INTRABEAM

Targeted Radiotherapy

ZEISS

The moment radiotherapy can be ideally tailored to the needs of your patient.
This is the moment we work for.

// INNOVATION
MADE BY CARL ZEISS

Targeted intraoperative radiotherapy with INTRABEAM – Precision simplified

The trend in oncological therapy is moving towards the targeted, risk-adapted and interdisciplinary treatment of tumors. INTRABEAM®, the innovative radiotherapy system from Carl Zeiss, is an ideal system for these requirements. INTRABEAM uses low-energy, X-ray photons to deposit the high-dose radiation directly into the tumor or the tumor bed. The result is a localised and highly effective therapy. INTRABEAM received FDA approval in the USA in 1997 and was awarded the CE certification in Europe in 1999. INTRABEAM provides key benefits for the intraoperative irradiation of solid tumors:

Localised tumor control – targeted effectiveness

Intraoperative radiotherapy (IORT) with INTRABEAM enables high dose treatment. INTRABEAM is used to irradiate the tumor bed, the area where the risk of recurrence is highest immediately after R0 resection. INTRABEAM can also be used for the irradiation of incomplete tumor resections in R1 and R2 scenarios.

Localised irradiation with a high radio-biological effectiveness

The relative biological effectiveness of low-energy X-rays is very high as a result of the higher ionization density of radiation in tissue. At the same time, due to the steep dose falloff, a special characteristic of the low-energy radiation, the tissue of interest is irradiated avoiding collateral damage.

Practical mobility and fast workflow integration

The mobile INTRABEAM system is a flexible instrument that can also be implemented without high investment costs for complex radiation protection measures in the building. The miniaturized mobile accelerator permits easy and safe operation and simple integration into the existing workflow. It can be deployed in multiple operating rooms and managed by a single radiation oncologist.

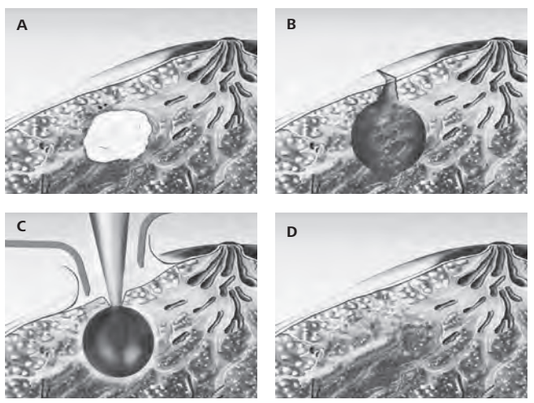
Versatility of the clinical application

INTRABEAM has been approved for the treatment of all areas of the body. In addition to the successful treatment of breast cancer, INTRABEAM opens up entirely new radiotherapy alternatives for a wide range of tumors.

Higher quality of life outcomes and treatment comfort for patients

Irradiation with INTRABEAM enables localised treatment. The tumor is irradiated avoiding collateral tissue damage. A shortened overall treatment regime can also reduce associate side effects and is gentle on patients – a key element in increased quality of life.

TARGIT – targeted intraoperative radiation therapy with INTRABEAM from Carl Zeiss.

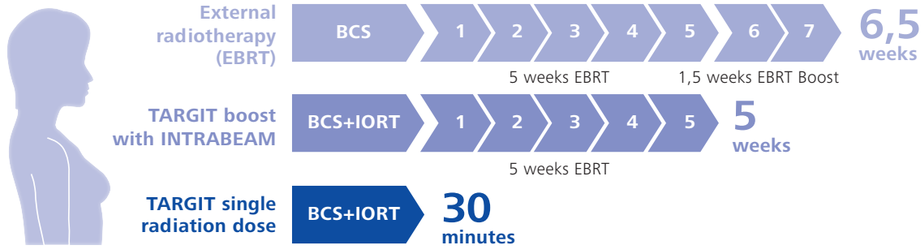


A: Step 1 *The position of the tumor is determined.*
B: Step 2 *The tumor is surgically removed.*
C: Step 3 *The INTRABEAM applicator tip is positioned in the tumor cavity in the breast.*
D: Step 4 *The radiation is applied for about 30 minutes. The applicator is removed and the incision closed.*

TARGIT radiation therapy for breast cancer:
Effective, risk-adapted and targeted

In recent years, a new approach has been gaining ground in the treatment of breast cancer: radical surgical methods are being replaced by less-invasive, breast-conserving therapy. Such a trend is now also appearing in radiotherapy. Oncologists are moving away from the current, largely standardized treatment plan to risk-adapted individualised therapy.

Radiotherapy – risk-adapted alternatives following breast-preserving surgery of the mammary carcinoma (BCS)



Targeted irradiation avoids collateral tissue damage

In traditional radiotherapy the tumor bed is frequently missed due to postoperative changes or oncoplastic reconstruction. The exact position of the tumor cavity is difficult to localize, even with modern-day imaging techniques.[1]

This issue is negated with the targeted intraoperative irradiation using INTRABEAM by Carl Zeiss. The 30-minute irradiation procedure is performed during the operation immediately after the tumor is excised. During this procedure, the isotropic dose distribution is applied directly into the tumor cavity using a spherical applicator in a way that ensures direct contact with the target tissue. Radiation is applied precisely to the area with the highest risk of tumor recurrence. The surrounding healthy tissue is spared.

Shorter treatment duration is gentle on patients

Unlike traditional irradiation, radiotherapy with INTRABEAM can be adapted to the needs of the patient. The standard approximate six weeks of post-op irradiation is reduced and can be completely eliminated for selected patients with a low risk profile. The shorter irradiation period eliminates repetitive journeys for treatment and also considerably lowers the overall physical and physiological stress on the patient.

TARGIT single fraction treatment for breast cancer:

Radiotherapy administered in 30 minutes instead of approximately six weeks

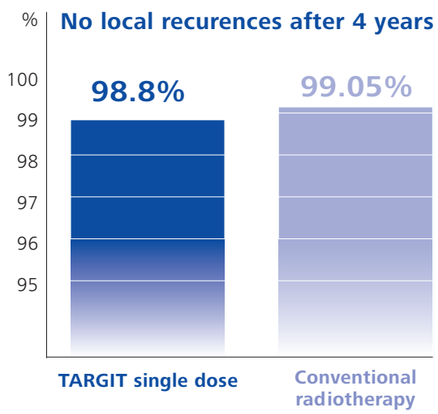
The targeted, intraoperative single dose of radiation with INTRABEAM is on the way to becoming the new treatment standard of care for breast cancer. This risk-adapted therapeutic solution makes it possible for a patient cohort with a favorable prognosis to complete surgery and irradiation in a single session. Traditional radiotherapy, including the stress of protracted treatment regimes, is eliminated for these patients. In situations, in which definitive irradiation cannot be performed, such as local recurrence, the TARGIT single dose of radiation* also provides an opportunity for a second attempt at breast-preserving therapy.

Study verifies effectiveness of the TARGIT single radiation dose

The results of a multinational, randomized clinical study (TARGIT A) of 2,232 patients at 28 centers in nine countries verifies: for patients with a favorable prognosis, the intraoperative, targeted radiotherapy (TARGIT) with INTRABEAM is equivalent to traditional external beam radiotherapy (EBRT) for invasive ductal mammary carcinomas. After a follow-up of 4 years, no statistically significant difference was established between the rate of local recurrence (primary endpoint) in EBRT and TARGIT. A collective with a favorable risk profile (median age 63 years, median tumor size 13 mm, 83% pN0, 91% estrogen receptor positive) was treated.[2]

Tolerance in the TARGIT single fraction cohort

Both study groups in the TARGIT-A study showed good tolerance of the radiotherapy. More seroma aspirations were carried out in the TARGIT Arm; however, there were fewer radiation-induced skin complications in this group. The results of the study show that the TARGIT treatment is a safe method.



Targeted irradiation allows second breast-conserving therapy

A special case is the treatment of patients in whom a tumor recurrence is found in an already treated breast. Here, thanks to the targeted irradiation of the tumor bed and the protection of the surrounding tissue, the therapy with the INTRABEAM can offer the patient the possibility of a second breast-conserving treatment.[3, 4]

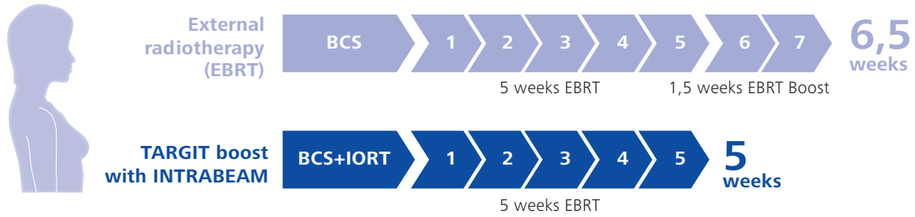
Key advantages for patients with lower risk profile

- Reduction of the radiotherapy treatment duration to around 30 minutes.
- Targeted irradiation of the tissue of interest, avoiding collateral damage.
- Less physical and psychological stress on patients.
- Time and cost savings.

** The use of the TARGIT single dose of radiation should comply with local/national clinical directives. In some countries, the single dose of radiation is only permitted within the scope of clinical studies.*

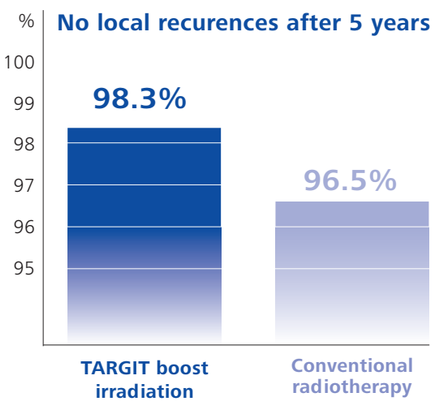
TARGIT boost irradiation for breast cancer:
High effectiveness through targeted irradiation

Local recurrences after breast-preserving surgery and postoperative EBRT normally occur within the original index quadrant of the primary. Additional irradiation of the tumor bed (boost) is therefore part of the standard of care in breast cancer therapy. In intraoperative radiotherapy with INTRABEAM, the boost element of the EBRT regime can be replaced with INTRABEAM and be administered to the target tissue immediately after wide local excision. This boost element of the overall treatment regime is highly accurate as it is applied at the time when the tumor bed is visualised during surgery.



Very good effectiveness and shorter treatment times

More than 13 years of clinical experience on more than 7,000 patients attest to the effectiveness of IORT in the treatment of breast cancer The study results show that the recurrence rate is very low after an intraoperative boost with INTRABEAM with subsequent shorter external radiotherapy. In two studies on the intraoperative boost with INTRABEAM comprising a total of 450 patients, the five-year recidivism rate was a low 1.5 to 1.7 percent. These are not selected patients with a low recurrence rate.[5, 6]



Targeted intraoperative radiotherapy (TARGIT) with INTRABEAM compared to two studies (EORTC study [7] and START B study [8])

Radiotherapy with fewer side effects

The intraoperative boost therapy is tolerated very well by patients. As studies on acute and long-term toxicity following the intraoperative boost of 20 Gy have shown, there are no abnormalities. Doctors and patients also found the cosmetic result following the intraoperative boost with INTRABEAM to be very good.[9,11]

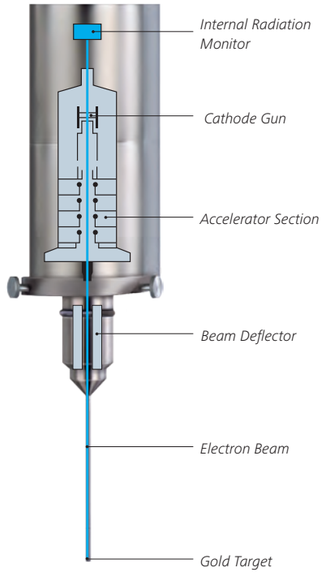
Benefits of boost treatment with INTRABEAM

- Very low local recurrence rate.
- Low rate of side effects.
- Very good cosmetic result.
- Reduction in conventional radiotherapy by around 25%.

** The use of the TARGIT boost treatment should comply with local/national clinical directives. In some countries, the boost treatment is only permitted within the scope of clinical studies.*

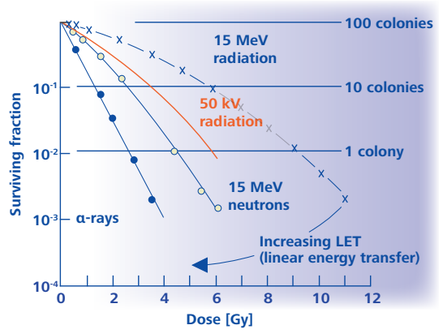
XRS 4 miniaturized accelerator –
the heart of INTRABEAM

Electrons are emitted and accelerated to a potential of 50 kV in this miniaturized accelerator. The electron beam is guided through a 3 mm drift tube before interacting with a 1 µm thick gold target which results in the generation of low-energy X-rays. The miniaturized accelerator has been designed to generate the unique spherical dose distribution emitted from the center to the tip of the tube.



The miniaturized INTRABEAM accelerator –
Targeted radiotherapy

The low-energy X-ray photons used by INTRABEAM are known for their physical and radiobiological characteristics which can lead to superior benefits in radiotherapy. The relative biological effectiveness (RBE) increases as the photon energy decreases. The increased ionization density of the radiation in the tissue leads to the relatively high biological effectiveness of low-energy X-rays in the near range. At the same time, the periphery is protected through the steep physical depth dose gradient of this type of radiation. This means that the radiotherapeutic dose can be targeted at the area of interest only sparing healthy tissue.



Unlike megavolt X-rays, low-energy X-rays have an increased RBE3.

Source: Wenz F, Steil V, Herskind C et al. Intraoperative Radiotherapie (IORT) beim Mammakarzinom mit dem INTRABEAM-System. Aktueller Stand der TARGIT-Studie. Gynäkologe 2007· 40:464–467

Innovative technology that brings extra benefits to everyday hospital case loads

Safety for doctors and patients

During radiotherapy, the dose can be monitored with the INTRABEAM control panel in situ. The system records the physical dose rate constantly and checks the critical treatment parameters automatically and indicates any deviations. A complete set of quality assurance tools ensure consistency, tolerance and aid in the daily checks.

Ease of use and precise positioning

Thanks to the perfectly balanced suspension system, the applicator can be effortlessly moved into any position and locked with pinpoint accuracy. During irradiation, electromagnetic couplings hold the applicator exactly in the set treatment position.

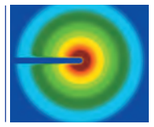
Mobility for workflow integration

INTRABEAM can be easily moved to different operating rooms and thus deployed flexibly throughout the hospital.

INTRABEAM:

Targeted radiotherapy for a wide range of applications

Local control of tumors is vital in oncology. With INTRABEAM, targeted radiotherapy can be performed during surgery without delay. Following the successful R0 resection of a tumor, the tumor bed, the area with the highest risk of recurrence can be irradiated directly. INTRABEAM can also be used for the irradiation of incomplete tumor resections in R1 and R2 scenarios. Furthermore an in-vitro study showed, that intraoperative irradiation with INTRABEAM exhibits a positive effect on wound fluid within the tumor bed environment.[10]

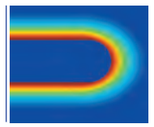


Spinal metastases

For many cancer patients who develop spinal metastases in the natural course of their disease, percutaneous kyphoplasty and vertebroplasty are a valuable treatment option. By using intraoperative-radiotherapy with INTRABEAM during kyphoplasty or vertrebroplasty, the metastasis can be sterilized and if necessary simultaneously stabilized, a solution that results in reduction of patient's discomfort. It also restores mobility, significantly enhancing the patient's quality of life. The first clinical trial experience of this approach has yielded very promising results.[12]

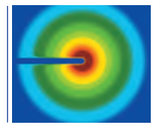
Gastrointestinal cancer

In cancer surgery, the primary goal is to completely excise the tumor. However, incomplete resection is sometimes the outcome. INTRABEAM can be used to improve local control of colorectal tumors.[13] The value of INTRABEAM has also been demonstrated in the setting of laparoscopic hemicolectomy in patients with colon cancer and gastrectomy in patients with gastric cancer.[14]



Endometrial cancer

In endometrial cancer – the most common malignancy of the female reproductive system – the use of INTRABEAM is also feasible and has some potential advantages compared to brachytherapy, which requires complex radiation protection. By comparison, INTRABEAM can be implemented without high investment costs.



Cerebral metastases

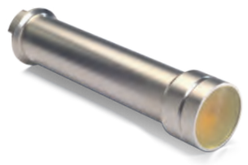
Post-operative irradiation of brain tumors and cerebral metastases is often delayed due to wound healing problems and long patient recovery times following the operation. INTRABEAM offers a cost-efficient and immediate treatment. A substantial number of studies have proven the value of INTRABEAM in the treatment of brain and cerebral tumors in both children and adults.[16,17,18]

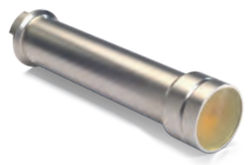
Skin cancer

The versatility of INTRABEAM is also displayed in the treatment of skin cancer. Particularly in the treatment of non-melanoma skin cancer, Irradiation is an important therapy option. In a prospective study, it was shown that intraoperative radiotherapy with INTRABEAM was as effective in the management of non-melanoma skin cancer as conventional radiotherapy techniques. The well-known advantages of INTRABEAM – targeted radiation delivery, low shielding requirements, and cost effectiveness – also hold true for the treatment of skin cancer.[19,20]

Oral cancer

Delivering a boost radiation intraoperatively with INTRABEAM has potential advantages in the treatment of oral cancers. After resection, the margins of the tumor can be sterilized immediately, which may have a positive impact on local recurrence rate. Additionally, the numerous sensitive structures in this anatomical region can be spared due to the steep fall-off of the low-energy radiation emitted by INTRABEAM. A geographical miss is unlikely since the applicator can be positioned directly in the tumor bed. First study data have convincingly demonstrated the value of this concept.[21]





The benefits of the simple implementation of radiotherapy alternatives in your hospital

With INTRABEAM, you are offering your patients one of the most innovative radiotherapy methods with considerable treatment comfort. The system can be easily installed in your hospital. Unlike linear accelerators and radioactive preparations, INTRABEAM does not require any structural radiation protection measures. This saves time and money. The very low shielding requirements also mean maximum safety for your patients and staff.

Increase effectiveness with INTRABEAM
Intraoperative radiotherapy with INTRABEAM shortens the duration of treatment, sometimes considerably. The resulting time savings enable higher throughput in your hospital without changing personnel expenses. Fewer days of treatment also mean that patients have lower travel costs. With INTRABEAM, you can react flexibly to the fluctuating use of your linear accelerator, thus providing you with more freedom to plan your treatments.

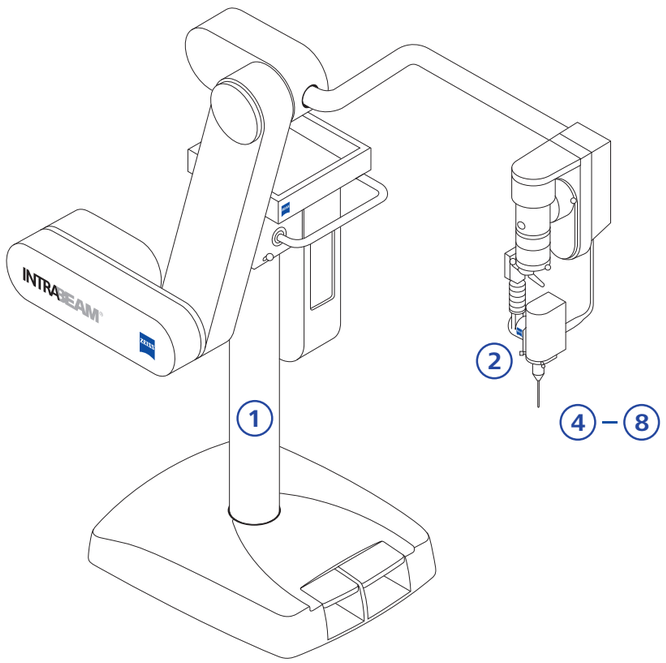
Mobility delivers more flexibility
Furthermore, the mobile INTRABEAM system provides the medical team with a physically flexible device. The 1.6 kg miniaturized accelerator can be removed from the suspension system quickly and mounted to a suspension system in a second or third operating room. This allows radiotherapy at multiple locations by a single radio oncologist.

Made by Carl Zeiss
With INTRABEAM, you are purchasing not only an innovative irradiation system, but also the quality and precision that has been associated with the name Carl Zeiss for more than 160 years. As a global company, we invest considerably in research and education – for the safety of our products and for the good of your patients.

INTRABEAM also stands for customized service:
- Intensive clinical training at the TARGIT Academy
- Application training during the installation
- Supervised training in hospitals
- More than 40 sales companies and more than 100 representatives around the world ensure fast, on-site service

System overview

General technical information



① INTRABEAM Floor Stand

The floor stand combines performance with maximum reliability and flexibility. Electromagnetic couplings lock the miniaturized accelerator in the treatment position with millimeter accuracy. Usable in any OR.

Weight: 275 kg | Transport position: 740 x 1940 x 1500 mm (width x height x length) | Rated voltage: 100V / 115V / 230V

② XRS 4 Miniaturized Accelerator

The miniaturized accelerator emits low-energy X-rays (max. 50 kV) with isotopic dispersion. The target tissue is evenly irradiated.

Weight: 1.6 kg | Dimensions: 70 x 175 x 110 mm (width x height x length)

③ INTRABEAM Cart

The cart provides an easy means of transport in and out of the OR. The generously designed workstation of the cart enables quality inspections directly on the cart. The touch pad terminal, control unit and dosimeter, as well as all components required for quality inspection and treatment are ergonomically arranged on the cart.

Max. load: 95 kg | dimensions: 900 x 1690 x 600 mm (width x height x length) | Rated voltage: 230 V

④ INTRABEAM Spherical Applicator

The INTRABEAM Spherical Applicator is used to irradiate the tumor bed, e.g. in breast-conserving treatment for breast cancer patients. A complete set of spherical applicators with diameters from 1.5 to 5.0 cm enables exact adaptation to the size of the tumor bed. The applicators are sterilizable and can be re-used.

Spherical applicators are available in diameters of 1.5, 2, 2.5, 3, 3.5, 4, 4.5 and 5 cm.

⑤ INTRABEAM Needle Applicator

The INTRABEAM Needle Applicator can be used for the interstitial irradiation of tumors, e.g. in the treatment of spinal metastases. The single-use INTRABEAM Needle Applicator has a diameter of 4 mm.

The needle applicator has a diameter of 0.4 cm.

⑥ INTRABEAM Flat Applicator

The INTRABEAM Flat Applicator is used in the treatment of tumors on surgically exposed surfaces such as the gastrointestinal tract. The INTRABEAM Flat Applicator has an optimized flat radiation field of 5 mm from the applicator surface. The applicators are sterilizable and can be re-used.

Flat applicators are available in diameters of 1, 2, 3, 4, 5 and 6 cm.

⑦ INTRABEAM Surface Applicator

The INTRABEAM Surface Applicator is used to treat tumors on the surface of the body, e.g. non-melanoma skin cancer. The applicator generates an optimized flat radiation field. The applicators are sterilizable and can be re-used.

Surface applicators are available in diameters of 1, 2, 3 and 4 cm.

⑧ INTRABEAM Cylindrical V Applicator

The INTRABEAM Cylinder V Applicator is used for the irradiation of vaginal wall tumors and consists of a cylindrical applicator and a probe guard which may be inserted in the applicator. The Dwell Stepper allows the probe guard which encases the tip of the miniaturized accelerator to be precisely positioned in the INTRABEAM Cylinder V Applicator. This enables manual stepping of the probe tip and establishment of a homogeneous cylindrical dose distribution of a user defined length.

Cylindrical V applicators are available in diameters of 2, 2.5, 3 and 3.5 cm.

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