PURPOSE:
This policy outlines the necessary MRI screening and scanning requirements to provide a safe environment for patients with Depuy Synthes and Stryker (Hoffman III) external fixator devices.

POLICY STATEMENT:
All patients requiring an MRI with Depuy Synthes and Stryker (Hoffman III) external fixator devices shall be screened and scanned as outlined below.

ENTITIES AFFECTED BY THIS POLICY (SCOPE):
Imaging Services MRI Technologists at the Raleigh and Cary Campuses

WHO SHOULD READ THIS POLICY:
This policy should be read by the MRI Technologists at the Raleigh and Cary campuses, the radiologists and any provider that orders an MRI on a patient with a Depuy Synthes and Stryker (Hoffman III) external fixator. Furthermore, any individual considering issuing, revising, assisting in the drafting of, or archiving this policy should read it.

PROCEDURES:

Overview

I. Currently there are two External Fixator systems being used at WakeMed: Depuy Synthes and Stryker (Hoffman III) The Synthes is the most commonly used system. Very rarely a patient may be transferred to WakeMed with an external fixator placed at an outside facility. External fixator devices other than Depuy Synthes or Stryker (Hoffman III) will not be scanned.

   a. The Depuy Synthes external fixator literature for the MRI conditional devices states the device is MR conditional at 1.5T and 3T, regarding displacement, torque, and RF heating. The manufacturer states the external fixator may be safely scanned with the fixator frame positioned outside the MRI bore and specific absorption rate (SAR) of 2 W/kg at normal operator mode and 4 W/kg for first level-controlled mode for 15 minutes of scanning. The spatial gradient magnetic field should be no higher than 720-Gauss/com. To minimize heating the device should be as far as possible from the edge of the bore.

   b. The Stryker (Hoffman III) external fixator literature states that the device is MR Conditional at 1.5T only and has clearly identified colors and

labeling of the components identifying them as MR conditional. The manufacturer states the external fixator may be safely scanned with the fixator positioned outside the bore and a SAR of 2 W/kg for 15 minutes of scanning under normal operating mode. The spatial gradient magnetic field should be no higher than 900-Gauss/cm.

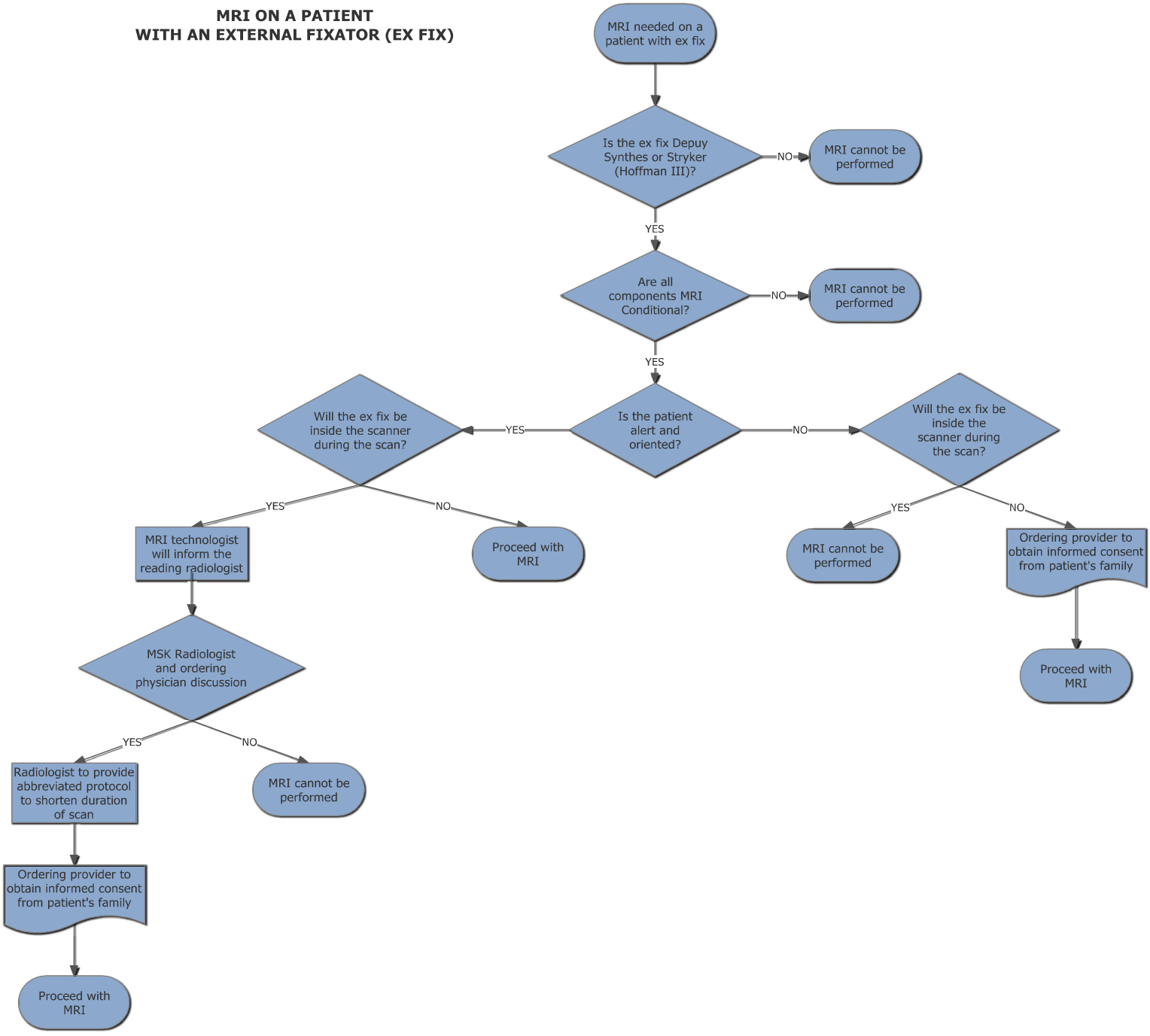
II. Providers, radiologists and MRI technologists will adhere to the following procedure regarding patients with external fixators covered under this policy. This procedure is necessary to ensure patient safety during the MRI exam and should be performed prior to the patient entering the MRI scanner room (Zone IV).

a. All patients will be assessed prior to scanning following the MRI screening procedure. If the patient has a contraindication to MRI, the exam will not be performed.

b. The MRI Technologist will determine the MRI safety status of the external fixator device through review of surgical reports to confirm all parts of the external fixator used are MRI conditional. If any part of the device is MRI unsafe the MRI will not be performed.

c. The following flowchart shall be used to determine if the MRI can or cannot be performed:

MRI ON A PATIENT WITH AN EXTERNAL FIXATOR (EX FIX)



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Approved by: *IMAGING SERVICES LEADERSHIPIMAGING SERVICES LEADERSHIP*
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III. If the patient is able to proceed with the MRI, the MRI technologist will perform the following steps:

a. The external fixator will be positioned so that it does not come in contact with the bore of the scanner.

b. Cold packs will be placed at the pin-skin interfaces to minimize potential skin burns.

c. The knee coils will not be used to scan extremities with an external fixator in place because these coils are transmit/receive. Local receive only coils (e.g. flex coils, body array coils) will be used for extremities with external fixators in place.

d. If the patient is alert and oriented there will be communication between the performing technologist and the patient at the end of each sequence to determine whether the patient is experiencing any heating or discomfort at the external fixation site. If the patient is not alert the technologist will check the pin-skin interfaces between each sequence for heating. If the skin is hot to the touch the MRI will be aborted.

e. The technologist, with guidance from the radiologist, will keep the scan time as short as possible while still obtaining diagnostic images. The specific absorption rate (SAR) levels will be kept as low as possible when the external fixator is inside the bore. The SAR level must not go higher than normal operator mode at any time when a patient with an external fixator is being scanned, regardless of whether it is positioned inside or outside of the scanner.

f. The technologist will get radiologist approval of all acquired images prior to getting the patient off of the MRI table. The radiologist will determine if the images are of diagnostic value regarding sequence type, artifact and indication for the MRI.

g. In the event the patient experiences any heating or discomfort the scan should be aborted immediately and the patient removed from the scanner.

i. At the time symptoms occur, the sequence that was running should be recorded and documentation sent to the MRI Supervisor. This will enable possible identification in the future to allow for modified MRI protocols without adverse experiences.

ii. In the event of such an occurrence, the radiologist as well as the ordering provider should be notified immediately. The radiologist, ordering provider or nurse must assess the patient as soon as possible. The MRI Technologist will complete an incident report.

DEFINITIONS:
The U.S. Food and Drug Administration has a labeling criterion, created by the American Society for Testing and Materials (ASTM) International, which is used to designate portable metallic objects as MR safe, MR conditional and MR unsafe when introduced into Zone IV.

MR Safe is defined as "An item that poses no known hazards in all MRI environments. Using the terminology, "MR Safe" items are non-conducting, non-metallic, and non-magnetic items such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data."

MR Conditional is defined as "An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. "Field" conditions that define the MR environment include static magnetic field strength, spatial gradient magnetic field, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system), may be required."

MR Unsafe is defined as "An item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors."

THIS POLICY IS CROSS REFERENCED IN:

I. ASSOCIATED DOCUMENTS
a. MRI - Safety

II. ADDITIONAL RESOURCES
a. MRI Screening Form

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