



## Press Information

# Orfit Industries Received FDA 510(k) Clearance for the new AIO Solution®

Norfolk, VA, August 30, 2019

Orfit Industries today announces that it has received FDA 510(k) clearance for its third generation "All-in-One" patient positioning and immobilization system, which is now widely available in the North American market. The AIO Solution® combines a Breast and Lung Board with a Brain and Head & Neck immobilization system.

Since its launch in 2005, The AIO Solution® facilitates and refines cancer treatment by limiting potential changes in the position of a patient during treatment to an absolute minimum. With one base plate, four cushion sets and a variety of thermoplastic masks, all parts of the human body are positioned and immobilized in a comfortable, precise and reproducible way, and with increased ergonomics and ease of use for the therapist.

Up to 700 systems have been brought to the market since more than a decade. *"This positive response from clinicians from around the world made us look for further improvement"*, says Steven Cuypers, Orfit CEO. *"With this third generation product, nearly all parts of the patient's body can be positioned for an even more patient-friendly, user-friendly and efficient radiotherapy treatment. The new AIO Solution was developed by combining science and innovation to make a patient-centric product that assures healing in comfort."*

The AIO Solution® avoids daily positioning uncertainties and limits patient setup time. It is easy to use and allows all state-of-the-art radiotherapy procedures in practically any anatomical location. The soft cushions ensure a comfortable position for the patient. The reduced height of the full AIO set-up fits in small bores and reduces the risk of collision with the gantry. Cushions can now be used directly onto the couchtop with the help of a 2-pin indexing bar.

The blue cushion set of The AIO Solution® is primarily intended for the treatment of malignancies in the thorax and breast and can be used with or without the base plate. The base plate is used for head and neck treatment. The grey cushion set comfortably positions knees and feet.

The AIO immobilization system is available in an MR safe version, which makes the product suitable for MRI-guided radiation therapy.

In a next stage, a new Belly board and Breast-in-prone system will be added to the product package.

In all, the system will feature four interchangeable, color-coded cushion sets, providing precise immobilization that is both reproducible and comfortable. The cushions are made with an entirely new production technique that assures durability in the busiest radiation therapy departments. Hand grips and head supports are helpful in finding the correct patient position and will further improve treatment. With this third generation AIO, Orfit product designers managed to improve the ergonomics for therapists, eliminate potentially cumbersome pressure points for patients and increase the lifespan of the product.

This third generation AIO Solution is lightweight and therefore easy to handle.

Finally, the fact that cushions and base plate can easily and effectively be cleaned fulfills the requirement of absolute hygiene in a hospital environment.



Orfit will showcase the AIO breast- and lung board set at the 2019 American Society for Radiation Oncology (ASTRO) Annual Meeting in Chicago, September 15-17.

You are welcome to visit Orfit at ASTRO, booth 3039.  
Discover The AIO Solution® online on [www.orfit.com/aio](http://www.orfit.com/aio)

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**About Orfit Industries**

Orfit Industries brings high precision, comfort and an efficient workflow to the positioning and immobilization of cancer patients in radiation oncology. Our family of systems handles with all types of treatments. The combination of Orfit thermoplastic masks and positioning devices provides optimal stability to a point where daily reproducibility and patient movement are limited to less than 1.5 millimeter. Orfit Solutions assure patient comfort that reduces anxieties and displacement of the anatomical area of treatment.

Orfit products are the result of a unique internal ecosystem in which R&D, Production, QA/QC, Sales Product Education/ Support and Post market surveillance through customer feedback are housed under one roof.

Orfit Product Specialists provide product training and education anywhere in the world, paying special attention to local regulations, cultures and habits. This assures a trouble-free experience for customers, so that they can concentrate on the management and planning of the care of their patients.

Orfit products are used in more than 100 countries worldwide. Orfit invests 15% of its annual revenue into R&D. The company employs over 100 team members, based in Belgium, the USA, Germany, France, the Netherlands and Hong Kong.

Additional information on [www.orfit.com](http://www.orfit.com).

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