

## Blood Flow Restriction Rehabilitation: FDA Requirements for Devices and for Health Care Professionals

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### 1. In the United States, healthcare practitioners must use an FDA listed device to safely and effectively perform blood flow restriction rehabilitation

Rehabilitation of patients by healthcare practitioners using a device clearly comes within the scope of “cure”, “treatment”, or “affect the structure or any function of the body” per the FDA definition of a medical device:

*"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*

- *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
- *intended for use in the diagnosis of disease or other conditions, or in the **cure**, mitigation, **treatment**, or prevention of disease, in man or other animals, or*
- *intended to **affect the structure or any function of the body** of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."*

For safety reasons, based on decades of clinical experience with and peer reviewed publications on pneumatic tourniquets in surgery, surgical caliber pneumatic tourniquets are used for blood flow restriction rehabilitation of patients by healthcare practitioners.

The FDA regulates pneumatic tourniquets as medical devices under 21 CFR 878.5910

Sec. 878.5910 Pneumatic tourniquet.

(a) Identification. A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to reduce or totally occlude circulation during surgery.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 878.9.

Per this classification, FDA requires companies designing, manufacturing, installing, servicing, and marketing such devices to comply with the following regulations:

- 21 CFR 807 “ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES” (except for subpart E, subject to the limitations in 878.9)
  - Registering the company’s establishments which are involved in design, manufacturing, installation, servicing, and distribution of medical devices
  - Listing the company’s medical devices



Personalized Tourniquet Systems

- 21 CFR 801 LABELING
  - Labeling the medical device with required information
  - Developing and providing directions for use for the medical devices that includes required information
- 21 CFR 830 UNIQUE DEVICE IDENTIFICATION
  - Labeling or marking the medical devices with unique identifiers for identifying and tracing the medical devices in distribution and in the field
- 21 CFR 820 QUALITY SYSTEM REGULATION
  - Establishing and maintaining a quality management system for the design, manufacturing, installation, and servicing of medical devices and other activities for the control of these processes
- 21 CFR 803 MEDICAL DEVICE REPORTING
  - Reporting of significant adverse events with a company's medical devices
- 21 CFR 806 MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS
  - Reporting of field corrections and removals of a company's medical devices and required conduct of the field corrections and removals
- 21 CFR 7 ENFORCEMENT POLICY (RECALLS)
  - Mandatory compliance with a FDA directive on recall (correction or removal) of a medical device from the field or voluntary action by the company to do the same

As part of listing their device and registering their establishment with the FDA, and maintaining the listing and annually re-registering their establishment, the manufacturer must certify it has complied with the applicable regulations, which in part requires maintaining evidence that the device is safe and effective for its intended use and that there are adequate directions for use for the device to be used safely and for the purposes for which it is intended.

Finally, as indicated in United States law 21 U.S.C. 360(h), all medical device manufacturers are subject to inspection by the FDA for compliance to all applicable United States medical device regulations.

## **2. In the United States, healthcare practitioners must have certification to perform blood flow restriction rehabilitation**

As part of 21 CFR 801 Labeling, FDA requires medical device manufacturers to provide adequate directions for use to ensure that the device is used safely and effectively. Part of determining adequacy is determining whether licensed healthcare practitioners have already received and understood safety and effectiveness knowledge relevant to the device or type of device as part of an accredited educational program and for their licensure.

If they have not received this knowledge and been certified (as part of their education or licensure), then it is required of the medical device manufacturer to ensure that the licensed healthcare practitioners have received and understood this knowledge (through training, testing, and certification of the required knowledge base to safely and effectively use the device).

Since Blood Flow Restriction Rehabilitation education and certification is not yet part of a physical therapist's or physician's educational and licensure training and certification, it must be provided by the medical device manufacturer or a body accredited by the medical device manufacturer to provide such training and certification.

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