CFI MEDICAL

RADIATION EXPOSURE IN THE INTERVENTIONAL LAB:

THE MEANING BEHIND THE NUMBERS

INTRODUCTION

As the use of fluoroscopic imaging in cardiovascular and radiologic interventional procedures continues to rise, many are beginning to express concern that the current institutional safety protocols are not enough to adequately protect medical staff from health risks associated with radiation exposure and the musculoskeletal consequences of wearing heavy lead shielding during these procedures.

Interventionists experience radiation coming from the fluoroscopy unit in three different ways. The first is primary radiation, which comes directly from the fluoroscopy unit. Secondary, or primary scatter radiation, is reflected off of the patient or table before coming into contact with the interventionist. The third is tertiary, also known as secondary scatter radiation, which is reflected off of walls, other people, or other equipment before coming into contact with the interventionist.

Radiation emissions is a natural product of fluoroscopy, and is important to study due to the serious medical effects it can have on the body. Continued exposure to radiation may result in cancers and also genetic effects. It has been recognized that persons working in interventional environments tend to develop fluoroscopy-related illnesses including leukemia, thyroid disease, and cataracts at a higher incidence than other medical personnel.

In order to combat the effects of radiation exposure, lead shielding was developed to protect patients and radiologists. The traditional standard for personal protection is a heavy, one-piece lead apron, supported by the back, shoulders, and neck. Over time, this weight results in musculoskeletal stress and possible damage leading to early retirement. A recent SCAI survey revealed that nearly half of interventional cardiologists suffer at least one orthopedic injury as a result of their work. Due to this high incidence of injury, more effective, safer methods of radiation shielding are necessary to protect those who are occupationally exposed.

RADIATION MEASUREMENTS

In order to understand the effectiveness of various forms of radiation shielding, the way radiation itself is measured must be understood. Radiation is measured in four ways, which can be remembered by the mnemonic device R.E.A.D; for radioactivity, exposure, absorbed dose and dose equivalent.

Radioactivity - is ionizing radiation released by the material. Quantities of radioactive materials are expressed in terms of radioactivity, or how many atoms decay in a given time period. Radiation is measured in units of curie (Ci) or Becquerel (Bq).

Exposure - is the amount of radiation traveling through the air. Most radiation monitors measure exposure, measured in units of roentgen (R) and coulomb/kilogram (C/kg).

Absorbed dose - is the amount of radiation absorbed by a person or object, and is measured in radiation absorbed dose (rad) or gray (Gy).

Dose equivalent (effective dose) - combines the radiation absorbed and the medical effects of that type of radiation on the body and is measured in roentgen equivalent in man (rem) or sieverts (Sv).

Effective doses are commonly expressed in millirems, (mrem, or thousandths of a rem) or as microSieverts (μSv, or millionths of a Sv). It is important to recognize the relationships between these units. For example, for gamma rays, 1 R (exposure) roughly equates to 1 rad (absorbed dose) and to 1 rem, (1000 mrem) or 10,000μSv (dose equivalent).

1 R	≅	1 rad	≅	1 rem (1000 mrem)	=	10,000μSv
100 mR	≅	100 mrad	≅	100 mrem	=	1 mSv
1 mR	≅	1 mrad	≅	1 mrem	=	10μSv

DOSE LIMITS

European Standard

When studying the effectiveness of radiation shielding, understanding dose limits is crucial. According to the European Nuclear Society, the effective dose for various parts of the human body must not surpass the following:

Tissue or Organ	Limit (mSv/year)	Limit (rem/year)
Effective Dose	20 mSv/year	2 rem/year
Bone marrow (red), gonads, uterus	50 mSv/year	5 rem/year
Adrenals, bladder, brain, breast, lens of eye*, small intestine, upper large intestine, kidney, liver, lung, muscle, esophagus, pancreas, spleen, stomach, thymus	150 mSv/year	15 rem/year
Bone surface, thyroid	300 mSv/year	30 rem/year
Ankles, feet, forearms, hands, skin	500 mSv/year	50 rem/year

*There is speculation that the European standard for eye exposure may be drastically reduced in the near future.

American Standard

According to the United States Nuclear Regulatory Commission, (U.S.NRC) an individual adult has an annual limit of 5 rem/year; OR the sum of the deep-dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye, which should be less than or equal to 50 rem/year.

The deep-dose equivalent is the external body's exposure dose equivalent at a tissue depth of 1 cm. The committed dose equivalent is the dose to a specific organ or tissue.

Tissue or Organ	Limit (mSv/year)	Limit (rem/year)
Effective Dose	50 mSv/year	5 rem/year
Deep-Dose Equivalent + Committed Dose Equivalent	500 mSv/year	50 rem/year
Lens of eye	150 mSv/year	15 rem/year
Skin of whole body or extremity	500 mSv/year	50 rem/year

The American radiation standards are slightly less stringent than European standards, allowing for a total of 3 more rem per year as the effective dose, and provides limits for a secondary calculation. However, the standard for skin exposure is the same for both (500 mSv/yr or 50 rem/yr).

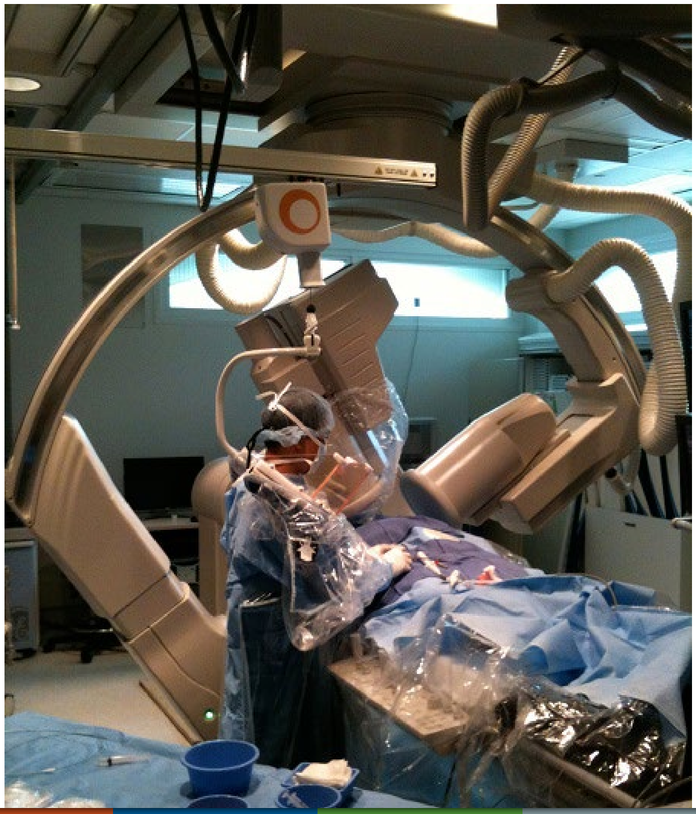
ALARA

Knowing the limits that are set for occupationally exposed persons allows us to measure the effectiveness of radiation shielding, and how we might lower the amount of radiation interventionists are exposed to throughout their career. All radiation shielding is subject to ALARA, which is an acronym for As Low As Reasonably Achievable, and is the radiation safety guiding principle for minimizing radiation doses and releases of radioactive materials.

ALARA assumes that there is no "safe" level of exposure to radiation, and that all measures should be taken to reduce any and all exposures by employing any and all reasonable methods.

ALARA adheres to six basic principles, which include:

1. eliminating or reducing the radioactive source,
2. containing the source,
3. minimizing the time spent in a radiation field,
4. performing optimizing analyses,
5. using radiation shielding, or
6. maximizing the distance from the source of radiation.



EXPOSURE CATEGORIES

There are several sources of radiation in the catheterization laboratories.

Background radiation is from the earth and cosmic rays and ranges in Europe from approximately 2- 7 mSv/year (200 – 700 mRem) and is not of importance for radiation safety considerations.

The predominant source of exposure to the patient is from the **primary beam** which exits the tube and is absorbed by the patient or transmitted through the patient to the image receptor to form the image. A portion of it also emitted from the patient in all directions and is called **primary scatter**, which is the major source of operator exposure.

Protection from **primary scatter** is challenging due to its wide dispersal and the need for the operator to be able to access the patient, thereby creating a challenge to the interposition of expansive and thick shields, and a limit on how much weight they can bear on their heads and bodies to support protective clothing and headgear, as well as a need for proximity to the source.

The final source of exposure is **secondary scatter** emitted from other objects in the room as a result of exposure to the primary scatter. It is extremely small due the effects of the inverse square law and the very low ratio of scattered to absorbed radiation from the objects. It is generally estimated to be approximately one one thousandth of the incident radiation at one meter distance, which in the case of walls and room objects has already been drastically reduced by the inverse square law due to their distance from the source of primary scatter (the patient). Secondary scatter has therefore not been an object of concern for protective gear and methods, being so small compared to the primary scatter arising from the patient and to which the operator is exposed, and is why the traditional one piece 0.5 mm thick lead apron focuses on protecting operators from the front and sides, with rear protection not being a major consideration. The drawback of protective clothing is that it is limited by how much weight the operator can bear, and leaves the head and lower extremities vulnerable to primary radiation exposure. In addition, it tends to cause weight-related musculoskeletal problems.

Leakage from the tube due to defects in its shielding comprises a minor source of exposure to workers, and should be periodically checked by safety officers.

In summary, the operator in a cath lab is exposed to three sources of man-made radiation, which are collectively referred to as **"stray radiation"**:

- Tube housing leakage (minor unless defects present),
- Primary scatter from the patient and table (by far the major source of exposure to the interventionist and the subject of protective measures geared towards protection of their front and sides), and
- Secondary scatter from other objects in the room (minor and not requiring shielding)

RADIATION EXPOSURE EFFECTS

Doctor Lloyd Klein, MD, a professor of medicine at Rush Medical College in Chicago, best sums this issue up in his op-ed article, "Take A Stand on Cath Lab Health Hazards," where he reports that *"I know of physicians in my community who have died of brain cancers and developed leukemia. Others have developed early cataracts and some have retired early or left the lab because of neck and back issues."*

The facts stand with Dr. Klein. The SCAI survey he references reveals that nearly half of interventional cardiologists have suffered one or more orthopedic injuries as a direct result of their work in the cath lab with 7% having to limit the number of procedures they perform due to radiation exposure and 9% taking a health-related leave of absence.

PERSONAL RADIATION PROTECTION ALTERNATIVES

In an effort to provide protection from radiation exposure, several personal radiation protective devices and configurations have been developed. Here are some of the more popular ones:

The traditional **one piece lead apron**, while being reasonably effective at providing the desired level of protection, has been identified by many as the weighty culprit in causing musculoskeletal strain resulting in career limiting neck, back, hip, knee and ankle issues and does not protect the head, eyes or throat. Other alternatives include:

- **vest and skirt** configuration - designed to combat the weight issues by distributing the weight more evenly between the shoulders and waist
- **wrap-around style** with a 0.25 mm lead equivalency, with 0.5 mm protection in the overlap areas
- **throat shields** that wrap around and protect the throat
- **leaded glasses** to protect the eyes of the operator
- **protective caps** to protect the operator's head
- **alternative materials** that provide a degree of **lead equivalency** protection, but are lighter
- **robotics and remote cabins** that are quite expensive and remove the operator from direct access to the patient
- **suspended total body shield** that removes the weight of the flexible shield from the operator and includes a lead-acrylic shield to protect the head and throat of the operator.

In some protective apparel items all three alternatives - the skirt and vest configuration, wrap-around style and alternative materials - are combined in an attempt to provide safety from radiation exposure and musculoskeletal issues. However, the skirt and vest configuration, if designed in a way to provide the same lead protection of the traditional one piece apron, still exerts the same level of stress on the hips, knees and ankles. The wrap-around style may provide adequate protection in the overlap (front) area, but it leaves the sides inadequately protected.

The throat shield, eye shield and lead glasses are essential add-ons for the traditional one-piece lead apron and its popular alternatives.

The use of alternative metals, including titanium, barium, or bismuth, was tested by the Health Physics Society and resulted in an article called Lead Garments (Aprons, Gloves, etc.). This study showed that a titanium apron would have to be 16.4 times as thick and weigh about 6.6 times as much as a lead apron to provide the same degree of radiation protection. This finding effectively proves that alternative materials are not the answer.

Robotics and remote cabins certainly protect the operator from radiation exposure and musculoskeletal stress, but in doing so, they remove that operator from the side of the patient, and the hospital incurs a very significant expense.

The total body shield eliminates the musculoskeletal stress on the operator by suspending the flexible lead shield from a ceiling-mounted or floor-supported boom. This provides maneuverability along with easy access to the patient.

The Zero-Gravity™ Total Body Shield is such a suspended personal protective system. It utilizes a 1.0 mm lead shield that protects the entire torso, upper arms and legs and engages magnetically to a vest worn by the operator under their sterile gown so it can move with them or be easily moved out of the way when not needed. In addition, it also employs a 0.5 mm lead equivalent lead-acrylic face shield that protects the head, eyes and throat of the operator.

PROTECTION COMPARISONS

Chet Rees, MD, an Interventional Radiologist at Baylor University in Texas, compared the attenuation characteristics of the traditional one-piece lead apron, wrap-around vest & skirt configurations and the Zero-Gravity™ Total Body Shield. He found the following:

Device	Style	Exposure To Operator (uSV/h)	Transmission (%)	Exposure Relative to Zero Gravity™
None		478.3	100.0%	119.6
Skirt and Vest #1	Wrap-around, frontal overlap	83.5	17.5%	20.9
Skirt and Vest #2	Wrap-around, front overlap	41.7	8.7%	10.4
Skirt and Vest #3	Wrap-around, no frontal overlap, partial back coverage	36.5	7.6%	9.1
Apron	No back coverage or overlap	15.4	3.2%	3.8
Zero-Gravity™	No back coverage or overlap	4.0	0.8%	1.0

A graphic representation of the dose to operator follows:

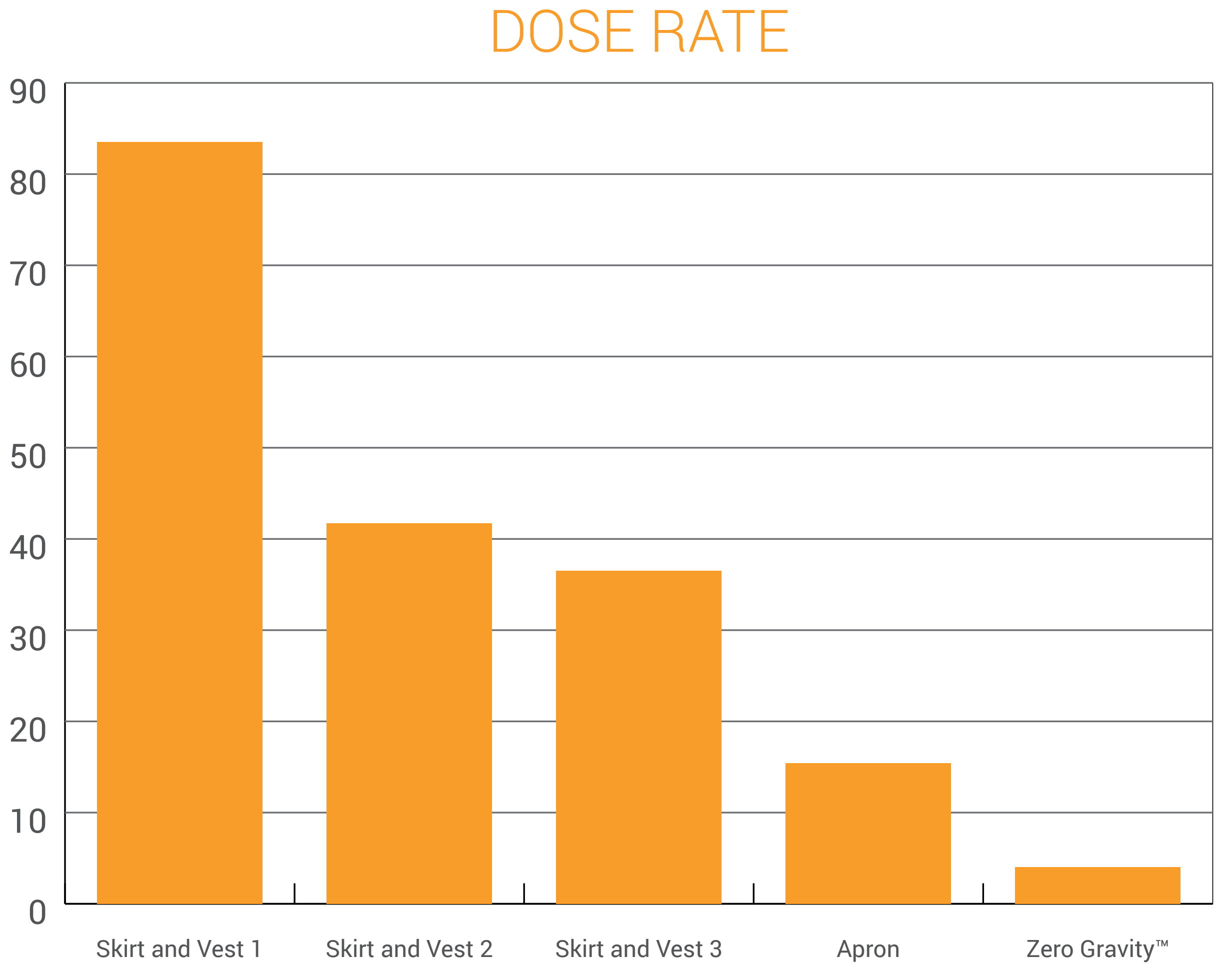


Figure 1

This study shows that, although the two leading protective garments, the single piece design lead apron and Zero-Gravity™, have no back coverage, they both provide the greatest degree of attenuation and protection. This is because operator exposure depends on the attenuating capacity of the material in the path of the primary scatter to a much greater degree than it depends on back coverage. Primary scatter is vastly greater than the relatively inconsequential secondary scatter (that which could reach the back) in intensity.

PROTECTING THE EYES AND BRAIN

While the established limits are designed to provide a level of protection from the deleterious effects of radiation exposure, there is good reason to be cautious of any exposure that is greater than that which is As Low As Reasonably Achievable. The need for this ALARA philosophy, as applied to radiation exposure, is well presented in a recent study that relates the effects of radiation to left-sided brain tumors and another study that addresses the occurrence of cataracts in interventional physicians.

The Zero-Gravity™ system not only protects the body of the operator, but the eyes and brain as well. This pictorial presentation clearly depicts the degree to which the lead/acrylic face shield of the Zero-Gravity™ system provides protection to the eyes and head of the interventionist compared to conventional protective clothing.
This graphic makes it easy to see the difference in radiation protection. Operators using the Zero-Gravity™ system were exposed for much longer periods of time, with minimal exposure doses. It is important to take note that the operator using the Zero-Gravity™ received only 1.2% of the dose experienced by the unprotected one. Operators may spend more time working while protected by the Zero-Gravity™, but their exposure is drastically reduced, while experiencing no stress on the musculoskeletal system.

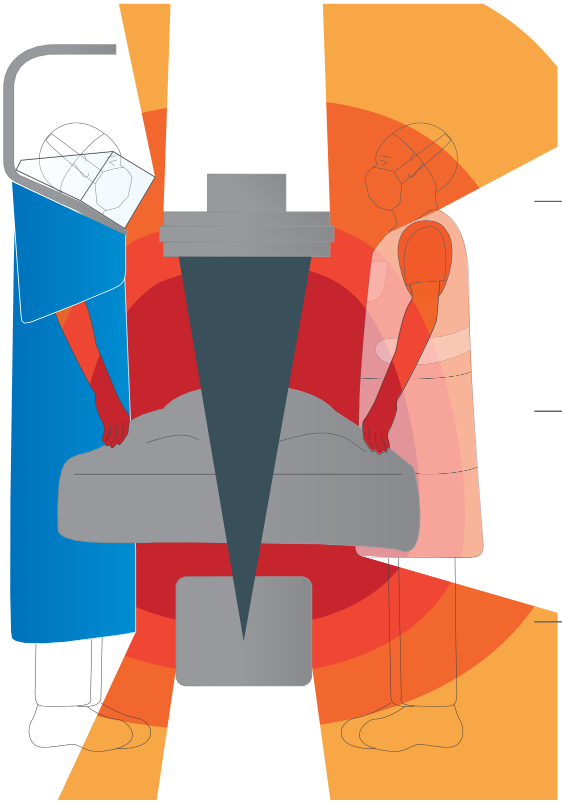
Zero-Gravity vs. Conventional Lead Shields

Comparison of operator eye exposures when working from femoral region, side or head of patient.[7]

HEAD
215 Fluoroscopy Minutes
0.022 Operator Exposures (microSV/min)

SIDE
67 Fluoroscopy Minutes
0.035 Operator Exposures (microSV/min)

FEMORAL
47 Fluoroscopy Minutes
0.013 Operator Exposures (microSV/min)



HEAD
97 Fluoroscopy Minutes
1.817 Operator Exposures (microSV/min)

SIDE
32 Fluoroscopy Minutes
4.762 Operator Exposures (microSV/min)

FEMORAL
35 Fluoroscopy Minutes
3.466 Operator Exposures (microSV/min)

THE COST OF PROTECTION

Maybe it is a better approach to pose the question, "What is the cost of improper or inadequate protection?" We have already seen that heavy one piece lead aprons, while providing adequate protection to the body, do not provide protection to the eyes, brain or throat of the operator. In addition, they improperly put potentially debilitating stress on the neck, spine, hips, knees and ankles. These inadequacies lead to excessive radiation exposure to vital organs of the operator on the one hand and to excessive muscular strain on the other. Both of these situations can lead to lost days of work and shortened careers for the physician and loss of patient procedure volumes and reimbursements for the hospital.

The ALARA concept can be applied to all three considerations involved in radiation protection:

- the amount of radiation exposure experienced,
- the amount of physical stress and strain endured, and
- the amount of monetary investment required.

They should all be as low as reasonably achievable.

One Piece Lead Apron

The traditional one-piece lead apron provides the protection to the body, but not to the throat, eyes, brain, the lower legs or arms. The armhole is quite large and allows considerable exposure to the chest especially with many vascular procedures where the scatter is predominantly from the side. It is relatively inexpensive, but creates significant stress on the neck, back, hips, knees and ankles.

Score -

- **Radiation Exposure - Low**
- **Physical Stress - High**
- **Monetary Costs - Low**

Two Piece/Wrap-Around Garment

Some operators believe the two piece, wrap-around garments reduce back pain, although many still experience significant back and neck discomfort and disability. Attempts to reduce this by using lightweight materials and/or relying on full coverage in only the overlap zones leads to substantially reduced protection as shown in numerous studies and as seen in Table 1. The two-piece, wrap-around and alternative material configurations help to relieve the weight-related stress, but they tend to do so at the cost of providing adequate radiation exposure protection. Garments that are light and comfortable do not provide good protection and there are no miracle materials despite much of the marketing hype.

Score -

- **Radiation Exposure - Moderate to High**
- **Physical Stress - Moderate**
- **Monetary Costs - Low**

Robotic/Cabin Devices

The robotic and protective cabin devices appear to be able to totally protect the operator from the negative effects of both the radiation emissions and muscular strain, but at an extremely significant financial outlay and awkwardness of function.

Score -

- **Radiation Exposure - Very Low**
- **Physical Stress - Very Low**
- **Monetary Costs - High to Very High**

Zero-Gravity™

The Zero-Gravity™ suspended personal protective system by CFI Medical provides superior protection from radiation exposure to the body, brain and eyes of the operator compared to conventional protective clothing and shields. Being a suspended system, it eliminates the weight-bearing burden on the operator with great reductions in musculoskeletal stress. There is a moderate cost for acquisition and installation, but it is not unreasonable. The monetary costs are easily offset by a couple weeks of lost interventional procedures.

Score -

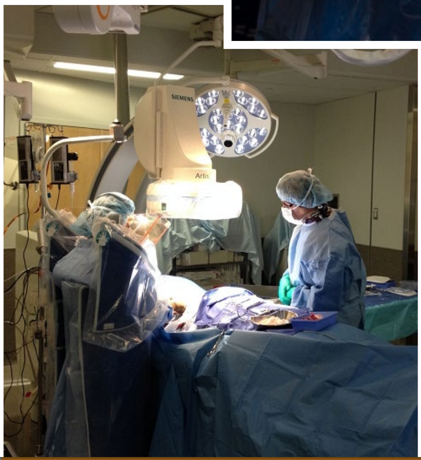
- **Radiation Exposure - Very Low**
- **Physical Stress - Very Low**
- **Monetary Costs - Moderate**

THE SOLUTION

The Zero-Gravity™ suspended personal radiation protection system should be the option of choice to minimize exposure, eliminate muscle strain, and keep expenses low, all in accord with the ALARA principles. The Zero-Gravity™ system is available in three different configurations to best meet your operational needs or financial constraints.

- The Floor Unit
- The Ceiling Mounted Monorail, and
- The Ceiling Mounted Monorail Hinged Swing Arm

Visit us at our website or call us at (810) 750-5300 for more information.



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