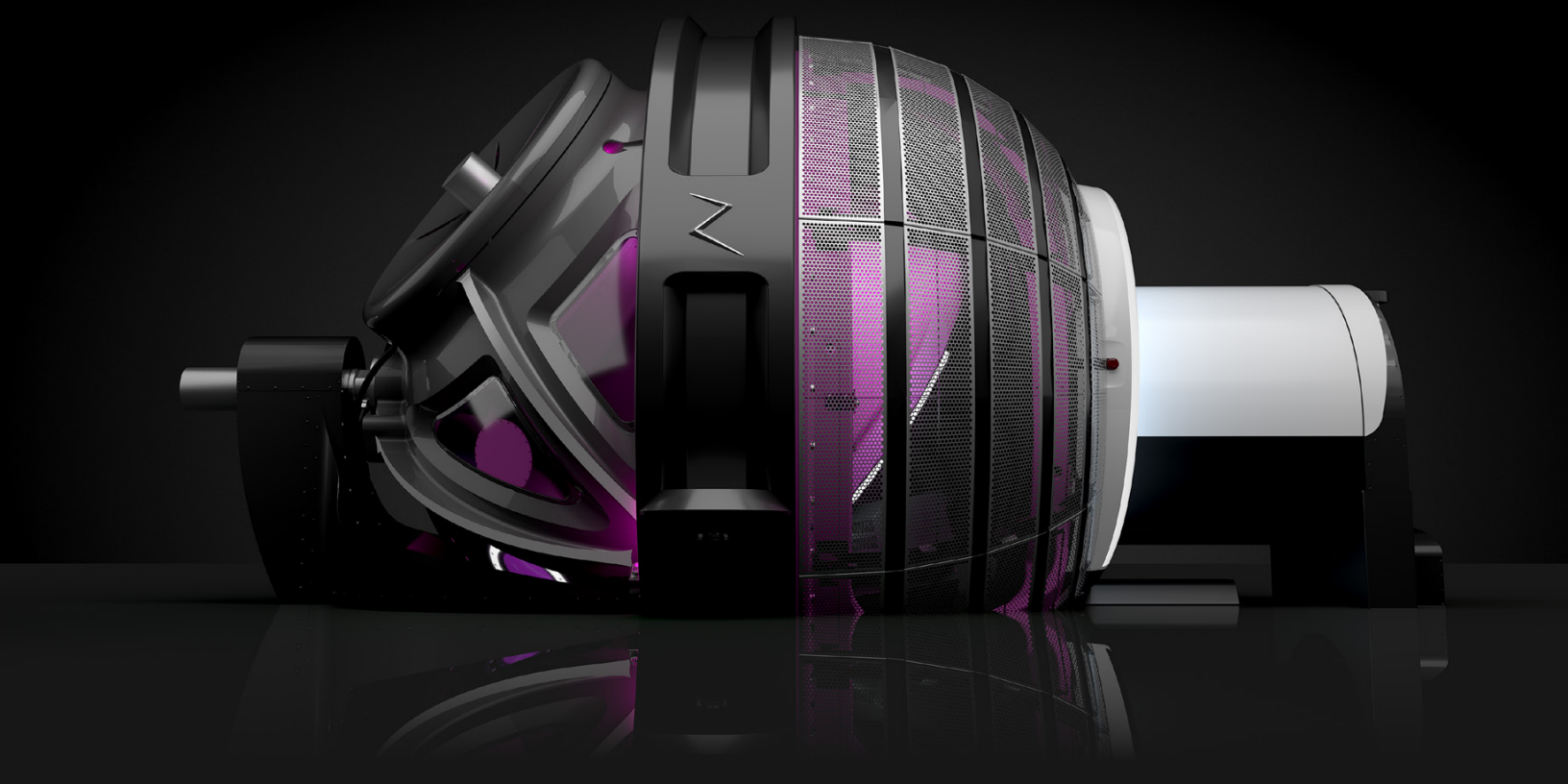
ZAP-X®

PLATFORM SPECIFICATIONS



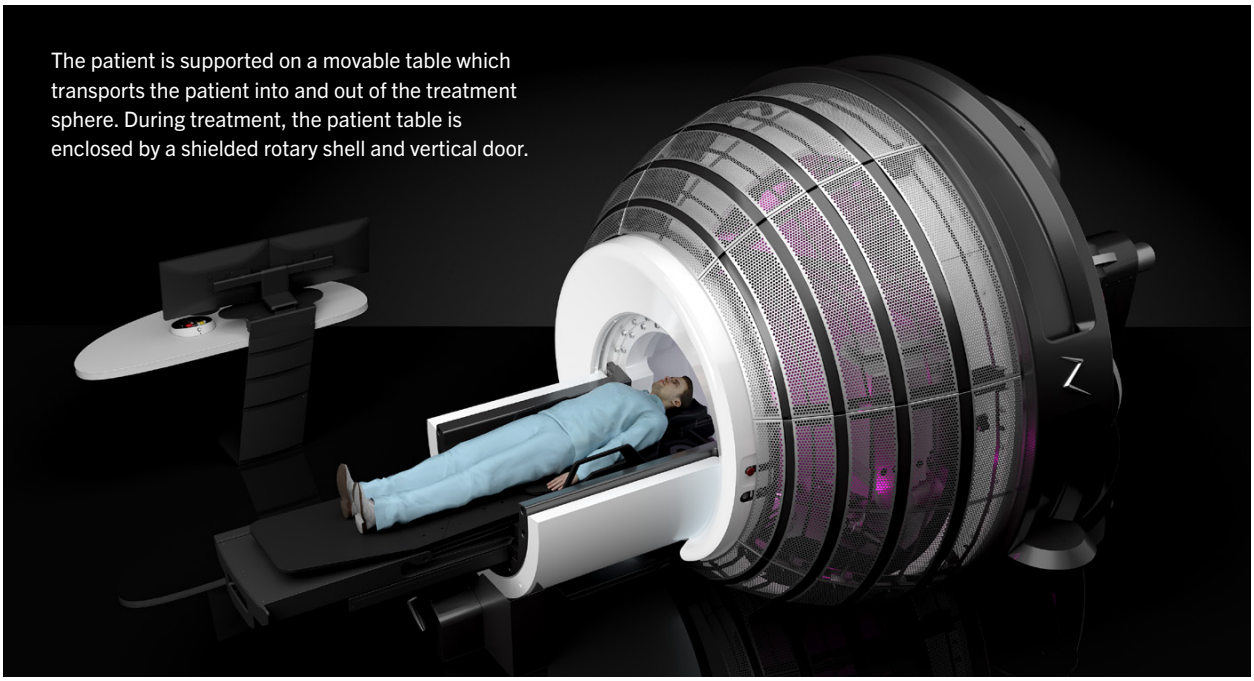
INTRODUCTION

The ZAP-X® Gyroscopic Radiosurgery™ platform is a dedicated self-contained and self-shielded radiosurgery system developed and manufactured by ZAP Surgical Systems, Inc. of San Carlos, California. This device is intended for stereotactic radiosurgery (SRS) treatment of tumors, lesions and conditions in the brain, head and neck when radiation treatment is indicated.

ZAP-X® Gyroscopic Radiosurgery™ Platform

Akin to a large gyroscope, the LINAC is mounted within a combination of yoked self-shielded gimbals that rotate precisely around a common isocenter. This mechanical construct enables the LINAC beam to fire from a wide variety of positions, resulting in excellent solid angle coverage, as is ideally suited for cranial SRS.

Accurate radiosurgical beam delivery is accomplished by positioning the accelerator with the two above-mentioned axes and precise movements of a robotic patient table, as guided by an x-ray imaging system. Most components needed to produce the beam, such as the radiofrequency power source, waveguide system, and beam control electronics are mounted on the rotating patient treatment chamber sphere. In addition to providing the physical structure for mounting and positioning these components, the sphere is designed as a radiation shield.



The unique design of the patient treatment sphere and patient entry allow radiation exposure levels outside the system to be deemed safe to the public by *National Council on Radiation Protection and Measurements* (NCRP) standards when operating under a typical full clinical workload.

The ZAP-X platform is a fully integrated radiosurgery solution including both treatment planning and treatment delivery software built to work seamlessly together. Prior to a treatment, the clinical team uses the treatment planning software to delineate the tumor and critical structures, plan beam deliveries and calculate the resulting dose and treatment time. The plan is then transferred to the treatment delivery system where the physician can deliver the treatment.

Advantages of the ZAP-X Platform:

Self-Shielded

- In most cases, does not require complex radiation vaults or costly physical infrastructure.

Flexible Installation Location

- Now feasible for point of care delivery in more locations—i.e. physician office, outpatient surgery center, etc.

Linear Accelerator-Based

- No recurring radioactive source replacements.
- No ongoing regulatory and security burden.

Ground-Breaking Safety Innovations

- Significant reduction in peripheral body dose as compared to conventional radiotherapy and robotic SRS linear accelerator systems.
- Novel radiation detector system validates treatment accuracy as it's being delivered.
- Dedicated, streamlined SRS without the overhead and complexity of full-body delivery.

RADIATION SHIELDING

ZAP-X is a first-of-its-kind self-shielded radiosurgical device dedicated to brain, head and neck applications. By utilizing a 3 megavolt (MV) linear accelerator and integrated mechanical shielding structures, ZAP-X does not typically require the additional shielding of a radiation bunker.

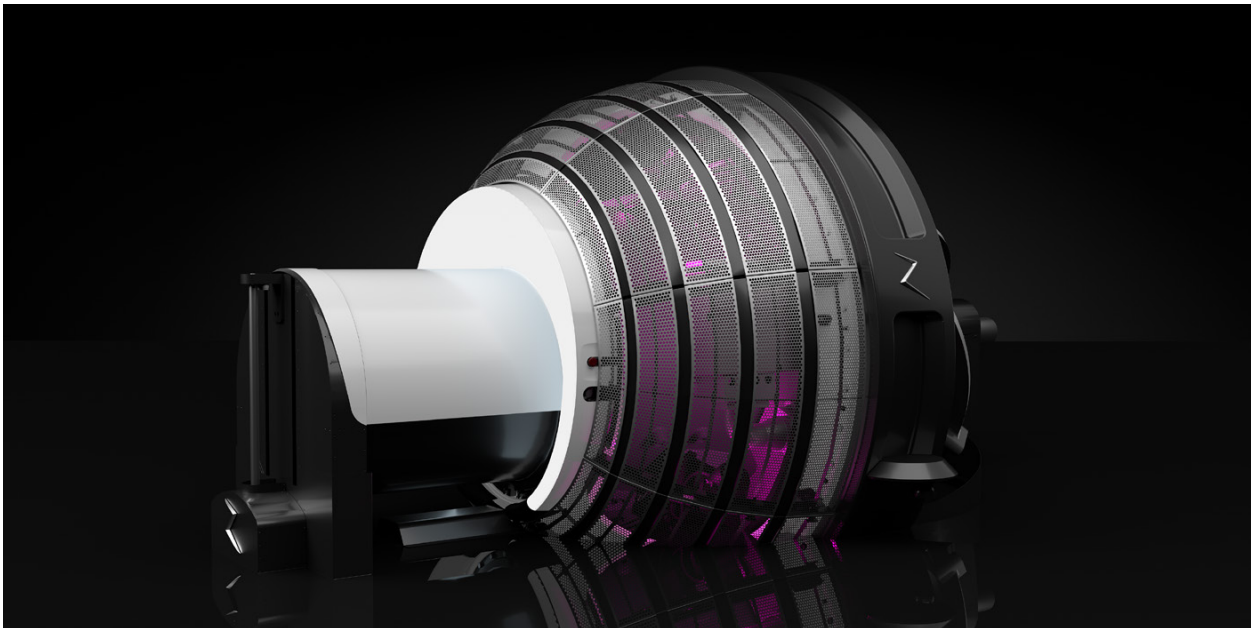
More specifically, the shielding was designed to:

- Provide shielding to personnel outside a 1-meter (m) safety zone from the perimeter of the ZAP-X system to levels that are acceptable to the public (1 millisievert (mSv)/year).
- Provide shielding such that all points on the above-described perimeter line experience an instantaneous exposure rate of no more than 3.0 milliroentgens per hour.

During treatment delivery, ZAP-X is restricted such that no user can be closer than 1 m from the perimeter of the system without triggering a radiation interruption. Based on the maximum practical amount of MUs delivered in a typical 8-hour period, and typical working days per year, cumulative exposure measurements result in annual dose equivalents below 1.0 mSv/year, which is the generally suggested maximum annual radiation dose for the public, according to the NCRP. In light of this, the ZAP-X platform, under the specified workload, would allow unrestricted access for non-radiation workers outside a 1 m system perimeter and to all areas on the floor above the ZAP treatment room.

Dose and Exposure

Estimated annual dose (outside 1 m perimeter)	**Below 1.0 mSv / year, based on typical patient workload**



TREATMENT PLANNING

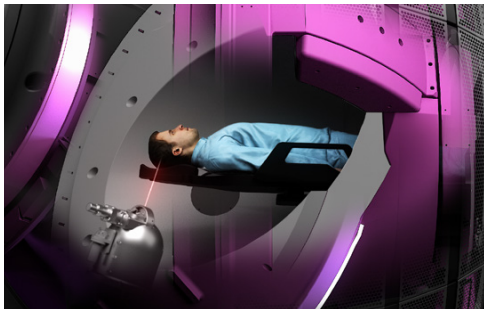
ZAP-X treatment planning consists of a seamlessly-integrated, proprietary software platform, and provides the tools for image registration, target and critical structure delineation, dose calculation and plan review.

ZAP-X Treatment Planning

Primary image type	**X-Ray Computed Tomography (CT)**
Secondary image fusion types	**Magnetic Resonance Imaging (MRI)** **Additional X-Ray Computed Tomography (CT)**
Planning type	**Isocentric**
Dose calculation algorithm	**Ray tracing**

BEAM DELIVERY

The ZAP-X platform utilizes a 3 megavolt (MV) S-band linear accelerator with a nominal dose rate of 1500 MU/minute. The isocenter is located at a source axis distance of 450 millimeters (mm).



ZAP-X Beam Delivery

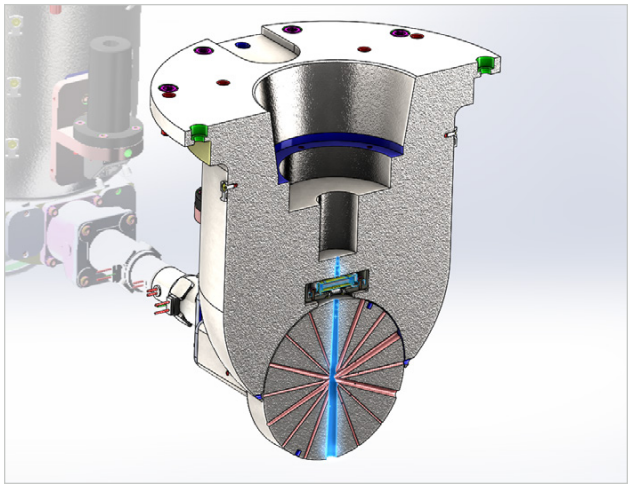
Source	**S-band linear accelerator**
Energy	**3 MV**
Nominal dose rate	**1500 MU/minute**
Source axis distance	**450 mm**

BEAM COLLIMATION & RADIATION LEAKAGE

ZAP-X is equipped with a uniquely designed collimation system that enables rapid changes in collimator size while reducing the radiation leakage to the patient plane. The collimator consists of a shielded tungsten wheel oriented with its rotational axis perpendicular to the beam's central axis.

The system can change the collimator automatically during treatment. Beam selection is accomplished by rotating the wheel within its tungsten-shielded housing. Eight cone collimators of different diameters are available: 4.0, 5.0, 7.5, 10.0, 12.5, 15.0, 20.0, and 25.0 mm.

The ZAP-X collimator is encased in a tungsten shield that lowers the radiation exposure in the patient plane and outside the immediate treatment area to less than 0.01% of the primary radiation area.



ZAP-X Beam Collimation and Radiation Leakage

Number of conical collimators	**8**
Sizes	**4.0, 5.0, 7.5, 10.0, 12.5, 15.0, 20.0, and 25.0 mm**
Collimator change mechanism	**Unlimited changes may occur via an automated carousel, as defined per the treatment plan**
Collimator radiation leakage	**Less than 0.01% of the primary radiation area**

PATIENT IMMOBILIZATION & POSITIONING

Patient immobilization is achieved via a custom molded thermoplastic mask.

The ZAP-X treatment table is equipped with two rotational, and one translational degrees of freedom, allowing the patient to be positioned precisely within the available treatment volume.

ZAP-X Patient Immobilization & Positioning

Load limit	**135 kg (297 lb)**
Lateral range of motion (cm)	+/– **100 mm around the isocenter**
Vertical range of motion (cm)	+/– **100 mm around the isocenter**
Longitudinal range of motion (cm)	+/– **100 mm around the isocenter**

TARGET LOCALIZATION & IMAGE GUIDANCE

ZAP-X accomplishes precise three-dimensional (3D) patient positioning by means of an integrated planar kilovolt (kV) imaging system that rotates around the patient's head. Non-coaxial X-ray images, patient CT data and image-to-image correlation are utilized to determine the location of the patient's anatomy with respect to the machine isocenter, both prior to and during radiosurgical treatment.

REAL-TIME DOSIMETRY

The ZAP-X platform utilizes a novel exit dosimetry system that monitors treatment delivery in real-time using a factory-commissioned megavoltage (MV) imager. This is accomplished by measuring the transmitted beam intensity for each beam and comparing this to the expected value calculated from treatment planning data.

APPENDIX

Additional details regarding system principles and methods can be found via the following peer-reviewed publications:

Data indicated in the following publications may not reflect the current platform specifications.

- Weidlich G A., Schneider M, Adler J R. (December 06, 2017) **Self-Shielding Analysis of the Zap-X System**. Cureus 9(12): e1917. doi:10.7759/cureus.1917
  View Publication Online

- Adler J R., Schweikard A, Achkire Y, et al. (September 08, 2017) **Treatment Planning for Self-Shielded Radiosurgery**. Cureus 9(9): e1663. DOI 10.7759/cureus.1663
  View Publication Online

- Weidlich G A., Schneider M, Adler J R. (February 02, 2018) **Characterization of a Novel Revolving Radiation Collimator**. Cureus 10(2): e2146. doi:10.7759/cureus.2146
  View Publication Online

- Jenkins C H, Kahn R, Weidlich G A., et al. (November 29, 2017) **Radiosurgical Treatment Verification Using Removable Megavoltage Radiation Detectors**. Cureus 9(11): e1889. doi:10.7759/cureus.1889
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THAT WAS THEN.
THIS IS NEXT.

ZAP®

ZapSurgical.com

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The ZAP-X® gyroscopic radiosurgery platform received FDA 510(k) clearance in SEP. 2017. It is currently not available in all markets.

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