INTRABEAM™ System

For Intraoperative Radiation Therapy

PeC

Radiation Dose Directly to the Target

ZEISS

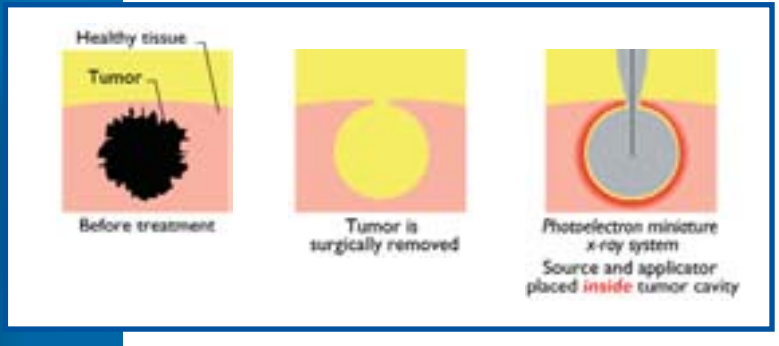
INTRABEAM™ System for IORT

INTRABEAM is a complete system for the delivery of intraoperative radiation therapy (IORT) to tumors and tumor beds following re-section. The powerful miniature x-ray source of Photoelectron's PRS400 is combined with the flexibility ofthe INTRABEAM Floor Stand to enable radiation therapy treatments in any operating theater.

The PRS 400

INTRABEAM delivers radiation with the PRS400. The PRS400 is a proven radiation therapy treatment device, having been used successfully in many treatments including brain, breast, spine, gynecological and colo-rectal tumor sites.The PRS400 includes a miniature x-ray source, control console and a complete set of quality assurance tools.

INTRABEAM IORT



Conventional IORT

Conventional intraoperative radiotherapy
Radiation projected into cavity

The INTRABEAM Floor Stand provides a mobile, flexible and extremely reliable platform for treatment delivery in any operating room. The stand is based on the time-tested Contraves technology. This stable platform is a proven design that has provided support for surgical systems in operating rooms throughout the world. The INTRABEAM Floor Stand has been optimized to balance the PRS400 miniature x-ray source during positioning and treatment delivery. The

optimization included the addition of ergonomic features for guiding the x-ray source to the target with ease.

INTRABEAM™ System Features

■ A truly flexible system for IORT, INTRABEAM delivers treatment by a number of methods, including intraoperative, interstitial, intra-cavity and surface treatments.

■ A mobile stand that enables use in any operating room; can easily roll the stand from OR to OR. The high dose, low energy x-rays of the PRS400 do not require special shielding.

■ A balanced system with six (6) degrees of freedom to gain access to target sites throughout the body. The electric clutches and braking system ensure safe and accurate delivery of the probe to the target.

■ The Spherical Applicator Set, with applicators ranging from 1.5-5.0cm diameter, is ideal for intraoperative treatments, distributing the dose evenly to all surfaces of the tumor cavity.

System Specifications

Floor Stand:

- Weight-balanced, effortless positioning
- Six (6) degrees of freedom
- Magnetic brake locking
- Hand or foot pedal activated
- Stores in 34" x 48" x 60" high profile
- Mobile base with leveling pads
- Sterile drape
- Voltage: 100/120/230 VAC +/-10%
- Frequency: 50/60Hz

Miniature X-Ray Source:

- Photoelectron Corporation PRS400
  Miniature X-ray Source
  Energy (max): 50kV, 40µA
  Weight: approx. 1.6kg (3 lbs)
  Probe dimensions:
  3.2mm diameter, 10cm long
- Control Console
  Weight: 18kg
  Dimensions: (length x width x height)
  47cm x 39.4cm x 20.3cm
  Voltage (supply): 100/120/230/240 VAC
  Frequency: 50/60Hz

Spherical Applicators:

- 1.5cm to 5.0cm in diameter
- Steam sterilizable
- Integral radiation filters to ensure radiation uniformity

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PRS400 complies with the following:
MDD 93/42/EEC (Medical Device Directive)
IEC 601-1/EN 60601-IEC 601-1-2, IEC 601-2-8 (International Electrotechnical Commission)
Quality System Regulation (QSR) 21 CFR Part 820
ISO 9001/EN 46001 (International Standards Organization)

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30-239 e Printed in Germany W-TBM-III/2002 Printed on environement-friendly paper, bleached without the use of dorine