

TaiChiPro

Category:

Best Medical Technology

Company Name:

OUR United

Product/Solution Name:

TaiChiPro

Compound/Tech Name:

X/γ-ray integrated radiotherapy system

Trade Name:

TaiChiPro Digital Radiotherapy System

Corporate Name:

NA

Date of Approval:

2023-02-17

Indications:

TaiChiPro is a teletherapy device intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

The device is equipped with two radiation beam delivery units within an enclosed gantry:

(1) The electron linear accelerator (LINAC) producing 6MV photon beam is indicated to provide precision radiotherapy and stereotactic radiosurgery for larger lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

(2) The rotating focused gamma beam emitting unit with multiple Cobalt-60 sources

is indicated to provide precise stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Therapeutic Areas:

Oncology

General Information File Document upload:

[OUR United_TaiChiPro_Overview_Video.mp4](#)

Background information and need for drug / device:

Cancer remains a global crisis, causing nearly 10 million deaths in 2022 alone, with cases expected to rise significantly.[1] Radiation therapy is a vital weapon, needed by roughly half of all cancer patients and offering a cost-effective cure, particularly where surgery is limited.[2]

However, current radiation therapy systems face key challenges: they struggle with complex or multiple tumors, variations within tumors making some areas resistant, and the inability to easily adjust treatment in real-time as tumors move or the patient's anatomy changes during the treatment.

OUR United addresses these critical needs with TaiChiPro, the first and only multimodal radiation therapy device combining two powerful technologies (X-ray and γ -ray therapies) in one system. Recognized by the FDA as a "\"Breakthrough Device\"" in 2023, TaiChiPro represents a new class of radiotherapy.

Here's how TaiChiPro innovates and delivers value:

1. **Two Therapies, One Precise Strategy:** TaiChiPro's X-ray system administers the primary, broad-spectrum radiation treatment to the tumor. Simultaneously, its γ -ray system functions as a precision strike force, delivering highly focused, intense boosts specifically to stubborn areas. These stubborn or radiation-resistant areas are typically identifiable via pre-treatment PET or fMRI imaging. This seamless combination of broad coverage and focused power exemplifies TaiChiPro's singular strategy: maximizing tumor destruction while minimizing collateral damage.
2. **Personalized Power:** This unique combination allows doctors to tailor treatment like never before. They can adjust the radiation dose within a single tumor - giving more to resistant areas and less to sensitive healthy tissues nearby. It also enables efficient, simultaneous delivery of tailored precision treatments to multiple distinct tumors in a single session.

3. Real-Time Adaptation: Patients aren't statues. TaiChiPro images the patient immediately before each treatment session, adjusting for daily changes in anatomy. Crucially, it can also make adjustments during treatment delivery itself ("real-time adaptive therapy") if the tumor shifts, ensuring radiation hits the target precisely and spares healthy organs.

4. Simplified Workflow: TaiChiPro integrates real-time imaging, X-ray therapy, and γ -ray boosting into a single platform. This consolidation streamlines the entire clinical workflow - from treatment planning and patient positioning to quality control - reducing complexity, cost, and patient burden while enabling more advanced therapies.

The Critical Outcome: The ultimate goals of radiation therapy are to destroy the cancer while minimizing harm to the patient. By enabling this unprecedented level of targeting precision, adaptability, and personalized treatment, TaiChiPro aims to significantly improve local tumor control (increasing cure rates) and dramatically reduce damaging side effects for patients. This breakthrough offers new hope in tackling the complexities of modern cancer care.

Background File Document upload:

N/A

History of the development of the solution/product:

1. Clinical Inspiration: From Problem to Breakthrough (2013-2015)

TaiChiPro's genesis lies in addressing critical clinical challenges in radiation therapy:

- Treating complex tumors requiring both stereotactic radiosurgery and adjacent subclinical lesion clearance often forced patients through two separate treatment courses on different devices;
- Dose escalation to radioresistant/hypoxic regions in locally advanced tumors remained technically unfeasible, compromising tumor control;
- Bulky tumors were nearly untreatable with conventional radiotherapy due to dose penetration limits;
- Unpredictable intrafraction motion (e.g., coughing, swallowing) prevented accurate targeting during delivery;
- Involuntary movement in low-compliance patients (pediatric, claustrophobic) introduced dangerous targeting errors or rendered treatment impossible.

Recognizing the limitations of standalone radiotherapy systems, OUR United analyzed

how X-rays' broad coverage and γ -rays' precision could be synergized. In 2013, OUR United conceptualized TaiChiPro and filed core patents. In 2015, OUR United launched formal R&D to transform vision into reality.

2. Pioneering Engineering: Solving the \"Impossible\" Integration (2016-2020)

TaiChiPro is the first radiotherapy system to successfully merge three complex technologies into one device:

- Medical Linear Accelerator (LINAC): Delivers high-power X-rays for broad tumor coverage.
- Rotating Gamma System (RGS): Acts as a \"gamma sniper\" for ultra-precise radiation boosts.
- 3D Imaging (CBCT): Provides dual-modal, real-time tumor tracking and positioning.

Key Development Breakthroughs:

The team conquered spatial alignment challenges by ensuring all components target a single point within sub-millimeter accuracy - even during rotation - while resolving electromagnetic interference between systems. An integrated LINAC water cooling ensured thermal stability. RGS rapid-switching collimators enable adaptive precision, protecting healthy tissue. Dual-modal imaging provides real-time motion tracking for instant beam correction.

3. Capabilities Validated: From Lab to Clinic (2021-Present)

Systems were installed at Peking Union, Xijing, and Chang'an Hospitals in 2021, initiating trials. Published results show significant dosimetric advantages for lung, pancreatic, and breast cancers:

- Dosimetric precision: Rigorous testing confirmed TaiChiPro's ability to deliver sharp, focused gamma beams (RGS) with minimal scatter to healthy tissue; combining LINAC and RGS doses simultaneously - a previously unattainable feat.
- Multiple cancer: TaiChiPro's hybrid radiotherapy demonstrates superior clinical advantages by integrating LINAC and RGS technologies to achieve optimal critical organ protection while maintaining high target conformity, steep dose gradients, and clinically feasible treatment efficiency for two-lung lesions with overlapping organs at risk.
- Advanced cancer: TaiChiPro's X-ray and γ -ray combination strategy enables significant dose escalation to pancreatic tumors while reducing radiation exposure to critical organs like the stomach and liver, thereby improving tumor control probability and lowering gastrointestinal toxicity risks for locally advanced pancreatic cancer patients.

TaiChiPro provides direct patient benefits. The traditional approach requires separate machines for broad radiation and precision boosts. TaiChiPro's integrated delivery

streamlines care and reduces patient transfers. Conventional devices only offer limited real-time adaptation, whereas TaiChiPro provides live tumor tracking and adjust beams mid-treatment for accuracy. TaiChiPro also treats complex and resistant tumors more effectively via simultaneous LINAC and gamma dose escalation.

Ongoing research includes multiple global clinical trials for soft tissue sarcoma and head and neck cancers, and other studies exploring immunotherapy combinations leveraging TaiChiPro's immune-modulating effects.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

TaiChiPro: Redefining Radiotherapy Innovation

TaiChiPro isn't just an upgrade - it's a fundamentally new approach to fighting cancer with radiation. By seamlessly integrating two powerful radiation technologies (X-ray and γ-ray) with precision imaging in one device, it solves critical limitations of current systems and opens new frontiers in treatment.

Why It's Innovative & Transformative:

1. Precision Meets Power: TaiChiPro uniquely combines broad coverage (X-ray LINAC) with pinpoint accuracy (Gamma \"Sniper\"). This allows doctors to simultaneously treat large tumor areas and deliver intense, focused boosts to resistant spots within the tumor - all in a single session, without moving the patient. No other system can do this.
2. Smarter Targeting, Safer Treatment: Advanced 3D imaging ensures the radiation beams align perfectly with the patient's anatomy each day, reducing setup errors. Real-time monitoring during treatment can even adjust for tumor movement (like breathing), ensuring radiation stays precisely on target. This protects healthy tissue better than ever before.
3. Faster, More Efficient Care: High-speed radiation delivery and continuous rotation

significantly shorten treatment times. This improves patient comfort (less time immobilized) and enhances accuracy by minimizing shifts during treatment.

4. Proven Clinical Advantage: Clinical studies (e.g., in lung and pancreatic cancers) [3-5] demonstrate TaiChiPro's ability to deliver more effective radiation doses to tumors while significantly reducing exposure to nearby critical organs. This translates to potentially better tumor control with fewer side effects.

Unlocking Future Potential:

TaiChiPro isn't just a treatment device; it's a powerful research platform:

1. Personalized Cancer Therapy: It enables entirely new strategies, like delivering different radiation doses to different parts of a tumor based on its biology (e.g., resistant areas get more), paving the way for ultra-personalized treatment plans.
2. Understanding Radiation Biology: It allows scientists to study fundamental questions, like how X-rays and γ-rays affect tumors and the immune system differently, potentially leading to more effective combinations with immunotherapy.
3. Expanding Treatment Possibilities: Its ability to deliver precise γ-rays anywhere in the body opens research into treating complex or recurring tumors previously difficult to target effectively, and even non-cancerous conditions causing severe pain.
4. Smarter, Adaptive Systems: Integrated imaging and real-time control accelerate the development of AI-driven treatments that instantly adapt to changes during a session.

Improving the Human Condition:

TaiChiPro directly addresses the core goals of modern cancer care: cure more patients and cause less harm. By enabling unprecedented precision, adaptability, and efficiency, it aims to:

- Increase cancer control and survival rates.
- Reduce debilitating side effects, improving patients' quality of life during and after treatment.
- Offer new hope for complex or recurrent cancers.
- Streamline care, making advanced radiotherapy more accessible and less burdensome for patients.

Ultimately, TaiChiPro represents a paradigm shift, offering not just a superior treatment tool today, but a vital platform driving the future of precise, personalized, and effective cancer care for tomorrow.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract,

Website):

Citations:

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12. J Li^{1*}, H Yan¹, J Zhang¹, P Zan¹, X Li², J Li¹, C Ma³, H Liu¹, 1) OUR United Corporation, Xi'an, China (2) Tsinghua University, Beijing, China (3) Fox Chase Cancer Center, Philadelphia, PA, A New Stereotactic Radiotherapy Machine for Whole Body Cancer Treatment with Automatic Beam Quality Assurance and End-To-End Image Guidance.

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