X-RAY DANGERS IN INTERVENTIONAL CATH LABS

RISKS, REGULATIONS
AND RADIATION PROTECTION SOLUTIONS

INTRODUCTION

Although the benefits of catheter-guided procedures are certainly unquestionable in terms of patient health outcome, X-rays used during these interventions are extremely harmful to the operator[1]. **Great attention is paid towards the minimization of exposure to the patient, however the occupational effects of cumulative dose for medical professionals are still underestimated.**

For instance, interventional cardiologists can reach an annual exposure two to three times higher than the one of diagnostic radiologists[2]. **The effect of X-rays is alarming on long term and can cause irreversible health damages. Since 1970s, among multiple health hazards, scientific litterature reveals cases of brain[3] and thyroid[4] tumors, cataracts[5], reproductive organ impairment[6], skin cancers[7], vascular disease[8] and DNA alterations[9].**

International and national authorities such as the ICRP (International Commission on Radiological Protection) strive to reduce the maximal dose received by the medical personnel. In this regard, advance is encouraging: as an illustration, the equivalent dose limit for the eye lens has been recently lowered from 150 mSv to 20 mSv to avoid cataract development. Unfortunately, personal dosimeters are often worn improperly or not worn at all[10]. The collected values can be therefore non-representative and much lower than the real dose that cath lab workers are receiving.

The use of existing individual and collective protection equipment is not sufficient to provide an optimal protection to the operators. **Protective aprons are effective only at the body zone that they are covering, and their weight may cause orthopaedic problems[11].** Besides, lead caps and glasses that cover body parts unprotected by the lead apron have a poor performance as far as scattered radiation is concerned[12].

Medical professionals can no longer continue to sacrify their long-term health.
Necessary measures have to be taken to ensure the safety of all.

[1] Andreassi MG, et al., *Occupational health risks in cardiac catheterization laboratory workers.* Circ Cardiovasc Interv. 2016 Apr;9(4).
[2] Picano E. et al., *Cancer and non-cancer brain and eye effects of chronic low-dose ionizing radiation exposure.* BMC Cancer, 2012 Apr 27;12:157.
[3] Roguin A. et al., *Brain and neck tumors among physicians performing interventional procedures.* Am J Cardiol, 2013 May 1;111(9):1368-72.
[4] Völzke H. et al., *Occupational Exposure to Ionizing Radiation Is Associated with Autoimmune Thyroid Disease,* J Clin Endocrinol Metab. 2005 Aug;90(8):4587-92.
[5] Miller D., et al., *Occupational Radiation Protection in Interventional Radiology: A Joint Guideline of the Cardiovascular and Interventional Radiology Society of Europe and Society of Interventional Radiology.* Cardiovasc Intervent Radiol, 2010 Apr; 33(2): 230–239.
[6] Latini G. et al., *Reproductive effects of low to moderate medical radiation exposure.* Current Medical Chemistry, 2012, 19:6171-6177.
[7] Balter S. et al., *Fluoroscopically guided interventional procedure: a review of radiation effects on patient’s skin and hair.* Radiology, 2010, 254, 326-41.
[8] Andreassi M. et al., *Subclinical Carotid Atherosclerosis and Early Vascular Aging From Long-Term Low-Dose Ionizing Radiation Exposure.* JACC: Cardiovascular Interventions VOL. 8, NO. 4, 2015.
[9] Acharya MM et al., *Consequences of ionizing radiation-induced damage in human neural stem cells.* Free Radic Biol Med 2010, 49:1846–1855.
[10] Padovani et al., *Reference levels at European level for cardiac interventional procedures. Radiat.* Prot. Dosimetry 2008. 129, 104–107.
[11] Klein LW, et al., *Occupational health hazards of interventional cardiologists in the current decade: Results of the 2014 SCAI membership survey.* Catheter Cardiovasc Interv. 2015;86:913–924.
[12] Fetterly K. et al., *Head and neck radiation dose and radiation safety for interventional physicians.* J Am Coll Cardiol Cardiovasc Intv. 2017 Mar 13;10(5):520-528.

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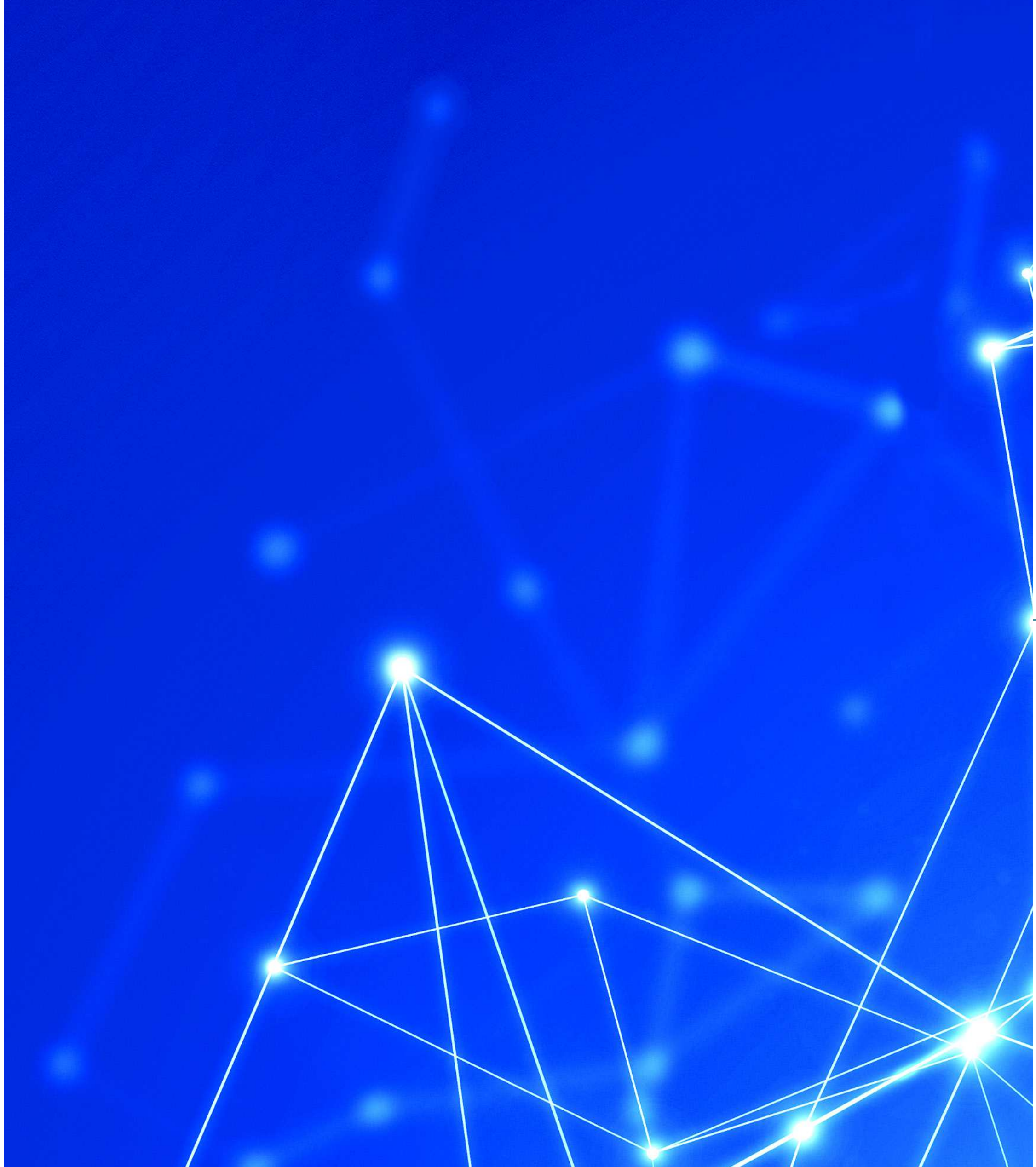
X-RAY EXPOSURE
CAUSES IRREVERSIBLE HEALTH DAMAGES



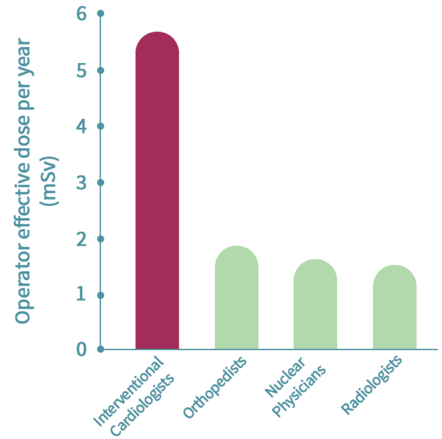
X-RAY EXPOSURE OF CATH LAB WORKERS
is much higher than the one of diagnostic radiologists

Interventional cardiologists can reach an annual exposure two to three times higher than the one of diagnostic radiologists. The use of X-rays during catheterization procedures raises particular awareness because of its extremely harmful effects. Great attention is paid to assure the minimum patient exposure, but what about the operators?

The safety of healthcare workers frequently receives far less consideration, neglecting the risks they experience and sacrifices they make on a daily basis to save other people's lives.

Whereas the patient is exposed to X-rays only during a limited timeframe, the medical staff deals with ionizing radiation on a consistent, repetitive basis. Each operator performs up to several hundred or even thousand of procedures per year, and the cumulative dose has to be taken into serious consideration.

Annual exposure of different physicians



Source: Picano E (2012)

Cardiologists in most high-volume cath labs can reach an annual exposure of more than 5 mSv[13]: a value two to three times higher than the one of diagnostic radiologists.

Interventional cardiologists accumulate a lifetime radiation exposure of 50 to 200 mSv, which corresponds to a whole body dose equivalent of 2.500 to 10.000 chest X-rays[1]

[13] Picano E., et al., The Radiation Issue in Cardiology: the time for action is now. Cardiovasc Ultrasound 2011 Nov 21, 9:35.

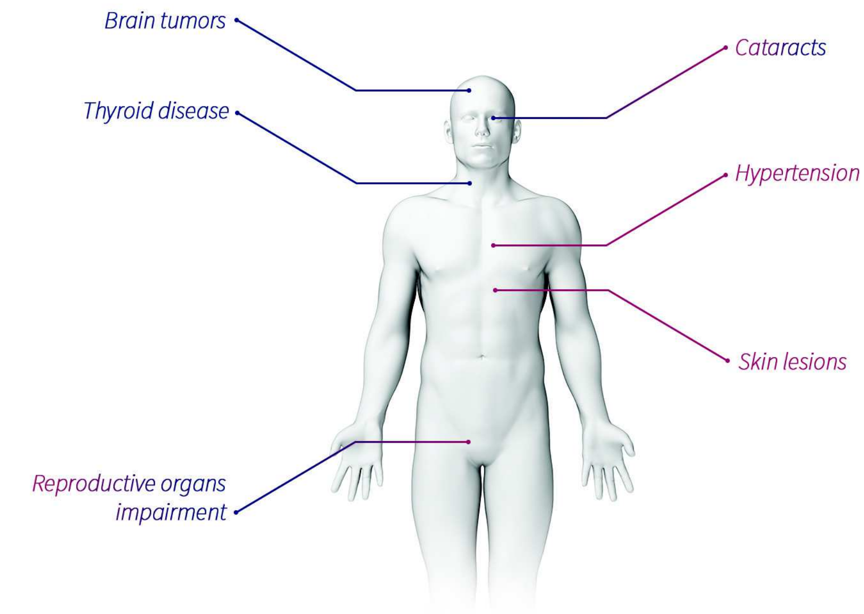
An exposure to ionizing radiation may induce two types of biological effects:

Stochastic effects

It includes genetic defects and therefore possible carcinogenic consequences. *Stochastic effects are believed not to depend on a threshold level, since a DNA injury to even a single cell can theoretically result in the development of a disease. Among stochastic effects are for example radiation-induced cancer and thyroid disease.*

Deterministic effects

Such effects refer to an immediate and predictable tissue reaction. *Deterministic effects occur when the received dose exceeds a certain level and the severity increases as more cells are killed or damaged. The development of radiation-induced skin lesions is an example of deterministic events[14].*



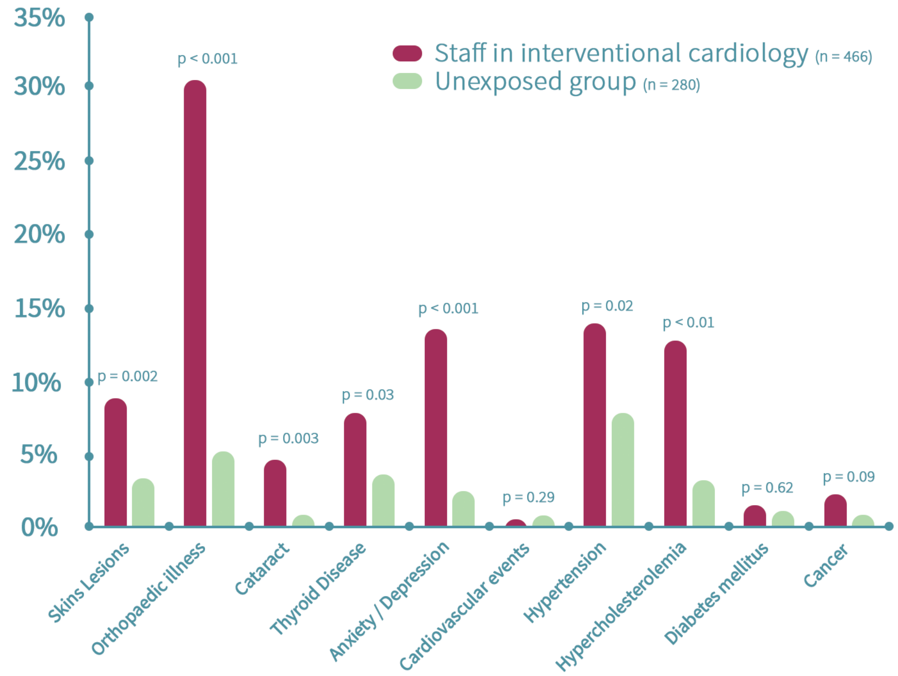
[14] Sun Z. et al., *Radiation-Induced Noncancer Risks in Interventional Cardiology : Optimisation of Procedures and Staff and Patient Dose Reduction.* BioMed Res Int, 2013.

A recent study[1] comparing medical conditions of staff exposed to X-rays versus non-exposed personnel revealed that the first group had developed higher rates of several health problems. **Statistical difference was found in the development of skin lesions, orthopaedic illness, cataracts, thyroid disease, confirming previous results.**

New findings of this study were discovered regarding the prevalence of hypertension and hypercholesterolemia. Anxiety and depression occurred in 12% of exposed subjects, compared with 2% of controls.

Authors suggest that this might be a newly discovered effect of radiation, which is especially relevant on the unprotected head of the operator. At chronic low doses ionizing radiation may impact detrimentally on hippocampal neurogenesis and neuronal plasticity.

Comparison of medical conditions of cath lab workers vs control group



(The p-value as well as in any figure in this paper corresponds to the result of statistical tests)

Source: Andreassi M (2016)

POSTERIOR SUBCAPSULAR CATARACTS

are found in up to 50% of interventional cardiologists

Cataract development is one of the primary health complications observed in cath lab team members.

Previously cataracts were considered as a deterministic effect of radiation exposure, and it is believed today that they are rather a stochastic consequence, as an increasing number of cataracts are developing following an exposure to low-dose radiation[5].

The eye lens is one of the most radiosensitive tissues in the body, and as such, the cataract development is one of the primary health complications observed in cath lab team members. In progressive cataracts, surgical removal is the only effective treatment.

Normal vision

Vision with cataract

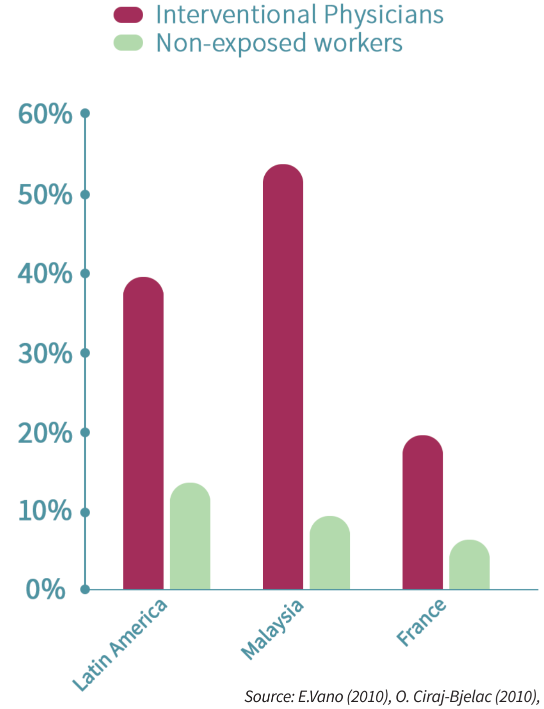
According to the International Atomic Energy Agency (IAEA)[15], exposing eyes to excessive radiation results in aberrant crystalline protein folding and dysregulation of lens morphology, causing cortical and posterior subcapsular cataracts. These types of cataracts are different from the nuclear type, which is the most common form of age-related cataracts. It is therefore possible to determine the cause of the cataract depending on its morphology.

A cataract is even more dangerous as it might remain asymptomatic for several years, as the first stages may not cause visual disability. With time, clumps of proteins aggregate and form larger opacities, greatly imparing the vision.

[15] https://www.iaea.org/resources/rpop/health-professionals/radiology/cataract/staff#1

Excess posterior subcapsular opacities among the cath lab workers were observed in cohort studies performed in Latin America[16], Malaysia[17] and France[18]. Results from the French analysis reflect the investigation from the O'CLOC study (Occupational Cataracts and Lens Opacities in interventional Cardiology) in 106 exposed interventional cardiologists and 99 non-exposed workers (S. Jacob, 2013).

Prevalence of cataract development among medical personnel



Source: E.Vano (2010), O. Ciraj-Bjelac (2010), S.Jacob (2013)

A study by E. Vano in 2013[19] confirmed these results:

Posterior subcapsular lens changes characteristic of ionizing radiation exposure were found in 50% of interventional cardiologists and 41% of nurses and technicians compared with findings of similar lens changes in <10% of controls.

[16] Vano E. et al., *Radiation cataract risk in interventional cardiology personnel,* Radiat Res.2010Oct;174(4):490-5.
[17] Ciraj-Bjelac O. et al., *Risk for radiation-induced cataract for staff in interventional cardiology: Is there reason for concern?* Catheter Cardiovasc Interv. 2010 Nov 15;76(6):826-34.
[18] Jacob S. et al., *Interventional cardiologists and risk of radiation-induced cataract: Results of a French multicenter observational study.* Int J Cardiol. 2013 Sep 1;167(5):1843-7.
[19] Vano E. et al., *Radiation-associated Lens Opacities in Catheterization Personnel: Results of a Survey and Direct Assessments* J Vasc Interv Radiol. 2013 Feb;24(2):197-204.

THYROID GLAND DISEASE

caused by sensitivity to ionizing radiation

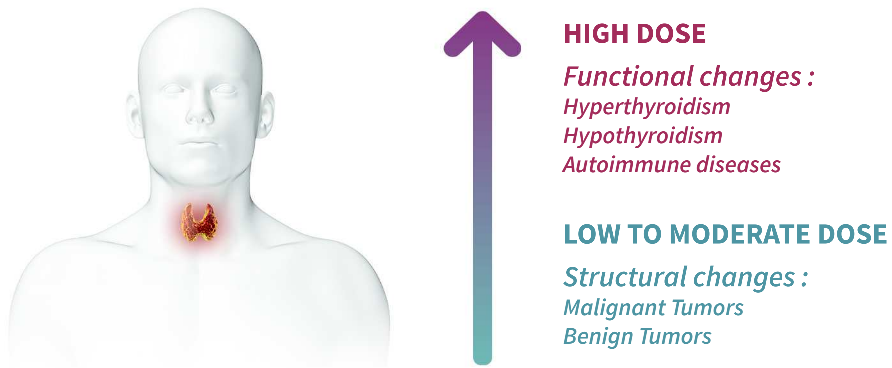
Interventional lab personel is also at risk of developing various thyroid diseases due to the anatomical location and radiosensitivity of this gland.

An exposure of the thyroid gland to ionizing radiation induces a linear response and subsequent structural changes, characterized by the development of benign and malignant tumors.

Although the effects of chronic, intermittent radiation are unknown, studies have reported that elevated doses of external exposure may also induce functional changes, such as hyper or hypo-thyroidism[20].

A cross-sectional study in Germany[4] revealed that females exposed to ionizing radiation developed more often autoimmune thyroid disease (10% vs 3.4%, $P<0.05$) in comparison to non-exposed ones.*

Effects of X-ray exposure on the thyroid gland



Source: Metab, August 2005, 90(8):4587–4592
H. Völzke, Occupational Exposure to Ionizing Radiation Is Associated with Autoimmune Thyroid Disease, J Clin Endocrinol

*This study investigated a relatively small number of exposed personnel.
Women are also 2.9 times more likely to develop thyroid cancer as compared to men[21].

[20] Ron E., Brenner A. *Non-malignant thyroid diseases after a wide range of radiation exposures.* Radiat Res. 2010 Dec; 174(6): 877-888.
[21] Rahbari R., et al., *Thyroid cancer gender disparity.* Future Oncol. 2010 Nov; 6(11): 1771–1779.

RISKS ON PROGENY

Progeny is put at risk when exposed to ionizing radiation

Over a professional lifetime of 30 years, the cumulative exposure to ionizing radiation of testes and ovaries of interventional cardiologists can reach 0.5 to 1 Sv[6].

For males, this might result in a reduced sperm count[22]. Pregnant female workers may also take into consideration the potential danger on the developing foetus, typically associated with central nervous system problems[23].

The embryo and foetus are at risk of developing stochastic and deterministic effects, which are more significant during organogenesis at early stages of pregnancy.

The main deterministic effects in the developing embryo or foetus consist of intrauterine growth retardation, pregnancy loss, mental retardation, small head size, reduced intelligence quotient (IQ) and congenital malformations.

Stochastic effects are characterized by childhood risk of cancer and hereditary diseases in the descendants[24].

The International Comission on Radiation Protection (ICRP) allows pregnant medical professionals to continue working with fluoroscopy-guided procedures, as long as they wear protective garments and respect radiation control procedures. The fetal dose should be kept below 1 mSv for 12 consecutive months, corresponding to the public zone.

[22] Latini G et al., *Reproductive effects of low to moderate medical radiation exposure.* Curr Med Chem. 2012;19(36):6171-7.
[23] Budorf A. et al., *Effects of occupational exposure on the reproductive system: core evidence and practical implications,* Occup Med (Lond). 2006 Dec;56(8):516-20.
[24] Best P., et al., *SCAI Consensus Document on Occupational Radiation Exposure to the Pregnant Cardiologist and Technical Personnel.* EuroIntervention. 2011 Feb;6(7):866-74.

SKIN CANCER

Exposure to ionizing radiation puts the operator at risk of developing cutaneous lesions

According to the ICRP[25], the lowest dose that is considered to induce noticeable skin alterations is considered to be 2 Gy – an equivalent of 2 Sv when using X-rays.

First symptoms of exposure to ionizing radiation include the skin reddening due to dilated capillaries, an effect that might fade after 24 hours and be under-reported due to its brief duration. As the received dose increases, there is a risk of destruction of proliferative basal cells in the epidermis and consequent erythema, characterized by oedematous skin, burning and itching.

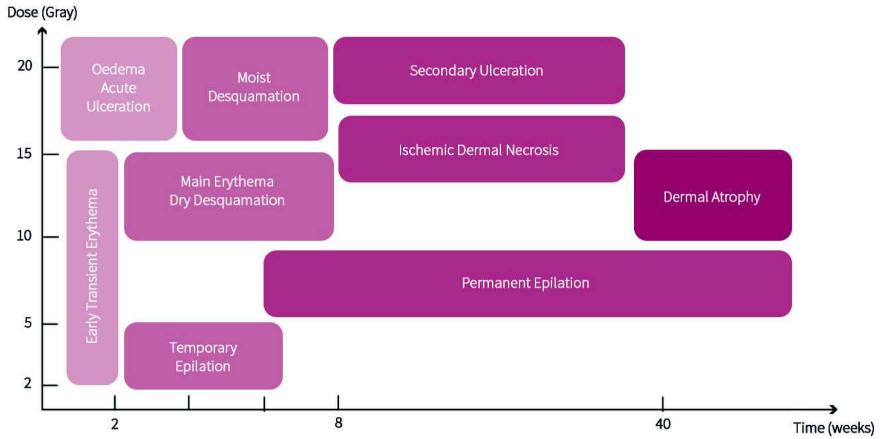
Above 15 Sv the inflammation progresses to dry desquamation, and development of cutaneous blisters. At this stage, the skin is vulnerable to infection.

After a long time of exposure to ionizing radiation the operator might develop dermal atrophy and skin cancer.

A clinical case reported a 50-year old interventional cardiologist who had developed 41 skin lesions over a 4-year period[26], all of them being basal-cell carcinomas, most of them located on the left side.

There is often a latent period of several months before the development of the lesion, making its diagnosis delayed[7].

Effects of exposure to ionizing radiation to the skin in a dose and time dependent manner



Source: ICRP Publication 120, 2011

[25] ICRP, 2013. *Radiological protection in cardiology.* ICRP Publication 120. Ann. ICRP 42(1).
[26] Eagan Jet al., *Cutaneous Cancers in an Interventional Cardiologist: A Cautionary Tale.* J Interv Cardiol. 2011 Feb;24(1):49-55.

VASCULAR DISEASE

caused by low-dose radiation exposure

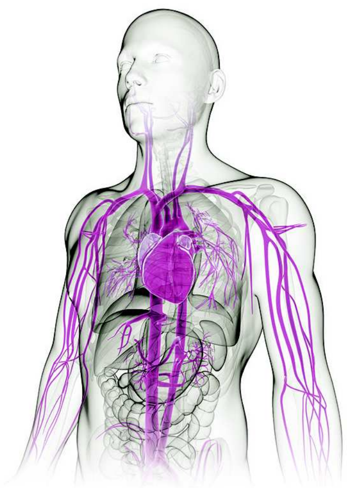
Dr. Andreassi's group[8] reports that exposure to low-dose radiation may over time increase carotid intima-media thickness, an early indicator of vascular injury.

These findings were also associated with increased leukocyte telomere shortening and excessive DNA damage, signs of **accelerated vascular ageing.**

Further experimental evidence support the role of low-dose ionizing radiation in long-term **alterations in lipid metabolism and endothelial functions[27].**

These results are supported by previous studies establishing the relationship between exposure to ionizing radiation and development of cardio-vascular or cerebro-vascular circulatory disease[28].

Vascular radiation may affect even small-sized arterioles. Capillary microscopy analysis reveals morphological and functional alterations of dermal microcirculation in physicians exposed to low-dose ionizing radiation[29].



Low doses of ionizing radiation induce inflammatory processes, eventually leading to ischemia, myocardial cell death and fibrosis, decreased cardiac function, and fatal congestive heart failure[18].

[27] Borghini A., et al., *Ionizing radiation and atherosclerosis: current knowledge and future challenges.* Atherosclerosis. 2013;230:40–47.
[28] Metz-Flamant C., et al., *Low doses of ionizing radiation and risk of cardiovascular disease: Areview of epidemiological studies.* Rev Epidemiol Sante Publique 2009,57:347–359.
[29] Tomei F., et.al.,*Vascular effects of occupational exposure to low-dose ionizing radiation.* Am J Ind Med 1996, 30:72–77.

BRAIN TUMORS
caused by low-dose radiation exposure

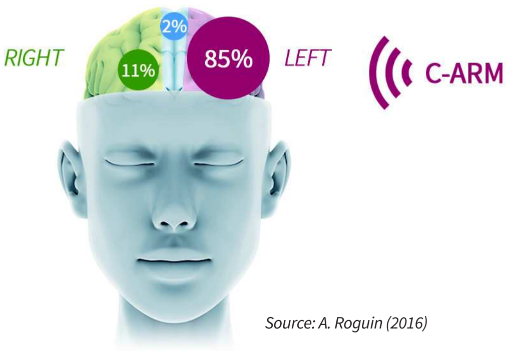
The possible neurological impact of X-rays was suggested in 1975 by Matanoski[30].

Then, in 1998 two Canadian interventional cardiologists were diagnosed with brain tumors[31]. However, it is only in 2013, after the publication of A. Roguin[3], that awareness on this issue was raised.

In his article, A. Roguin studied a cohort of 31 interventional physicians who developed a brain cancer. More precisely, the tumors were glioblastoma multiforme, astrocytoma and meningioma.

The results showed that in 85% of cases, the malignancy was left-sided. The majority of physicians died shortly after diagnosis.

Location of brain tumor



Source: A. Roguin (2016)

Dr. Roguin's findings have been recently extended to an analysis of 12 additional cases, resulting in total of 43 cases of physicians exposed to X-rays[32]. In this study, data for 35 patients was available concerning the localization of the brain tumor. These results confirm that the malignancy is prevalently located on the left side. Often, the X-ray generator is located on the left side of the operator, therefore the left part of the brain can receive up to twice as much radiation as the right part[33]. **This strong association suggests that left-sided brain tumors correlate with the ionizing radiation to which medical workers are exposed.**

It should be noted that given the small population study, this data provides only a basis for a speculation of a direct correlation between radiation exposure and brain tumor incidence.

[30] Matanoski GM, et al. *The current mortality rates of radiologists and other physician specialists: specific causes of death.* Am J Epidemiol. 1975;101(3):199-210.
[31] Finkelstein MM, et al., *Is brain cancer an occupational disease of cardiologists?* Can J Cardiol 1998;14:1385-8.
[32] Roguin A., *Radiation and your Brain: possible measures to reduce radiation in your cath lab.* Endovascular Today Vol. 15, No. 8 August 2016.
[33] Picano E. et al., *Cancer and non-cancer brain and eye effects of chronic low-dose ionizing radiation exposure* BMC Cancer 2012, 12:157.

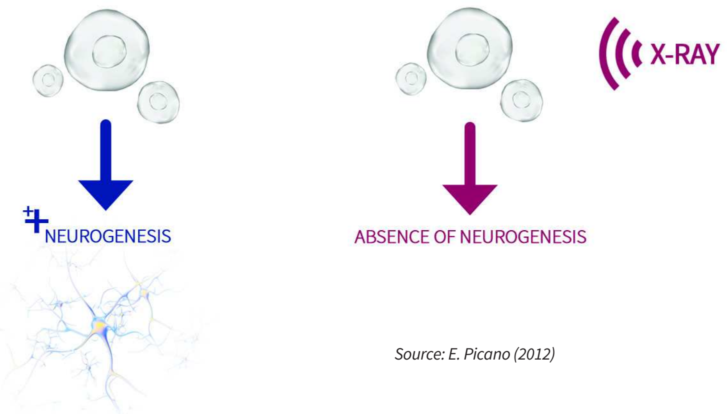
NEUROCOGNITIVE DECLINE
induced by genetic damage

An investigation on chromosomal abnormalities in two 37 year-old identical twins (one interventional cardiologist in a high-volume cath lab and the other twin a lawyer) revealed that the interventional cardiologist had a higher frequency of chromosomal aberrations (3.2% vs 1.2%)[34].

Human brain cells are particularly sensitive to low-dose radiation and the associated DNA alteration may result in their structural change and pro-oxidant, pro-inflammatory and enhanced apoptotic responses[9].

Significant DNA damage has also been previously observed in circulating lymphocytes of interventional cardiologists[35]. A multinational study confirmed that exposure to ionizing radiation results in a higher chromosomal damage and modulation of some immune responses[36].

Exposure to X-ray results in an inhibited neurogenesis



Source: E. Picano (2012)

Further results show that brain exposure to ionizing radiation is associated with development of deficits in attentional and executive functioning and information processing speed[37] as well as in an important decline in memory, verbal fluency performances, delayed recall, visual short-term memory and semantic lexical access ability[38].

These findings suggest that such reduced skills may result from alterations of the left brain hemisphere structures that are more exposed to ionizing radiation in interventional cardiac procedures.

[34] Andreassi MG et al., *Chronic low-dose radiation exposure from interventional cardiology procedures induces chromosomal abnormalities in originally genetically identical twins.* Int J Cardiol. 2007;118(1):130-1.
[35] Andreassi MG et al., *Somatic DNA damage in interventional cardiologists: a case–control study.* FASEB J 2005, 19:998– 999.
[36] Zakeri F., et al., *Biological effects of low-dose ionizing radiation exposure on interventional cardiologists.* Occup Med (Lond). 2010;60(6):464-9.
[37] Douw L., et al., *Cognitive and radiological effects of radiotherapy in patients with low-grade glioma: long-term follow- up.* Lancet Neurol 2009, 8:810–818.
[38] Marazziti D, et al., *Neuropsychological testing in interventional cardiology staff after long-term exposure to ionizing radiation.* J Int Neuropsychol Soc. 2015;21:670–676.

REGULATION TENDS TO REDUCE THE EXPOSURE OF WORKERS

FUNDAMENTAL PRINCIPLES OF RADIATION PROTECTION BY THE ICRP

On the international scale, the ICRP regularly issues new publications concerning the radiation protection of workers.

The recommendations of this organism rely particularly on three fundamental principles of radiological protection: justification of X-ray use, optimisation of protection, and application of dose limits.

These principles and recommendations are then applied on the European level by the Euratom directives and integrated in the national laws and regulations of EU member states.

Fundamental principles of radiation protection ICRP recomendations

JUSTIFICATION

"Any decision that alters the radiation exposure situation should do more good than harm"

OPTIMISATION

"The likelihood of incuring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors"

LIMITATION

"The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits recommended by the Commission"

EUROPEAN
EURATOM DIRECTIVES
(2013/59/Euratom)

NATIONAL
NATIONAL REGULATION

Source : ICRP Publication 103 (2007)

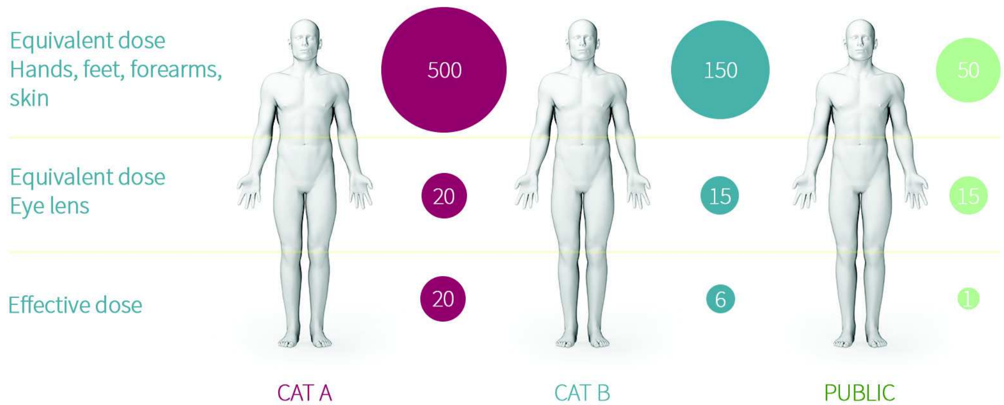
CURRENT LIMITS OF EXPOSED PERSONNEL

Medical workers are classified in category “A” or “B” depending on the level of ionizing radiation they are likely to be exposed.
The *equivalent dose* limits the exposure of body parts that are not protected by lead aprons, such as hands or eye *lens.* The *effective dose* corresponds to the whole body exposure.

The ICRP is systematically striving to reduce the exposure to ionizing radiation of workers and prevent associated diseases of any type. In this regard, the acceptable annual effective dose has been lowering since the year 1928, reaching 20 mSv in 1990: a value that is still valid nowadays.

A recent recommendation from ICRP lowered the equivalent dose to the eye lens for category “A” workers from 150 mSv on 12 consecutive months to 20 mSv. This recommendation was adopted by Euratom and its Directive 2013/59 enters into force in February 2018.

Effective and equivalent dose on 12 consecutive months (mSv)



Source: Directive 2013/59/Euratom

The use of ionizing radiation in diagnostic and therapeutic procedures in catheterization laboratories implies the monitoring of the effective dose received by the operators with special badge or ring dosimeters.

However a study shows that often these personal dosimeters are worn improperly or not worn at all[10].

Collected values are therefore often non-representative and much lower than the real dose received by cath lab workers.

KEY FACTORS FOR REDUCING RADIATION EXPOSURE

The key factors of reducing radiation exposure in fluoroscopically guided procedures are **distance, shielding** and **time.**

DISTANCE

The amount of radiation varies inversely with the square of the distance: for example, the exposure at two meters from the source will be one fourth of the exposure at one meter from the source.

SHIELDING

Shielding reduces the intensity of radiation depending on its thickness. This is an exponential relationship with a gradually diminishing effect as equal slices of shielding material are added.

Lead is the material that was conventionally used to put a barrier from X-rays, but because of its non-ecological characteristics and sanitary hazards, it is now often replaced by other type of protective materials.

TIME

The received dose also varies according to the duration of X-radiation exposure.

The longer the fluoroscopy time during a procedure, the higher the direct and scattered radiation received by the operator. This aspect also depends on the complexity of the intervention, patient anatomical morphology and experience of the operator.

AN OVERVIEW OF CURRENT RADIATION PROTECTION SOLUTIONS

SHIELDING IN CATH LABS

Medical staff limit the radiation exposure by reducing the fluoroscopy time, the distance to the X-ray emitter and by using protective shielding.

There are three types of shielding in cath labs: *architectural shielding, equipment-mounted shielding and personal protective equipment*[39].

ARCHITECTURAL PROTECTION

Walls and doors of catheterization laboratories are designed with lead, steel and other components to stop X-rays. Rolling shields provide additional protection to the operator and staff.

EQUIPMENT AND CEILING MOUNTED SHIELDS

Soft radiation protection equipment are mounted on patient tables and protect the lower body of the operator. Ceiling-suspended see-through shields present sometimes a soft radiation protection material that comes into contact with the patient.

PERSONAL PROTECTIVE EQUIPMENT

Cath lab workers are using radiation protection aprons, leaded glasses and thyroid shields.

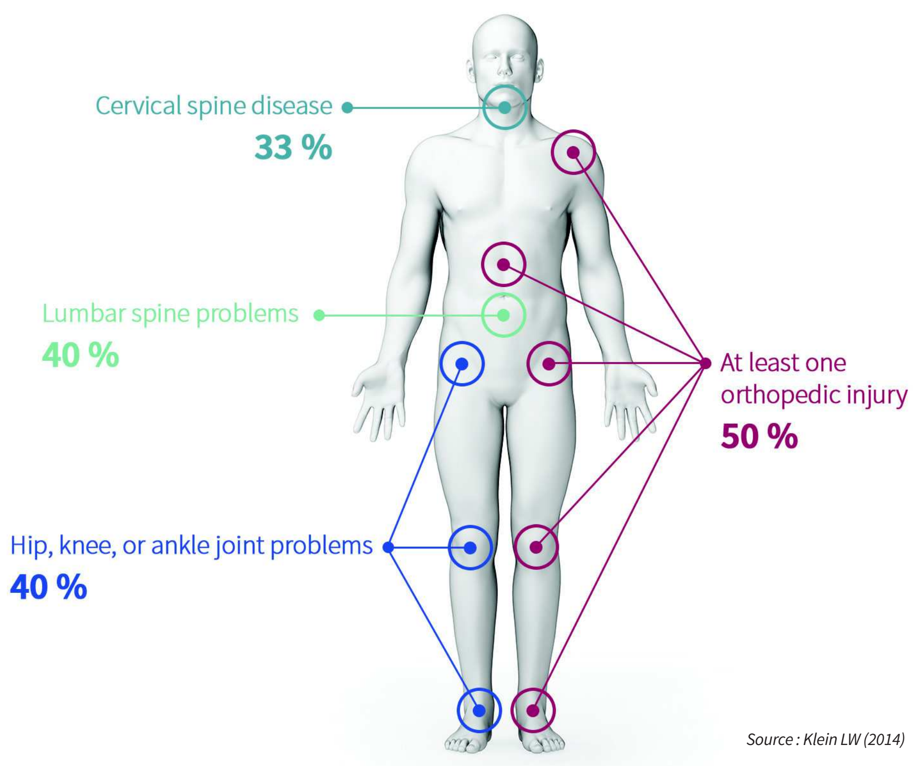
[39] Duran A., et al, *A summary of recommendations for occupational radiation protection in interventional cardiology.* Catheter Cardiovasc Interv. 2013 Feb;81(3):562-7

LEAD APRONS
cause orthopaedic problems

Personal protection equipment is available in different lead equivalences ranging from 0.25 mm to 0.5 mm. **These aprons are effective at the body zone that they are protecting, but are very heavy (up to 6-7 kg).**

Wearing these protections for long period of time may cause back problems[40 41].

Interventional cardiologists frequently present orthopaedic disease



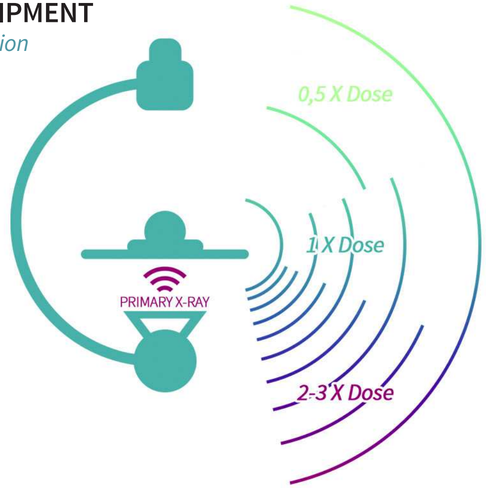
Source : Klein LW (2014)

An electronic survey on 314 members of the Society for Cardiovascular Angiography and Interventions showed that approximately 1 out of 2 operators reported at least one orthopaedic injury[42].

[40] Goldstein JA, et al., *Occupational hazards of interventional cardiologists: prevalence of orthopedic health problems in contemporary practice.* Catheter Cardiovasc. Interv. 2004 Dec 63(4), 407–411.
[41] Report No. 168, *Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures.* NCRP, 2010.
[42] Klein LW, et al., *Occupational health hazards of interventional cardiologists in the current decade: Results of the 2014 SCAI membership survey.* Catheter Cardiovasc Interv. 2015;86:913–924.

ADDITIONAL PROTECTIVE EQUIPMENT
might not protect from scattered radiation

Although suspended lead shields may protect the sensitive region of the operator's head from the direct beam, they do not protect from scattered radiation from the patient, which represents a higher danger[43].



Operators may also use special radiation absorbent surgical caps and lead glasses to protect the brain and the eyes. However, the scattered radiation coming from below might still affect these sensitive organs.

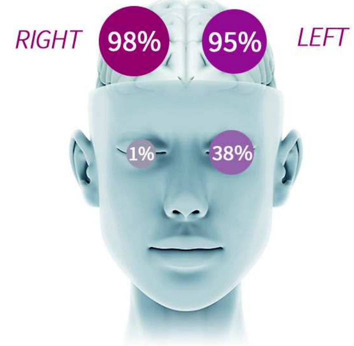
A recent study demonstrated that when using a cap, despite an attenuation of 67% of radiation to the face, the brain region received a protection of only <2% on the right side and <5% on the left side. Similar results showed that radiopaque eye glasses provide incomplete and uneven ocular protection: 62% and less to the left eye, and they *"neglected to protect the right eye".*

Radiation-attenuating sterile gloves are available to lower the dose received by the hands. It is advised to use such gloves only for protection against the scattered radiation, as it is not safe to put the hands in these gloves through the primary beam[44]. Besides, the reduction of the tactile sensitivity when using these gloves may lead to higher fluoroscopy time[45], and consequently to a higher exposure of the patient and operator.

X-Ray penetration to the eyes and brain despite the use of lead caps and glasses

Lead caps and glasses have a poor performance of radiation protection[12].

They provide insufficient protection to the brain and eye lens.



Source : K. Fetterly (2017)

[43] Struelens L., et al., *Characterization of the scattered radiation field around an x-ray tube,* Physics in Medicine and Biology, 56(9) 2011.
[44] Kamusella P., et.al., *Interventional Angiography: Radiation Protection for the Examiner by using Lead-free Gloves.* J Clin Diagn Res. 2017 Jul;11(7):TC26-TC29
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THE RADIATION PROTECTION CABIN

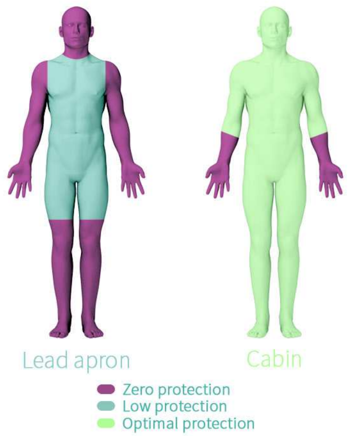
an all-in-one highly protective solution

The radiation protection cabin* provides an optimal protection to the whole body of the operator performing interventional radiology procedures.

The particularity of this cabin is that it enables the operator to work without wearing the lead apron nor any additional protective equipment.

The protection offered by the cabin is optimal with 2 mm lead eq. materials (versus 0.25-0.5 mm lead eq. for a lead apron and 0.5 mm lead eq. for suspended shields).

Radiation Protection Comparison



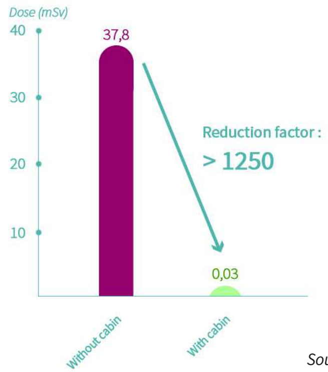
The radiation protection efficiency of this cabin has been evidenced by multiple studies.

B. Strohmer has demonstrated that after 138 Electro-physiology procedures, the cumulative dose outside the Cathpax® was 37,8 mSv whereas inside the cabin this value was 0,03 mSv[46].

Besides, this cabin provides a significant protection to the head, as proven by S. Ploux[47] and O. Dragusin[48].

*All the studies and technical information hereunder refer to the model Cathpax® AF.
A new cabin model, Cathpax® AIR, is currently being tested for radiation protection.

Radiation protection capacity of the cabin (Cathpax® AF)



Source : Klein LW (2014)

[46] Schernthaner C, al., *Significant reduction of radiation exposure using a protection cabin for electrophysiological procedures.* Medical Imaging and Radiology, 2013.
[47] Ploux S., et al., *Performance of a Radiation Protection Cabin During Implantation of Pacemakers or Cardioverter Defibrillators.* J Cardiov Electrophysiol, 2009.
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TESTIMONIALS

"With the use of the Cathpax® AF, catheter ablation can be performed comfortably with insignificant exposure rendering lead apparel superfluous."

Pr. Michel Haïssaguerre
Professor of University - Hospital Practitioner
Bordeaux University Hospital / IHU LIRYC, France

"The cabin has changed my life as an electrophysiologist: it takes away all my concerns that I might harm my own health and the future of my dependants while taking care of patients."

Pr. Hein Heidbüchel
Professor, Cardiology – Arrhythmology,
University Hospital Gasthuisberg Leuven, Belgium

"Fluoroscopy remains the key non-virtual imaging tool in several areas: for cryoballon pulmonary vein isolation, for left atrial appendage occlusion, for obtaining difficult intravascular / intrapericardial access, for management of periprocedural complications. Cathpax® makes all these procedures truly operator-safe and it should be a must in all up-to-date cath labs."

Pr. Robert Hatala
Professor, Head of the National Cardiovascular Institute Bratislava, Slovakia

"As a busy practicing electrophysiologist, the accumulated X-ray exposure and lead burden on my spine have been major health concerns. Cathpax® applied breakthrough radiation protection materials with ergonomic design so I can perform catheter ablation comfortably, conveniently while under ultimate protection."

Pr. Lin Chen
Professor, Chief physician, Fujian Medical University /
Fujian Inst. Of Cardiovascular Diseases, China

"On a daily basis, the Cathpax® AIR brings a protection that is far superior to the conventional equipment used in an interventional cath lab, while respecting the working environment required for an optimal patient safety."

Pr. Patrice Guérin

Professor of University - Hospital Practitioner, Nantes University Hospital, France

"Cathpax® AIR is a disruptive platform that provides unprecedented protection to interventional physicians who have been exposed for so many years to ionizing radiation. The system also provides ergonomic and orthopaedic relief to the interventionalist thereby improving occupational health."

Pr. David Keane

Professor, Cardiologist, St-Vincent's Hospital Dublin, Ireland

"Cathpax® has become one of the most necessary devices in my lab, especially when performing complicated cases such as atrial fibrillation ablations and substrate-guided ventricular tachycardia ablations, where a longer procedure time is usually required."

Pr. Kazutaka Aonuma

Professor, Director of Cardiovascular Division, Tsukuba University Hospital, Japan

"We use the cabin for almost all procedures, from placing the introducer until finalizing the EP study or ablation procedure. The mobility and free moving space allows using it for even the most complex procedures. For us it is the perfect solution for optimum radiation protection."

Pr. Thomas Arentz

Professor, Clinical Head at Universitäts-Herzzentrum Freiburg Bad Krozingen, Germany

"For personal reasons, and due to my exposure to ionizing radiation detected by close medical monitoring, I had to take increasingly strict precautions. I heard about the Cathpax® I can't imagine working without it now. I've totally embraced it, and my radiation doses have literally plummeted."

Dr. Yann Valy

Hospital Practitioner, Hospital Group of La Rochelle - Ré - Aunis, France

"The use of the Cathpax® cabin turned out to be one of the most important achievements in my daily EP practice as far as radioprotection is concerned."

Dr. Bernhard Strohmer

Priv.-Doz Paracelsus Private Medical University, Salzburger Landeskliniken, Austria

"The Cathpax® is a major breakthrough in the area of radiation safety for the busy practicing cardiac electrophysiologist. I found it easy to use with excellent visibility, catheter stability and most important whole body radiation protection without using lead apron."

Dr. Nidal Asaad

Hospital Practitioner, Hamad General Hospital Doha, Qatar

"I use the Cathpax® AF for all my ablation procedures. Radiation protection is a very important issue for me, and the Cathpax® offers the highest protection. It allowed me to continue working in the cath lab during my pregnancy."

Dr. Isabelle Nault

Hospital Practitioner, IUCPQ, Laval, Quebec, Canada

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NOTES

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Worldwide leader in innovation in the radiation sector, Lemer Pax creates, designs, and engineers efficient radiation protection solutions for medical, research, industry and nuclear sectors.

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Lemer Pax, protecting life, we strive for excellence to protect the most important thing: **Life !**

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