FDA Requirements for Pneumatic Tourniquets in the United States

J.A. McEwen PhD
www.tourniquets.org

What are pneumatic tourniquets?

A pneumatic tourniquet is a medical device consisting of a pressure-regulating unit which can be operated manually or automatically, connecting tubing, and an inflatable cuff. Pneumatic tourniquets are intended to reduce or totally occlude circulation to a patient's limb to enable a licensed healthcare practitioner to perform a therapeutic function. Note that this definition covers pneumatic tourniquets intended to restrict blood flow to a limb, as well as pneumatic tourniquets intended to completely occlude or stop blood flow to the limb.

For patient safety, the design of inflatable tourniquet cuffs is fundamentally different than the design of other cuffs such as blood pressure cuffs. The special design of tourniquet cuffs allows a user to safely and accurately apply a desired pressure level and gradient uniformly around a limb for a prolonged time period sufficient for performing a therapeutic function. (Further information about safe tourniquet cuff design can be found on www.tourniquets.org)

Why does the FDA regulate pneumatic tourniquets as medical devices?

In the United States, pneumatic tourniquets are regulated as medical devices by the Food and Drug Administration (FDA) because they meet the "diagnose, cure, mitigate, treat or prevent disease" and "affect the structure or function of the body" clauses in the definition of a medical device[1] in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act.

How does the FDA regulate pneumatic tourniquets?

Pneumatic tourniquets are regulated as Class I medical devices under 21 CFR 878.5910 "Pneumatic Tourniquet" which requires the manufacturer to comply with the following regulations and to maintain evidence that the device is safe and effective for its intended use and indications for use:

21 CFR 801 LABELING	Specifies requirements for labeling of the medical device and its packaging including intended use, indications for use, contraindications, warnings, precautions, adverse effects, and instructions for the device's safe and effective use
21 CFR 830 UNIQUE DEVICE IDENTIFICATION	Specifies requirements for unique identifiers on medical devices for in field tracking purposes
21 CFR 807 ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES	Specifies requirements for registering with FDA the manufacturer's or distributor's establishment and listing its devices
21 CFR 820 QUALITY SYSTEM REGULATION	Specifies requirements for a quality system for the design, manufacture, installation, servicing of the medical devices and management and control of these processes
21 CFR 803 MEDICAL DEVICE REPORTING	Specifies requirements for reporting to FDA injuries and adverse events involving a manufacturer's medical devices

21 CFR 806 MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS	Specifies requirements for reporting to FDA field corrective actions involving a manufacturer's medical devices
21 CFR 7 ENFORCEMENT POLICY	Specifies requirements for reporting to FDA and conducting field corrective actions involving a manufacturer's medical devices

What penalties can be applied to manufacturers and distributors of pneumatic tourniquets not meeting FDA requirements?

Medical device manufacturers and distributors are subject to inspection by the FDA. Noncompliance with the FDA's regulations, or distribution of adulterated, unsafe or ineffective medical devices, can result in an increasing severity of mandated actions and penalties. The mandated actions and penalties range from completing corrective actions within given time frames, to detention, seizure and forfeiture of devices, and ultimately civil and criminal penalties.

What additional risks and liabilities arise for individual users of pneumatic tourniquets not meeting FDA requirements?

Risks of injuries to patients and legal liability for users arise from pneumatic tourniquet not meeting FDA requirements. The legal liability for a user extends to the user's employer and facility. Such user legal liability is separate from, and in addition to, the legal liability of the manufacturer and distributor. User legal liability may not be covered by the insurance policy of the user, the insurance policy of the user's employer, or the insurance policy of any facility in which pneumatic tourniquets not meeting FDA requirements are used.

How can a user of a pneumatic tourniquet minimize risks by assuring that the manufacturer and distributor meet all FDA requirements?

To help assure safety and minimize risks, a user should ask for specific written confirmation from the manufacturer and distributor that any pneumatic tourniquet offered for sale in the United States meets all relevant FDA requirements for these medical devices. This recommendation applies for all pneumatic tourniquets intended to reduce or totally occlude circulation to a patient's limb.

What 3 key questions should a supplier be asked prior to deciding whether to purchase a specific pneumatic tourniquet to restrict or occlude circulation?

1. Is the pneumatic tourniquet's manufacturer registered as an establishment with the FDA and has the manufacturer device listed the pneumatic tourniquet product with the FDA?
If 'yes', please provide the manufacturer's Establishment Registration Number and the description and Device Listing Number of the tourniquet's device listing.

2. Does the labelling and packaging of the pneumatic tourniquet product comply with all relevant requirements specified by the FDA?
If 'yes', please provide a copy of the labelling that includes the instructions for safe and effective use, contraindications, warnings, precautions, adverse effects, and prescription device statement.

3. Does the pneumatic tourniquet's manufacturer have an appropriate and certified quality system for the design, manufacture, installation and servicing of its pneumatic tourniquet products, and management and control of these processes?
If 'yes', please provide a copy of the appropriate quality system certificate (e.g. ISO 13485) or evidence of quality system compliance with 21 CFR 820.

Further reading

Link to FDA regulations
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

FDA Establishment Registrations and Device Listings Database
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

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[1] Medical Device Definition (section 201(h) of the US Federal Food Drug & Cosmetic Act)

"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 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."