

Fludeoxyglucose F 18 Injection, USP For intravenous use

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For intravenous use
Initial U.S. Approval: 2005

INDICATIONS AND USAGE

Fludeoxyglucose F 18 Injection is indicated for positron emission tomography (PET) imaging in the following settings:

- **Oncology:** For assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities, or in patients with an existing diagnosis of cancer.
- **Cardiology:** For the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging.
- **Neurology:** For the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

- **Radiation Risks:** Radiation-emitting products, including Fludeoxyglucose F 18 Injection, may increase the risk for cancer, especially in pediatric patients. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker.
- **Blood Glucose Abnormalities:** In the oncology and neurology setting, suboptimal imaging may occur in patients with inadequately regulated blood glucose levels. In these patients, consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to administration.

ADVERSE REACTIONS

Hypersensitivity reactions with pruritus, edema and rash have occurred; have emergency resuscitation equipment and personnel immediately available.

- **To report SUSPECTED ADVERSE REACTIONS, contact PETNET Solutions, Inc. at 877-473-8638 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Rx Only

See package insert for full prescribing information.

Manufactured by:
PETNET Solutions Inc.
810 Innovation Drive
Knoxville, TN 37932

Distributed by:
PETNET Solutions Inc.
810 Innovation Drive
Knoxville, TN 37932

PETNET Solutions

Shaping the Future of Cancer Care with Personalized Radiation Therapy Planning

Utilizing high-resolution Biograph mCT PET•CT, Stanford Cancer Institute in Palo Alto, CA, USA; Rigshospitalet in Copenhagen, Denmark and Chang Gung Memorial Hospital in Taipei, Taiwan are increasing the success of cancer treatment.

By James Brice

The prospects were bleak for a 53-year-old Taiwanese man with a large, basaloid, squamous cell carcinoma tumor partially blocking the sinus cavities behind his nose. Without aggressive treatment, the cancer could further spread through the head and neck, causing additional damage.

Physicians treating his case at the 3600-bed Chang Gung Memorial Hospital in Taipei, Taiwan, had divided opinions about the proper response. Surgical removal of the tumor was the surest way to keep the highly proliferative cancer from metastasizing, but it would probably also inflict devastating damage

to the patient's face and head. The surgical mutilation would last as long as he lived.

Alternatively, chemo- and radiation therapy*—would spare his face, but its selection would run the risk of failing to fully treat the cancer. Incomplete radiation coverage could lead to the tumor's return. It could again threaten his survival, but due to the tumors location, over radiation could result in significant damage to healthy tissue, impacting the patient's vision as well as his laryngeal and pharyngeal muscles.

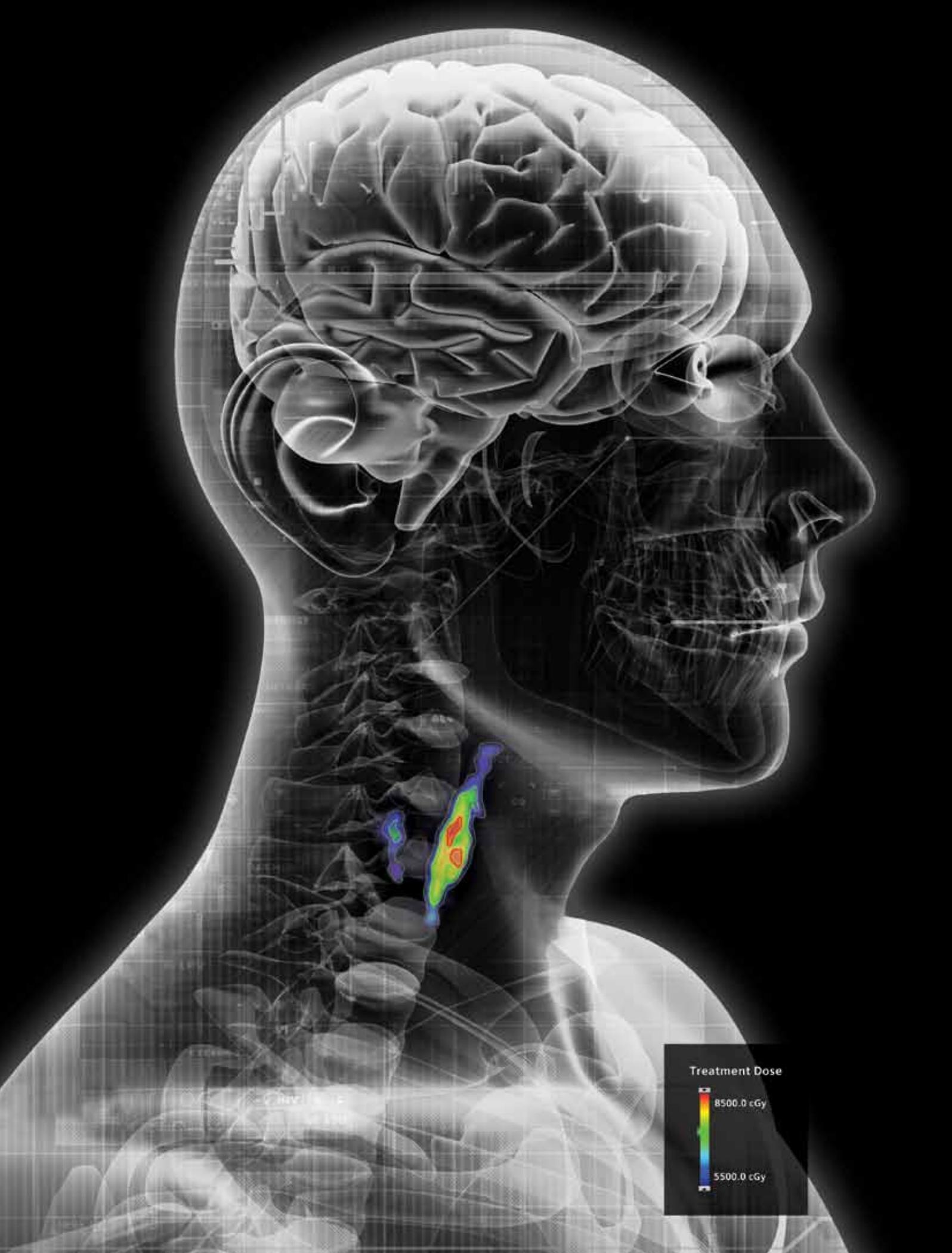
The feared downside of chemoradiation never materialized after it was chosen for the patient's care, thanks to his physicians' medical judgment and applications of the most advanced medical imaging and radiation therapy technologies available.

The nature of cancer treatment is changing as more hospitals adopt Biograph mCT PET•CT for cancer staging, radiation therapy planning and therapy monitoring. Fludeoxyglucose F 18** (¹⁸F FDG) PET•CT imaging uses an analog of glucose and the radioisotope, fluorine 18, to create a 3D map of the metabolic status of the tumor. Because active cancer cells metabolize the glucose at several thousand times the rate of normal cells, they

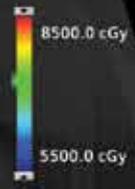
Siemens and Varian Partner to Advance Radiation Therapy

The recently announced global partnership between Siemens Healthcare and Varian Medical Systems provides advanced diagnostic and therapeutic solutions and services for treating cancer with image-guided radiotherapy and radiosurgery. The Siemens/Varian collaboration covers imaging and treatment products for global radiation oncology, including the Biograph™ mCT PET•CT scanner and Varian TrueBeam™ system, and is effective in most international markets including North America. The partnership will leverage both companies' strengths and technology

in order to provide advanced solutions to cancer centers, clinicians and patients. Through this collaboration, clinicians will be enabled to support the entire clinical workflow and optimize personalized cancer care by combining state-of-the-art imaging and precise and powerful radiotherapy. Siemens and Varian are also developing interfaces to enable Varian's ARIA® oncology information system software to support Siemens accelerators and imaging systems, providing clinics with more options for streamlining operations.



Treatment Dose



Plan radiation therapy with High Resolution Biograph mCT

Radiation therapy is only as good as the imaging guiding it.

This cardinal rule of radiation therapy planning deserves consideration when selecting instruments that aid medical decisions that ultimately determine the success of cancer treatment. It is the strongest argument for acquiring a Siemens Biograph mCT with OptisoHD. Anatomic and physiological studies from this unique PET•CT technology have become an essential part of the clinical decision-making process. Radiation oncologists benefit from the Biograph mCT's innovative high-resolution technology for definition of dose delivery in radiation therapy treatment. When radiation therapy is required, it sets a sure course to its effective use.

Offering PET•CT imaging solutions for a wide range of medical institutions – including large academic hospitals, community hospitals, smaller imaging centers, and emerging markets – the Siemens Biograph™ mCT provides facilities with the ability to make excellent progress in cancer diagnosis and precise physiologic-based radiation treatment planning.

As the product of more than 25 years of continuous research and development, the Biograph mCT scanner has the industry's finest volumetric resolution***

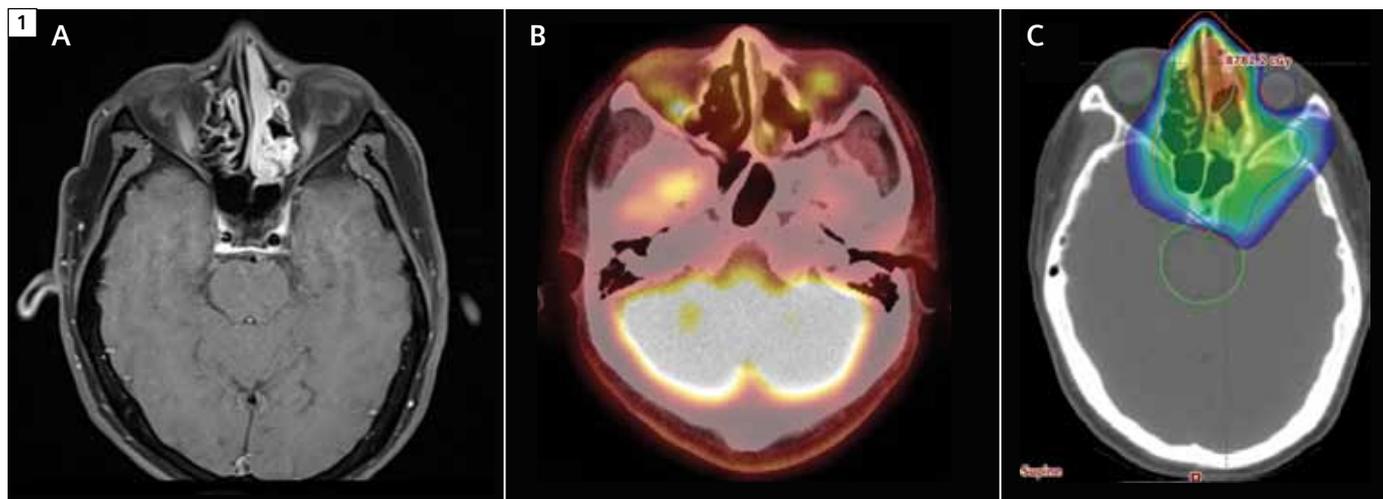
of 87 mm³ for precise contouring, as well as ultraHD•PET, which combines time of flight for additional sensitivity and point spread function characterization for uniform resolution across the entire field of view for more accurate lesion detection and contouring. Boasting a compact design, Biograph mCT has a large 78 cm bore optimized for patient access, easily accommodating radiotherapy positioning devices for more accurate treatment planning and offers unique imaging technologies to ensure precise physiologic information and anatomic clarity from its premium CT solution, which is available in 20, 40, 64, and 128 slices. Biograph mCT also features HD•Chest, a technology that reduces blur created by respiration during PET•CT studies.

Additionally, Biograph mCT ensures quantitative accuracy and reproducibility through Quanti•QC with automated daily normalization and calibration; SMART PHS, which has a cantilever bed designed to reduce deflection and misregistration between CT and PET images; and Accu-Line radiation therapy installation for accurate image registration. This makes Biograph mCT the choice for physiologically targeted radiation therapy planning.

glow brightly, on the PET image. For radiation therapy planning, PET•CT is the new method of choice and used to more precisely define the target volume based on tumor physiology. The multi-slice CT portion of the exam is used to three dimensionally define the tumor's anatomic margins. The addition of physiologic information is vital to assure the viable tumor is treated; additionally, not all tumors are visible with CT that are visible with PET. Tumors are not homogenous. High-resolution ¹⁸F FDG PET•CT reveals variations in metabolic activity throughout their volume. So-called dose painting techniques calibrate the intensity of the radiation therapy beam to match this pattern. A linear accelerator will later rotate around the patient aiming beams of radiation at the tumor from various angles to destroy cancerous tissue inside. Tissues expressing the most metabolic activity selectively receive an elevated radiation dose.

For the cancer patient in Taipei, high-spatial-resolution 40-slice CT images from the Biograph mCT, were used to delineate the three-dimensional position and volume of the tumor. The location of important nerves, vessels and musculature wall were circumscribed. Contouring techniques were then applied by Dr. Chien-Yu Lin, a radiation oncologist at Chang Gung Hospital, and colleagues using a radiation treatment planning system. Their plan assured normal tissues near the tumor were spared from radiation exposure. Dose painting is now performed at Chang Gung Memorial Hospital as part of radiation therapy planning whenever radiation therapy is ordered for oral cavity tumors, Dr. Dorothy Yen, molecular imaging center director notes. The patient's nuclear medicine physician and radiation oncologist agree that radiation therapy plan developed with the help of molecular PET•CT from a Siemens Biograph™ mCT scanner provided the best course of





1 A questionable density at the junction of the ethmoid-sphenoid sinus appears highly suspicious at MRI (1A). The radiologist suspects the abnormality could be one of several types of benign tissue after PET•CT (1B) that reveals little ^{18}F FDG uptake within their margins. This area was covered with a prophylactic dose during image modulated radiation therapy (1C) without dose escalation to preserve left eye integrity and vision. Data courtesy of Chang Gung Memorial Hospital, Taipei, Taiwan.

treatment. The clinical specificity and anatomic precision possible with this high-definition molecular PET•CT tool contributes in numerous ways to effective cancer treatments.

“The preliminary data from our experience show it is fantastic,” Yen says. High-resolution PET•CT based radiation therapy plans with dose escalation to viable tumor, while sparing surrounding normal tissue from unnecessary radiation, along with precise radiation dose delivery enables improved local control of tumor along with dramatically lower levels of peritumoral tissue toxicity, especially inflammation of the oral cavity, parotid glands and the ability to swallow.

Many cases, like this patient whose sinuses were filled with cancer, illustrate the value of Biograph mCT in radiation therapy planning. Accurate localization of metabolically active tumor by Biograph mCT with the industry’s finest volumetric resolution*** of 87 mm³ combined with the precise application of radiation dose, may have spared the vision in the patient’s left eye, as well as his laryngeal and pharyngeal muscles, which control the swallowing function.

Biograph mCT in Denmark

Nearly half a world away, dose painting is stirring interest at Rigshospitalet, the national hospital of Denmark in Copenhagen. Opportunities to sharpen the delineation of tumors targeted for radiation therapy and to improve tumor response assessments have drawn attention to Biograph mCT.

The high-volume teaching hospital is a center of clinical excellence for a broad spectrum of medical specialties with a strong reputation for world class research in oncology, nephrology and cardiology. More than 2,000 patients annually receive services at the hospital’s Center for the Integrated Rehabilitation of Cancer Patients. Additionally, two-thirds of the pediatric oncology cases in Denmark are treated at the facility, and it is the regional center for mesothelioma treatment for patients throughout Scandinavia. A doctoral fellow—the department supports 25 doctoral fellows—in addition to employing a 100-person staff—drew the faculty’s attention to dose painting this year with research demonstrating that regions within head and neck

cancers with the highest metabolic activity delineated on PET/CT are at abnormally high risk for cancer recurrence after radiation therapy, says Dr. Anna Kiil Berthelsen, chief radiologist. The findings suggest elevated radiation could be directed at these specific regions during radiation therapy.* Overall, Biograph mCT has proved popular for radiation therapy planning at Rigshospitalet for both practical and technical reasons.

Its 78 cm wide patient bore is well-suited for radiation therapy simulations, a procedure used to rehearse the often complex application of high-energy X-ray beams during radiation therapy using relatively lower dose CT. Simulation also establishes optimal patient position and is used to fabricate immobilization devices to freeze the patient into the preferred position during therapy. The wide bore gives staff more room to work than earlier generation PET/CT systems during simulations.

Improved Tumor Delineation

Berthelsen expressed support for PET/CT-based radiation therapy planning in a 2011 published review on the subject.¹

After examining the medical literature, she concluded that improved target delineation with PET/CT-planning leads to better radiation treatment.

"The benefit for the patient is that you can end up having a higher dose actually in the tumor," she says.

The radiation oncologist is more likely to escalate the amount of radiation directed to the tumor because he or she is more confident the beam will hit the targeted mass. Vital organs and neighboring normal tissues may be spared. Major complications from radiation therapy, such as losing the ability to swallow or salivate, may occur less often.

"We feel safer doing tumor delineation when it is performed with Biograph mCT," Berthelsen explains. "It couldn't be more precise. We are defining smaller gross tumor margins, because we are highly certain about the accuracy of our margins." Berthelsen was part of a recent study by Rigshospitalet oncologists and radiologists, which supports her belief in the precision of Biograph mCT. The study found Biograph mCT PET•CT scans led to the consistent calculation of peripheral lung tumor volumes among six physicians. An evaluation of the physicians'

radiation therapy plans for 22 consecutive patients with 26 tumors found little variation in the calculated tumor volumes targeted for stereotactic radiotherapy. The median tumor volume was 14 cm³, while the overall average standard deviation (representing 66 percent of the calculations around the mean value) was only 0.15 cm³.²

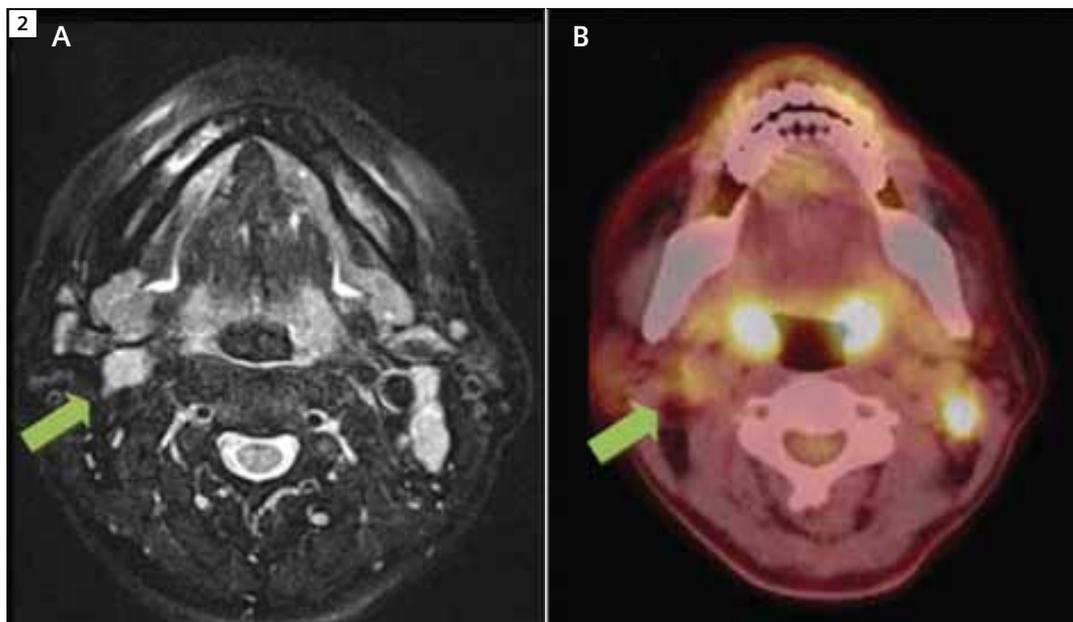
Rigshospitalet has published numerous studies confirming the merit of PET•CT in cancer staging, survival prediction and recurrence monitoring. A breast cancer staging trial confirmed the value of ¹⁸F FDG PET•CT for uncovering previously undetected primary cancers, malignant extra-axillary lymph nodes and distant metastases. Because of PET•CT, staging was altered for 14 percent of patients, while planning clinical management was modified for 8 percent.³ Another study, established ¹⁸F FDG PET•CT's superiority over abdominal/transvaginal ultrasound and CT for diagnosing recurrent ovarian cancer. PET•CT was 97 percent sensitive to recurrence, compared to 81 percent and 66 percent sensitivity for CT and ultrasound, respectively.⁴ Rigshospitalet's department of clinical

physiology, nuclear medicine and PET is an early adopter of new technology and therapy. Since the department's acquisition of Siemens Biograph mCT with 64-slice CT, the PET•CT scanner has become one of the mainstays of the hospital's radiation therapy service.

An Even Sharper Edge at Stanford

Stanford first brought PET/CT into its radiation therapy planning lab in 2004 for cancer staging and radiation therapy simulations for intensity modulated radiation therapy. The coregistration capabilities of the multi-slice PET/CT scanner led to "dramatic improvements in tumor target identification and delineation," says Dr. Billy W. Loo, Jr., Stanford Medical Center.

Before the introduction of PET/CT, the hospital's radiation oncologists performed awkward side-by-side comparisons of PET and treatment planning CT to establish important spatial correlations. On CT alone, tumor and partially collapsed lung (atelectasis) blended together into a single indecipherable mass. "But having PET information co-registered exactly with the patient in the



2 Inconsistent findings of right side neck nodes (arrow) rose from positive MRI (2A) and negative PET•CT (2B).

treatment position allowed us to make that distinction," he says. With the 8-year-old scanner now operating at full patient capacity, the department anticipates substantially better performance from its new 128-slice Biograph mCT. Installation will be completed in December.

Stanford's decision to acquire the advanced system represents a break with tradition for the hospital's medical imaging departments. "That is one of the exciting things about the new scanner," Loo says. "It will be the first major Siemens technology brought into our radiation oncology department."

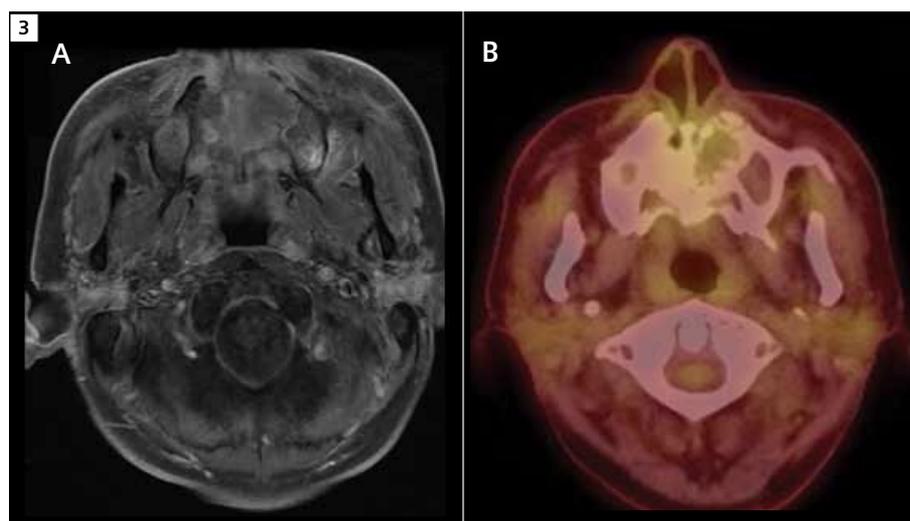
The decision by department chair Dr. Quynh-Thu Le to align with Siemens was not made lightly. It came after her New Technology Committee determined that the 128-slice Biograph mCT offered the best combination of features to support radiation therapy planning for their sophisticated state-of-the-art linear accelerators.

Better CT performance from the Biograph mCT will help improve tumor edge detection and target definition, especially for relatively small tumors for SABR therapy, Loo says.

The Biograph mCT scanner has optimized HD 87 mm³ volumetric resolution for precise contouring and ultraHD•PET, which combines with time of flight for additional sensitivity and point spread function characterization for uniform resolution across the entire field of view for more accurate lesion detection and contouring.

"All those image quality characteristics will help us create carefully sculpted, highly focused plans," he says.

Loo is eager to capitalize on the Biograph's wide CT detector to reduce the incidence of 4D CT reconstruction artifacts. For years, they have been a source of irritation and wasted radiation oncologist time. A published analysis at Stanford in 2008 found artifacts in the radiation therapy planning scans of 45 of 50 patients who awaited abdominal



3 MRI images (3A) acquired three months post-treatment showed evidence of residual primary tumor that was not seen on corresponding ¹⁸F FDG PET/CT images that revealed metabolic complete remission (3B). Unnecessary biopsy was avoided because of ¹⁸F FDG PET/CT findings. Data courtesy of Chang Gung Memorial Hospital, Taipei, Taiwan

and thoracic radiotherapy.⁴ With access to Biograph mCT, the staff will no longer have to electronically stitch together a series of CT images with the patient in varied bed positions to produce complete images. "We will get a boost in both spatial and temporal resolution," he says. The sensitivity of PET will also rise because of larger detectors and time of flight acquisition with Biograph mCT. Their benefits will be seen clinically with improved target delineation

during radiation therapy planning and scientifically with higher signal-to-noise (SNR) ratios for applications development. In addition, faster PET and CT acquisition will help Stanford researchers find better solutions to the problem of patient motion during radiation therapy planning and treatment as well. The Stanford group already has considerable experience devising 4D CT respiratory gating strategies to limit the application of the beam to only when the tumor is moving through specified treatment window.



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Chief Radiologist,
Rigshospitalet - Copenhagen, Denmark.



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Dr. Billy W. Loo, Jr.,
Stanford Medical Center
Stanford, CA, USA

A lung tumor can move more than an inch during a normal cycle of free breathing, Loo notes. Motion correction must be applied to radiation therapy to protect normal lung tissue from irradiation. The larger detector size, wider field of view and faster scanning with the 128-slice Biograph mCT are all expected to help improve motion tracking and correction. ^{18}F FDG PET will be used for the first time to aid target delineation.

Adaptive Radiation Therapies

As Stanford's Biograph mCT program moves forward, Loo expects that in addition to its utilization for staging, simulation and planning, the PET•CT scanner will drive progress in the development of adaptive radiation therapies. Sequential imaging with ^{18}F FDG PET•CT illustrates the response of the tumor to radiation therapy. Although

inflammation secondary to radiotherapy may cause increased uptake of tracer in the tumor bed, quantitative evaluation of ^{18}F FDG PET•CT has been successfully used to track tumor response, and in some cases, optimize the radiation beam during the course of therapy to take into account the change in tumor metabolism and volume following the initial radiation or chemoradiation. This approach, termed adaptive radiotherapy has the potential of further improving dose delivery to tumor while sparing healthy tissue, especially in head and neck tumors where dose restriction to normal structures is of critical importance. (Read more about radiation therapy planning for head and neck cancer on page 24)

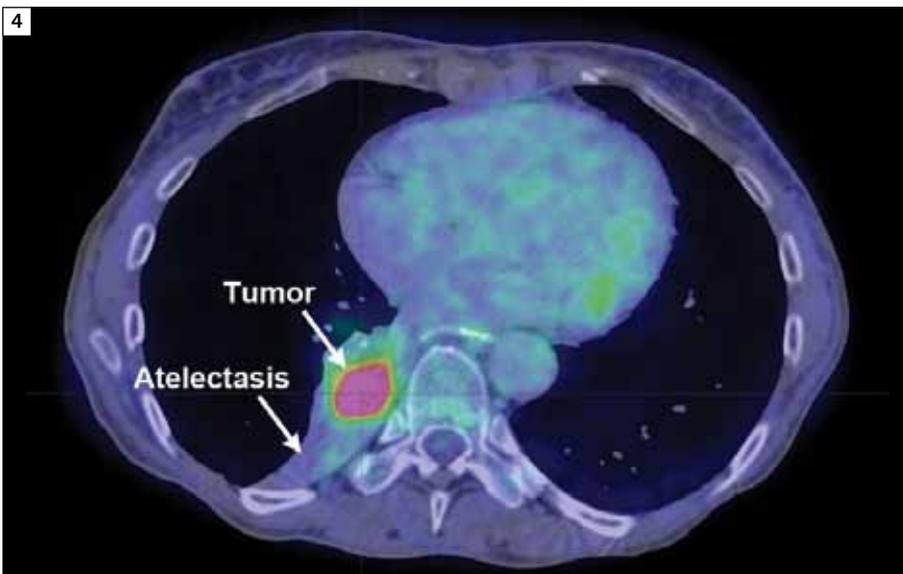
“We are just starting to perform adaptive therapy,” says Loo. “We image again part way through the treatment to

decide if we should modify the volume that is being treated. If the tumor shrinks in a certain way or has residual activity, we may concentrate more of the dose there for more of the treatment course. Adaptive therapy is just starting to come into play.”

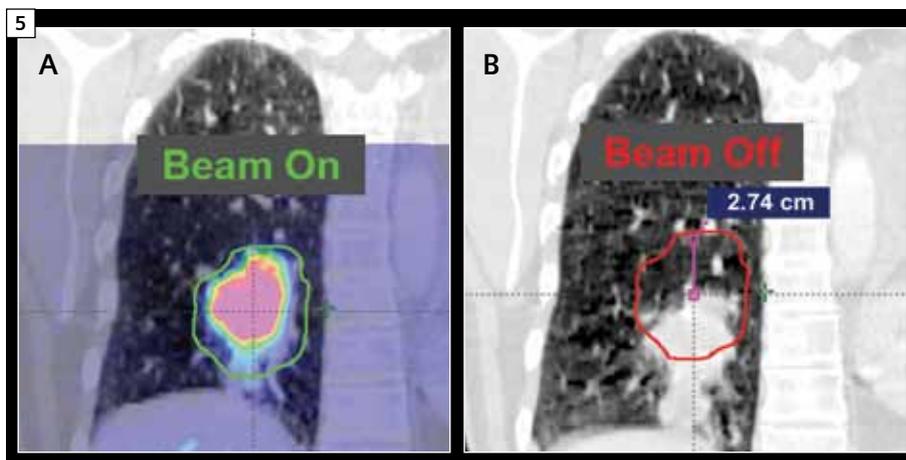
Possible Hypoxia Solutions

Stanford researchers look forward to seeing how higher SNR affects the sensitivity of custom PET imaging biomarkers designed to image hypoxia, a critical physiological factor that blocks the effectiveness of chemo- and radiotherapies. The combination of an appropriate PET biomarkers and Biograph mCT may some day produce imaging studies that reveal the presence and extent of hypoxia. Radiation dose during therapy can then be raised to overcome its effect, according to Dr. Albert Koong, the director of clinical radiation therapy operations at Stanford.

Stanford's ambitious plans for the Biograph mCT are also reflected in its placement in the imaging suite a few steps way from its linear accelerator. The configuration will allow Koong and colleagues to investigate the potential of high-speed 128-slice CT perfusion for extremely rapid responses to radiation therapy.



4 ^{18}F FDG PET clearly distinguishes tumor from a large area of adjacent collapsed lung (Atelectasis). CT alone is considered poorly suited for this role. Stanford's radiation oncologists assumed the entire abnormality was malignant in such situations, before gaining access to PET•CT. A larger than necessary section of normal lung was irradiated as a result. Data courtesy of Stanford Medical Center, Palo Alto, CA, USA



4 CT respiratory gating was applied to patient with severe tumor motion. The linac was instructed to turn the beam on at exhale (5A) and off at inhale (5B) when the tumor moves too far from its exhale position. Overlay of 4D PET also shown at exhale phase. It reveals CT abnormality below the tumor is atelectasis, not part of the active tumor. Ungated 3D PET scan would be smeared in the direction of tumor motion making this distinction difficult to determine. Data courtesy of Stanford Medical Center, Palo Alto, CA, USA

Such blood flow changes have been observed in animal studies, but have yet to be tested extensively in humans, Koong says. Increased blood flow could help identify the optimal time to administer chemotherapy after radiation because more blood flowing to the tumor would allow more infused therapy to permeate the diseased tissue. Decreased blood flow would suggest if treatment should be delayed until at least the next radiation session.

The nearly side-by-side configuration of the Biograph mCT and a high-precision linear accelerator will be crucial for a proposed application that is already all about timing, Koong says. Relevant blood flow changes will probably occur in the first 30 to 60 minutes after radiation treatment. The results of perfusion CT performed after this diagnostic window closes will probably be irrelevant, according to Koong.

"To study these rapid changes, you need to have these machines situated side-by-side," he says.

Biograph mCT combines the industry's finest volumetric resolution*** for precise contouring of the tumor, combined with ultraHD•PET for additional sensitivity and uniform resolution, provides images with the clarity and sharpness to precisely identify tumor edges and volumes and to help anticipate and control their motion during therapy. High-resolution and sensitivity means more precise data for radiation therapy planning, which leads to better tumor contouring, more precise dose escalation and less radiation exposure to critical organs and neighboring tissues. Radiation therapy plans will be adjusted as the tumor shrinks and the pattern of elevated metabolic activity changes. With Siemens Biograph mCT, radiation treatment plans will become personalized for each patient – each tumor – helping improve cancer care.

Indications

Fludeoxyglucose F 18 Injection is indicated for positron emission tomography (PET) imaging in the following settings:

- **Oncology:** For assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found by other testing modalities, or in patients with an existing diagnosis of cancer.
- **Cardiology:** For the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging.
- **Neurology:** For the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

* Radiation treatments are not appropriate for all types of cancers and serious side effects can occur.

** The full prescribing information for the Fludeoxyglucose F 18 injection can be found on page 10.

***Based on competitive information available at time of publication. Data on file.

The statements by Siemens' customers described herein are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, level of IT adoption) there can be no guarantee that other customers will achieve the same results.

Important Safety Information

- **Radiation Risks:** Radiation-emitting products, including Fludeoxyglucose F 18 Injection, may increase the risk for cancer, especially in pediatric patients. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker.
- **Blood Glucose Abnormalities:** In the oncology and neurology setting, suboptimal imaging may occur in patients with inadequately regulated blood glucose levels. In these patients, consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to Fludeoxyglucose F 18 Injection administration.
- **Adverse Reactions:** Hypersensitivity reactions with pruritus, edema and rash have been reported; have emergency resuscitation equipment and personnel immediately available.

References

- ¹ Current Medical Imaging Reviews 2011; 7[3]: 210-215
- ² Br J Radiol 2012; 85[1017]: e654-660
- ³ Ann Oncol 2012; 23[9]: 2277-2282
- ⁴ Int J Radiat Oncol Biol Phys 2008; 72[4]: 1250-1258

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Fludeoxyglucose F 18 Injection safely and effectively. See full prescribing information for Fludeoxyglucose F 18 Injection.

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-----RECENT MAJOR CHANGES-----

Warnings and Precautions (5.1, 5.2) 7/2010
Adverse Reactions (6) 7/2010

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- Neurology: For the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures (1).

-----DOSAGE AND ADMINISTRATION-----

Fludeoxyglucose F18 Injection emits radiation. Use procedures to minimize radiation exposure. Screen for blood glucose abnormalities.

- In the oncology and neurology settings, instruct patients to fast for 4 to 6 hours prior to the drug's injection. Consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to the drug's administration (5.2).
- In the cardiology setting, administration of glucose-containing food or liquids (e.g., 50 to 75 grams) prior to the drug's injection facilitates localization of cardiac ischemia (2.3).

Aseptically withdraw Fludeoxyglucose F18 Injection from its container and administer by intravenous injection (2).

The recommended dose:

- for adults is 5 to 10 mCi (185 to 370 MBq), in all indicated clinical settings (2.1).
 - for pediatric patients is 2.6 mCi in the neurology setting (2.2).
- Initiate imaging within 40 minutes following drug injection; acquire static emission images 30 to 100 minutes from time of injection (2).

-----DOSAGE FORMS AND STRENGTHS-----

Multi-dose 30mL and 50mL glass vial containing 0.74 to 7.40 GBq/mL (20 to 200 mCi/mL) Fludeoxyglucose F18 Injection and 4.5mg of sodium chloride with 0.1 to 0.5% w/w ethanol as a stabilizer (approximately 15 to 50 mL volume) for intravenous administration (3).

-----CONTRAINDICATIONS-----

None

-----WARNINGS AND PRECAUTIONS-----

- Radiation risks: use smallest dose necessary for imaging (5.1).
- Blood glucose abnormalities: may cause suboptimal imaging (5.2).

-----ADVERSE REACTIONS-----

Hypersensitivity reactions have occurred; have emergency resuscitation equipment and personnel immediately available (6).

To report SUSPECTED ADVERSE REACTIONS, contact PETNET Solutions, Inc. at 877-473-8638 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----USE IN SPECIFIC POPULATIONS-----

- Pregnancy Category C: No human or animal data. Consider alternative diagnostics; use only if clearly needed (8.1).
- Nursing mothers: Use alternatives to breast feeding (e.g., stored breast milk or infant formula) for at least 10 half-lives of radioactive decay, if Fludeoxyglucose F 18 Injection is administered to a woman who is breast-feeding (8.3).
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established in the oncology and cardiology settings (8.4).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 1/2011

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* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

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Fludeoxyglucose F18 Injection is indicated for positron emission tomography (PET) imaging in the following settings:

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1.2 Cardiology

For the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function in patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging.

1.3 Neurology

For the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.

2 DOSAGE AND ADMINISTRATION

Fludeoxyglucose F18 Injection emits radiation. Use procedures to minimize radiation exposure. Calculate the final dose from the end of synthesis (EOS) time using proper radioactive decay factors. Assay the final dose in a properly calibrated dose calibrator before administration to the patient [see Description (11.2)].

2.1 Recommended Dose for Adults

Within the oncology, cardiology and neurology settings, the recommended dose for adults is 5 to 10 mCi (185 to 370 MBq) as an intravenous injection.

2.2 Recommended Dose for Pediatric Patients

Within the neurology setting, the recommended dose for pediatric patients is 2.6 mCi, as an intravenous injection. The optimal dose adjustment on the basis of body size or weight has not been determined [see Use in Special Populations (8.4)].

2.3 Patient Preparation

- To minimize the radiation absorbed dose to the bladder, encourage adequate hydration. Encourage the patient to drink water or other fluids (as tolerated) in the 4 hours before their PET study.
- Encourage the patient to void as soon as the imaging study is completed and as often as possible thereafter for at least one hour.
- Screen patients for clinically significant blood glucose abnormalities by obtaining a history and/or laboratory tests [see Warnings and Precautions (5.2)]. Prior to Fludeoxyglucose F 18 PET imaging in the oncology and neurology settings, instruct patient to fast for 4 to 6 hours prior to the drug's injection.
- In the cardiology setting, administration of glucose-containing food or liquids (e.g., 50 to 75 grams) prior to Fludeoxyglucose F 18 Injection facilitates localization of cardiac ischemia

2.4 Radiation Dosimetry

The estimated human absorbed radiation doses (rem/mCi) to a newborn (3.4 kg), 1-year old (9.8 kg), 5-year old (19 kg), 10-year old (32 kg), 15-year old (57 kg), and adult (70 kg) from intravenous administration of Fludeoxyglucose F 18 Injection are shown in Table 1. These estimates were calculated based on human² data and using the data published by the International Commission on Radiological Protection⁴ for Fludeoxyglucose ¹⁸F. The dosimetry data

show that there are slight variations in absorbed radiation dose for various organs in each of the age groups. These dissimilarities in absorbed radiation dose are due to developmental age variations (e.g., organ size, location, and overall metabolic rate for each age group). The identified critical organs (in descending order) across all age groups evaluated are the urinary bladder, heart, pancreas, spleen, and lungs.

Table 1. Estimated Absorbed Radiation Doses (rem/mCi) After Intravenous Administration of Fludeoxyglucose F 18 Injection^a

Organ	Newborn (3.4 kg)	1-year old (9.8 kg)	5-year old (19 kg)	10-year old (32 kg)	15-year old (57 kg)	Adult (70 kg)
Bladder wall ^b	4.3	1.7	0.93	0.60	0.40	0.32
Heart wall	2.4	1.2	0.70	0.44	0.29	0.22
Pancreas	2.2	0.68	0.33	0.25	0.13	0.096
Spleen	2.2	0.84	0.46	0.29	0.19	0.14
Lungs	0.96	0.38	0.20	0.13	0.092	0.064
Kidneys	0.81	0.34	0.19	0.13	0.089	0.074
Ovaries	0.80	0.8	0.19	0.11	0.058	0.053
Uterus	0.79	0.35	0.19	0.12	0.076	0.062
LLI wall*	0.69	0.28	0.15	0.097	0.060	0.051
Liver	0.69	0.31	0.17	0.11	0.076	0.058
Gallbladder wall	0.69	0.26	0.14	0.093	0.059	0.049
Small intestine	0.68	0.29	0.15	0.096	0.060	0.047
ULI wall**	0.67	0.27	0.15	0.090	0.057	0.046
Stomach wall	0.65	0.27	0.14	0.089	0.057	0.047
Adrenals	0.65	0.28	0.15	0.095	0.061	0.048
Testes	0.64	0.27	0.14	0.085	0.052	0.041
Red marrow	0.62	0.26	0.14	0.089	0.057	0.047
Thymus	0.61	0.26	0.14	0.086	0.056	0.044
Thyroid	0.61	0.26	0.13	0.080	0.049	0.039
Muscle	0.58	0.25	0.13	0.078	0.049	0.039
Bone surface	0.57	0.24	0.12	0.079	0.052	0.041
Breast	0.54	0.22	0.11	0.068	0.043	0.034
Skin	0.49	0.20	0.10	0.060	0.037	0.030
Brain	0.29	0.13	0.09	0.078	0.072	0.070
Other tissues	0.59	0.25	0.13	0.083	0.052	0.042

^a MIRDOSE 2 software was used to calculate the radiation absorbed dose. Assumptions on the biodistribution based on data from Gallagher et al.1 and Jones et al.2

^b The dynamic bladder model with a uniform voiding frequency of 1.5 hours was used. *LLI = lower large intestine; **ULI = upper large intestine

2.5 Radiation Safety – Drug Handling

- Use waterproof gloves, effective radiation shielding, and appropriate safety measures when handling Fludeoxyglucose F18 Injection to avoid unnecessary radiation exposure to the patient, occupational workers, clinical personnel and other persons.
- Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.
- Calculate the final dose from the end of synthesis (EOS) time using proper radioactive decay factors. Assay the final dose in a properly calibrated dose calibrator before administration to the patient [see Description (11.2)].
- The dose of Fludeoxyglucose F18 used in a given patient should be minimized consistent with the objectives of the procedure, and the nature of the radiation detection devices employed.

2.6 Drug Preparation and Administration

- Calculate the necessary volume to administer based on calibration time and dose.
- Aseptically withdraw Fludeoxyglucose F18 Injection from its container.
- Inspect Fludeoxyglucose F18 Injection visually for particulate matter and discoloration before administration, whenever solution and container permit.
- Do not administer the drug if it contains particulate matter or discoloration; dispose of these unacceptable or unused preparations in a safe manner, in compliance with applicable regulations.
- Use Fludeoxyglucose F 18 Injection within 12 hours from the EOS.

2.7 Imaging Guidelines

- Initiate imaging within 40 minutes following Fludeoxyglucose F 18 Injection administration.
- Acquire static emission images 30 to 100 minutes from the time of injection.

3 DOSAGE FORMS AND STRENGTHS

Multiple-dose 30mL and 50mL glass vial containing 0.74 to 7.40 GBq/mL (20 to 200 mCi/mL) of Fludeoxyglucose F 18 Injection and 4.5 mg of sodium chloride with 0.1 to 0.5% w/w ethanol as a stabilizer (approximately 15 to 50 mL volume) for intravenous administration.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Radiation Risks

Radiation-emitting products, including Fludeoxyglucose F 18 Injection, may increase the risk for cancer, especially in pediatric patients. Use the smallest dose necessary for imaging and ensure safe handling to protect the patient and health care worker [see Dosage and Administration (2.5)].

5.2 Blood Glucose Abnormalities

In the oncology and neurology setting, suboptimal imaging may occur in patients with inadequately regulated blood glucose levels. In these patients, consider medical therapy and laboratory testing to assure at least two days of normoglycemia prior to Fludeoxyglucose F 18 Injection administration.

6 ADVERSE REACTIONS

Hypersensitivity reactions with pruritus, edema and rash have been reported in the post-marketing setting. Have emergency resuscitation equipment and personnel immediately available.

7 DRUG INTERACTIONS

The possibility of interactions of Fludeoxyglucose F 18 Injection with other drugs taken by patients undergoing PET imaging has not been studied.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with Fludeoxyglucose F 18 Injection. It is also not known whether Fludeoxyglucose F 18 Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Consider alternative diagnostic tests in a pregnant woman; administer Fludeoxyglucose F 18 Injection only if clearly needed.

8.3 Nursing Mothers

It is not known whether Fludeoxyglucose F 18 Injection is excreted in human milk. Consider alternative diagnostic tests in women who are breast-feeding. Use alternatives to breast feeding (e.g., stored breast milk or infant formula) for at least 10 half-lives of radioactive decay, if Fludeoxyglucose F 18 Injection is administered to a woman who is breast-feeding.

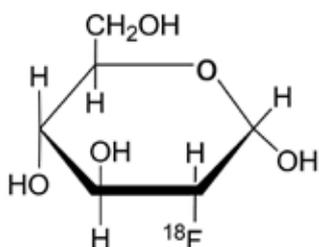
8.4 Pediatric Use

The safety and effectiveness of Fludeoxyglucose F 18 Injection in pediatric patients with epilepsy is established on the basis of studies in adult and pediatric patients. In pediatric patients with epilepsy, the recommended dose is 2.6 mCi. The optimal dose adjustment on the basis of body size or weight has not been determined. In the oncology or cardiology settings, the safety and effectiveness of Fludeoxyglucose F 18 Injection have not been established in pediatric patients.

11 DESCRIPTION

11.1 Chemical Characteristics

Fludeoxyglucose F 18 Injection is a positron emitting radiopharmaceutical that is used for diagnostic purposes in conjunction with positron emission tomography (PET) imaging. The active ingredient 2-deoxy-2-[¹⁸F]fluoro-D-glucose has the molecular formula of C₆H₁₁18FO₅ with a molecular weight of 181.26, and has the following chemical structure:



Fludeoxyglucose F 18 Injection is provided as a ready to use sterile, pyrogen free, clear, colorless solution. Each mL contains between 0.740 to 7.40GBq (20.0 to 200 mCi) of 2-deoxy-2-[¹⁸F]fluoro-D-glucose at the EOS, 4.5 mg of sodium chloride and 0.1 to 0.5% w/w ethanol as a stabilizer. The pH of the solution is between 4.5 and 7.5. The solution is packaged in a multiple-dose glass vial and does not contain any preservative.

11.2 Physical Characteristics

Fluorine F 18 decays by emitting positron to Oxygen O 16 (stable) and has a physical half-life of 109.7 minutes. The principal photons useful for imaging are the dual 511 keV gamma photons, that are produced and emitted simultaneously in opposite direction when the positron interacts with an electron (Table 2).

Radiation/Emission	% Per Disintegration	Mean Energy
Positron(β ⁺)	96.73	249.8 keV
Gamma(±)*	193.46	511.0 keV

*Produced by positron annihilation
From: Kocher, D.C. Radioactive Decay Tables DOE/TIC-1 1026, 89 (1981)

The specific gamma ray constant (point source air kerma coefficient) for fluorine F 18 is 5.7 R/hr/mCi (1.35 x 10⁻⁶ Gy/hr/kBq) at 1 cm. The half-value layer (HVL) for the 511 keV photons is 4 mm lead (Pb). The range of attenuation coefficients for this radionuclide as a function of lead shield thickness is shown in Table 3. For example, the interposition of an 8 mm thickness of Pb, with a coefficient of attenuation of 0.25, will decrease the external radiation by 75 percent.

Table 3. Radiation Attenuation of 511 keV Photons by lead (Pb) shielding

Shield thickness (Pb) mm	Coefficient of attenuation
0	0.00
4	0.50
8	0.25
13	0.10
26	0.01
39	0.001
52	0.0001

For use in correcting for physical decay of this radionuclide, the fractions remaining at selected intervals after calibration are shown in Table 4.

Table 4. Physical Decay Chart for Fluorine F 18

Minutes	Fraction Remaining
0*	1.000
15	0.909
30	0.826
60	0.683
110	0.500
220	0.250

*calibration time

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Fludeoxyglucose F 18 is a glucose analog that concentrates in cells that rely upon glucose as an energy source, or in cells whose dependence on glucose increases under pathological conditions. Fludeoxyglucose F 18 is transported through the cell membrane by facilitative glucose transporter proteins and is phosphorylated within the cell to [¹⁸F] FDG-6-phosphate by the enzyme hexokinase. Once phosphorylated it cannot exit until it is dephosphorylated by glucose-6-phosphatase. Therefore, within a given tissue or pathophysiological process, the retention and clearance of Fludeoxyglucose F 18 reflect a balance involving glucose transporter, hexokinase and glucose-6-phosphatase activities. When allowance is made for the kinetic differences between glucose and Fludeoxyglucose F 18 transport and phosphorylation (expressed as the "lumped constant" ratio), Fludeoxyglucose F 18 is used to assess glucose metabolism.

In comparison to background activity of the specific organ or tissue type, regions of decreased or absent uptake of Fludeoxyglucose F 18 reflect the decrease or absence of glucose metabolism. Regions of increased uptake of Fludeoxyglucose F 18 reflect greater than normal rates of glucose metabolism.

12.2 Pharmacodynamics

Fludeoxyglucose F 18 Injection is rapidly distributed to all organs of the body after intravenous administration. After background clearance of Fludeoxyglucose F 18 Injection, optimal PET imaging is generally achieved between 30 to 40 minutes after administration.

In cancer, the cells are generally characterized by enhanced glucose metabolism partially due to (1) an increase in activity of glucose transporters, (2) an increased rate of phosphorylation activity, (3) a reduction of phosphatase activity or, (4) a dynamic alteration in the balance among all these processes. However, glucose metabolism of cancer as reflected by Fludeoxyglucose F 18 accumulation shows considerable variability. Depending on tumor type, stage, and location, Fludeoxyglucose F 18 accumulation may be increased, normal, or decreased. Also, inflammatory cells can have the same variability of uptake of Fludeoxyglucose F 18.

In the heart, under normal aerobic conditions, the myocardium meets the bulk of its energy requirements by oxidizing free fatty acids. Most of the exogenous glucose taken up by the myocyte is converted into glycogen. However, under ischemic conditions, the oxidation of free fatty acids decreases, exogenous glucose becomes the preferred myocardial substrate, glycolysis is stimulated, and glucose taken up by the myocyte is metabolized immediately instead of being converted into glycogen. Under these conditions, phosphorylated Fludeoxyglucose F 18 accumulates in the myocyte and can be detected with PET imaging.

In the brain, cells normally rely on aerobic metabolism. In epilepsy, the glucose metabolism varies. Generally, during a seizure, glucose metabolism increases. Interictally, the seizure focus tends to be hypometabolic.

12.3 Pharmacokinetics

Distribution: In four healthy male volunteers, receiving an intravenous administration of 30 seconds in duration, the arterial blood level profile for Fludeoxyglucose F 18 decayed triexponentially. The effective half-life ranges of the three phases were 0.2 to 0.3 minutes, 10 to 13 minutes with a mean and standard deviation (STD) of 11.6 (\pm) 1.1 min, and 80 to 95 minutes with a mean and STD of 88 (\pm) 4 min.

Plasma protein binding of Fludeoxyglucose F 18 has not been studied.

Metabolism: Fludeoxyglucose F 18 is transported into cells and phosphorylated to [18 F]FDG-6-phosphate at a rate proportional to the rate of glucose utilization within that tissue. [18 F]-FDG-6-phosphate presumably is metabolized to 2-deoxy-2-[18 F]fluoro-6-phospho-D-mannose([18 F]FDM-6-phosphate).

Fludeoxyglucose F 18 Injection may contain several impurities (e.g., 2-deoxy-2-chloro-D-glucose (CIDG)). Biodistribution and metabolism of CIDG are presumed to be similar

to Fludeoxyglucose F 18 and would be expected to result in intracellular formation of 2-deoxy-2-chloro-6-phospho-D-glucose (CIDG-6-phosphate) and 2-deoxy-2-chloro-6-phospho-D-mannose (CIDM-6-phosphate). The phosphorylated deoxyglucose compounds are dephosphorylated and the resulting compounds (FDG, FDM, CIDG, and CIDM) presumably leave cells by passive diffusion. Fludeoxyglucose F 18 and related compounds are cleared from non-cardiac tissues within 3 to 24 hours after administration. Clearance from the cardiac tissue may require more than 96 hours. Fludeoxyglucose F 18 that is not involved in glucose metabolism in any tissue is then excreted in the urine.

Elimination: Fludeoxyglucose F 18 is cleared from most tissues within 24 hours and can be eliminated from the body unchanged in the urine. Three elimination phases have been identified in the reviewed literature. Within 33 minutes, a mean of 3.9% of the administered radioactive dose was measured in the urine. The amount of radiation exposure of the urinary bladder at two hours post-administration suggests that 20.6% (mean) of the radioactive dose was present in the bladder.

Special Populations: The pharmacokinetics of Fludeoxyglucose F 18 Injection have not been studied in renally-impaired, hepatically impaired or pediatric patients. Fludeoxyglucose F 18 is eliminated through the renal system. Avoid excessive radiation exposure to this organ system and adjacent tissues.

The effects of fasting, varying blood sugar levels, conditions of glucose intolerance, and diabetes mellitus on Fludeoxyglucose F 18 distribution in humans have not been ascertained [see Warnings and Precautions (5.2)].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been performed to evaluate the Fludeoxyglucose F 18 Injection carcinogenic potential, mutagenic potential or effects on fertility.

14 CLINICAL STUDIES

14.1 Oncology

The efficacy of Fludeoxyglucose F 18 Injection in positron emission tomography cancer imaging was demonstrated in 16 independent studies. These studies prospectively evaluated the use of Fludeoxyglucose F 18 in patients with suspected or known malignancies, including non-small cell lung cancer, colo-rectal, pancreatic, breast, thyroid, melanoma, Hodgkin's and non-Hodgkin's lymphoma, and various types of metastatic cancers to lung, liver, bone, and axillary nodes. All these studies had at least 50 patients and used pathology as a standard of truth. The Fludeoxyglucose F 18 Injection doses in the studies ranged from 200 MBq to 740 MBq with a median and mean dose of 370 MBq.

In the studies, the diagnostic performance of Fludeoxyglucose F 18 Injection varied with the type of cancer, size of cancer, and other clinical conditions. False negative and false positive scans were observed. Negative Fludeoxyglucose F 18 Injection PET scans do not exclude the diagnosis of cancer. Positive Fludeoxyglucose F 18 Injection PET scans can not replace pathology to establish a diagnosis of cancer. Non-malignant conditions such as fungal infections, inflammatory processes and benign tumors have patterns of increased glucose metabolism that may give rise to false-positive scans. The efficacy of Fludeoxyglucose F 18 Injection PET imaging in cancer screening was not studied.

14.2 Cardiology

The efficacy of Fludeoxyglucose F 18 Injection for cardiac use was demonstrated in ten independent, prospective studies of patients with coronary artery disease and chronic left ventricular systolic dysfunction who were scheduled to undergo coronary revascularization. Before revascularization, patients underwent PET imaging with Fludeoxyglucose F 18 Injection (74 to 370 MBq, 2 to 10 mCi) and perfusion imaging with other diagnostic radiopharmaceuticals. Doses of Fludeoxyglucose F 18 Injection ranged from 74 to 370 MBq (2 to 10 mCi). Segmental, left ventricular, wall-motion assessments of asynergic areas made before revascularization were compared in a blinded manner to assessments made after successful revascularization to identify myocardial segments with functional recovery.

Left ventricular myocardial segments were predicted to have reversible loss of systolic function if they showed Fludeoxyglucose F 18 accumulation and reduced perfusion (i.e., flow-metabolism mismatch). Conversely, myocardial segments were predicted to have irreversible loss of systolic function if they showed reductions in both Fludeoxyglucose F 18 accumulation and perfusion (i.e., matched defects).

Findings of flow-metabolism mismatch in a myocardial segment may suggest that successful revascularization will restore myocardial function in that segment. However, false-positive tests occur regularly, and the decision to have a patient undergo revascularization should not be based on PET findings alone. Similarly, findings of a matched defect in a myocardial segment may suggest that myocardial function will not recover in that segment, even if it is successfully revascularized. However, false-negative tests occur regularly, and the decision to recommend against coronary revascularization, or to recommend a cardiac transplant, should not be based on PET findings alone. The reversibility of segmental dysfunction as predicted with Fludeoxyglucose F 18 PET imaging depends on successful coronary revascularization. Therefore, in patients with a low likelihood of successful revascularization, the diagnostic usefulness of PET imaging with Fludeoxyglucose F 18 Injection is more limited.

14.3 Neurology

In a prospective, open label trial, Fludeoxyglucose F 18 Injection was evaluated in 86 patients with epilepsy. Each patient received a dose of Fludeoxyglucose F 18 Injection in the range of 185 to 370 MBq (5 to 10 mCi). The mean age was 16.4 years (range: 4 months to 58 years; of these, 42 patients were less than 12 years and 16 patients were less than 2 years old). Patients had a known diagnosis of complex partial epilepsy and were under evaluation for surgical treatment of their seizure disorder. Seizure foci had been previously identified on ictal EEGs and sphenoidal EEGs. Fludeoxyglucose F 18 Injection PET imaging confirmed previous diagnostic findings in 16% (14/87) of the patients; in 34% (30/87) of the patients, Fludeoxyglucose F 18 Injection PET images provided new findings. In 32% (27/87), imaging with Fludeoxyglucose F 18 Injection was inconclusive. The impact of these imaging findings on clinical outcomes is not known.

Several other studies comparing imaging with Fludeoxyglucose F 18 Injection results to subsphenoidal EEG, MRI and/or surgical findings supported the concept that the degree of hypometabolism corresponds to areas of confirmed epileptogenic foci. The safety and effectiveness of Fludeoxyglucose F 18 Injection to distinguish idiopathic epileptogenic foci from tumors or other brain lesions that may cause seizures have not been established.

15 REFERENCES

1. Gallagher B.M., Ansari A., Atkins H., Casella V., Christman D.R., Fowler J.S., Ido T., MacGregor R.R., Som P., Wan C.N., Wolf A.P., Kuhl D.E., and Reivich M. "Radiopharmaceuticals XXVII. 18F-labeled 2-deoxy-2-fluoro-d-glucose as a radiopharmaceutical for measuring regional myocardial glucose metabolism in vivo: tissue distribution and imaging studies in animals," *J Nucl Med*, 1977; 18, 990-6.
2. Jones S.C., Alavi, A., Christman D., Montanez, I., Wolf, A.P., and Reivich M. "The radiation dosimetry of 2 [F-18] fluoro-2-deoxy-D-glucose in man," *J Nucl Med*, 1982; 23, 613-617.
3. Koehler, D.C. "Radioactive Decay Tables: A handbook of decay data for application to radiation dosimetry and radiological assessments," 1981, DOE/TIC-1 1026, 89.
4. ICRP Publication 53, Volume 18, No. I-4, 1987, pages 75-76.

16 HOW SUPPLIED/STORAGE AND DRUG HANDLING

Fludeoxyglucose F 18 Injection is supplied in a multi-dose, capped 30 mL and 50 mL glass vial containing between 0.740 to 7.40GBq/mL (20 to 200 mCi/mL), of no carrier added 2deoxy-2-[F 18] fluoro-D-glucose, at end of synthesis, in approximately 15 to 50 mL. The contents of each vial are sterile, pyrogen-free and preservative-free.

NDC 40028-511-30; 40028-511-50

Receipt, transfer, handling, possession, or use of this product is subject to the radioactive material regulations and licensing requirements of the U.S. Nuclear Regulatory Commission, Agreement States or Licensing States as appropriate.

Store the Fludeoxyglucose F 18 Injection vial upright in a lead shielded container at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

Store and dispose of Fludeoxyglucose F 18 Injection in accordance with the regulations and a general license, or its equivalent, of an Agreement State or a Licensing State.

The expiration date and time are provided on the container label. Use Fludeoxyglucose F 18 Injection within 12 hours from the EOS time.

17 PATIENT COUNSELING INFORMATION

Instruct patients in procedures that increase renal clearance of radioactivity. Encourage patients to:

- drink water or other fluids (as tolerated) in the 4 hours before their PET study.
- void as soon as the imaging study is completed and as often as possible thereafter for at least one hour.

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