FDA Clearances and Explanation of Device Use

VersaWrap® Hydrogel Sheet

Overview

VersaWrap® is a class II (medium risk) medical device intended to provide a mechanical mechanism of action via a gliding surface for injured tendons, peripheral nerves (including nerve root), ligaments, and skeletal muscle that prevents unwanted postoperative soft tissue tethering. VersaWrap is a single-use, sterile, device that does not contain animal or human products (not a biologic / non a tissue product). The device is indicated for use on specific tissues and is procedure-agnostic. In other words, the device may be applied in any procedure where the surgeon is concerned about postoperative tethering of tendons, peripheral nerves (including nerve root), ligaments, and skeletal muscle.

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The table below provides a list of FDA clearances associated with VersaWrap use and a plain-speak explanation of what these clearances mean to clarify how the device may be used.

Clearance	Indication for use	Plain-speak description
K160364	To protect and manage tendon injuries where there is no substantial loss of tendon tissue	Device provides a gliding surface for injured tendons during healing to prevent postoperative tethering; injuries such as repaired or exposed tendon
K200311	To protect and manage tendon injuries where there is no substantial loss of tendon tissue	Device offered in an additional, smaller size sheet (5 x 2.5 cm)
K201631	To manage peripheral nerve injuries where there is no substantial loss of nerve tissue	Device provides a gliding surface for injured peripheral nerves (including nerve root) during healing to prevent post-operative tethering; injuries such as repaired, decompressed, or exposed nerves
K203600	To protect and manage tendon injuries where there is no substantial loss of tendon tissue; the device may also be used to protect and manage surrounding tissue such as ligament and skeletal muscle	Expand use of device to provide a gliding surface for ligament and skeletal muscle
K213163	To protect and manage tendon injuries where there is no substantial loss of tendon tissue; the device may also be used to protect and manage surrounding tissue such as ligament and skeletal muscle	Added a new delivery method; VersaWrap can be applied as a gel (tendon)
K232029	To manage peripheral nerve injuries where there is no substantial loss of nerve tissue	Device may be used for all ages (removal of pediatric restriction in labeling)
K240817	To protect and manage tendon injuries where there is no substantial loss of tendon tissue; the device may also be used to protect and manage surrounding tissue such as ligament and skeletal muscle. In these procedures, VersaWrap may encounter a variety of implanted structures such as anchors, grafts, staples, and sutures	Clarify device use on other implanted structures that VersaWrap can encounter such as anchors, grafts, staples, and sutures

Always refer to the package insert, product label, and/or user instructions before using any Alafair product.

The content of this document is for informational purposes only and is not intended to constitute medical advice. As with any medical device, there are multiple factors affecting patient outcomes, including post-operative recovery time and activity level. Patient outcomes may vary based upon, among other factors, the nature and extent of loss or damage, the time between injury or damage and surgery, and the natural course of the patient's recovery.

The availability of these products is in the United States only. Caution: Applicable laws restrict these products to sale by or on the order of a physician.

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