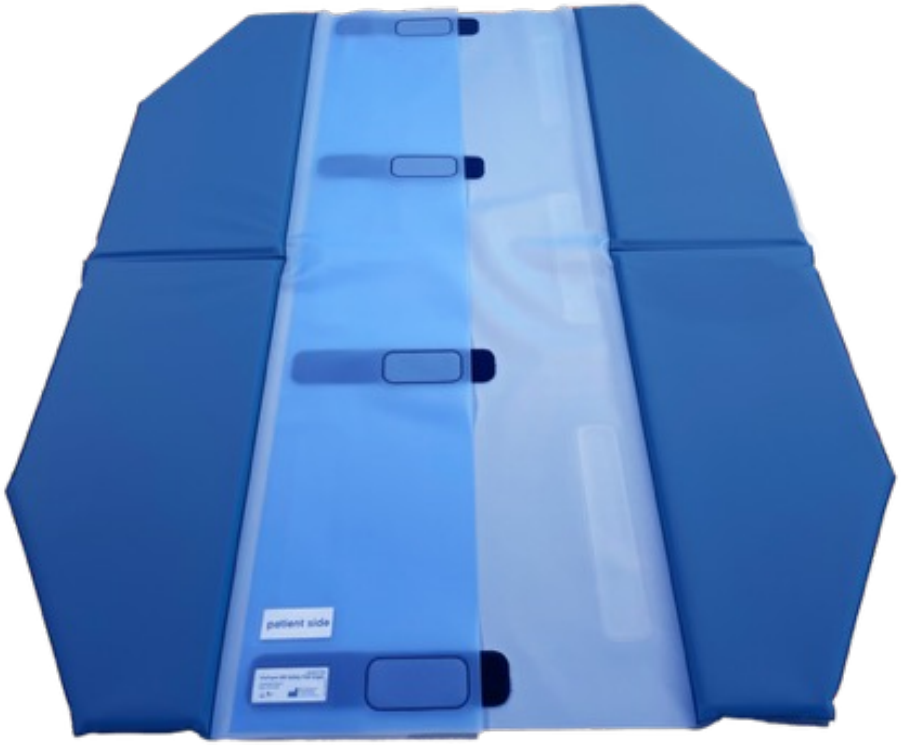
pearltechnology

MR Safety Angel Pad

Product Training and Supplemental Information



SWISS MADE

F25-012-EN Rev 2.0

Dedicated Pads to Help Prevent RF-induced Burns

The Issue of RF-Induced Patient Burns

Radiofrequency (RF) fields used during magnetic resonance imaging (MRI) exams may generate heat under certain operating conditions, which may result in burn injuries to patients. Among all physical injuries reported to be associated with MRI, RF-induced burns are the most frequent (Delfino et al., 2019). The incidence of RF-induced burns tends to increase with stronger static magnetic fields and RF frequencies (Delfino et al., 2019)

When patients contact the bore of the MR system, placing them in proximity of the transmit RF body coil, the risk of burns increases. This is especially the case for large patients, whether due to obesity or muscular build.

Figures 1 and 2. RF-induced burns from direct contact with the bore of the MR system. No padding was used in these cases. Images courtesy of Frank G. Shellock, Ph.D., www.MRIsafety.com

Delfino, J. G., Krainak, D. M., Flesher, S. A., & Miller, D. L. (2019). MRI-related FDA adverse event reports: A 10-yr review. Medical Physics, 46(12), 5562–5571. https://doi.org/10.1002/mp.13768

Figures 1 and 2. Images courtesy of Frank G. Shellock, Ph.D., www.MRIsafety.com

RF-Induced Burns: Possible Causes

- "Near Field" or Proximity Effect
- Conductive Materials
- Formation of Conductive Tissue Loops

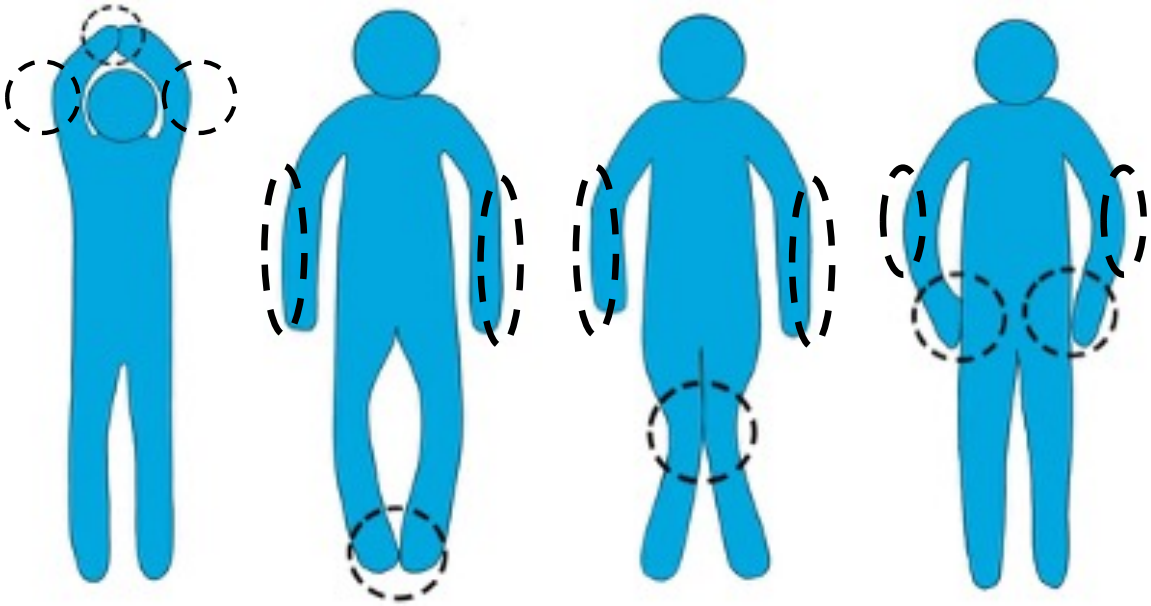


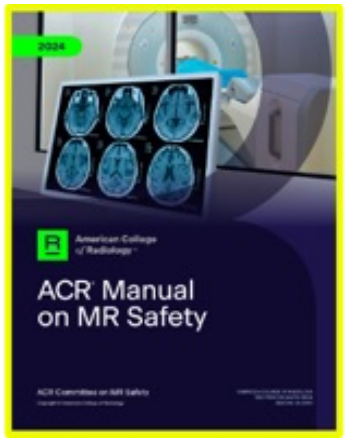
Image 3. Possible locations at risk that require padding

Regulatory Background

The American College of Radiology (ACR) states the following in its 2024 Manual on MR Safety:

"It is important to emphasize that insulating pads are necessary; a single-layer bedsheet is insufficient insulation or spacing to prevent burns."

– ACR, 2024, p. 64



"Insulation and appropriate distance should be placed between the patient and any external conductive material, including the bore wall."

– ACR, 2024, p. 68

American College of Radiology. (2024). ACR Manual on MR Safety. Retrieved from https://www.acr.org/-/media/ACR/Files/Clinical/Radiology-Safety/Manual-on-MR-Safety.pdf

Regulatory Background

The UK's regulatory agency (MHRA) states the following in its safety guidelines:

"The MHRA recommends that users use foam pads, 1 to 2 cm (0.39 – 79") thick, to insulate the patient from the bore."

"The use of clothing or blankets as a form of insulation is not recommended."

– MHRA, 2022, § 4.12.8 and SCoR, 2019, § 7.2.3

Medicines and Healthcare products Regulatory Agency. (2022, April 4). Safety guidelines for magnetic resonance imaging equipment in clinical use. GOV.UK.
The Society and College of Radiographers. (2019). Safety in Magnetic Resonance Imaging. 1st Edition.

The Issue of Worn-out Pads

"Attention to the physical condition of insulating padding is recommended, as with time, pads can degrade and become overly compressible such that their insulating capacity is compromised, and a sufficient distance from the bore wall is not maintained."

– ACR, 2024, p. 64

Figure 4. Example of a full thickness, third degree burn that resulted from contact of the patient with the bore of the MR system, using a transmit RF body coil. Note the use of a worn-out insulating pad that was overly compressed (central circled area). (ACR, 2024, p.64)

American College of Radiology. (2024). ACR Manual on MR Safety. Retrieved from https://www.acr.org/-/media/ACR/Files/Clinical/Radiology-Safety/Manual-on-MR-Safety.pdf

Current Practice

MRI technologists and radiographers struggle to add pads or towels around patients once they are in the bore of the MR system, to ensure that they are not in close proximity with the transmit RF body coil.

Furthermore, these healthcare professionals then attempt to keep the insulative materials in place, as the patient table moves into the scanner.

Small bore MR systems (e.g., 60 cm diameter bore size) make this situation even more of a challenge. As a result, the required distance of 1 cm of padding is often not achieved, leaving the patients potentially vulnerable to RF-induced burns.

ACR Manual on MR Safety, 2024, p. 108

Image: https://doi.org/10.1186/1532-429X-12-S1-P269

Our Solution: the MR Safety Angel Pad

The MR Angel Safety Pad independently wraps around the patient, reducing the risk of RF-induced burns, along with improving patient comfort.

Once installed, it can remain on the patient table for all patients as a standard. No need for improvisation.

As a means of prevention of painful RF-induced burns, this unique padding solution is a true guardian angel.

The New Standard of MR Safety

Slides Easily Into the MR System's Bore

The MR Safety Angel Pad gets into position without needing you – leaving you time for more important matters.

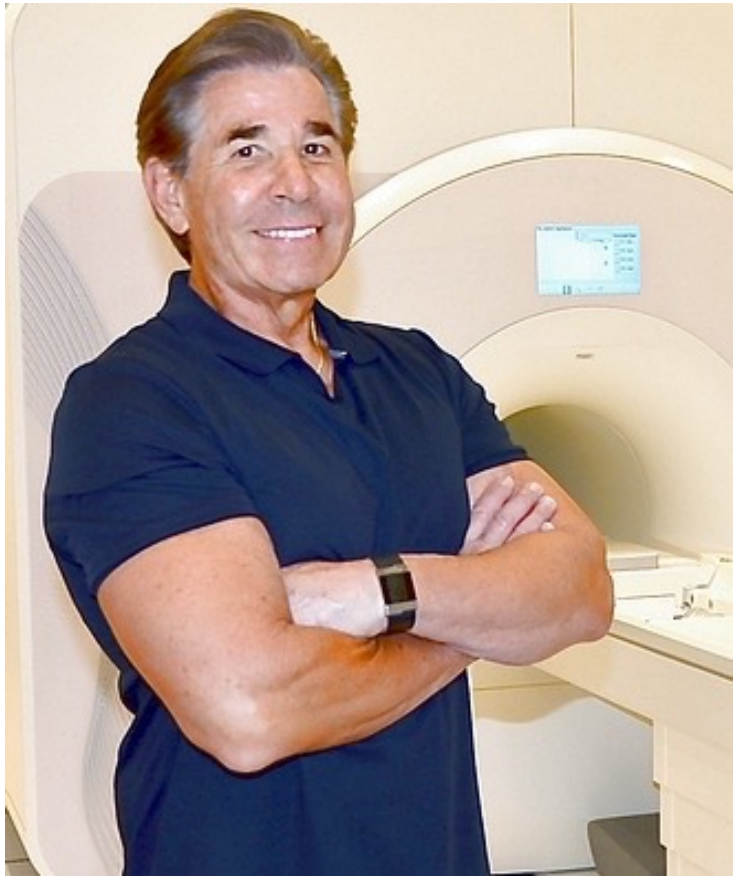
Video can be found on: https://www.pearl-technology.ch/en/mrsafetypad

Doesn’t Bother Patients That Don’t Need It

Feel free to leave it on – so it’s ready when you need it again. There’s even a small perk: it acts as a cushion for the patient’s elbow.

Video can be found on: https://www.pearl-technology.ch/en/mrsafetypad

Developed with World-leading Expert – Frank G. Shellock, Ph.D.



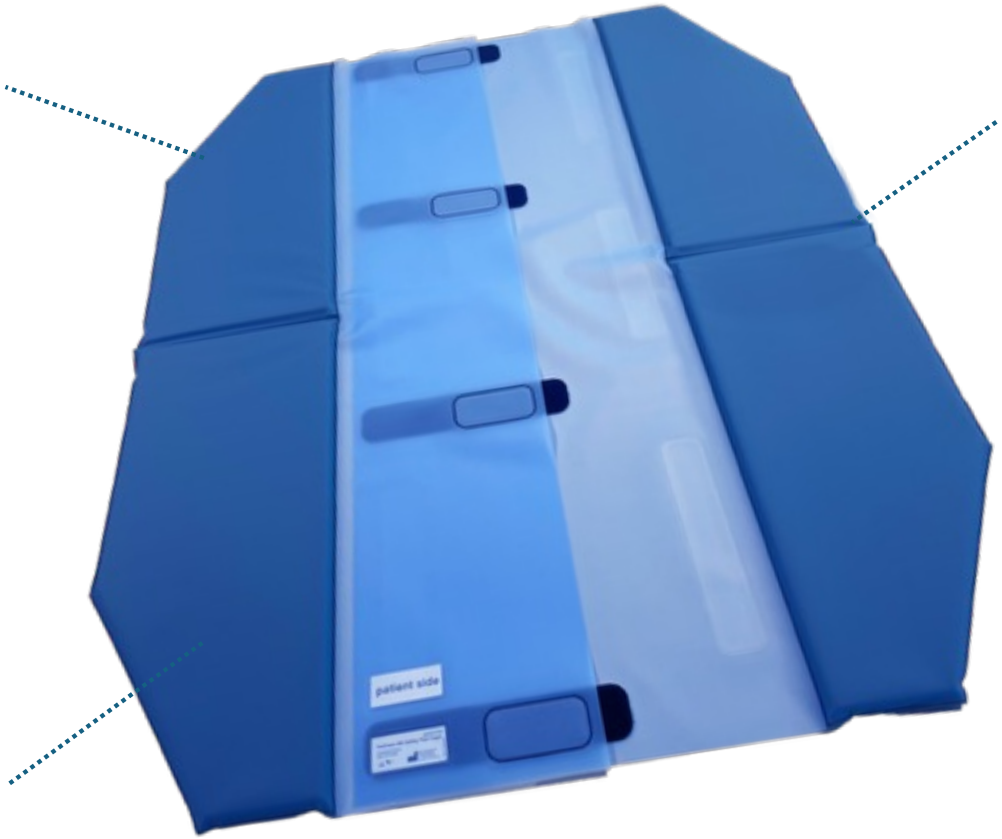
- Adjunct Clinical Professor of Radiology and Medicine, Keck School of Medicine, USC
- Director of MRI Safety, USC Stevens Neuroimaging and Informatics Institute
- President, Shellock R & D Services, Inc.
  www.MRIsafety.com

MR safety consultant for all major MRI system manufacturers.

Author of the leading textbook on MR Safety:
"MRI Bioeffects, Safety, and Patient Management"
www.MRIsafetybook.com

Top Side

120 cm (47”) long
1 cm (0.39”) thick
insulation material



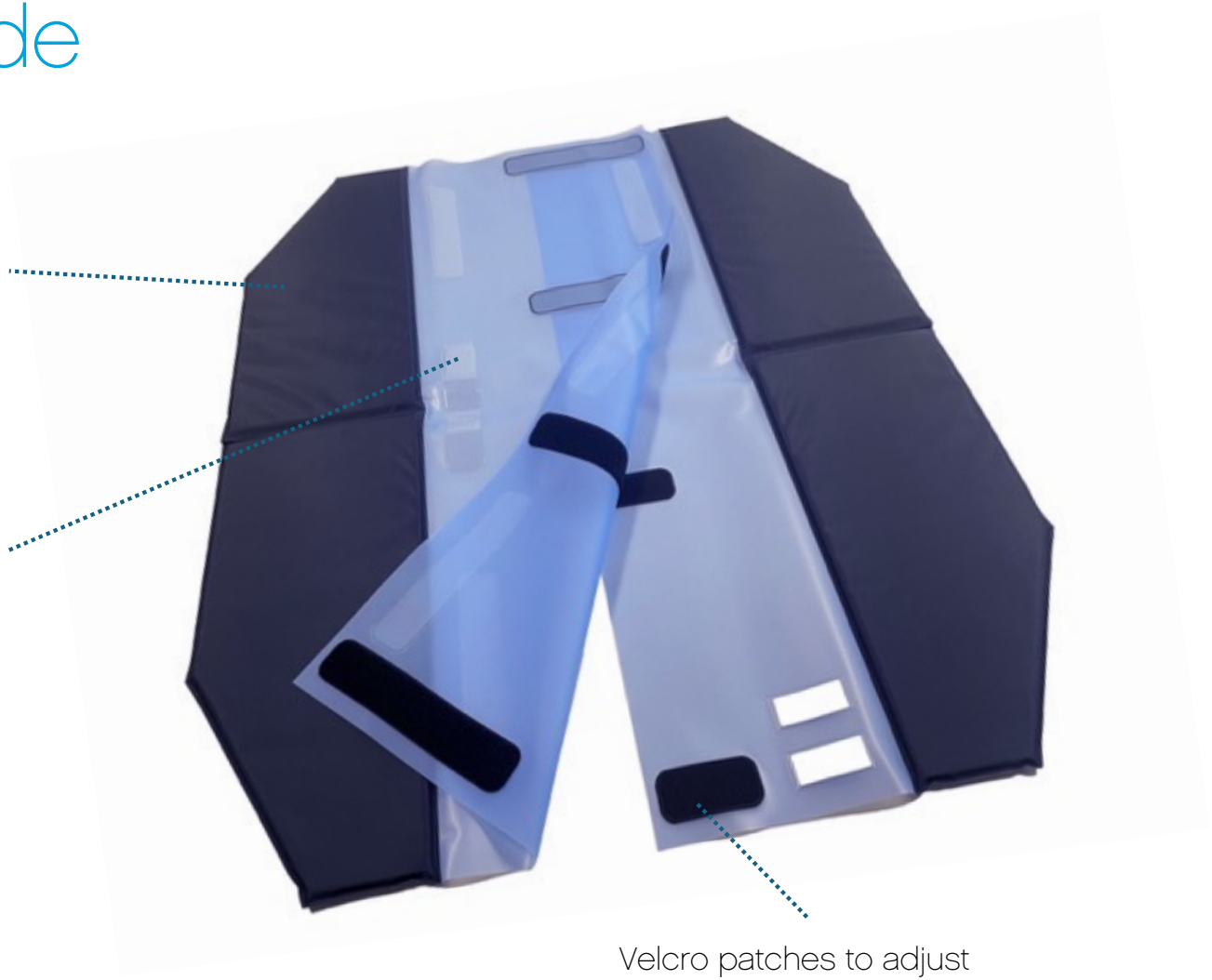
Foldable wings for
compact storage

Strong PU Foil to
withstand wear & tear
and disinfectants
even with 90% alcohol

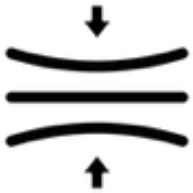
Bottom Side

Extra smooth black underside to easily slide into the MR system's bore

Six "anti-glide" patches to stay in place when transferring patients



Velcro patches to adjust the width to any MRI table

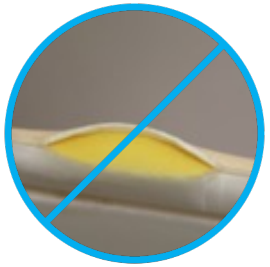


Strong

Maintains the distance to the MR bore even after long-term use.

Perfectly Hygienic

Designed for regular wipe disinfection even with 90% alcohol



High-quality

High-frequency welded seams are built to last.

Swiss Quality

Designed and manufactured in Switzerland

For Radiology / MRI

Tested for MRI / MR Safe

ISO-certified

Medical Device Class 1 according to ISO 13485.

Suits major MR System Manufacturers

The MR Safety Angel Pad may be used with all common whole-body, MR systems (60 and 70 cm diameter bores)

GE HealthCare

SIEMENS Healthineers

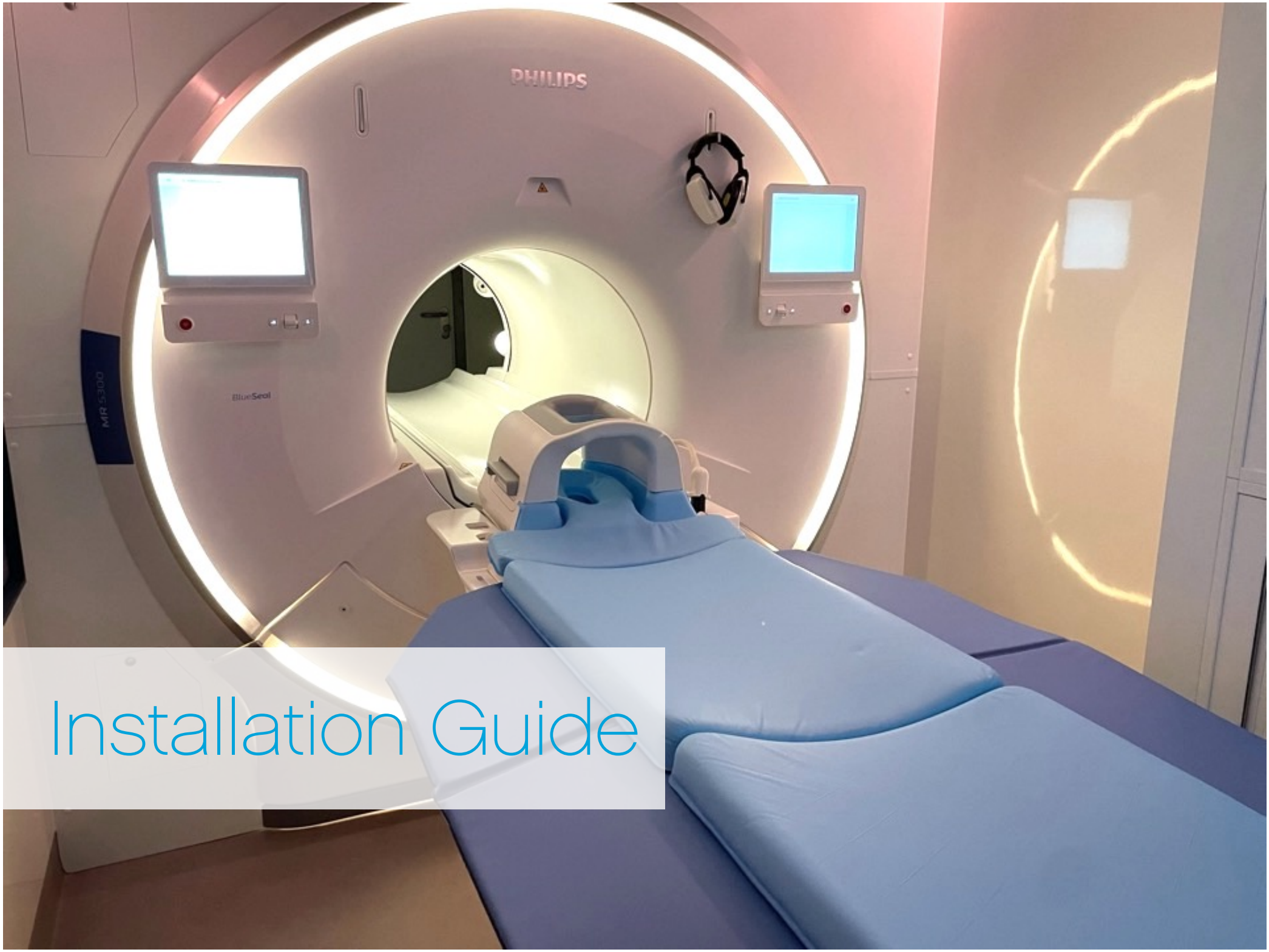
PHILIPS

UNITED IMAGING

Canon

Keeps Things Neat and Tidy

A small but important feature: cables or tubes may be neatly positioned in or around the pads, keeping them from getting stuck in the MR system, or contacting the patient's body. Also, the patient's elbow rests on the soft pad instead of the hard table.



Installation Guide

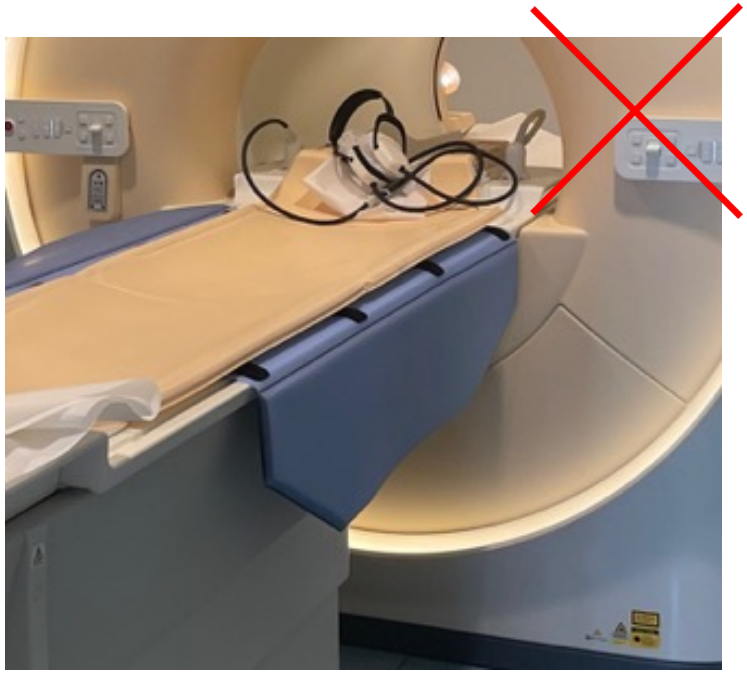
1. Adapt it to Your Table Size

Attach the black Velcro patches so the blue part fits your table exactly.

This works more easily when you do it right on the table!

If the Velcro patches are at the right distance, the wings should point outwards like in the picture on the left. This takes a bit of trial and error.

If the flaps hang too low, they risk getting blocked at the bore of the MR system – instead of folding up inwards.



2. Set it up on Your Table

Put it directly on the table – without the table mat. Make sure the black side faces down; this material is made extra smooth to slide into the bore of the MR system.

Video can be found on: https://www.pearl-technology.ch/en/mrsafetypad

3. Put your Table Mat on Top

It should fit neatly in between the wings.

Video can be found on: https://www.pearl-technology.ch/en/mrsafetypad

4. Done!

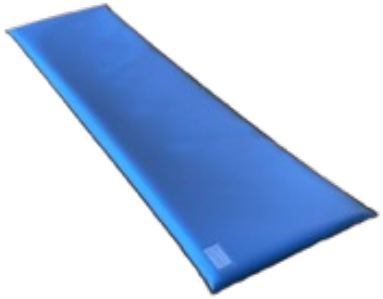
You can now leave it there for further examinations.

Video can be found on: https://www.pearl-technology.ch/en/mrsafetypad

Further Information

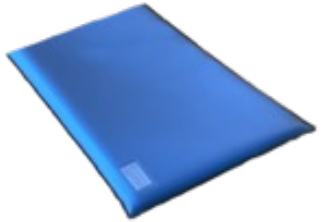
Prevent RF-Induced Burns Between Limbs

Single pads made of the same material can prevent skin-to-skin contact of arms, torso, or legs.



ProFoam Plate 50x25x1 DSR

The long version can prevent an arm from touching the torso, or two legs from touching each other.



ProFoam Plate 50 x25x1 DSR

This short version helps when little space is available.

Cleaning/Disinfection

The ProFoam MR Safety Angel Pad can be cleaned after every exam using commonly available hospital disinfectants, such as:

Active substance	Cleaning agent*	Concentration*	Recommendation
Water	Dest. Water	100%	Compatible
Surfactants	Detergent	1%	Compatible
Alcohol	Isopropanol	50%	Compatible
Alcohol	Ethanol	80%	Compatible
Alcohols	Bacillol AF	100%	Compatible
Hydrogen Peroxide	Incidin OxyFoam	15%	Not compatible
Sodium Hypochlorite	Javel	1%	Not compatible
Hypochlorous Acid	Hydroliq Prof.	0.05%	Not compatible
Benzalkonium Chloride	Biguanid Fläche N	8%	Compatible

*Cleaning agent and concentration used during testing

Caution:

Thoroughly clean and disinfect the entire product surface by wiping, for example with prefabricated disinfection tissues. Do not spray/apply cleaning agent directly onto product. Do not sterilize products.

Safety / Contraindications

MR Safe

Non-sterile, do not sterilize

Contraindication / warning:

Do not use the product for purposes other than those described. Do not allow direct contact with the skin. Use single-use sanitary cover. Do not use in case of acute open wounds.

Warnings: Dispose of any product that has a tear or appears damaged.

Remove the product from the device before calibration.

About Pearl Technology

Pearl Technology is the leading manufacturer of patient positioning solutions for radiology.

Simple, standardized positioning speeds up both frequent and infrequent examinations – and thus alleviates time pressure.

Comfortably positioned patients undergo examinations **calmly** and **satisfied** without complications.

Improved image quality and **fewer motion artifacts** thanks to effective immobilization.

MRI Core Portfolio

MULTIPAD

PearlFit

MR Safety Pads

ProBelt

Sandbag

Supporting References

American College of Radiology. (2024). ACR Manual on MR Safety. Retrieved from https://www.acr.org/-/media/ACR/Files/Clinical/Radiology-Safety/Manual-on-MR-Safety.pdf

Delfino, J. G., Krainak, D. M., Flesher, S. A., & Miller, D. L. (2019). MRI-related FDA adverse event reports: A 10-yr review. Medical Physics, 46(12), 5562–5571. https://doi.org/10.1002/mp.13768

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Shellock FG, Crues JV. MR procedures: Biologic effects, safety, and patient care. Radiology 2004;232:635-652.

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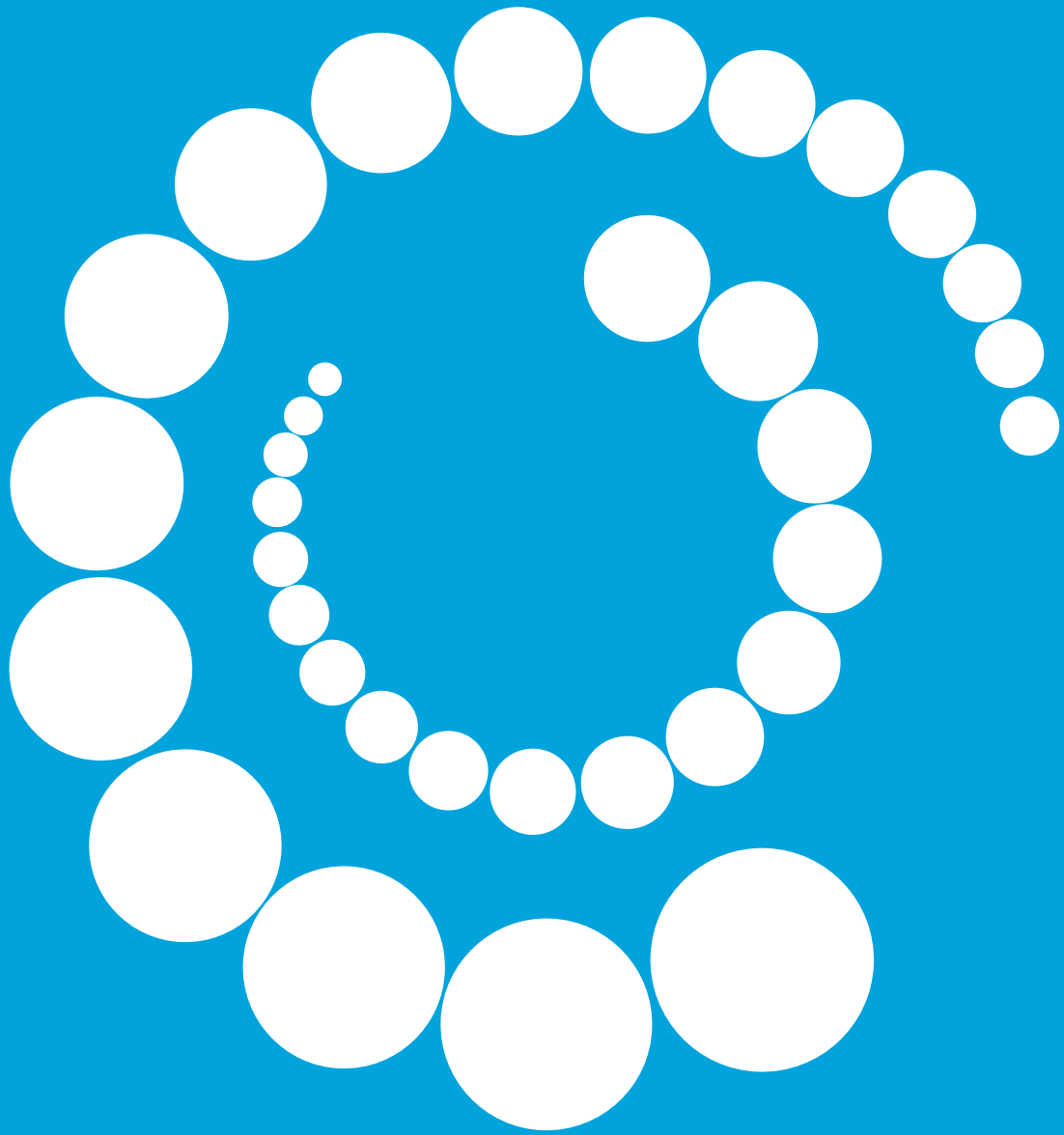

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