

Implantation of Sphenopalatine Ganglion Stimulator for Ischemic Stroke

March 8, 2022

CMS ICD-10 C&M Committee Meeting

BrainsGate



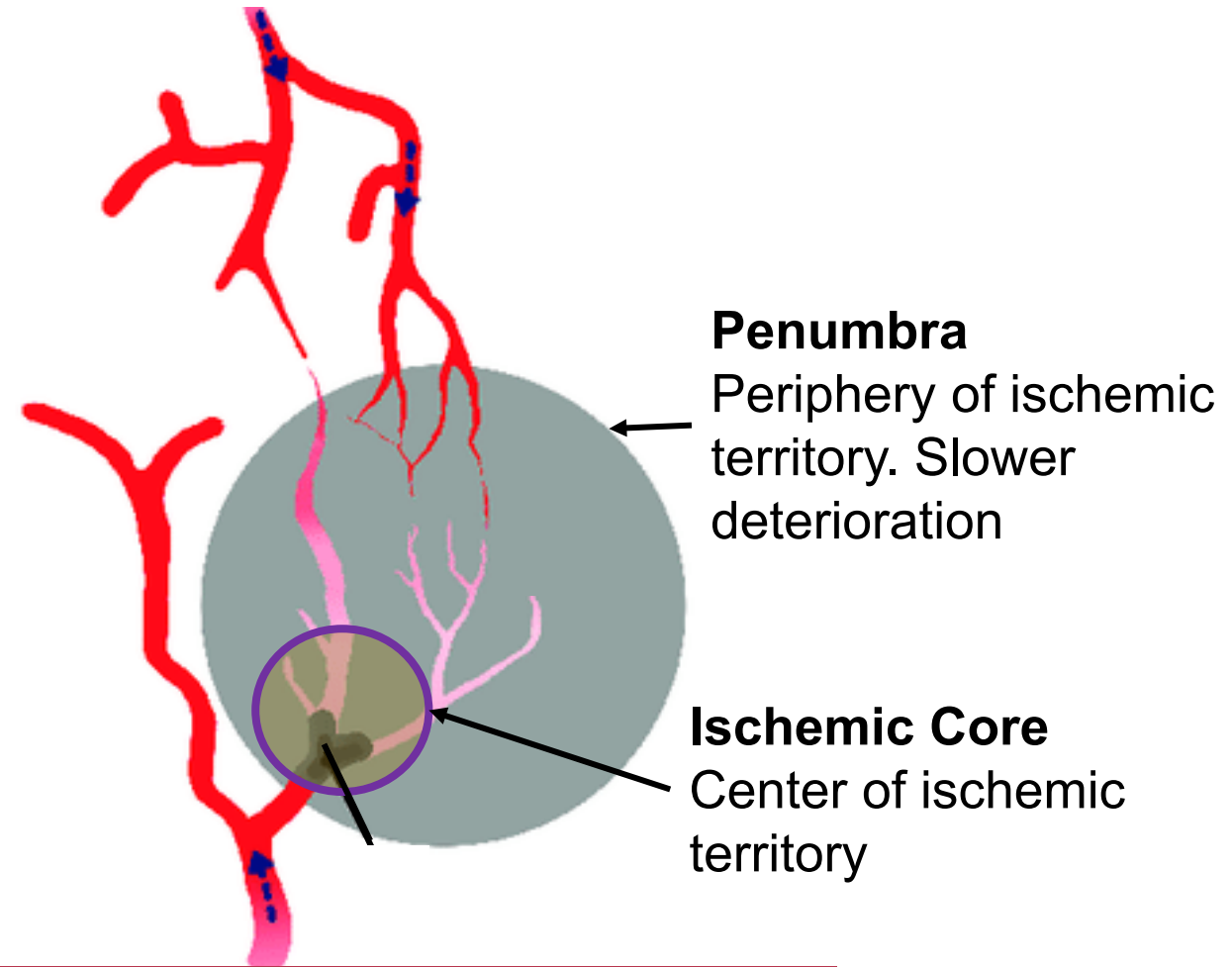
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Director, Chattanooga Center for Neurologic Research LLC
Professor of Neurology, University of Tennessee Health
Science Center

Acute Ischemic Stroke

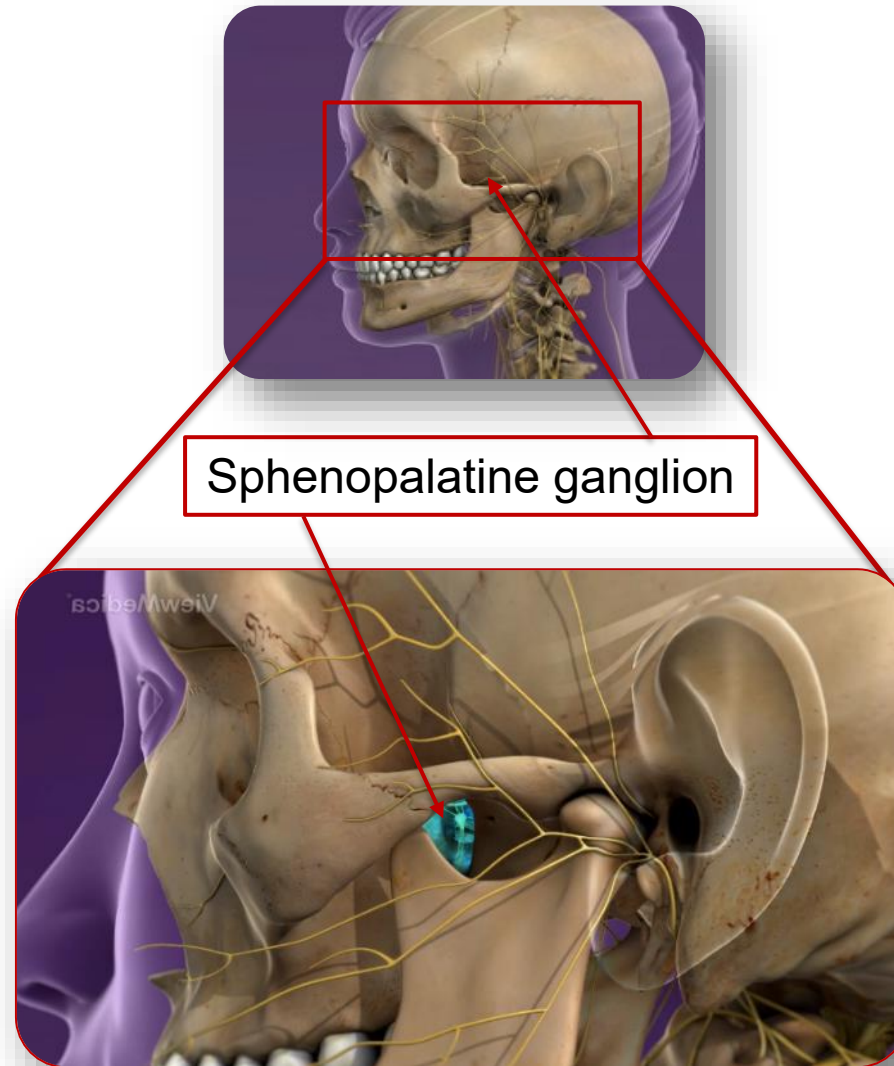
~700,000 patients experience ischemic stroke each year in US

- 1st leading cause of acquired neurological disability
- ~100,000 acute ischemic stroke deaths per year in US



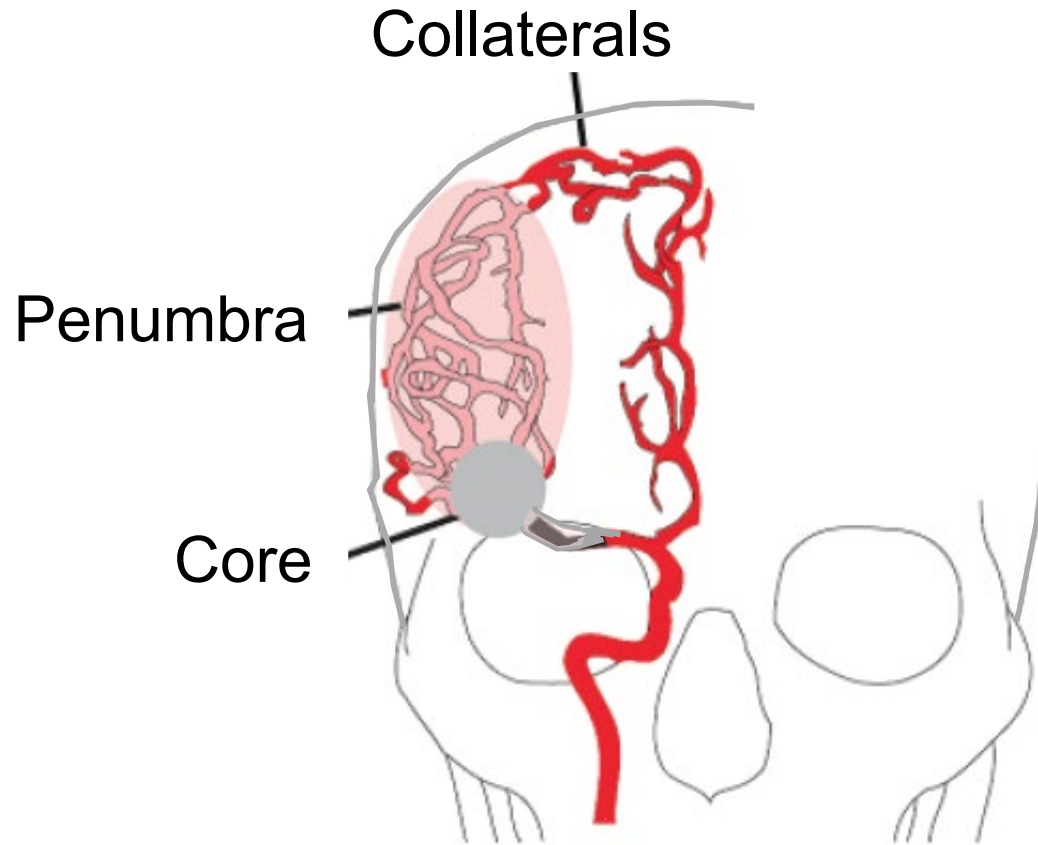
Occlusion of Main Artery

SPG Stimulation Augments Collateral Flow

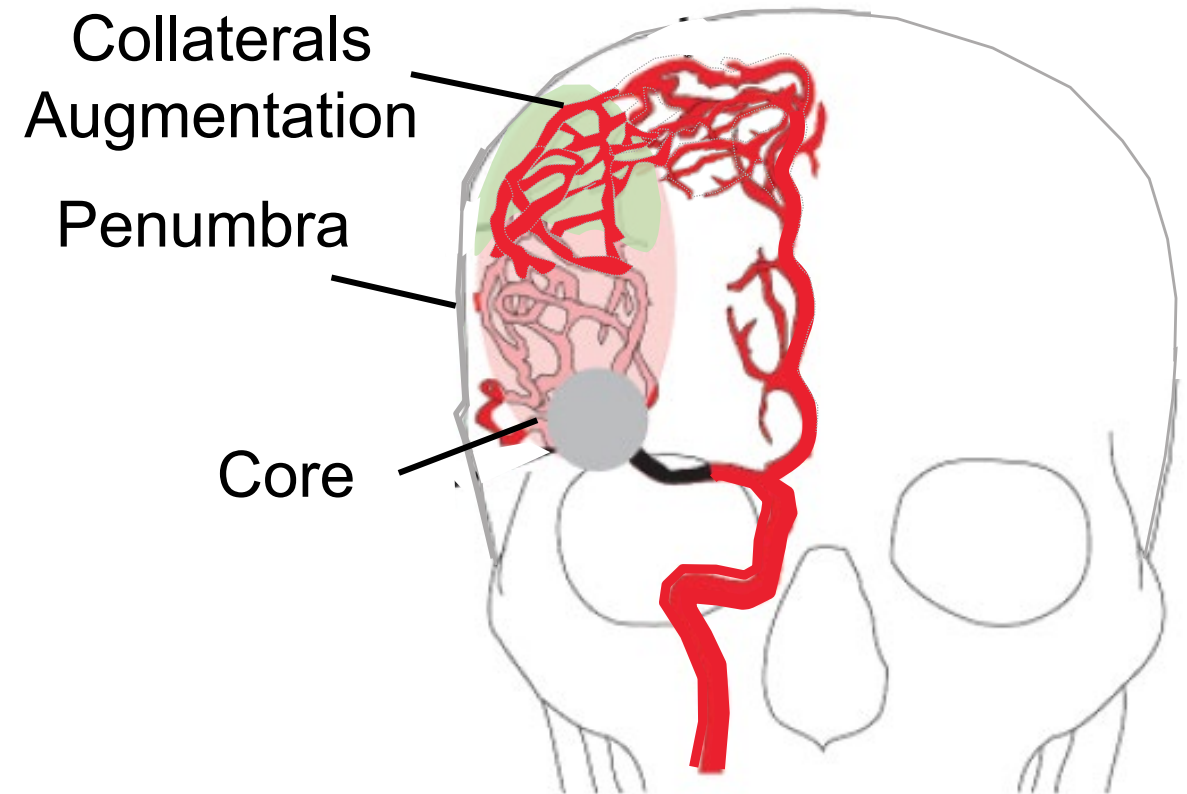


SPG Stimulation Augments Collateral Flow

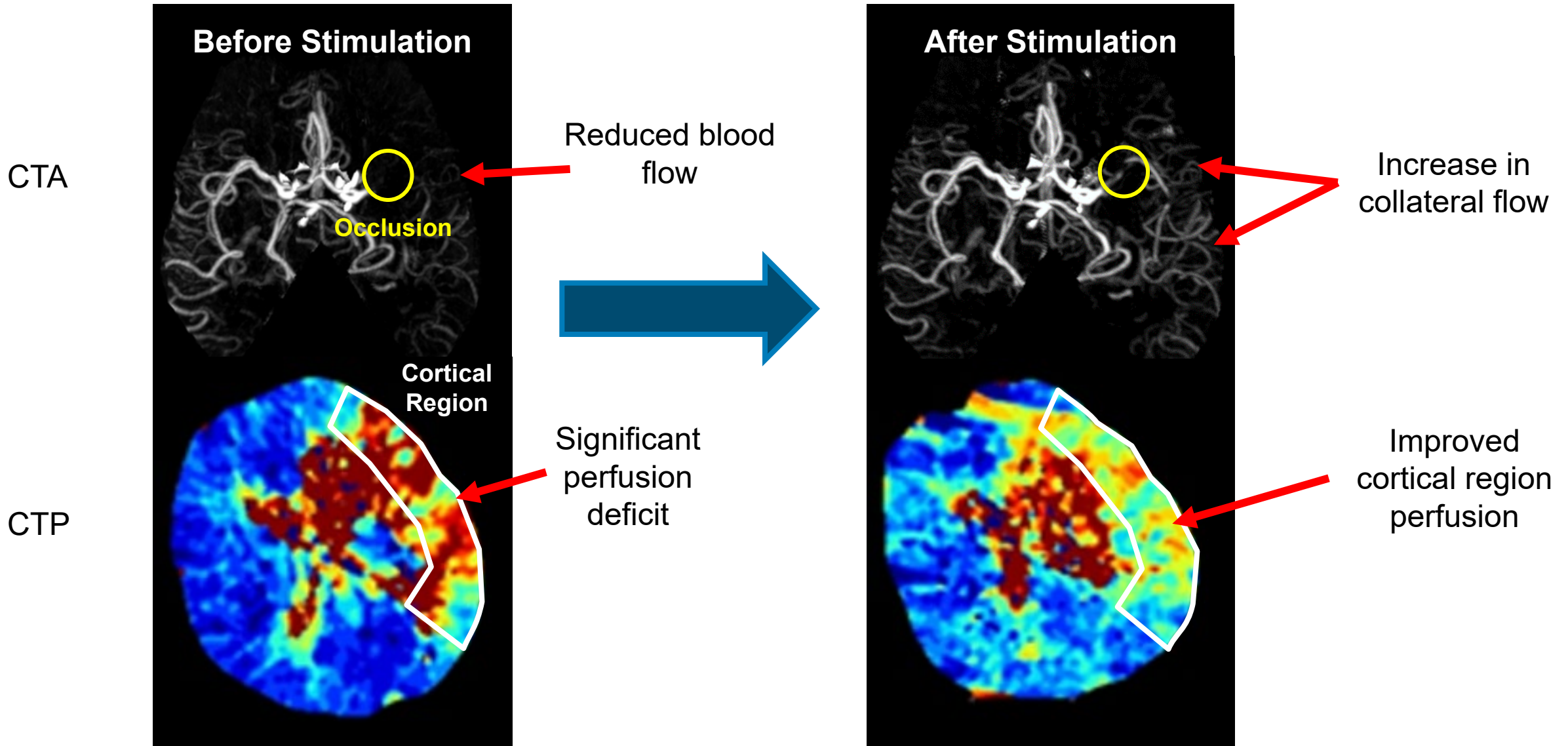
Without Stimulation



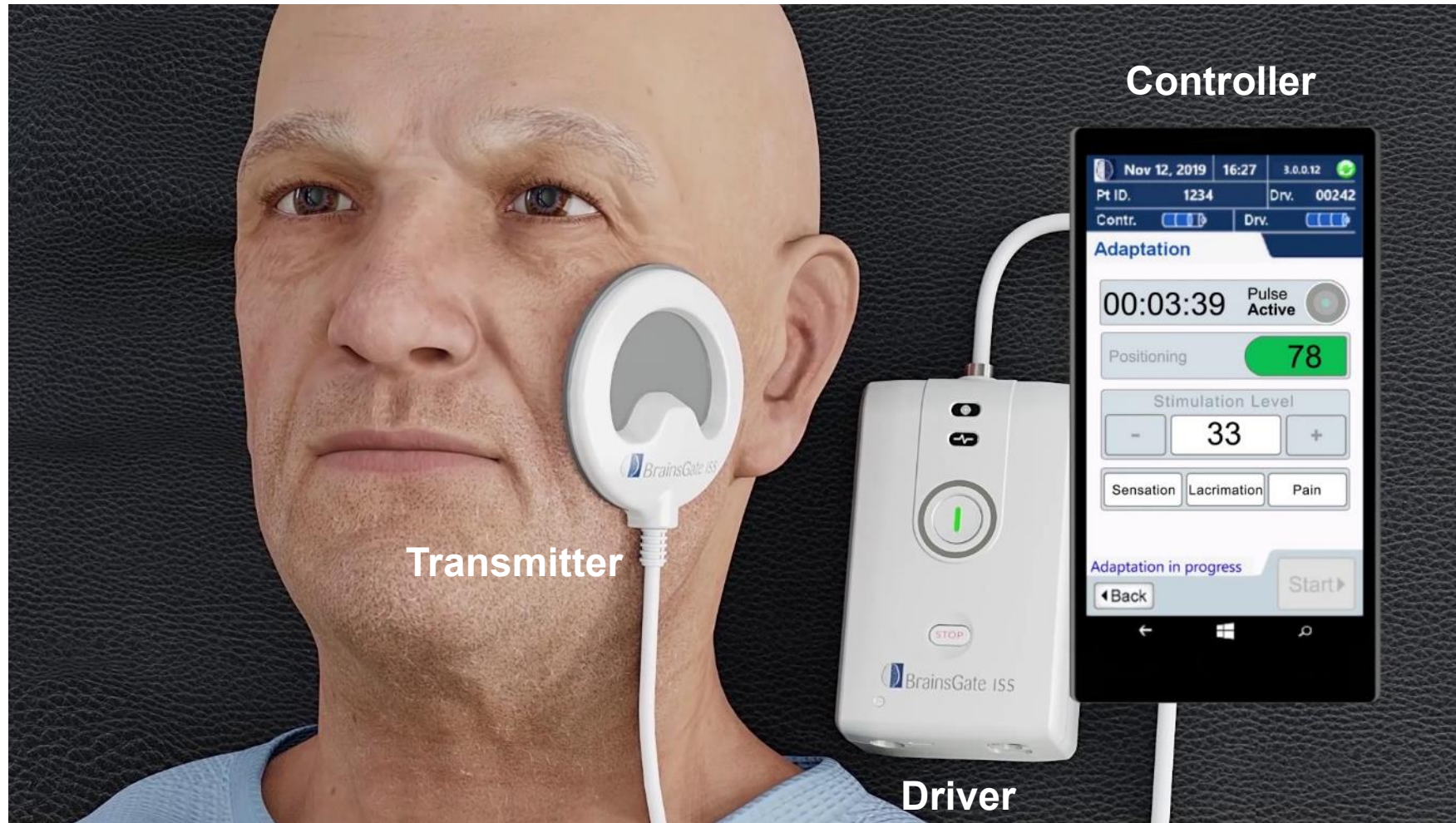
With Stimulation



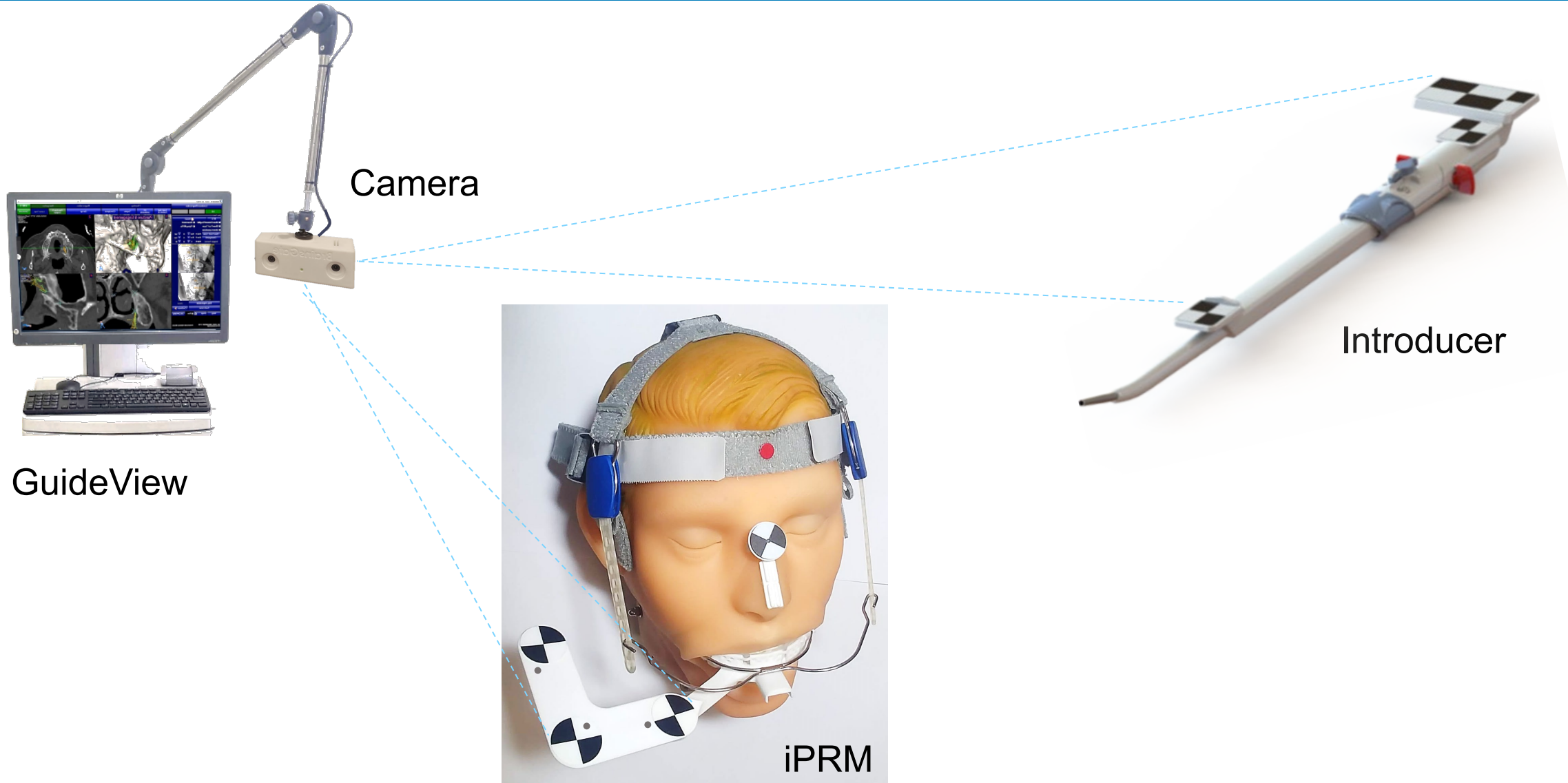
SPG Stimulation Case Study



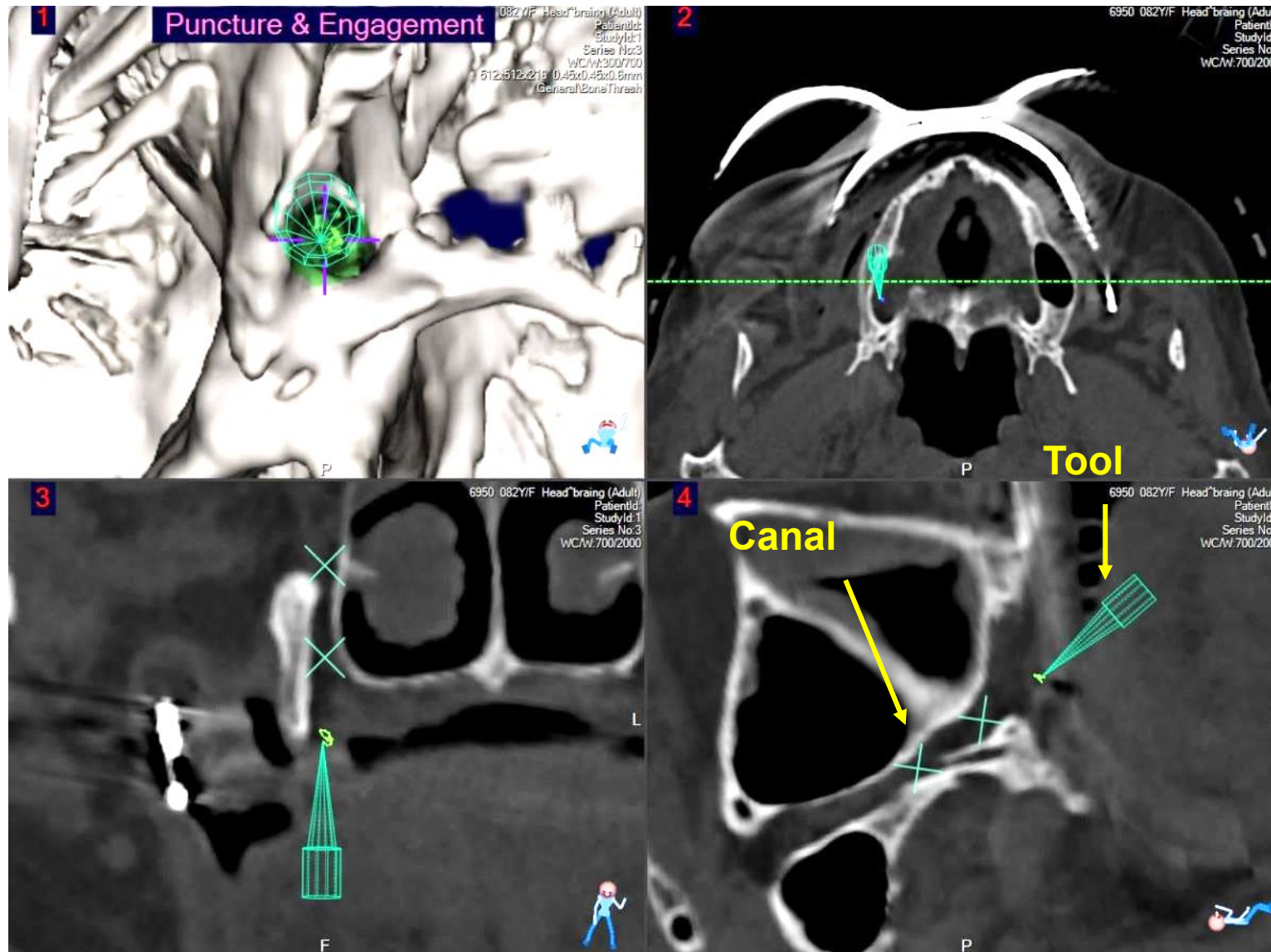
Treatment Delivery



Implantation Using an Optical Guidance System



Typical Navigation Screen



Preparation for Implant Procedure

1 Patient Preparation

- Patient reference marker
- Nose marker

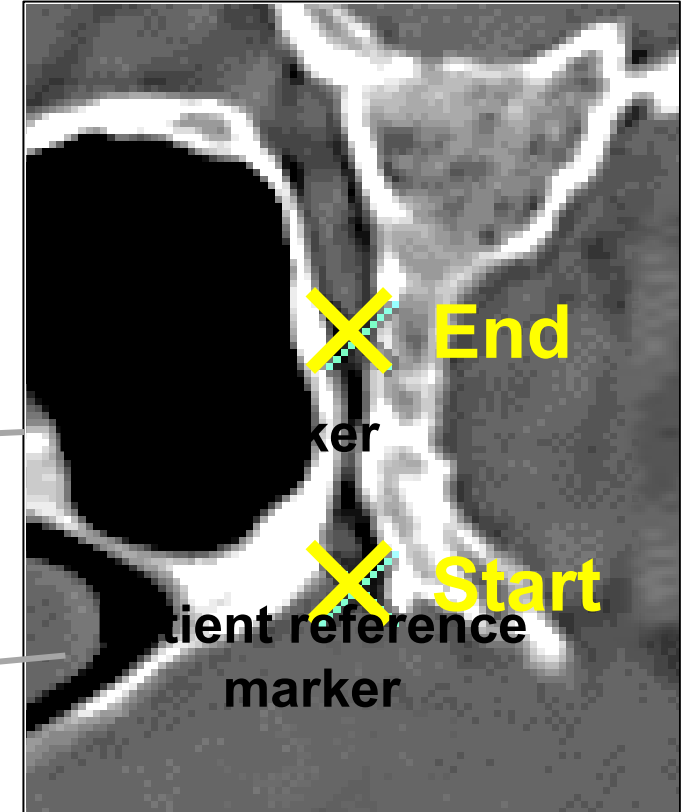
2 Implantation CT

3 Local Anesthesia

4 Planning

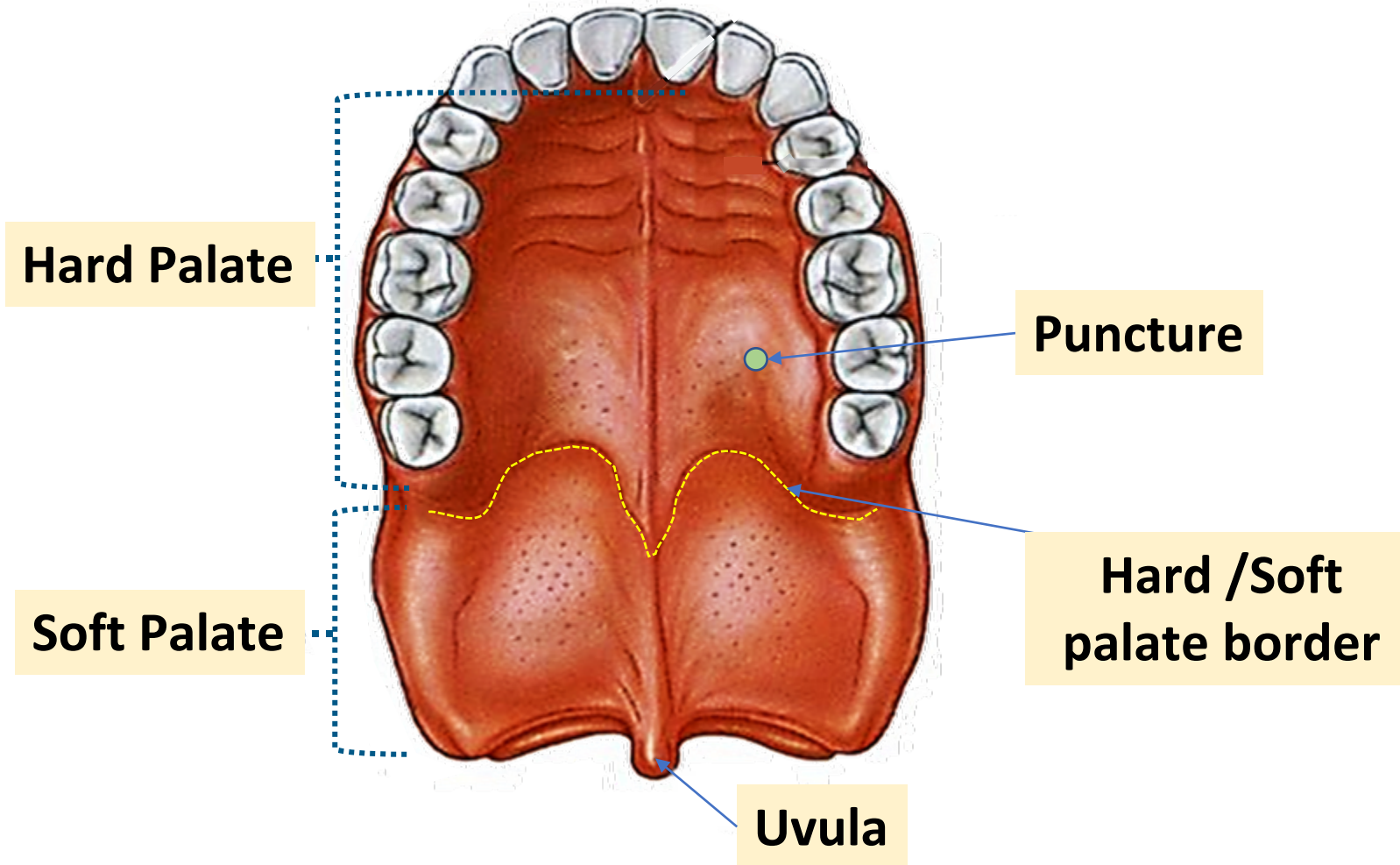


Reference Markers

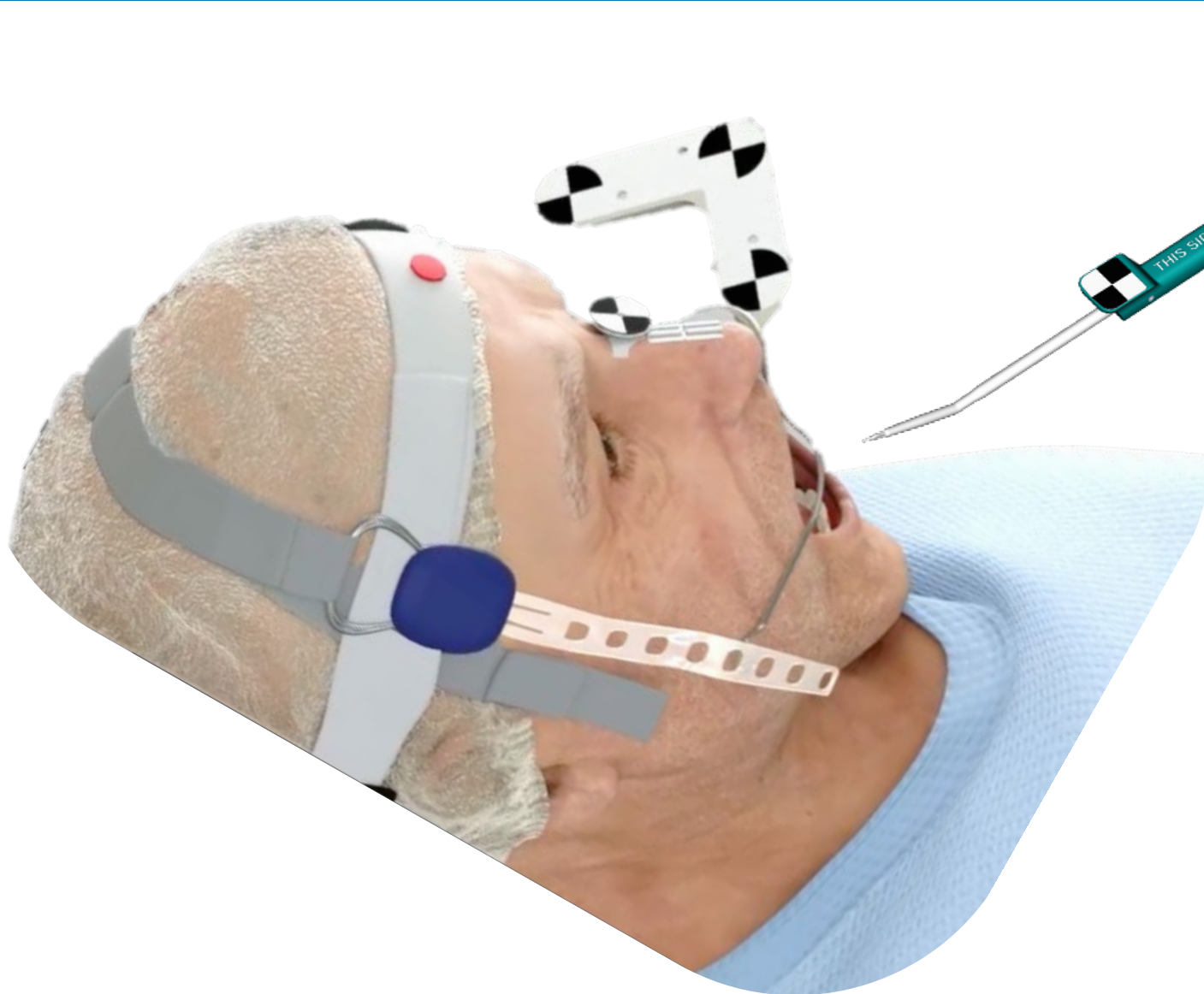


Implanter Marks
Canal Path on CT

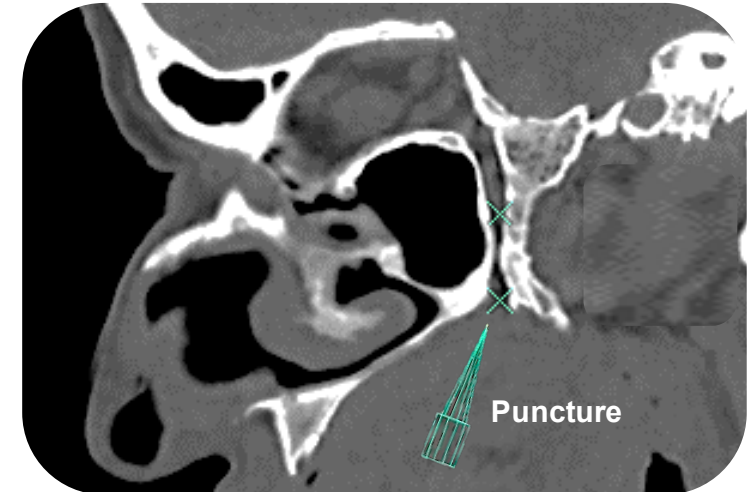
Puncture Point at the Upper Palate



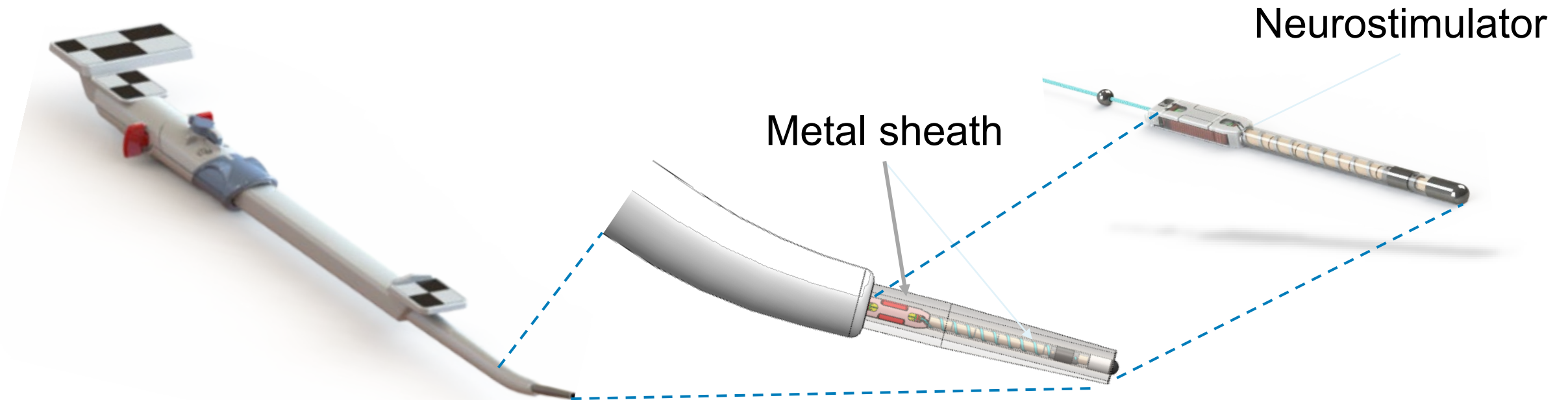
Puncturing the Mucosa



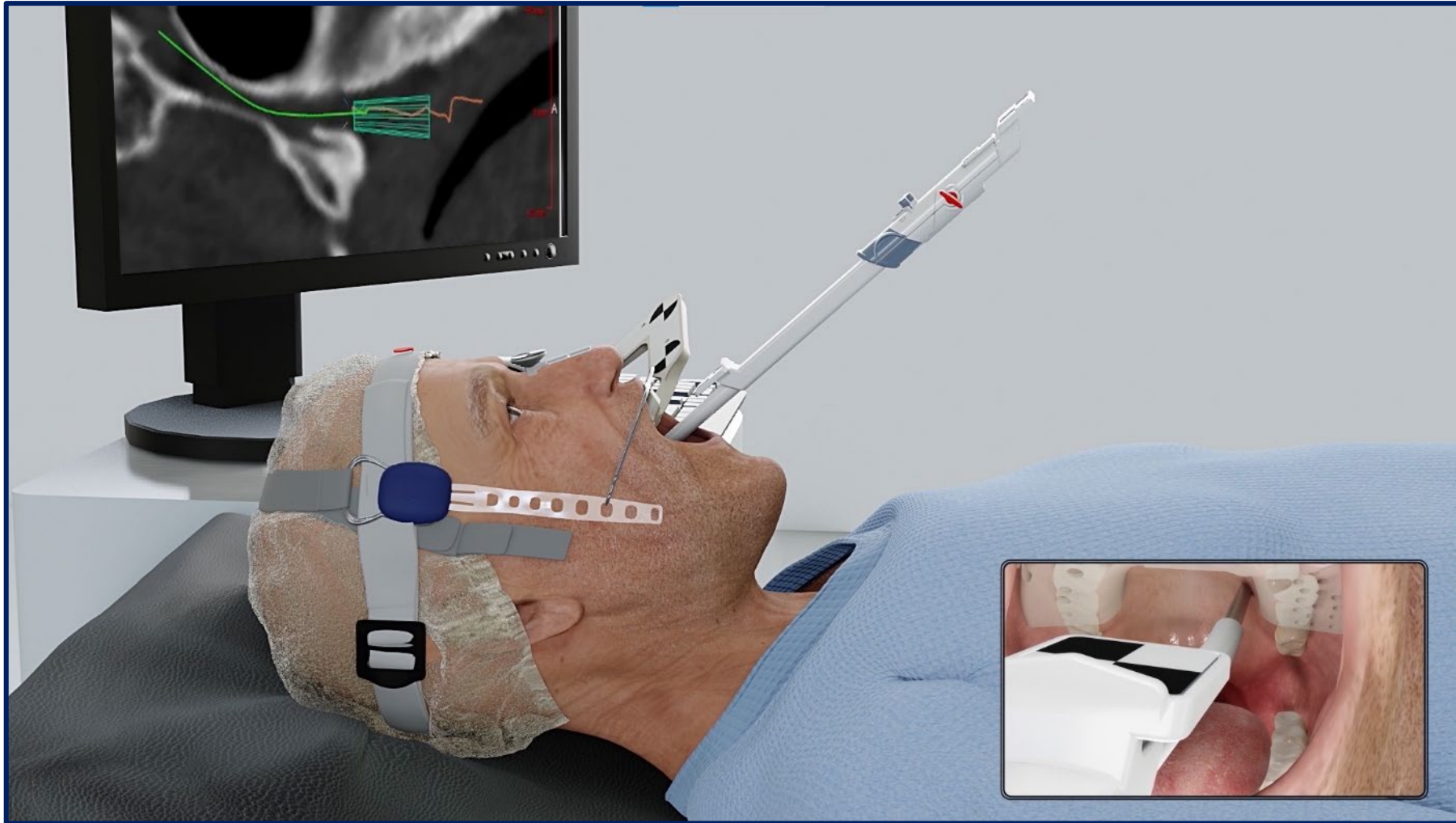
**Puncture
Tool**



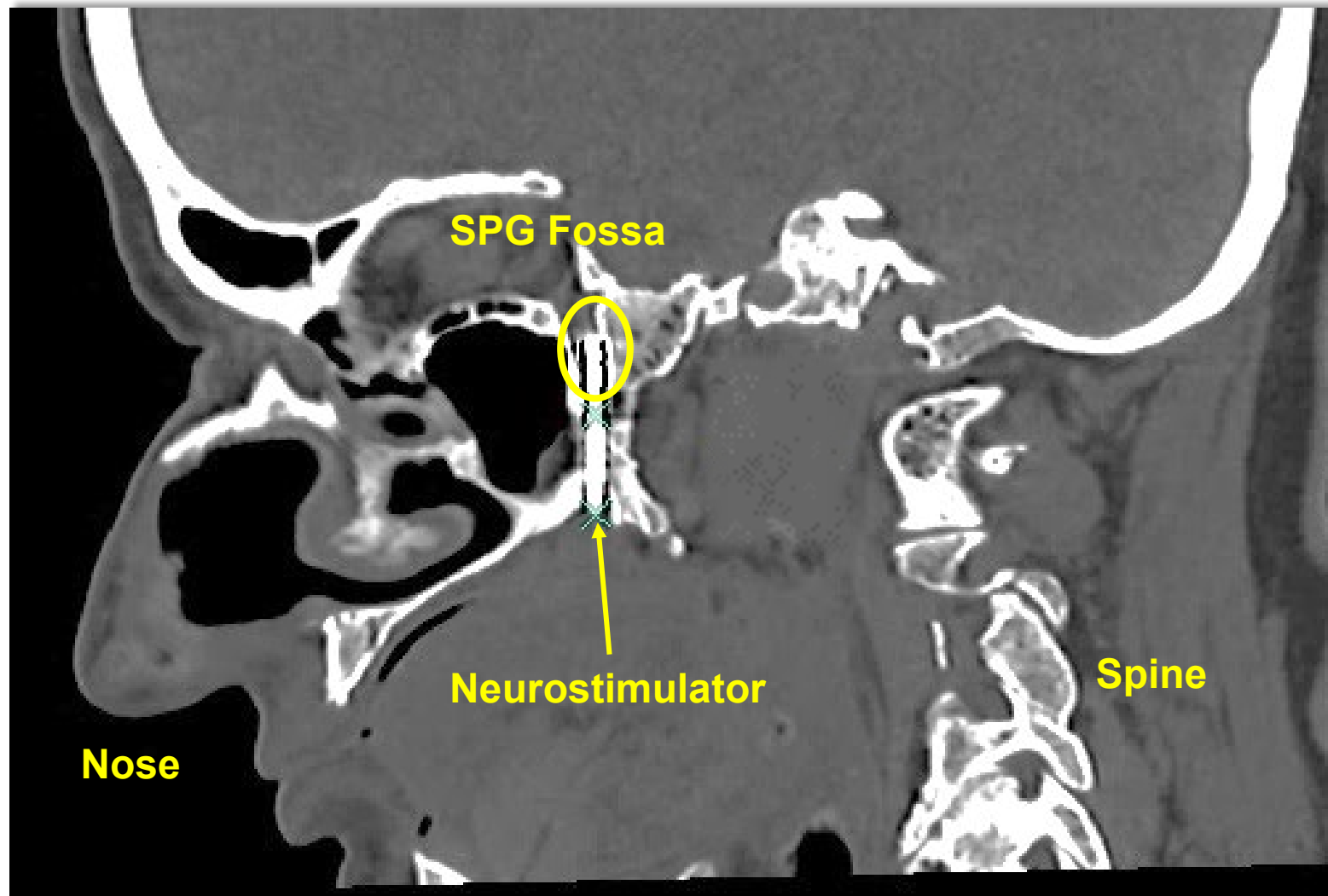
Introducer Used to Deliver the INS



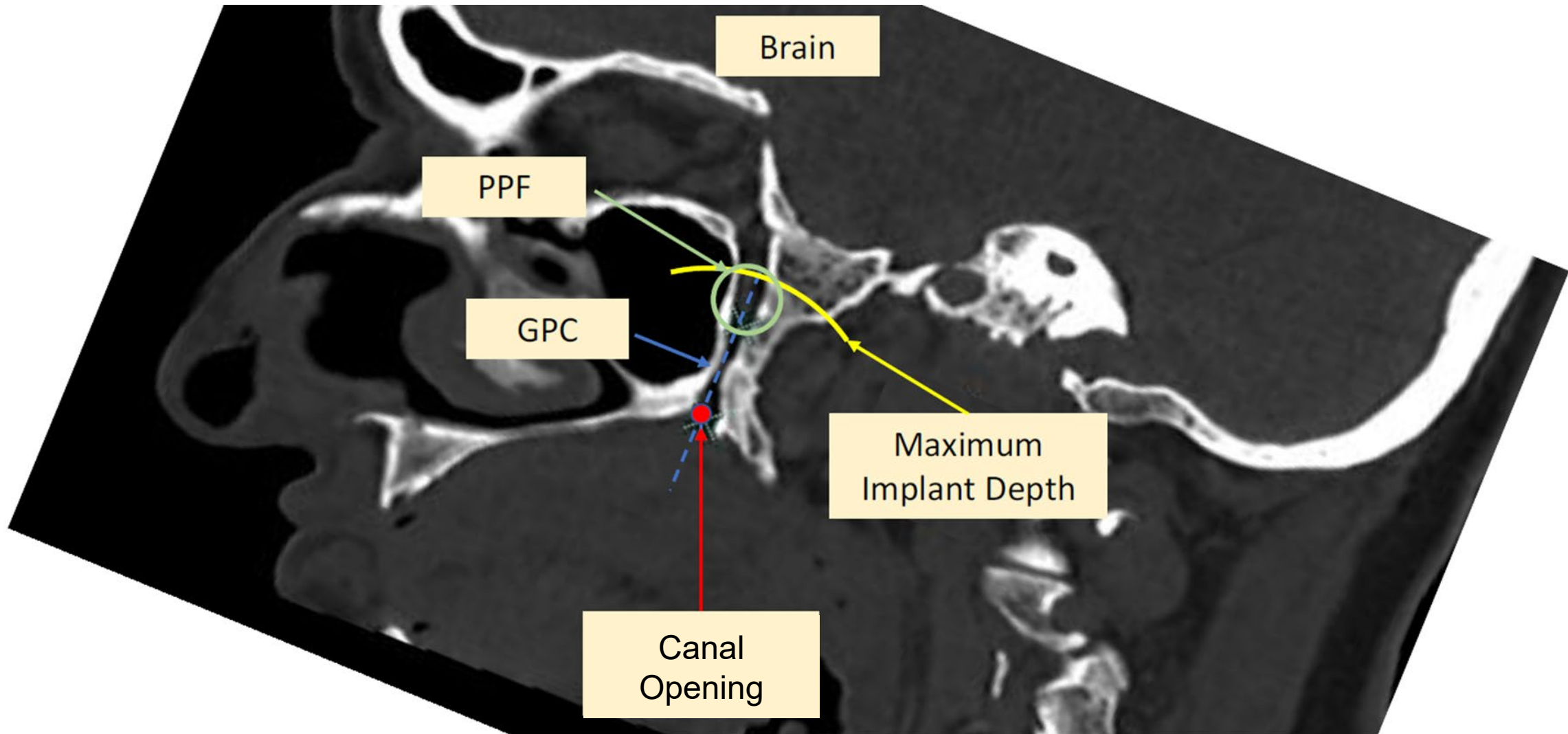
Implant is Injected Into The Canal



INS in the Greater Palatine Canal



Anatomy of Implantation

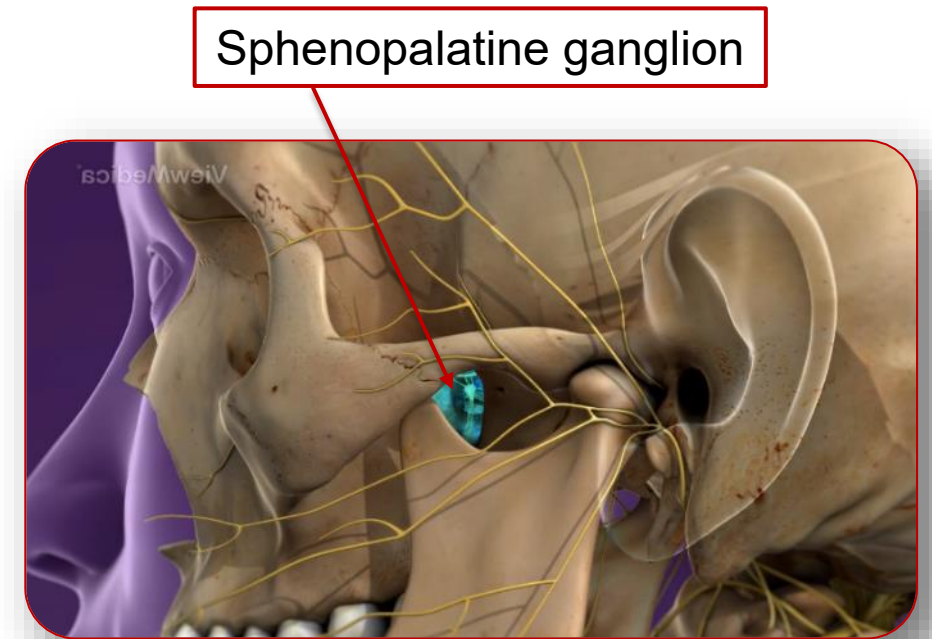


Implantation Related AEs with ISS500; All Resolved Without Sequela

	ImpACT-24B	
	Current Implant N = 197	First Implant N = 339
Acute pain	1% (2)	11.5% (39)
Bleeding (implant site hemorrhage)	0	3.8% (13)
Swelling (including Infection, Erythema)	0	1.5% (5)
Chronic neuropathic pain / nerve injury	0	1.5% (5)
Micro-aspiration		
Pneumonia Aspiration	0	0.6% (2)
Bronchopneumonia	0	0.3% (1)
Apnea	0	0.3% (1)
Airway endangerment / Laryngospasm	0	0
Palate laceration	0	0

Procedural Naming Conventions

- ISS500 procedure:
 - Percutaneous approach
 - Relevant body part: SPG
 - Head and neck sympathetic nerve
- Existing naming conventions do not uniquely identify the use of ISS500
- The ISS500 use will be dictated into the procedure section of the provider note in the medical record



Summary

- ISS500 is expected to be approved by the FDA by June 2022.
- ISS500 is indicated for acute ischemic stroke patients in a 24-hour window.
- ISS500 stimulates the SPG to reduce disability and improve patient's quality of life.
- The current procedure codes cannot identify use of the ISS500.

Thank You