

Indications for Use

510(k) Number (if known)
K162568

Device Name

INTRABEAM 600

Indications for Use (Describe)

The INTRABEAM 600 is indicated for radiation therapy treatments.

The INTRABEAM Spherical Applicators are indicated for use with the INTRABEAM 600 to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments.

The INTRABEAM Spherical Applicators used with the INTRABEAM 600 are able to deliver a prescribed dose of intraoperative radiation in conjunction with whole breast irradiation, based upon the medical judgment of the physician. The safety and effectiveness of the INTRABEAM 600 as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

The Needle Applicator set (comprising the Needle Applicator and guide shafts) is intended for use in combination with the INTRABEAM 600 to intraoperatively administer radiation to tissue including irradiation of intracranial tumors.

The INTRABEAM Flat Applicator is intended to supply a specified radiation dose during applications in combination with the INTRABEAM 600,

- during intraoperative radiotherapy, on a surgically exposed surface or in a tumor bed.
- during treatment of tumors on the body surface.

The INTRABEAM Flat Applicator is designed to deliver a flat radiation field at a distance of 5mm from its circular application surface in water.

The INTRABEAM Surface Applicator is intended to supply a specified radiation dose during applications in combination with the INTRABEAM 600.

- during intraoperative radiotherapy, on a surgically exposed surface or in a tumor bed.
- during treatment of tumors on the body surface.

The INTRABEAM Surface Applicator is designed to deliver a flat radiation field directly at the applicator's surface.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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