



MR NEURO PATIENT DRAPE

and

MR SCANNER BORE DRAPE w/ EXTENSION

Specifically designed for IMRIS Scanners.

INSTRUCTIONS FOR USE

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- I. **Intended Use:** The MRI Procedure Drapes are intended to provide sterile, disposable covering of the MRI instrumentation during surgical procedures conducted under MR imaging.

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

Caution: Federal Law restricts this device to sale by or on the order of a physician.

II. **Device Description:**

Package Contents:

NGS-PD-04: MR Scanner Bore Drape w/ Extension

MR Scanner Bore Drape w/ Extension

NGS-PD-05: MR Neuro Patient Drape

MR Neuro Patient Drape, Marker Pen, and Cable Cover

The Drapes are constructed with opaque cloth and clear plastic film to create a sterile barrier for a surgical procedure. The end of the clear plastic film on the Patient Drape is a section of adhesive area for attachment to the patient's scalp. The Drapes are packaged individually and can be purchased separately. The Drapes (Patient and Bore) are intended to be used together.

III. **General Warnings and Precautions**

- a. **Warning:** Both Drapes must be used together when performing a ClearPoint procedure.
- b. **Warning:** There are no known and reliable means of cleaning, disinfecting, repairing, and sterilizing these devices that returns them to original specifications and renders them safe and effective for reuse.
- c. **Warning:** Visually inspect all sterile barriers prior to use to determine if breaches to the sterile barrier system are evident. Do not use the device if any damage to the sterile barrier system is identified during visual inspection.
- d. **Caution:** Both Drapes are specifically designed for use with IMRIS scanner installations.
- e. **Caution:** Handle the Drape and other devices in the package with standard hospital sterile techniques.
- f. **Caution:** Do not move the scanner over the patient without both Drapes completely installed.
- g. **Caution:** Install both Drapes while the scanner and the surgical table are separated.
- h. **Caution:** Do not discard the other items that are included in the Patient Drape box. These may be necessary to complete the procedure.
- i. **Caution:** Do not handle the adhesive on the Drape prior to attaching to the scanner for best adhesion.

j. Caution: To prevent impaired patient airflow or suffocation, the following precautions must be taken when using the Patient Drape:

- It is preferred that the patient be intubated.
- The patient shall be monitored.
- All monitors and alarms shall be turned on prior to draping the patient.

IV. MRI Safety Information

V. Use Instructions – MR Neuro Patient Drape (Patient Drape)

A. Preparation – Patient Drape

1. The manufacturer recommends five persons for proper installation of the Patient Drape.
 - The patient should be positioned on the surgical table. The head shall have been prepped and secured in a Head Fixation Arc.
 - Five persons (four sterile and one non-sterile) should be available.
2. Remove all the items in the zip lock bag that are attached to the Patient Drape pouch and set aside. The items are in sterile barrier pouches. The contents of the pouches are sterile. The outside surfaces of the pouches are non-sterile. The contents include one (1) Sterile Marking Pen (to mark length on the stylet) and one (1) Cable Cover (to cover the Cable Extension).

B. Hanging the Patient Drape

CABLE COVER

1. Open the single sterile barrier Cable Cover pouch (Intraoperative Probe Cover) and remove the Cable Cover using standard hospital sterile techniques.
2. Unfold the protective outer Drape to access the Cable Cover.
3. The non-sterile person extends the cable from the Head Coil and grasps the connector(s).
4. The sterile person reaches into the center of the Cable Cover (see instructions and labeling that come with Cable Cover) and with their hand in the closed end of the cable cover, grasps the connector(s).

The non-sterile person slides the Cable Cover along the length of the cable and tapes the end near the Head Coil using tape provided with the cover or any sterile tape. The remaining contents of the pouch may be disposed as they are not required for the procedure.

5. The Sterile person remains holding the cable until the other individuals have completed draping the patient. At that time, the cable may be laid on or beside the patient without causing contamination. The end of the Cable
-

Cover does not need to be opened to expose the connectors until it is time for the first scan.

PATIENT DRAPE

6. Open the Patient Drape pouch and remove the Drape using standard hospital sterile techniques. A **“Non-Sterile” clinician opens clear pouch** and removes drape in overwrap. **Remove both layers of the header** at the top of the pouch to open correctly. **See Figures 1a and 1b.**

CORRECT



Figure 1a

WRONG

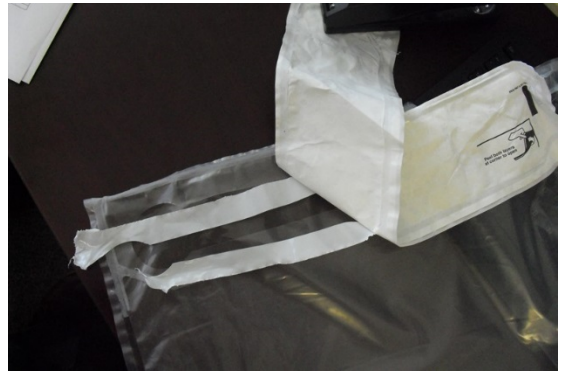


Figure 1b

7. Place the overwrapped drape on a Mayo stand (or equivalent non-sterile surface) and open dirty outer wrap so “Clean” clinician can access sterile drape.
8. Un-fold once to access the adhesive portion.
9. Have two sterile people hold each side of the folded Drape with the large central adhesive portion (incise tape) facing the patient’s head and the arrow facing UP. **See Figure 2 and Figure 3.**



Figure 2: Adhesive area of Drape with Protective Covering (white)

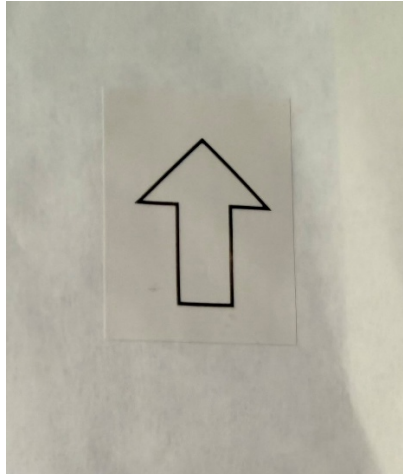


Figure 3: UP Arrow

10. The physician removes the white protective covering (when applicable) from the incise tape from the patient's side then comes around to the other side of the Drape. NOTE: For procedures that attach the Marking Grid directly to the incise tape provided with the drape, take care when removing the Marking Grid.
11. The physician affixes the incise portion to the previously applied surgical incise tape on the patient.
12. Un-fold the drape horizontally to either side of the end of the surgical table. **See Figure 4.**



Figure 4: Drape unfolded horizontally

13. Carefully look at the folds along the bottom edge of the drape. The portion closest to the patient has a seam running along it. The next piece of clear drape is NOT folded. This portion is the leading edge that goes under the table. The remaining sections of drape in this area are all folded. **See Figure 5.**

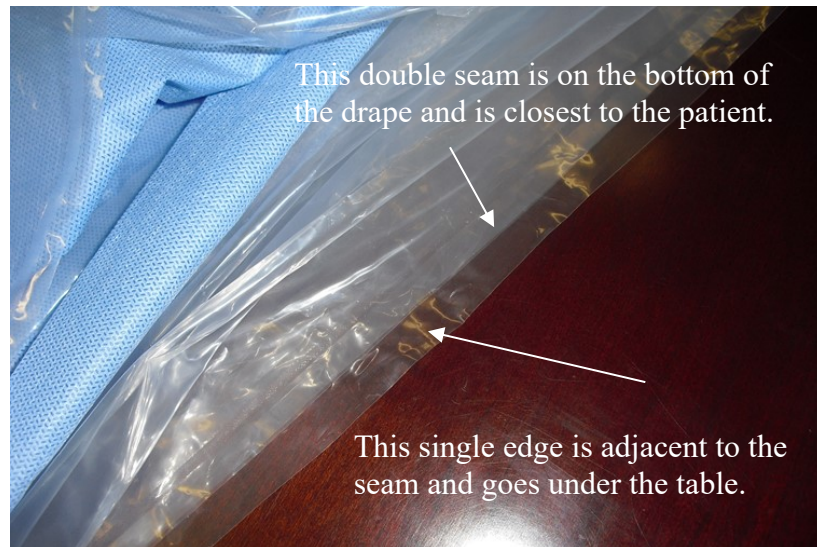


Figure 5

14. While the two sterile people hold either side of the drape, a third person grasps the edge of the single sheet, draws it out and down to go under the table. **See Figure 6.**



Figure 6

15. The two sterile people move down either side of the table, allowing the clear portion of the Drape to telescope over the patient. **See Figure 7.**



Figure 7

16. The Cable may be brought up between the clear and blue Drapes. The blue Drape shall be extended to cover the patient and the remaining table (Figures 3 and 4). The cable in its sterile pouch may lay on the draping. **See Figure 8 and Figure 9.**



Figure 8: Patient's Head Covered



Figure 9: Patient's Legs Covered

17. Perform intended procedure only after Bore Drape is installed.

C. Post Procedure - Patient Drape

1. When the procedure is complete, fold the blue cloth section up to the clear section.
2. Slide the clear section forward, gathering it together on the sides as proceeding.
3. Upon reaching the head, cut around the incise tape that is attached to the patient to free the Drape.
4. Extend the blue Drape around the clear section.
5. Bundle the clear section inside of the blue section to prevent any spillage of fluids.
6. Dispose of Drape per standard hospital practice.

VI. MRI Safety Information



MRI Safety Information: MR Safe

The devices listed below are MR Safe. Additional MRI Safety Information may be found at <https://www.clearpointneuro.com/eifus/> or by calling 888-287-9109.

Device Name

- | |
|---|
| <ul style="list-style-type: none"> • MR Neuro Drapes |
|---|

VII. Use Instructions – MR Scanner Bore Drape with Extension (Bore Drape)

A. Preparation – Bore Drape

1. The manufacturer recommends three persons for proper installation of the Bore Drape.
 - Three persons (two sterile and one non-sterile) should be available.
2. Remove the Bore Drape *from its pouch* in the manner described above for the Patient Drape. Obtain a small drape and place the small drape on the diagnostic table near the bore. Remove the overwrap layer from the Bore drape and leave contents on top of the small drape.
3. Un-do the cloth tie holding the drape sections together and discard.

B. Hanging the Bore Drape

1. Slide the small overwrapped drape that is sitting on top into the bore.
2. From the surgical side of the bore, draw the surgical side Drape (contained in the overwrap) through the bore. This will pull the clear bore Drape into the bore. Unwind the clear section of the drape at this time. **See Figure 10a and 10b.**



Figure 10a: *Before unwinding.*



Figure 10b: *After unwinding.*

3. Open the overwrapped surgical end of the Drape.
4. Take the left and right upper corners of the drape that are now exposed and lift the Drape up. **See Figure 11.**

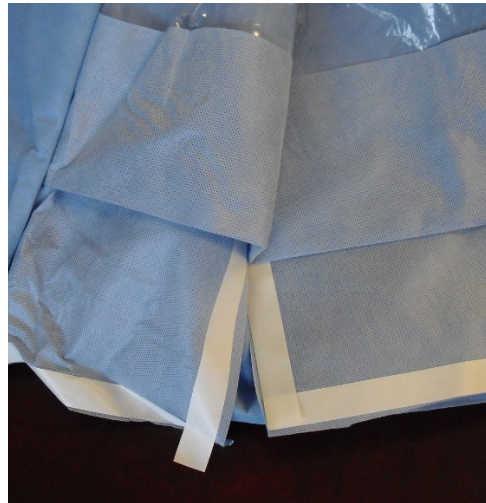


Figure 11

5. The non-sterile person removes the adhesive from the top of the Drape “only” and the sterile people adhere the top of the Drape to the surgical end of the scanner. **DO NOT ATTACH THE SIDES AT THIS TIME.**
6. The non-sterile person takes a position on the scanner side of the Drape in preparation of removing half of the circular strip of adhesive on the clear section.
7. The sterile person verifies that the clear section is centered. As the non-sterile person removes the table backing from the top of the bore downward (one side only) the sterile person adheres the clear section to the bore. The adhesive tape should be approximately 6” to 12” into the bore.
8. Repeat on the other side of the bore on the surgical end.
9. The non-sterile person removes the remaining adhesive on the sides of the blue Drape and the remainder of the surgical Drape is attached.
10. Returning to the diagnostic end, pull the Drape contents back onto the diagnostic table if they have moved into the bore.
11. Un-fold the diagnostic table portion of the Drape (tab #2) along the table. **DO NOT UNFOLD THE SIDES OF THE DRAPE AT THIS TIME. See Figure 12.**



Figure 12: *Diagnostic portion of drape prior to un-folding.*

12. This will expose the top left and right corners of the drape. **See Figure 13.**

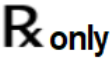


Figure 13: *Diagnostic table portion with tabs exposed*

13. Attach the diagnostic end in the same manner as the surgical end with the following reminders:
- Verify the clear section is straight in the bore (white line up, 12 o'clock position).
 - Adhere only the top of the Drape first being sure to pull the top of the clear, inner section tight while doing so.
 - While removing the tape on the inner clear (bore) section and adhering it to the bore, keep each section tight so the bore is as tight as possible.
14. Finish attachment by removal of the adhesive (non-sterile person) from the diagnostic sides of the drape.
15. The final step is to unfold the diagnostic table Drape so it covers the sides of the diagnostic table.
16. Perform intended procedure only after Patient Drape is installed.

C. **Post Procedure - Bore Drape**

1. Release the surgical end of the blue Drape and place inside the bore.
2. Release the surgical end of the clear bore Drape from the bore.
3. Release the diagnostic table end of the clear bore Drape from the bore.
4. Pull the clear bore Drape onto the diagnostic table.
5. Release the diagnostic end of the blue Drape and fold on top of the clear Drape.
6. Fold or roll the contents down the diagnostic table and finish by bringing the sides up to enclose the bundle.
7. Dispose of Drape per standard hospital practice.

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

Manufactured by:



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