

## RADIATION FACT SHEET

### WHAT IS RADIATION AND HOW ARE WE EXPOSED TO IT?

- The Centers for Disease Control and Prevention defines radiation as energy that comes from a source and travels through space at the speed of light. This energy has an electric field and a magnetic field associated with it, and has wave-like properties. You could also call radiation "electromagnetic waves."
- We are exposed to radiation through a few different ways. This includes in *medicine* through medical imaging, including plain radiographs, fluoroscopy, and CT-scans. We can also be exposed during *travel* through airport security screenings and in flight.
- Radiation exposure can also occur through UV rays, nuclear weapons testing, and other mechanisms.
- The type of radiation from radiographic imaging is ionization radiation.
- Ionizing radiation can damage DNA cells, which can repair themselves, but not always or entirely. The result is DNA mutations that may contribute to cancer and other diseases years later.

### WHAT ARE THE NEGATIVE EFFECTS OF RADIATION EXPOSURE?

- The FDA recognizes there are negative side effects to radiation exposure, in particular, after prolonged, high-dose exposure.
- A Joint Commission Sentinel Event Alert report issued in 2011, states that even though diagnostic radiation is an effective tool that can save lives, the higher the dose of radiation delivered at any one time, the greater the risk for long-term damage.<sup>1,2</sup> If a patient receives repeated doses, harm can also occur from the cumulative effect of those multiple doses over time.<sup>3,4,5</sup>
- A number of studies have shown a link between radiation exposure and serious health issues such as cancer, heart disease, cataracts and more.
  - One study concluded 50% of interventional cardiologists and 41% of nurses and technicians showed signs of cataracts because of overexposure to ionizing radiation.<sup>6</sup>
  - Potential adverse effects of radiation include coronary artery disease, pericarditis, cardiomyopathy, valvular disease and conduction abnormalities. The risk is life long, and absolute risk increases with length of time since exposure.<sup>7</sup>

### *Spine/orthopedic surgery*

- Spine surgeons are particularly at risk due to their high exposure to radiation via use of x-ray imaging.
- A spine surgeon will exceed his/her radiation exposure lifetime limit in 10 years of practice, per the National Council on Radiation Protection's current recommendations of lifetime dose limits.<sup>8</sup>
- Spine surgeons can sustain a 10-12x greater radiation exposure as compared with surgeons using fluoroscopy for nonspinal procedures, as observed in fluoroscopically assisted pedicle screw insertion

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<sup>1</sup> [https://www.jointcommission.org/assets/1/18/SEA\\_471.PDF](https://www.jointcommission.org/assets/1/18/SEA_471.PDF)

<sup>2</sup> A sentinel event is defined as an unexpected occurrence involving death or serious physical/psychological injuries or risk thereof.

<sup>3</sup> Amis ES Jr, Butler PF, Applegate KE, et al. American College of Radiology white paper on radiation dose in medicine. *J Am Coll Radiol* 2007;4(5):272-84.

<sup>4</sup> Holmberg O, Malone J, Rehani M, et al. Current issues and actions in radiation protection of patients. *Eur J Radiology* 2010;76(1):15-19.

<sup>5</sup> Smith-Bindman R, Lipson J, Marcus R, et al. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. *Arch Intern Med* 2009;169(22):2078-86.

<sup>6</sup> Vano E, Kleiman NJ, Duran A, et al. Radiation-associated lens opacities in catheterization personnel: results of a survey and direct assessments. *JVIR* 2013;24(2):197-204.

<sup>7</sup> Adams MJ, Hardenbergh PH, Constine LS, et al. Radiation-associated cardiovascular disease. *Crit Rev Oncol/Hematol* 2003;45(1):55-75.

<sup>8</sup> Ul-Haque M, Shufflebarger HL, O'Brien M, et al. Radiation exposure during pedicle screw placement in adolescent idiopathic scoliosis: is fluoroscopy safe? *Spine* 2006;31(21):2516-20.

procedures.<sup>9</sup> In short, spine surgeons receive 10 to 12 times more radiation than other surgeons using fluoroscopy.

- Orthopedic surgeons have a 5x higher risk of cancer than other surgeons.<sup>10</sup>
- Patients who undergo spine surgery have an increased cancer risk, and this risk increases as the patient's pathology requires multiple surgeries:
  - A female undergoing a one-level TLIF procedure will have a 1% increase in risk of getting cancer.<sup>11</sup>
  - A female being treated for adolescent idiopathic scoliosis (AIS) will have a 2% increase in risk of getting cancer.<sup>12</sup>

#### *MIS surgery*

- During minimally invasive surgery (MIS), surgeons rely on fluoroscopy to assist with e.g., pedicle screw placement as in the case of an MIS TLIF, an increasingly popular spine surgery procedure.
- MIS limits visualization compared to a traditional open approach because it uses a smaller incision size. This results in an increased reliance on fluoroscopy. The potential exists for both the surgeon and the patient to become exposed to significant amounts of radiation.<sup>13</sup>
- MIS TLIF procedures require more than twice the amount of intraoperative fluoroscopy when compared to a similar open procedure.<sup>14</sup>

#### **WHAT ARE WAYS TO REDUCE EXPOSURE?**

##### *ALARA principle*

- According to the CDC, the guiding principle of radiation safety in medical imaging is "ALARA."
- ALARA stands for "as low as reasonably achievable."
- Abiding by this principle means healthcare providers will make every reasonable effort to maintain exposure to ionizing radiation as far below the dose limits as practical.
- This goes for not only the patients being operated on, but also the healthcare practitioners in the OR.

##### *Low-dose imaging*

- Most C-arms used in the OR for imaging offer an option to lower the amount of radiation used when taking a shot.
- Lowering the dosage in the C-arms to the lowest possible dose prior to taking a shot is a step toward abiding by the principles of ALARA.
- GE C-arms have the capability to decrease the amount of radiation by 95%.
- A common challenge with low-dose images is that the quality significantly decreases so it becomes more difficult to see the operative site. This can make surgeons feel uncomfortable relying on low-dose images.

##### *Lead shielding*

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<sup>9</sup> Rampersaud YR, Foley KT, Shen AC, et al. Radiation exposure to the spine surgeon during fluoroscopically assisted pedicle screw insertion. *Spine* 2000;25(20):2637-45.

<sup>10</sup> Mastrangelo G, Fedeli U, Fadda E, et al. Increased cancer risk among surgeons in an orthopaedic hospital. *Occup Med* 2005;55(6):498-500.

<sup>11</sup> Bindal RK, Glaze S, Ognoskie M, et al. Surgeon and patient radiation exposure in minimally invasive transforaminal lumbar interbody fusion. *Neurosurg* 2008;9(6):570-3.

<sup>12</sup> Presciutti S, Karukanda T, Lee M. Management decisions for adolescent idiopathic scoliosis significantly affect patient radiation exposure. *Spine* 2013;14(9):1984-90.

<sup>13</sup> Bindal RK, Glaze S, Ognoskie M, et al. Surgeon and patient radiation exposure in minimally invasive transforaminal lumbar interbody fusion. *Neurosurg* 2008;9(6):570-3.

<sup>14</sup> McClelland S, Goldstein J. Minimally invasive versus open spine surgery: What does the best evidence tell us? *J Neurosci Rural Pract* 2017; 8(2):194-98.

- Lead shielding refers to the use of lead as a form of radiation protection to shield people or objects from radiation so as to reduce negative side effects of radiation exposure.
- Lead helps protect from radiation because of its high molecular density. It can be effective at stopping gamma rays and x-rays from reaching the body and is used in applications ranging from x-ray imaging to nuclear reactors.
- Studies have shown that lead shielding does not protect against all radiation exposure. While it can protect the parts of the body that are closest to the x-ray source, much of it still gets through.
  - About a third of the radiation the surgeon is exposed to gets through the thyroid shield.<sup>15</sup>
  - 84% of the radiation that hits the spine surgeon's chest gets through the lead apron and hits the level of the groin.<sup>16</sup>
- Even wearing lead, spine surgeons will exceed their lifetime occupational radiation limit in ten years.<sup>17</sup>

#### FDA programs

- The FDA's Center for Devices and Radiological Health (CDRH) is responsible for radiation safety programs that involve enforcement of mandatory requirements in addition to partnerships and voluntary programs that promote the safe use of radiation-emitting products.<sup>18</sup>
- The goal of these programs is to ensure that the public and professionals alike are informed of the risks posed by different types of radiation emissions and radiation-emitting products. It is also to balance the beneficial use of radiation by trying to limit each patient's exposure to only the lowest necessary radiation dose using the appropriate, medically necessary imaging exam at the appropriate time.
- Notable CDRH programs:
  - Initiative to Reduce Unnecessary Exposure from Medical Imaging: includes education and communications, appropriate use, equipment safety features, tracking radiation safety metrics, and more.<sup>19</sup>
  - NEXT survey: The Nationwide Evaluation of X-ray Trends (NEXT) survey program was initiated in 1972 and captures annual radiation exposure data from a nationally representative sample of U.S. clinical facilities.<sup>20</sup>

#### LessRay®

- LessRay is an image-enhancement platform which integrates with a standard C-arm and substantially improves the quality of low-dose images.
- When viewed on LessRay, low-dose images have similar diagnostic capabilities to full-dose images.
- This proprietary imaging algorithm results in significantly reduced radiation emissions in the O.R. LessRay helps to reduce radiation emissions by ~75% compared to standard fluoroscopy.<sup>21</sup>
- One study showed LessRay-enhanced imaging resulted in 84% less radiation emission during a cadaveric comparison of radiation exposure during a kyphoplasty procedure.<sup>22</sup>

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<sup>15</sup> UI Haque M, Shufflebarger HL, O'Brien M, et. al. Radiation exposure during pedicle screw placement in adolescent idiopathic scoliosis: is fluoroscopy safe? *Spine* 2006;31(21):2516-20.

<sup>16</sup> Bindal RK, Glaze S, Ognoskie M, et al. Surgeon and patient radiation exposure in minimally invasive transforaminal lumbar interbody fusion. *Neurosurg* 2008;9(6):570-3.

<sup>17</sup> UI Haque M, Shufflebarger HL, O'Brien M, et. al. Radiation exposure during pedicle screw placement in adolescent idiopathic scoliosis: is fluoroscopy safe? *Spine* 2006;31(21):2516-20.

<sup>18</sup> <https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/>

<sup>19</sup> <https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/default.htm>

<sup>20</sup> <http://www.crcpd.org/page/NEXT>

<sup>21</sup> Wang TY, Farber SH, Perkins SS, et. al. Internally randomized control trial of radiation exposure using ultra-low radiation imaging versus traditional C-arm fluoroscopy for patients undergoing single-level minimally invasive transforaminal lumbar interbody fusion. *Spine* 2017;42(4):217-23.

<sup>22</sup> Karikari IO, Brown C, Anderson G, et. al. Reducing radiation an order of magnitude during fluoroscopic-guided kyphoplasty. *Neurosurg* 2016;63(Suppl 1):S167.