. Any re-excision that may be necessary can be performed immediately; the need for subsequent surgery is

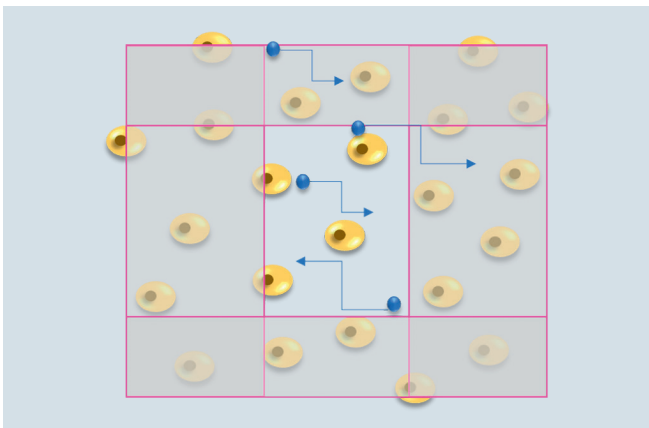
reduced significantly. Thanks to its intuitive operation, the ClearCoast™ MRI System can be easily integrated in existing workflows. It is mobile around the operating theatre and can be placed in different operating rooms.

The ClearCoast™ MRI System is an in vitro diagnostic device. Therefore, no radiation exposure occurs for the patient during imaging and no systemic media are required. No radiological or histopathological expertise is required to use the ClearCoast™ MRI System. Trained staff can use the ClearCoast™ MRI System easily.

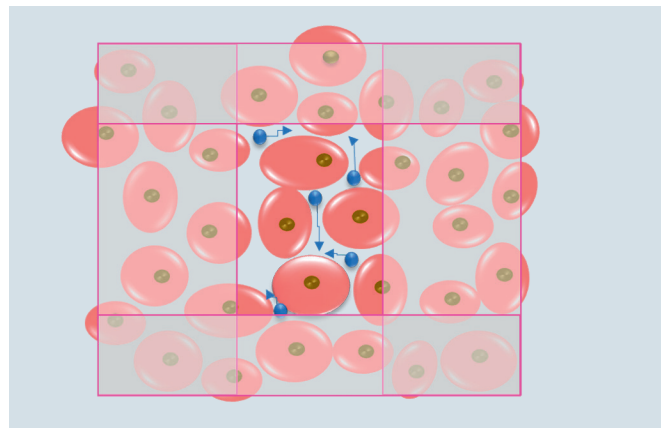
Technology

The ClearCoast™ is an innovative, mobile MRI System based on diffusion-weighted MRI (DW-MRI), which measures the mobility (diffusion speed) of water molecules on the tissue surface. The histological properties of the tissue determine the diffusion speed. Malignant tissue has a higher

cellularity, which restricts the diffusion speed of water between the cells. As such, diffusion-weighted MRI offers an ideal way to differentiate between physiological and pathologically altered (e.g. malignant) tissue - and without the administration of contrast media.⁵



Physiological tissue:
low cellularity = high diffusion speed



Malignant tissue:
high cellularity = low diffusion speed

Operation

To use the ClearCoast™ MRI System, the ClearCoast™ Tissue Containers are required. The applied vacuum of the excidate allows a rapid scan of all six sides of the tumour.



The removed tissue is placed in the ClearCoast™ Tissue Container.



The ClearCoast™ Tissue Container is slid into the vacuuming station and the tissue is vacuumed.



The ClearCoast™ Tissue Container is inserted into the ClearCoast™ MRI System and the scanning process can be started via the touchscreen.

Details

- ▶ Quick margin assessment: Process time comparable to - or less than - frozen section procedure analysis.
- ▶ Mobile MRI, which offers the advantages of MRI technology in any surgical environment.
- ▶ Shielded system without ionising radiation. No additional apparatus, equipment or a special room are needed and any precautions or measurements required.
- ▶ The use of contrast media is not necessary. The associated potential for allergic reactions or other side-effects can be avoided and patient preparation time can be reduced.
- ▶ Preserve the integrity and quality of the tissue sample so that the histopathological assessment can subsequently be carried out unimpeded.¹

Technical data

ClearCoast™ MRI System

- ▶ **Method of operation:** Magnetic resonance diffusion measurement
- ▶ **Dimensions (W/H/D):** 68.5* × 168.2 × 105.0 cm
- ▶ **Scan resolution:** 4 × 3.5 mm
- ▶ **Scan surface diameter:** max. 88 mm
- ▶ **Input voltage:** 100 - 240 V, 50 - 60 Hz
- ▶ **Weight:** 275 kg

ClearCoast™ Tissue Container

- ▶ Patient-specific consumable materials
- ▶ **Tissue volume:** max. 200 ml
- ▶ **Tissue-specimen diameter:** max. 7 cm
- ▶ **Weight:** 80 g

* with folded shelf 113.5 cm



Notes

A series of horizontal dotted lines for writing notes.

Ordering information

Device	Size / storage capacity	REF	PU
ClearCoast™ MRI System	W 68.5* × H 168.2 × D 105.0 cm	CC00	1
ClearCoast™ Tissue Container	max. 200 ml	CTC10	10

* with folded shelf 113.5 cm

Literature

1. Thill et al., Magnetic resonance imaging system for intraoperative margin assessment for DCIS and invasive breast cancer using the ClearSight™ system in breast conserving surgery – Results from a postmarketing study. J Surg Oncol, 2022, 125(3): 361-368
2. Maloney et al., Review of methods for intraoperative margin detection for breast conserving surgery. J Biomed Opt, 2018, 23(10): 1-19
3. Walijee et al., Predictors of re-excision among women undergoing breast-conserving surgery for cancer. Ann Surg Oncol, 2008, 15(5): 1297-303
4. Catsman et al., The COSMAM TRIAL a prospective cohort study of quality of life and cosmetic outcome in patients undergoing breast conserving surgery. BMC Cancer, 2018, 18(1): 456
5. Guo et al., Differentiation of clinically benign and malignant breast lesions using diffusion-weighted imaging. J Magn Reson Imaging, 2002, 16(2): 172-178

Links



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