



Fact or Fiction: Richway & Biomat[®] Myths Debunked

The internet is a powerful tool, but not everything that is on the internet is factual. We have compiled a list of statements found online about Richway and the Biomat[®] and officially answer whether the buzz is fact or fiction.

Be aware of paid-for reviews! Some companies compensate bloggers and reviewers of products to obtain a favorable review of their products. These reviews can contain inaccurate claims and false information about competitor products. Know the facts and research thoroughly!

Claim: Other competitor mats that have different stones on both sides (top and bottom) are better because of variety.

FICTION – Having stones on either side could be a safety hazard. Each Biomat® contains a thermal protection layer at the bottom (the side without the stones) to help keep excess far infrared heat from travelling under the mat and onto the surface it is lying on. This also means the user is receiving more of the beneficial far infrared heat.

Mats with stones on either side may not have this protection, because they are designed to be used on either side. This allows the heat to travel both up towards the user and down onto whatever surface the mat is placed on. Over time, surfaces in contact with double sided mats could be damaged more easily by the heat. Also, the user is losing more of the beneficial heat as it travels downward and away from the user.

Claim: Richway & Fuji Bio is actually based in South Korea NOT Hawaii.

FICTION – Richway & Fuji Bio is, in fact, based in Honolulu, Hawaii. All customer service, order processing, quality control, and product design is done at our office in Honolulu. The Biomat® is manufactured by our contract manufacturer, Richway & Life Co. (R&L), in South Korea.

Claim: The Biomat® only contains amethyst which makes it inferior. It needs jade, amethyst, and tourmaline to be effective.

FICTION – Through our 20 years of extensive research, we have found that amethyst produces the optimal amount of natural infrared rays over jade. The Biomat® also contains a layer within it called the TOCA layer.

The TOCA layer is a tourmaline layer, and in conjunction with the peach and grape seeds layer, allows the Biomat® to produce an abundance of negative ions.

Claim: The larger Biomats® do not contain tourmaline because it would greatly increase the cost of the product.

FICTION – As mentioned in the previous answer, all Biomats® contain a tourmaline layer within them. The Mini Biomat® includes alternating rows of amethyst and tourmaline stones to aid in producing the same amount of negative ions as the larger mats.

Claim: You have to pay extra for a cover for your Biomat®.

FICTION – Each Biomat® comes with a cotton pad that should be placed over it to protect it and allow the heat to be evenly dispersed. Each cotton pad includes the Hideo diagram – an energy pattern which incorporates sacred geometry.

Additionally, each Mini and Professional Biomat® comes with a hard-shell carry case for convenient mobility. Single, Queen and King Biomats® come with a duffel-like bag.

Hi-Pora waterproof pads may also be purchased separately. These special waterproof pads repel water while also remaining permeable enough for far-infrared rays and negative ions to easily pass through them.

Claim: Richway was issued an official warning letter from the FDA, and the company never took care of it.

FICTION – Richway's previous contract manufacturer, Richway NF, received a warning letter in 2013. Since this event, Richway & Fuji Bio

contracted a new manufacturer, R&L Co. R&L Co. has been our contract manufacturer since 2013 and meets or exceeds the standards and regulations set forth by the FDA. R&L Co. has never been issued a warning letter from the US FDA.

Claim: Richway does not produce their Biomats® and provide support after the purchase.

FICTION – Richway is registered with the FDA as the official importer, specification developer and complaint file establishment for the Biomat®. Our contact manufacturer, R&L Co. in South Korea, is also registered. Richway & Fuji Bio Inc is responsible for the designing, developing, manufacturing, and servicing of the Biomat®.

Claim: All infrared, gemstone heating mats are the same.

FICTION – Not all infrared, gemstone mats are the same. The Biomat®, for example, has been evolving since 1997 and contains unique layers to provide additional health benefits to the user. The Biomat® contains the Peach and Grape Seed Layer™ and provides organic energy, natural far infrared, and a class-leading amount of negative ions.

The TOCA Layer™ is a tourmaline layer within the mat which provides negative ions as well, and the surface layer of the Biomat® utilizes 100% cotton fabric (not including the urethane window which shows the gemstones). The state of the art IC chip within the Biomat's® controller controls the programming of the Biomat®. These innovate technologies set the Biomat® apart from the imitations.

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FDA 101

Responding to off-label claims

In order to make a fast buck, unscrupulous distributors of knock off mats have been quick to tout their product will treat and cure diseases. By saying so, they are breaking the law.

Since Richway & Fuji Bio manufactures and sells medical devices, we too are often asked if our products can be used to treat disease. If you are faced with related questions, this article should help you.

The U.S. Food and Drug Administration (FDA) has strict guidelines on what we can and cannot say and how we say it. Manufacturers of medical equipment can market their products after completing a clinical trial process and submission of data. The promotional materials must be consistent with FDA approved or cleared uses for the product.

All Independent Sales Associates (ISA) should be familiar with the approved uses of the Biomat®. It is listed on the approval notice we received from the FDA called a 510(k).

The 510(k) document states that “the Biomat® is indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis; the temporary relief of muscle spasms, minor sprains and strains, and minor muscular back pain; the relaxation of muscles; and the temporary increase of local circulation where applied.”

Jeff Morgan is Richway’s FDA consultant. We introduced him in Issue 3 of the Richway Wavelength. With a combined 30 years of clinical and research laboratory experience, Jeff is an expert when it comes to FDA policy.

“(All) distributor(s) should be familiar with the allowed claims in the FDA’s 510(k) approval notice and state to the customer that the only medical

uses the company can endorse are specifically listed in the 510(k),” said Morgan.

Any statements made beyond the scope of the 510(k) are considered “off-label,” or not approved and is considered misbranding under the Food, Drug, and Cosmetics Act.

“Richway cannot and does not endorse the use of the device other than the conditions specified in the Instructions for Use, Richway-developed brochures and flyers, and on the Richwayandfujibio.com website. The company cannot endorse off-label claims regardless of the source of the information,” said Morgan.

Furthermore, off-label claims may be viewed by the FDA as evidence of a new intended use.

For example: You make a flyer about the Biomat® and say it helps with minor back pain. The FDA views a video on your YouTube channel saying the Biomat® helps with cancer. The FDA will conclude that the true intent is not for back pain. Since the Biomat® is approved for a particular use, and you are promoting it for an off-label claim, the product can then be considered misbranded. This could, in turn, lead to civil and criminal penalties.

The FDA recognizes that companies, such as Richway, will be faced with many questions and does permit manufacturers to disseminate

off-label information as part of “scientific exchange” under prescribed circumstances. However, this is only permitted with Richway HQ (the manufacturer) and is not allowed by ISAs.

“Scientifically-exchanged ideas are interesting from only an academic point of view, but are not to be used to expand claims for the use of a device unless the manufacturer has peer-reviewed studies and submits a request for a new use to the FDA. However, this involves submitting a new 510(k), which is costly. And unless the data is convincing by the use of many subjects and proper conduct, it is likely FDA will not approve the new use. In addition, many studies are done without peer-review or without going through the proper clinical trials procedures mandated by FDA. In these cases, while the exchange of ideas is of minor interest, they are not to be construed either complete nor reproducible. Richway cannot endorse studies such as these because the results of these studies imply off-label use,” said Morgan.

Whenever you are asked what the Biomat® is good for, stick to what is listed on the 510(k). For other questions, have your customer contact Richway HQ directly.

Learn the dos and don’ts when promoting our products by reading the [Marketing Guide for Independent Sales Associates](#).