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Deep Brain Stimulation Procedure

ROSA ONE®

BRAIN APPLICATION

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ROSA One Brain Application provides an accurate[1-6] and versatile platform for placement of Deep Brain Stimulation (DBS) leads.[7] ROSA One is intended to guide a DBS Microdrive to the planned trajectory and hold it firmly at the correct position and orientation while the Microdrive advances electrodes.*

*The device is intended for the spatial positioning and orientation of instruments holders or tool guides to be used by trained neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic neurosurgery may be appropriate.

Microdrive Setup with the ROSA Microdrive Holder

Accurate Lead Placement

ROSA One's rigid robotic arm and secure patient fixation provide high accuracy in lead placement, as demonstrated by numerous clinical publications.

Mean Error in DBS Lead Placement Reported in the Literature

Date	Authors	# of Leads	Mean Error (mm)	Measurement Method
Aug-2014	Lefranc et. al.[1]	52	0.81±0.39	Radial Error
Oct-2018	Neudorfer et. al.[2]	80	0.76±0.37	Lateral Deviation
Jul-2019	Liu et. al.[3]	192	0.75±0.04	Radial Error
Aug-2019	Paff et. al.[4]	36	1.59±0.82	Vector Error
Mar-2020	Faraji et. al.[5]	20	1.46±0.19 (First 10) 0.86±0.09 (Second 10)	Radial Error
Oct-2020	Jin et. al.[6]	306	0.71±0.25 (Asleep) 0.76±0.23 (Awake)	X-Y Vector Error

Versatile Workflow and Compatibility

ROSA ONE Brain DBS module is designed to integrate seamlessly with your existing workflow and instrumentation: ROSA One is compatible with most common Microdrives, head frames, and workflows, making the switch to a ROSA-based DBS simple.

Options Supported by ROSA ONE Brain DBS

Registration - Bone Fiducials - Leksell Frame Registration	Microdrives - FHC - Alpha Omega - Inomed	Head Fixation - Leksell - CRW
Lead verification - Microelectrode Recordings (MER) - Intra-Operative CT	Access - Burr Hole - Twist Drill	Anesthesia[6] - Asleep - Awake

DBS Workflow

Below is one option of a standard bilateral workflow for an asleep, burr-hole approach using an intra-operative CT scanner for registration and post-operative verification.

1. Load MRI Images into ROSA
2. Define AC/PC Anatomical Points
3. Plan Trajectories
4. Pin and Position Patient with Leksell or CRW frame
5. Prepare Patient for Registration
6. Position Intraoperative Scanner
7. Scan Patient
8. Perform Robot Registration
9. Mark Scalp Entry Points with Pointer Probe (non-sterile)
10. Place Sterile Drapes
11. Create Incisions, Re-mark Entry Points on Skull with Microdrive Holder
12. Create Burr Holes
13. Drive Robot Arm to Trajectories
14. Place Electrodes to Targets
15. Intraoperative Spin and Image Merge to Verify Placement

Efficient Operating Times

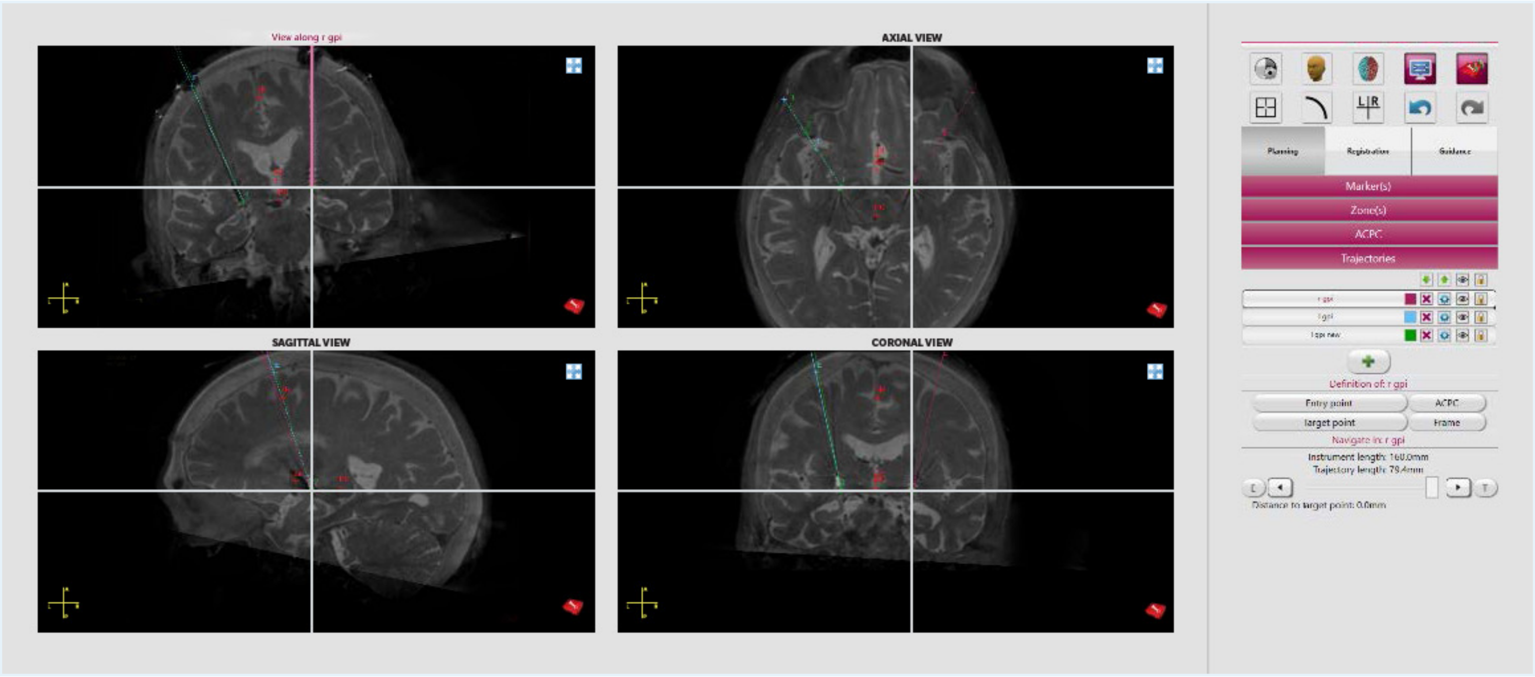
Streamlined robotic workflow may lead to reduced operation times when compared to traditional frame-based DBS implantation.[2]

Advantages of ROSA ONE Brain DBS

Eliminates need to change/check manual frame coordinates	No frame assembly or moving parts to adjust before or during the procedure	Rapid switching between right and left sides for bilateral approach
Easy for surgeon and assistant to work simultaneously	No expensive per-case disposable cost	Rigid support arm prevents head movement during the procedure

Simple and Intuitive Planning

Quickly create the surgical plan using the MRI and CT imaging of your choice and AC/PC coordinates. Easily adjust or modify your plan intraoperatively without cumbersome calculations or manual hardware adjustments.



Standard ROSA DBS Setup with Intra-Operative CT Scanner.

Required Equipment

ROSA One Brain Device	ROSA Frame Adapter	Registration Method - Bone Fiducials - ROSA Leksell Frame Registration Module
ROSA Pointer Probe	ROSA Microdrive Holder	

External Equipment

Microdrive - Alpha Omega - FHC - INOMED	Head Holder* - Leksell Frame Base - CRW Frame Base	Intra-operative CT scanner (optional)

*3-point fixation head-holders are compatible but not recommended for maximum accuracy

ROSA ONE Brain

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1) Lefranc M, Capel C, Pruvot AS, et al. The impact of the reference imaging modality, registration method and intraoperative flat-panel computed tomography on the accuracy of the ROSA® stereotactic robot. Stereotact Funct Neurosurg. 2014; 92(4):242-250. doi:10.1159/000362936

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4) Paff M, Wang AS, Phielipp N, et al. Two-year clinical outcomes associated with robotic-assisted subthalamic lead implantation in patients with Parkinson's disease. J Robot Surg. 2020;14(4):559-565. doi:10.1007 s11701-019-01025-x

5) Faraji AH, Kokkinos V, Sweat JC, Crammond DJ, Richardson RM. Robotic-Assisted Stereotaxy for Deep Brain Stimulation Lead Implantation in Awake Patients. Oper Neurosurg (Hagerstown). 2020;19(4):444-452. doi:10.1093/ons/opaa029

6) Jin H, Gong S, Tao Y, et al. A comparative study of asleep and awake deep brain stimulation robot-assisted surgery for Parkinson's disease. NPJ Parkinsons Dis. 2020;6:27. Published 2020 Oct 5. doi:10.1038/s41531-020-00130-1

7) Indications for Use, 510(k) Premarket Notification, K200511

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CURRENT ROSA USERS

Contact your local ROSA clinical representative for more information.

FUTURE ROSA USERS

Connect with your local ROSA sales representative by contacting 866-ROSA-BOT.

For more information on on ROSA ONE® Brain and other Robotic Technologies, please contact us at:

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