CLEARPOINT MR FIDUCIAL MARKERS

INSTRUCTIONS FOR USE

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I. Intended Use

The ClearPoint MR Fiducial Marker (Fiducial) is intended to be used to provide a visual locator on MRI images.

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

Caution: Do not use if there is evidence of damage to the fiducial, including leaking or if there is less than two thirds of the fluid remaining in the fiducial.

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

Note: For a complete procedure description, refer to ClearPoint System User's Guide.

II. Device Description

Package Contents:

REF **NGS-BM-05: ClearPoint MR Fiducial Markers (5)**

III. General Warnings and Precautions

The device is intended for single–use-only and is provided sterile. Do not re-sterilize.

General Precautions

- Handle all components using standard hospital sterile practices.

IV. MRI Safety Information



MRI Safety Information: MR Conditional

A patient may be safely scanned under the following conditions. Failure to follow these conditions may result in an injury. Additional MRI Safety Information may be found at https://www.clearpointneuro.com/eifus/ or by calling 888-287-9109.

Parameter	**Condition of Use / Information**
Static Magnetic Field Strength (B_0)	1.5T, 3T
Maximum Spatial Field Gradient (SPG)	22 T/m and 2,200 gauss/cm
RF Polarization	Circularly Polarized (CP)
RF Transmit Coil Type	Any Transmit RF Coil may be used
MR System (RF) Operating Modes or Constraints	Normal Mode
Whole-Body Averaged SAR	Whole-Body Averaged SAR ≤ 1.8 W/kg
Scan Duration and Wait Time	Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) with 30 mins cooling period.
Artifacts	The presence of the implant may produce an image artifact.
Additional Information	The health state of the patient or the presence of other implants may require a reduction of the MRI limits. Applicable Components: • Fiducial Markers

V. Use Instructions

A. Preparation

The MR Fiducial Marker is packaged with a double sterile barrier; a sealed Tyvek/mylar pouch is placed inside a larger sealed Tyvek/mylar pouch. Each double pouch contains one MR Fiducial Marker. The MR Fiducial Marker Box contains five (5) of these double pouched MR Fiducial Markers.

Warning: Do not use the MR Fiducial Markers if the packaging is damaged.

Use aseptic transfer if the MR Fiducial Marker is intended to be used in the sterile field.

B. Attaching the MR Fiducial Marker

1. The MR Fiducial Marker comes attached to a non-adhesive white backing, as shown in Figure 1.



Figure 1

2. Hold the white backing and Fiducial, and fold the backing near the small round tab. This will separate the tab from the backing as shown in Figure 2.

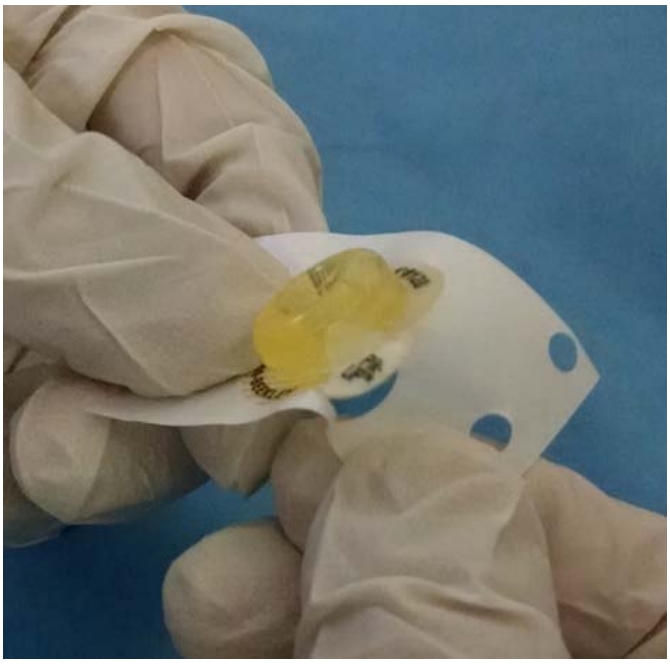


Figure 2

3. While holding the white backing, grab the small round tab and pull it away from the backing. The Fiducial with its adhesive backing will separate from the white backing as shown in Figure 3.

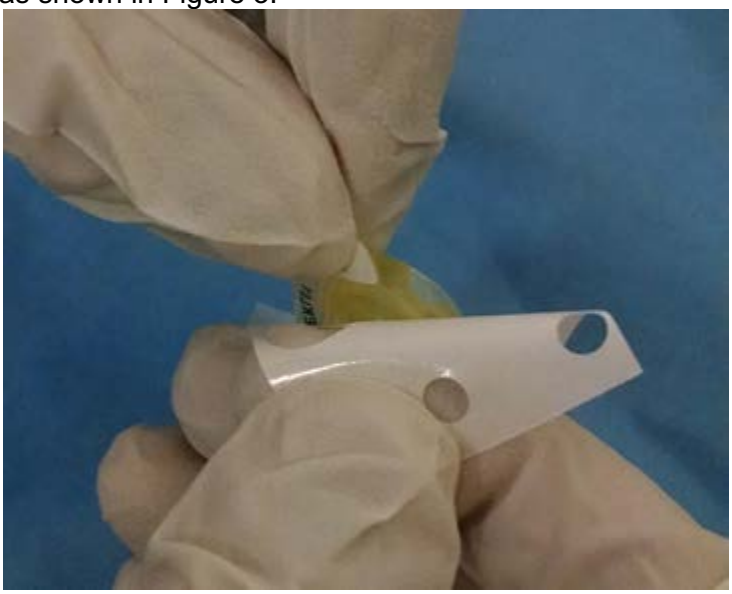


Figure 3

4. Once the fiducial is separated, continue to hold it by the round tab, as that will not stick to gloves as shown in Figure 4.

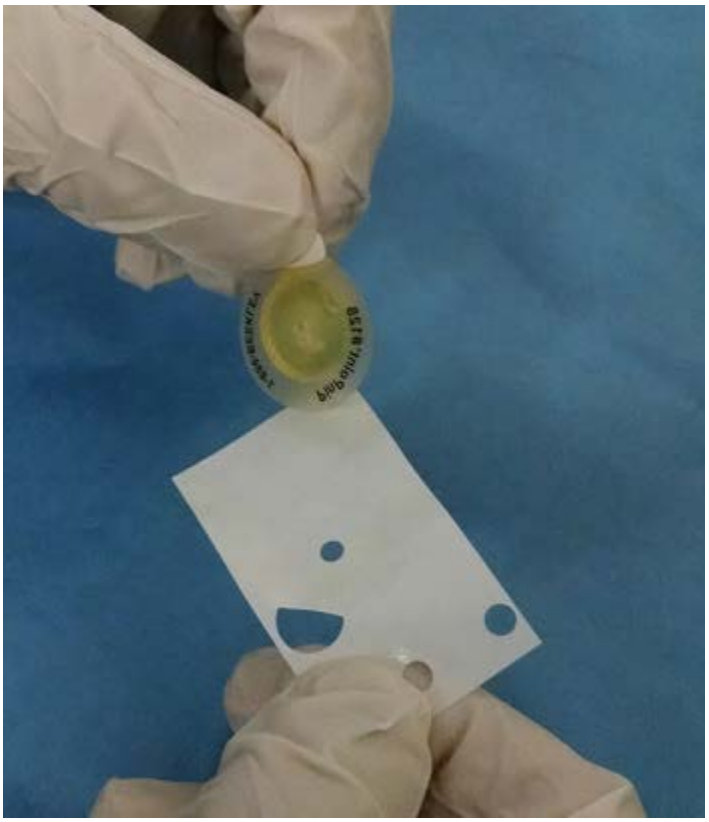


Figure 4

5. Place the fiducial on the desired surface, and gently press down to make sure it sticks well.
6. To remove the Fiducial, grasp the round tab and pull the Fiducial off the surface.

C. Storage and Technical Specifications

Storage

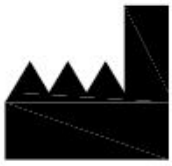
- Store in a cool dry place

Technical Specifications

	Outer Diameter (in/mm)	Inner Diameter (in/mm)	Height (in/mm)	Mass (g)
MR Visible portion	0.58 / 14.7	0.056 / 1.4	0.26 / 6.6	N/A
Overall (including Adhesive Backing)	0.88 / 22.3	0.056 / 1.4	0.26 / 6.6	0.88

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

Manufactured by:



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