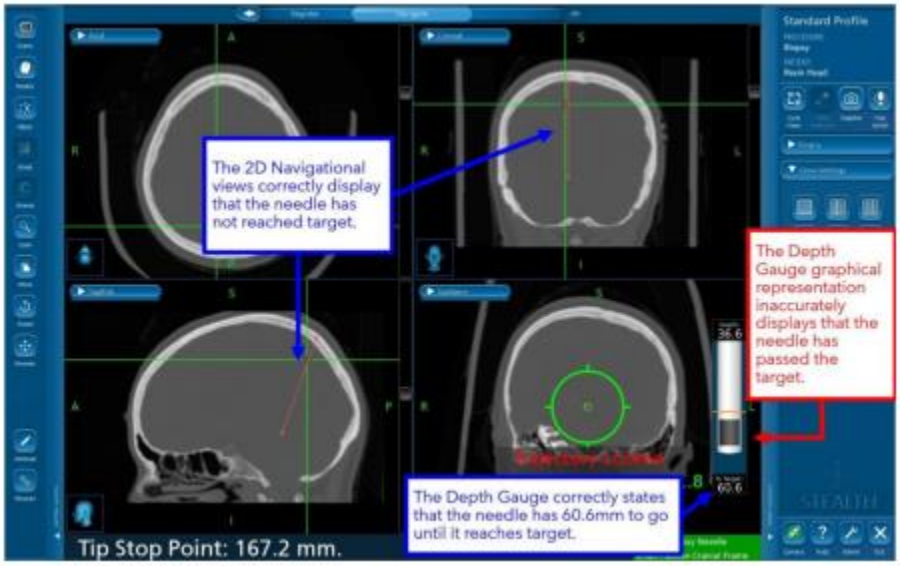
Safety Communication رسالة سلامة

Potential Inaccuracy During Biopsy Procedures

Device/ Product Description:	Synergy Cranial S7 and StealthStation Cranial
Affected product:	

Navigation System	Software Name	Model#/CFN	Version
StealthStation S7/i7	Synergy Cranial S7	9733763	2.2.8
StealthStation S7/i7	StealthStation Cranial	9735585	3.1.1
StealthStation S7/i7	StealthStation Cranial	9735585	3.1.2
StealthStation S7/i7	StealthStation Cranial	9735585	3.1.3

Manufacturer:	Medtronic Navigation, Inc.
Problem:	The software can enter a state where the Biopsy Depth Gauge is no longer synchronized with the rest of the navigational information on the screen and displays an inaccurate position of the biopsy needle. This issue can potentially lead to resection of normal brain tissue or eloquent anatomical regions of the brain. When this software anomaly is encountered, it may result in a prolonged procedure, the need for an additional surgical procedure, tissue injury, including potential for life-threatening injury (hemorrhage, unintended tissue damage, permanent neurological injury).

Recommendation /Actions:	Medtronic will provide a warning and instructional placard to be applied to impacted systems to maintain visibility to the mitigations until a software fix is available. Please attach the warning and instructional placard to your impacted StealthStation systems. A Medtronic representative can assist you with placing the placards. The Mitigation Steps should be utilized to prevent this software anomaly from occurring and to restore normal function if this anomaly is observed. For more information, please click here. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999)unified call center	
Devices/Products photo:		
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