Neurosurgical Robot with Evidence Based Approval by Both NMPA and FDA, from Idea to Product

——3D Structure Light Neurosurgical Robotic System- from China to World

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Solution of accurate diagnosis and treatment in neurosurgery

WE DO BETTER

Sinovation
华科精准

华科公众号　　华科3D展厅

手术机器人 | 手术导航 | 微型机器人 | 颅内电极 | LITT激光消融 | 手术计划软件

Neurosugical Robot　　Neurosugical Navigation　　Micro Robot　　Intercranial Electrode　　Laser Ablation　　Surgical Plan Software

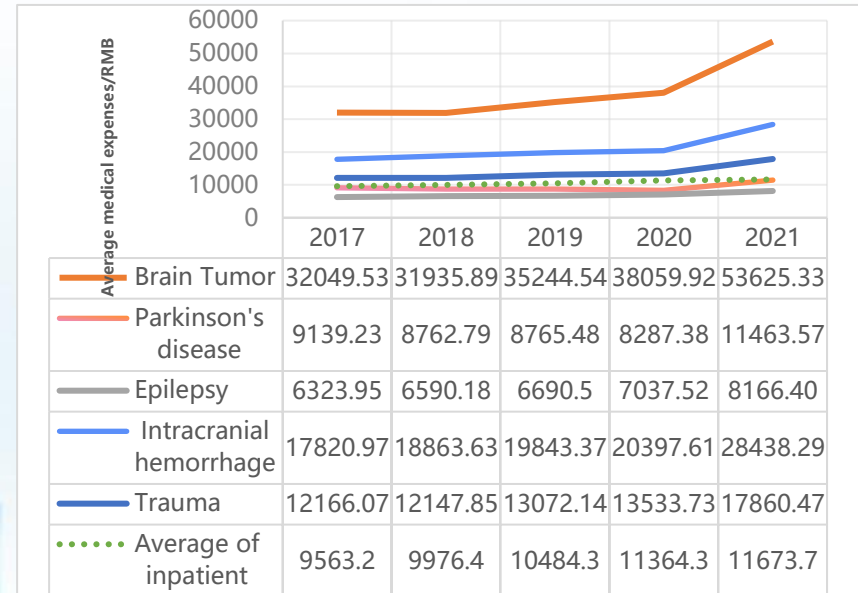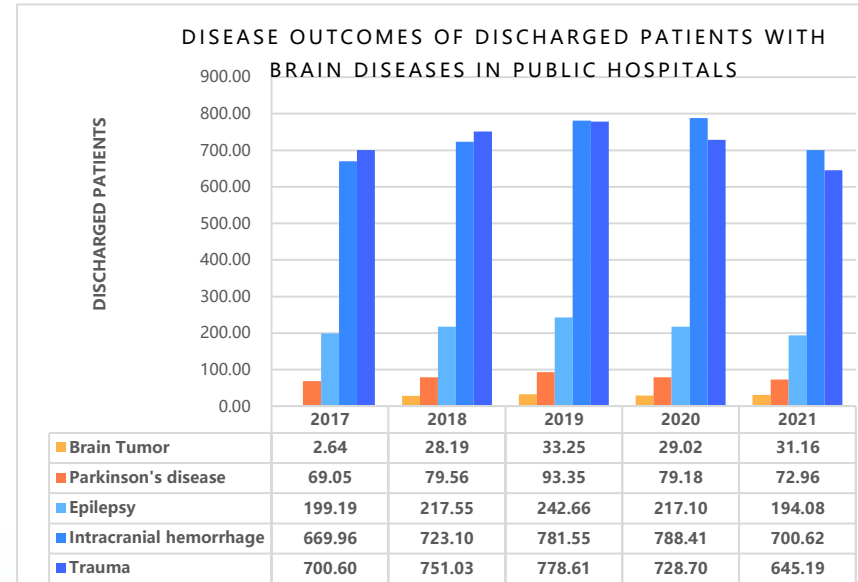# Neurosurgical robots are widely used to assist brain operations

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Review
Neurosurgical robots in China: State of the art and future prospect

Siyu Zhou,[1,2,3] Yuan Gao,[1,2,3] Renpeng Li,[1,2,3] Huizhi Wang,[1,2,3] Moxuan Zhang,[1,2,3] Yuzhu Guo,[4] Weigang Cui,[4] Kayla Giovanna Brown,[1,2,3] Chunlei Han,[2,3] Lin Shi,[2,3] Huanguang Liu,[2,3,*] Jianguo Zhang,[2,3,*] Yang Li,[4,*] and Fangang Meng[1,2,3,5,*]

- **Brain tumors, medically intractable epilepsy, movement disorders**, and other neurological conditions have a worldwide impact on healthcare and often require neurosurgical treatment. More than **10 million patients in China** are suffering from them.
- Chinese-made robots can be used in neurosurgery operations, such as **intracerebral lesion biopsy, ventriculoperitoneal shunt, Ommaya capsule implantation, intracerebral SEEG electrode implantation, and DBS electrode implantation**.
- Neurosurgical robots have been used in more than **200 hospitals** in China, with **more than 50000 operations**, and have accumulated a considerable amount of usage data.
- China has taken a **leading position** in certain local technologies, such as 3D structured light technology.
- Neurosurgical robotsare increasingly becoming the **ideal assistants for surgeons** in the field.

DISEASE OUTCOMES OF DISCHARGED PATIENTS WITH BRAIN DISEASES IN PUBLIC HOSPITALS

DISCHARGED PATIENTS	2017	2018	2019	2020	2021
Brain Tumor	2.64	28.19	33.25	29.02	31.16
Parkinson's disease	69.05	79.56	93.35	79.18	72.96
Epilepsy	199.19	217.55	242.66	217.10	194.08
Intracranial hemorrhage	669.96	723.10	781.55	788.41	700.62
Trauma	700.60	751.03	778.61	728.70	645.19

Average medical expenses/RMB	2017	2018	2019	2020	2021
Brain Tumor	32049.53	31935.89	35244.54	38059.92	53625.33
Parkinson's disease	9139.23	8762.79	8765.48	8287.38	11463.57
Epilepsy	6323.95	6590.18	6690.5	7037.52	8166.40
Intracranial hemorrhage	17820.97	18863.63	19843.37	20397.61	28438.29
Trauma	12166.07	12147.85	13072.14	13533.73	17860.47
Average of inpatient	9563.2	9976.4	10484.3	11364.3	11673.7

Neurosurgical robots are developing fast

1. How to reduce the extra injury when operating lesions deep seated and functional area?
2. Anatomical structures in brain are complex and the anastomosis is difficult.
3. Operation process is very difficult with highly demanding of surgeons.
4. Medical resources are distributed unevenly; basic level of hospitals need to improve techniques.
5. Surgeons need to be trained for 10-15 years which is far beyond other subjects.

Future?

Minimally invasive

Microneurosurgery

General neurosurgery
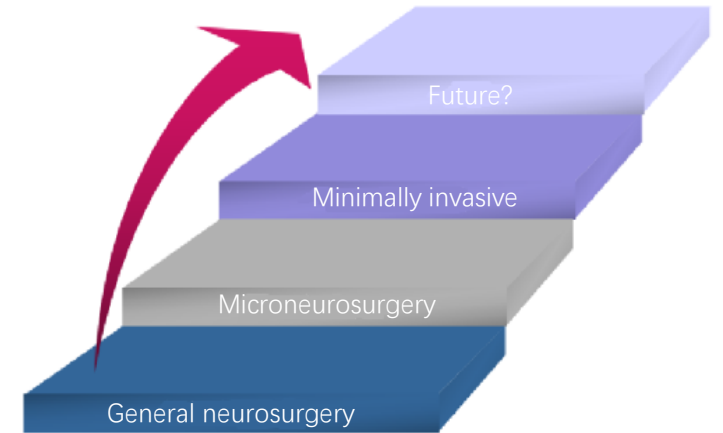
Minimally invasive, accurate, frameless and image guided surgeries with the assist of robots may take the place of open/frame based surgery.
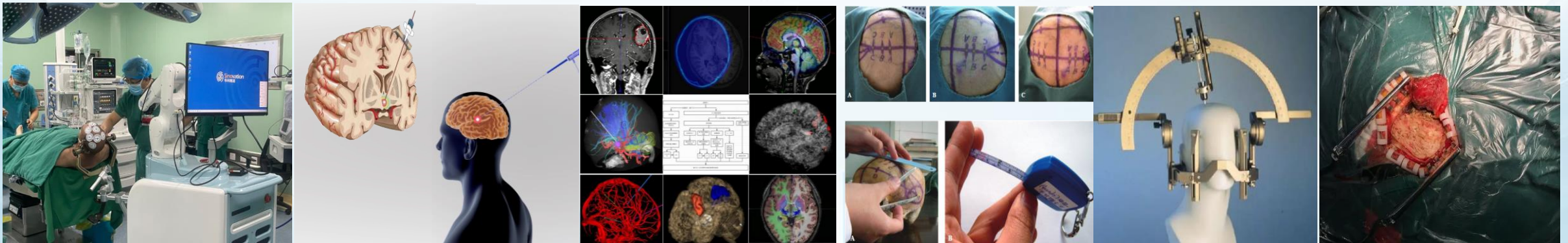
3 trends in neurosurgical robots development

different kinds of neurosurgical robots to satisfy the need s of clinial application

High-end oriented

Multilevel perception

Frameless and markerless

Ultra high precision

Generalization

Miniaturization

Multiple scenarios

Intelligent operation

Combination with treatment

Laser ablation

Drug injections

autonomous operation

Trends in neurosurgical robots: high-end oriented

➤ **Eye**

3D structured light Holoshot® positioning technology, with a positioning accuracy of 0.5mm.

➤ **Hand**

Six-degree-of-freedom robotic arm with repeat positioning accuracy of 0.02mm

➤ **Brain**

Powerful multimodal imaging surgery planning system

NMPA innovative medical device (2018)

NMPA approved in 2018 and 2020

Indicationa for use:
Navigation and stereotaxy for neurosurgical medical instruments and implant

FDA 510(k) clearance in 2023

Indicationa for use:
Any neurosurgical procedure in which the use of stereotactic neurosurgery may be appropriate

Eyes of neurosurgical robot

Marker registration
Sinovation/Rosa

Skin/bone markers
First generation
Manual > 60 min

Laser registration
Sinovation/Rosa
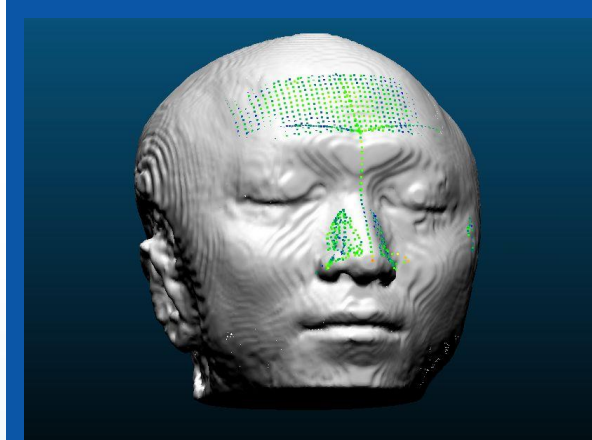
Laser scanning
Second generation
Automatic,≈10min

Structured light registration
Sinovaton

Structured light scanning
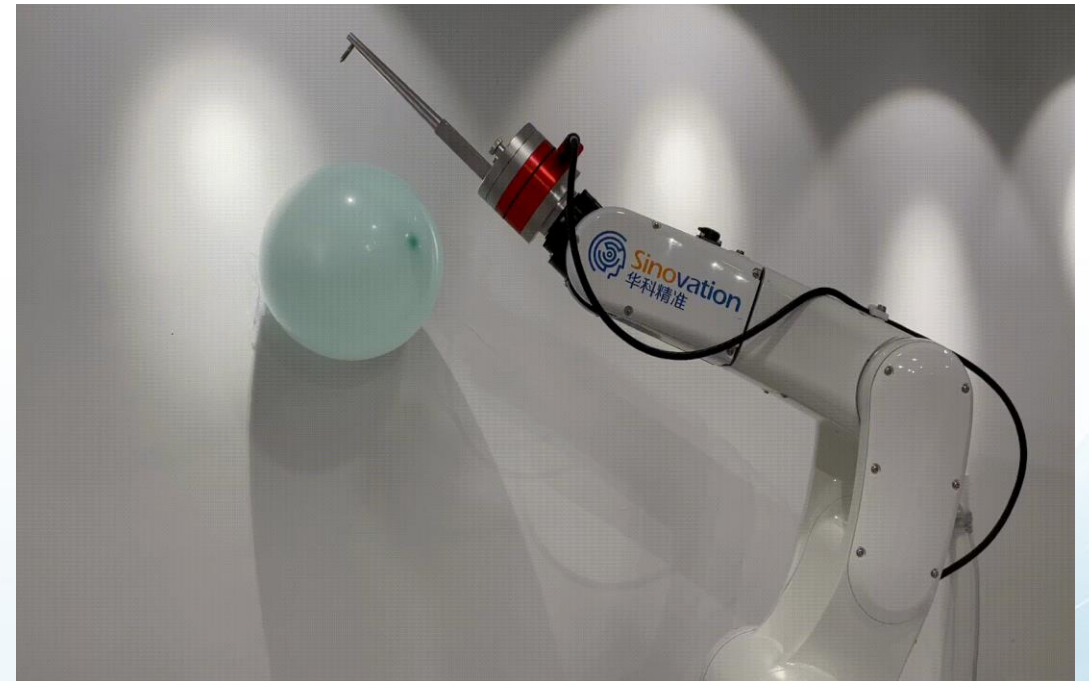Third generation
Automatic < 3min

Eyes of neurosurgical robot
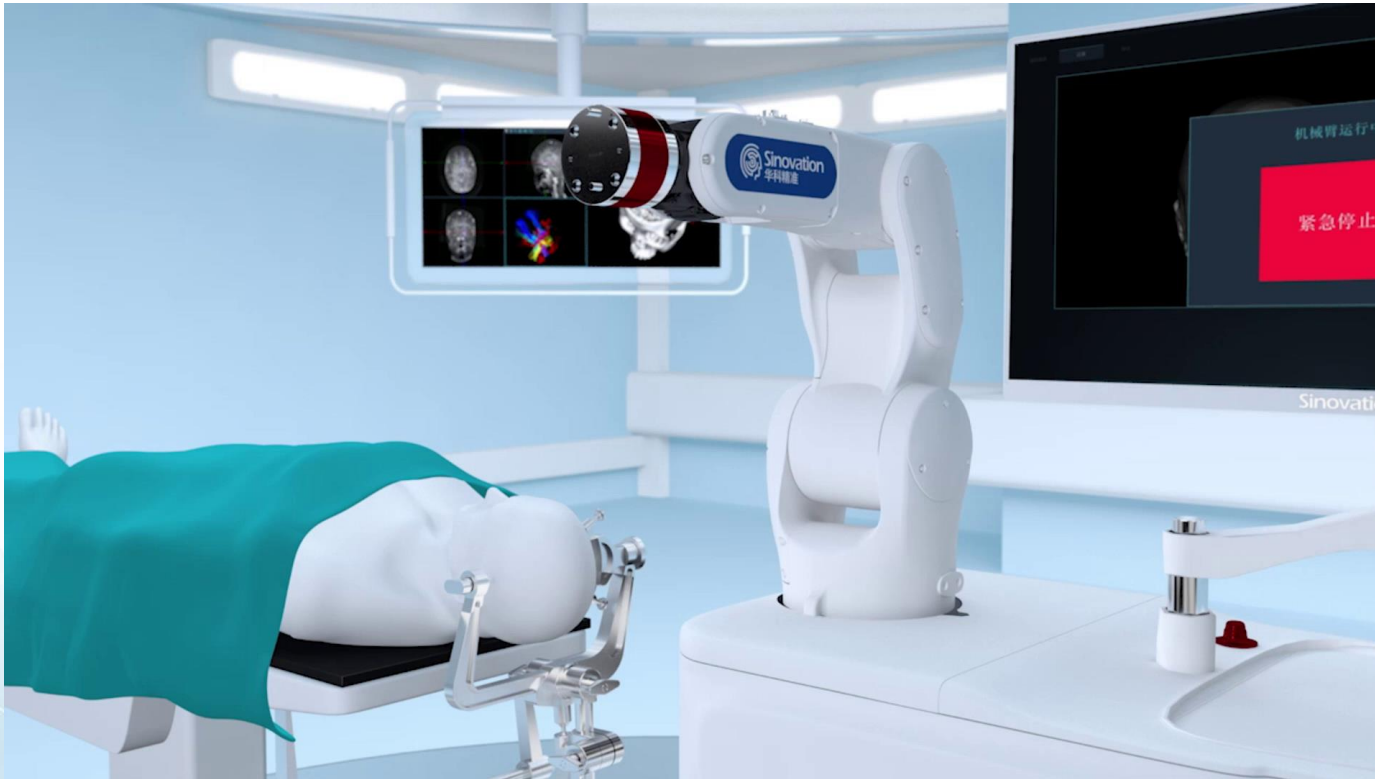
- Markerless registration technology: automatic scan with **3D structured light** held on the robot arm

- Fast and accurate: **registration time is less than 2 minutes and registration accuracy is within 0.5mm.**

Brain and arm of neurosurgical robot
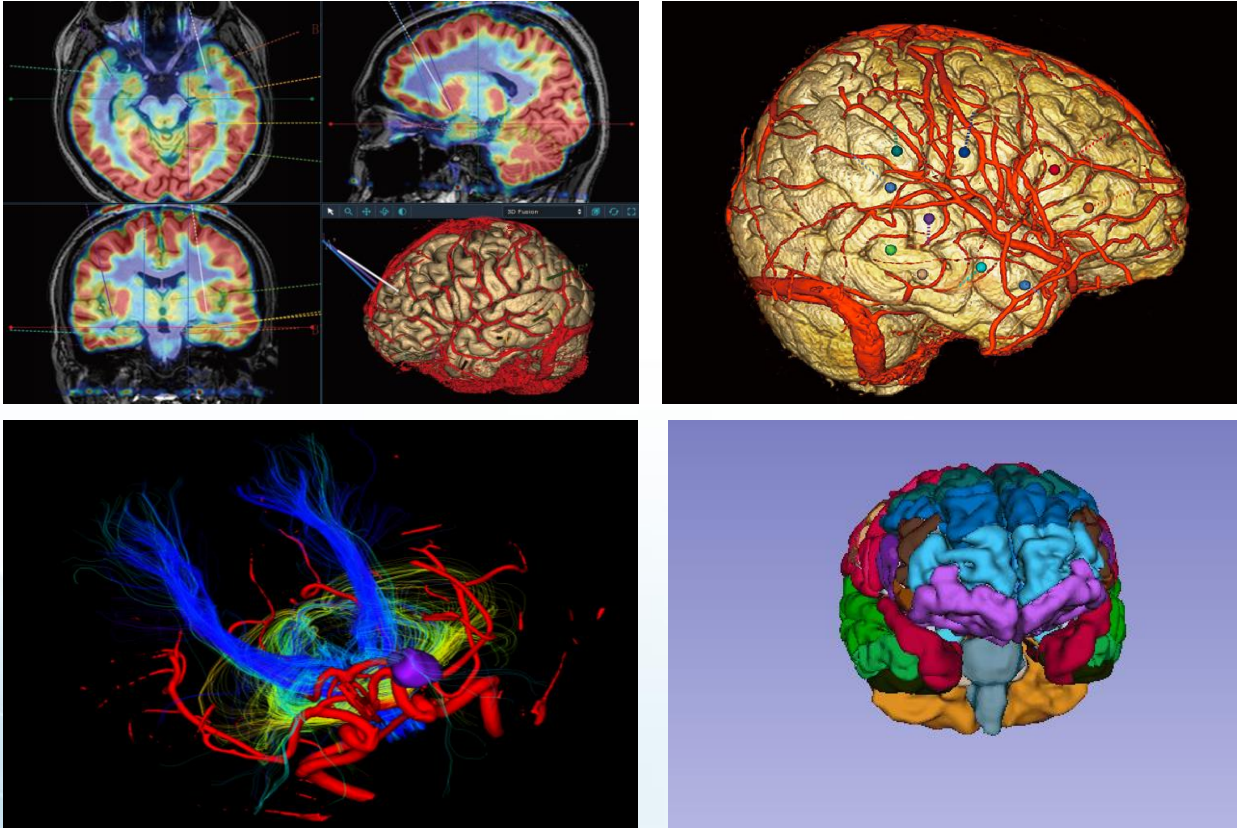
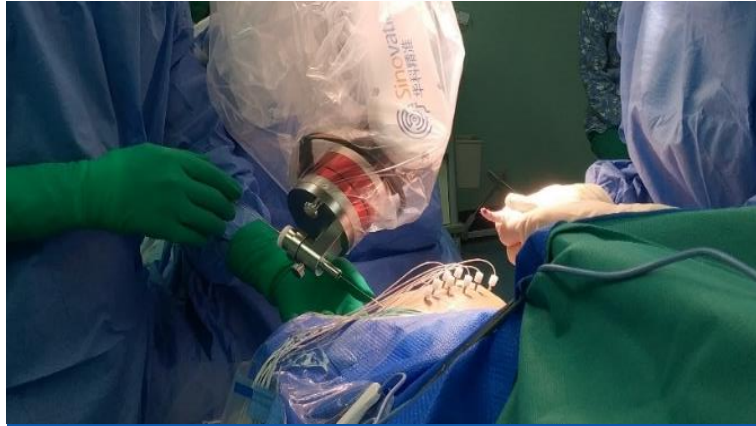Brain: multimodal imaging surgery planning software

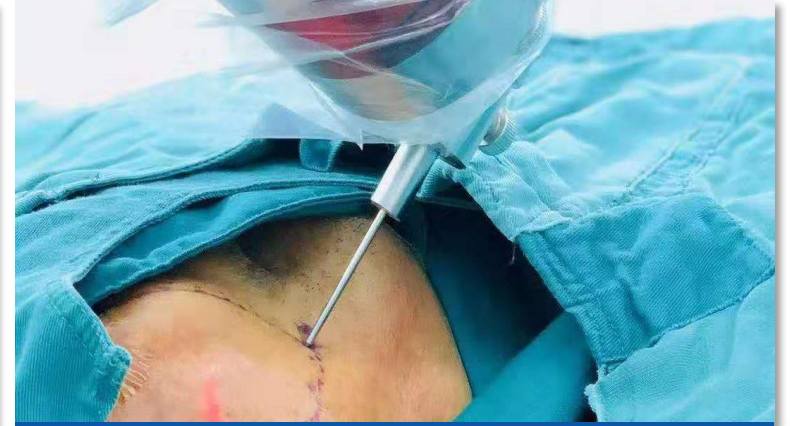Arm: active detection of collision to ensure the safety of patients and surgeons
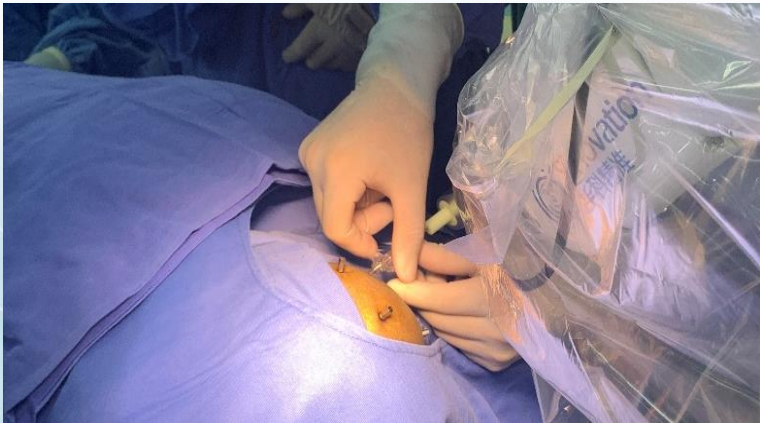
Clinical applications
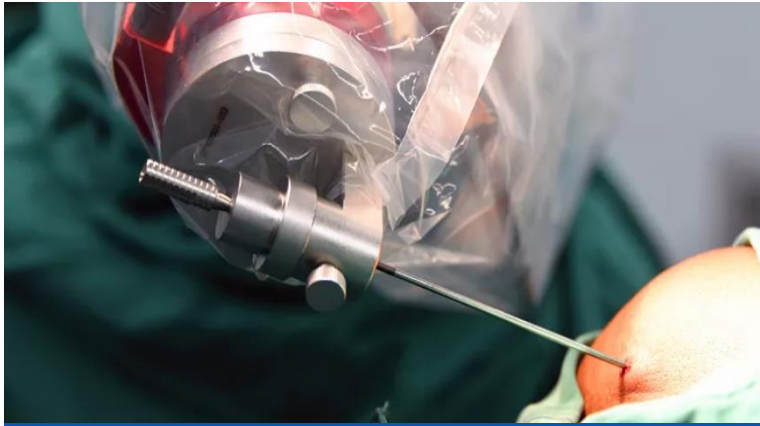
biopsy/cerebral hemorrage

stereotactic-electroencephalographySEEG

Trigeminal neuralgia microballoon implantation

Laser Interstitial Thermal Therapy LITT

Deep Brain Stimulation

Brain-computer interface Utah array electrode implantation

Trends in neurosurgical robots: generalization

国械注准20223010024

手术工作站
Sugical Station

手术计划系统
Sugical Software System

高清触控显示屏
HD Touchscreen Monitor

机器人控制系统
Robot Controling System

机器人手术平台
Robotic Guidance Platform

微型机器人模块
Mini Sugical Robot

手术套件
Surgical Instruments

追踪定位系统
Optical Tracking System

红外光学定位仪
Infrared Iamera

移动式支撑组件
Camera Cart Arm Components

Trends in neurosurgical robots: generalization

- May 31st, 2023
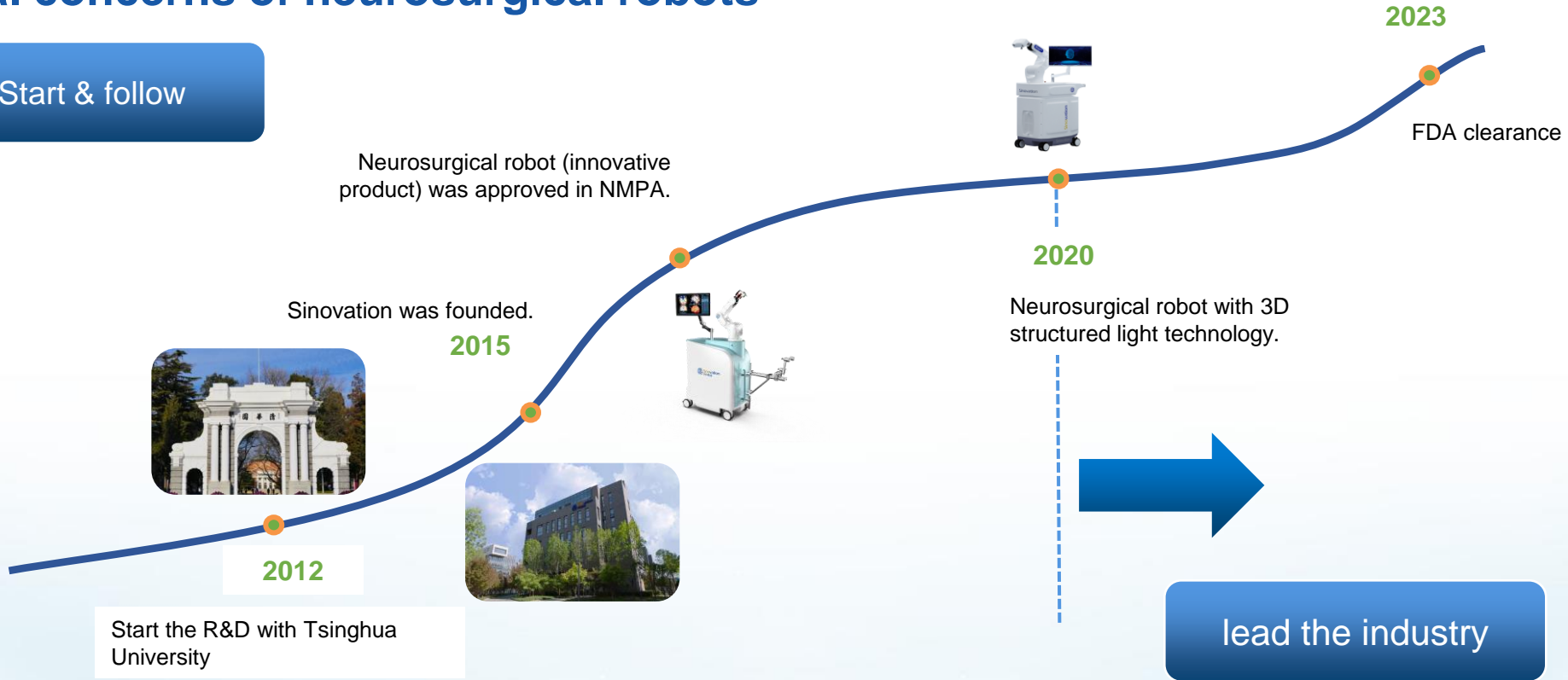- Northwest Women's and Children's Hospital, Xi'an, Shaanxi, China

- 28-week premature infant
- 3-day old
- Weight 1.26kg
- Head diameter 8cm
- Cerebral hemorrage about 14mL
- Very high operation risk
- The head is too small to use the head stand.
- The accuracy of stereotaxic is high.

28周早产儿脑
术前，出生第3天   血肿
术后第29天
血肿完全清除，无脑积水

Technical concerns of neurosurgical robots

Start & follow

2023

FDA clearance

Neurosurgical robot (innovative product) was approved in NMPA.

2020

Neurosurgical robot with 3D structured light technology.

Sinovation was founded.
2015

2012

Start the R&D with Tsinghua University

lead the industry

Robot arm control	Positional Accuracy	Angular error	Repeatability	Verification and Validation
Basic Safety	electromagnetic compatibility	Safty Protection	Image processing	......

Regulator's concerns of neurosurgical robots

	NMPA	FDA
Approval Date	2018-12-21	2023-06-18
Device Class	Class Ⅲ	Class Ⅱ , 510(k)
Application Period	4 months	18 months
Regulator's Concerns	Software and Cybersecurity	Software and Cybersecurity
	Accuracy	Accuracy
	Clinical Evaluation	/
	/	Usability

Future of neurosurgical robots

More quickly

More accurate

Better diagnosis and treatment

More intelligent

More flexible

Better life

Thank you for your attention!