Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Wear Face Masks with No Metal During MRI Exams

Device/ Product Description:	Face Masks
Problem:	Patients may be injured if they wear face masks (such as surgical or non-surgical masks and respirators) with metal parts and coatings during a Magnetic Resonance Imaging (MRI) exam. Metal parts, like nose pieces sometimes called nose clips or wires, nanoparticles (ultrafine particles), or antimicrobial coating that may contain metal (such as silver or copper), may become hot and burn the patient during an MRI.
Recommendation /Actions:	 Patients and Caregivers shall not wear a face mask containing metal parts, like a bendable nose piece or staples on the headband, nanoparticles, or antimicrobial coating that may contain metal, when having an MRI. An alternative face mask where the absence of metal can be confirmed should be used If the absence of metal cannot be confirmed. Alternatively, when this is not possible, metallic components from a face mask should be removed prior to, or when necessary, upon the patient's arrival at the MR suite. MRI examinations with non-MR Conditional masks is strongly discouraged. If absolutely necessary for unanticipated reasons, lowering SAR values and/or shortening RF transmission durations and/or introducing cool-down periods between scans may help minimize the risks of patient injury. Note: These will all result in longer study times for that patient. If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center

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