

## NOTICE: To the International Community - KNOW BEFORE YOU BUY

Thank you for your continued interest in the Axiom line of products to include the DRX non-surgical spinal decompression product for low back pain. Depending on your country the product may be referenced as a DRX9000, DRX5000 or the DRX3000 and it may even have a "C" in the product number indicating its expanded use for cervical pain. The Axiom Worldwide website is being maintained for the purposes of supporting the international community. If you are considering the purchase of a machine then it is important to read this notice.

In the past years Axiom has sold products in many different countries and Axiom even went so far as to negotiate, enter into detailed contracts and assign the rights to some countries through exclusive distribution companies. In many cases where the treatment has become popular it is because of the legitimate business efforts of Axiom's International Partners.

These Axiom International Partners have supported the product, their patients and their respective medical communities for years. They have fulfilled the stringent process of becoming registered with the respective Ministries of Health, or equivalent, and submitted all of the necessary paperwork to become legal representative in their country(s). Often times they have expended large sums of monies for clinical testing, the registration of the product and their contracts, in generating goodwill, product recognition, and doctor and patient support. They have been properly trained in the medical protocols, in installation, service and repairs, and have access to all aspects of the technology for warranty work and. In fact, these Partners have paid outright through various means for the exclusive rights to the Axiom products, the intellectual property rights, any trade names, trademarks usage and their independence for continued sales and support. Regardless of what some medical equipment distributors may espouse, these rights CAN NOT be taken away or circumvented unless the Axiom Partner agrees to such a change in writing.

So, how can you protect yourself and your patients? It is simple, KNOW BEFORE YOU BUY!

Ask the following questions:

1. Ask for a copy of the US FDA 510(k) in the name of the company and the individual who submitted such application which you intend to do business with. DO NOT accept a 510(k) unless it is in the name of that company or individual as it may not be valid. A Device Establishment Registration is NOT the same thing as a 510(k).
2. Ask for a copy of your federal government's Ministry of Health registration, or the equivalent of the US FDA 510(k) in the name of the company and the individual who submitted such application which you intend to do business with. DO NOT accept a document unless it is in the name of that company or individual as it may not be valid. Check with the Federal Government of your host country to authenticate any documents and to verify the validity of the seller, if in fact they are registered and their legal ability to import the product.
3. If the machine is being imported into your country then ask for a copy of the US FDA Certificate of Export in the name of the company which you intend to do business with. DO NOT accept a Certificate of Export unless it is in the name of that company as it may not be valid. A Certificate of Export is a document prepared by the FDA that contains information about a product's regulatory status in the United States. It can not be duplicated as it is an original that comes from the US Government and has a gold embossed seal and is specifically directed to the requesting foreign government. It is an extra measure of assurance that your product meets US FDA requirements for medical devices sold in the USA. Many, if not all foreign agencies rely on the FDACertificate of Export to help protect against illegitimate suppliers who may try to market a product overseas that cannot be legally sold in the US because it doesn't meet specific US regulations.
4. Ask for a Declaration of Conformity, this is a document on file for the USA FDA that is a statement, detailing each consensus standard, stating that all requirements were met. With the following

- exceptions noted on the declaration, any inapplicable requirements or deviations and should be itemized and detailed on the form to ensure that it meets or exceeds your country's requirements.
5. Ask for a copy of the ISO Certificate, and the date of last inspection. Again, this should be in the name of the company which you intend to do business with. **DO NOT** accept a Certificate unless it is in the name of that company as it may not be valid. A simple check with the registering body that issued the ISO Certificate can verify the credentials of that company.
  6. Ask for a copy of the CE Certificate, and the date of last inspection. Any time an organization relocates its business operations, especially from one country to another then the certificate is **NOT** valid unless a new inspection has been conducted. Again, this should be in the name of the company which you intend to do business with. **DO NOT** accept a Certificate unless it is in the name of that company as it may not be valid. A simple check with the registering body that issued the CE Certificate can verify the credentials of that company. Examine your mark CE Certificate to ensure it is authentic. Often companies "buy" the Mark CE Certificate only later to find that when the product is imported the customs agent will not allow passage because it did not meet regulatory requirements and is not on an approved list of notified bodies. There are only a handful of registered notified bodies throughout the world that are accepted by most countries and enable a legitimate exporter with very little difficulties to ship and import a product worldwide.
  7. And lastly, any modifications to an existing device already in the marketplace may require a resubmission of the above items to all of the respective governing bodies.

It is first and foremost imperative that whoever you do business with provides you with the above items in writing. Ask for and keep a copy in your files. While this may seem like a cumbersome process it may serve to assist in the safety of your patients in the long term. Additionally, this documentation will become important if you are brought into review by your medical licensing board and they inquire of the credentials of who sold you your machine and did they do so legally.

Recently there has been a flood of misinformation being disseminated by companies trying to circumvent the Axiom International Partners that have legally obtained the rights to Axiom's products. Be advised, any machines that are imported, exported, sold or being used to treat patients will be reported to the appropriate authorities. In past instances of such practices, the illegal devices have been seized and charges brought against all involved parties. Know before you buy and if you do not receive clear and satisfactory answers then contact your federal government and ask them to intervene and determine the legitimacy of a company.