



CLEARPOINT®
NEURO

WHAREN CENTERING GUIDE
INSTRUCTIONS FOR USE

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I. Intended Use

The Wharen Centering Guide is an accessory to the ClearPoint System. It is used to assist in centering the Scalp Mount Base over the desired entry point.

Warning: This device is intended for single use only. Contents of unopened, undamaged package are sterile. Do not re-sterilize.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Note: For complete instructions on using the SmartFrame XG and Scalp Mount Base, refer to the SmartFrame XG Instructions for Use.

Note: For complete instructions on using the SmartFrame, refer to the SmartFrame Instructions for Use

Note: For a complete procedure description, refer to ClearPoint Neuro ClearPoint[®] User's Guide.

II. Device Description

Package Contents:

NGS-CG-01: Wharen Centering Guide (1)

Associated Devices:

NGS-SF-02-11: **SMARTFrame[®] XG MRI-Guided Trajectory Frame**
MRI Stereotactic Frame, Dock, Device Lock, Large Device Lock, Screwdriver, Roll Lock Screw w/washer

CP-NGS-11-CG45-XG: **SMARTFrame XG Kit with Wharen Centering Guide and TE**
MRI Planning Grid, XG MRI-Guided Trajectory Frame, Accessory Kit, Thumb Wheel Extension, Scalp Mount Base, Wharen Centering Guide, MR Drill Kit, 4.5-mm / 3.2-mm, XG Exchangeable Device Guides, Guide Tubes

NGS-SG-01-11: **SMARTGrid[®] MRI Planning Grid**
Marking Grid and Marking Tool

NGS-SM-01: **Scalp Mount Base**
Scalp Mount Base and Scalp Mount Centering Tool

III. General Warnings and Precautions

Warning: Do not attach the Wharen Centering Guide to damaged or diseased bone. Only attach to stable bone to ensure a solid platform.

Warning: Before using the System on patients under the age of 16 years, measure the skull thickness on a CT scan to ensure that the system can be secured safely onto the skull.

Warning: When used with pediatric patients with open cranial sutures, take precautions to avoid placement that may result in placement of the screw into a cranial suture.

Caution: It is recommended that additional sterile product be available for use.

Caution: Do not place the Wharen Centering Guide bone attachment screw in the cranial suture area.

General Precautions

Handle all components using standard hospital sterile practices.

1.5T & 3T Environment Compatibility:

Non-clinical testing has demonstrated the ClearPoint[®] System is MR Conditional. It can be scanned safely under the following conditions:

Static magnetic field of 1.5 or 3 Tesla.

Spatial gradient field of 5000 Gauss/cm.

Maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning.

In non-clinical testing, the ClearPoint[®] System produced a temperature rise of less than 1°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in a 1.5T GE Signa MR scanner with Excite ver. 11.0 software and in a 3T Siemens Magnetom Trio MR scanner with ver. VB17 software.

IV. Use Instructions

A. Preparation

The Wharen Centering Guide is packaged with a double sterile barrier; a sealed Tyvek/mylar pouch is placed inside a larger sealed mylar/Tyvek pouch. Each double pouch contains one Wharen Centering Guide.

Warning: Do not use the Wharen Centering Guide if the packaging is damaged or open.

Use aseptic transfer if the Wharen Centering Guide is intended to be used in the sterile field.

B. Marking the Entry Point on the Marking Grid

1. Remove paper back from Marking Grid.
2. Affix sticky side of Marking Grid onto the patient's head (over the incise tape portion of the drape), centered at the approximate location for the burr-hole.
3. Determine the scalp mount entry point location on SmartGrid[®] per instructions from CLEARPOINT[®] workstation (alpha-numeric coordinates).
4. Slowly peel off top fluid filled layer of the SmartGrid[®] while firmly holding the lower layer in position.

Note: It is important to hold the lower layer as firmly as possible to minimize scalp movement during removal of the top layer.

5. Using a surgical marker and the coordinates, mark the scalp mount entry point location on the grid.

C. Using the Wharen Centering Guide

1. The Wharen Centering Guide has a small piece of protective tubing at the end of the screw. Remove the tubing prior to placing the guide on the Marking Grid.
2. Place the Wharen Centering Guide screw over the marked entry point as shown in Figure 1.

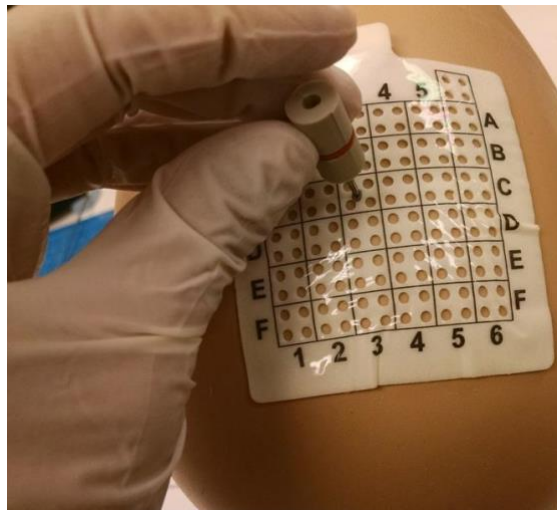


Figure 1

3. Hold the Wharen Centering Guide while inserting the Bone Screw through the Marking Grid, Scalp, and Skull as shown in Figure 2.



Figure 2

4. Insert the screw into the skull so that it is stable.
5. Grasp the Wharen Centering Guide above the O-ring and remove it by pulling it up. The screw will remain in place as shown in Figure 3.

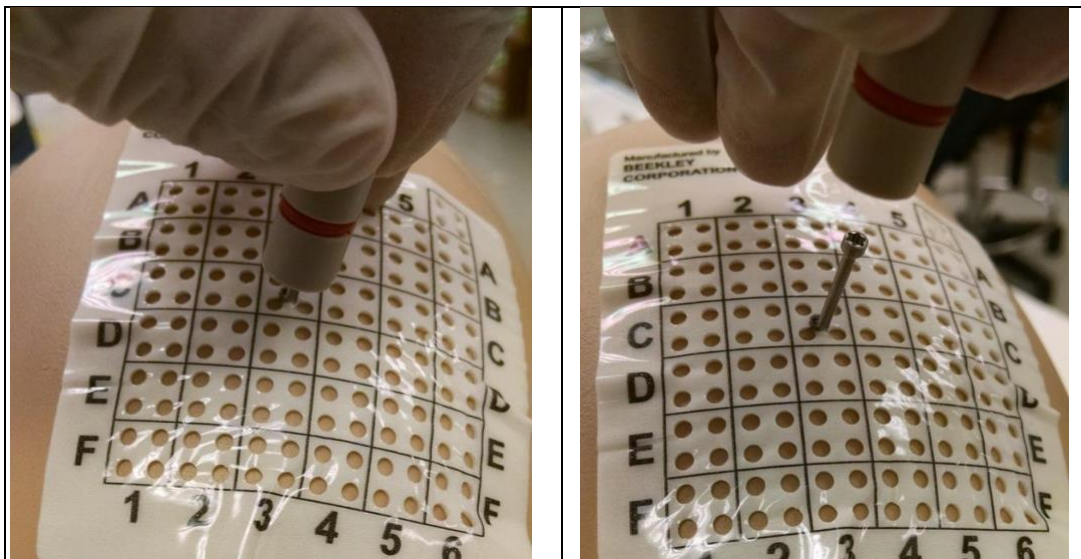


Figure 3

6. Remove the Marking Grid by peeling it away from the scalp. It will pull over the screw while the screw remains in place as shown in Figure 4.

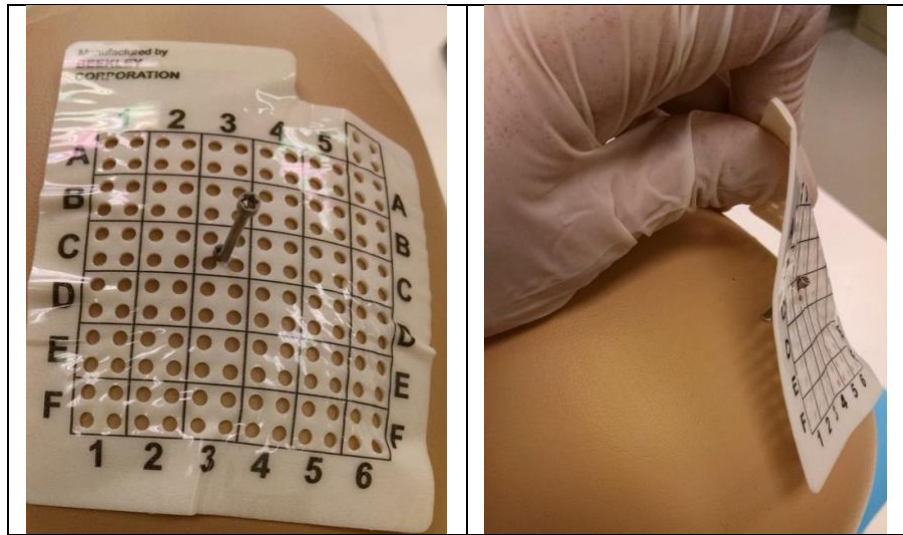


Figure 4

7. Grasp the Wharen Centering Guide above the O-ring and replace it over the screw as shown in Figure 5.



Figure 5

8. Place the SmartFrame Centering Ring over the Guide as shown in Figure 6. The Centering Ring is provided with the SmartFrame or SmartFrame XG.



Figure 6

9. Place the Scalp Mount Base over the Centering Ring as shown in Figure 7.



Figure 7

10. Secure the Scalp Mount Base per the instructions in the SmartFrame or SmartFrame XG IFU.

D. Removing the Wharen Centering Guide

1. Hold the Wharen Centering Guide while removing the screw from the skull.
2. Once the screw is out of the scalp, the Wharen Centering Guide and Screw may be removed from the surgical site.














E. Storage and Technical Specifications

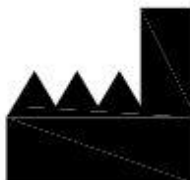
Storage

- Store in a cool dry place

Technical Specifications

Device	Outer Diameter (in/mm)	Inner Diameter (in/mm)	Height (in/mm)	Mass (g)
Wharen Centering Guide	0.76/19.3	0.07/1.78	1.3/33	1.8

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	MR Conditional		Sterilized through ethylene oxide
	Consult instructions for use		Manufacturer
	Catalogue number		Single use
	Batch code		Keep dry
	Use by date		Keep away from sunlight
	Double sterile barrier system		Not made with natural rubber latex
	Do not use if the product sterilization barrier or its packaging is compromised		



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