

DESCRIPTION

VersaWrap® is an absorbable implant (device), designed to serve as an interface between target tissues and surrounding tissues to provides a non-constricting, protective encasement. VersaWrap consists of a clear Sheet and a wetting Solution. The clear Sheet is a thin membrane of crosslinked calcium alginate and glycosaminoglycan. VersaWrap Sheet is easy to handle, conformable, and is designed for placement under, around, or over injured tissues and/or surrounding tissues. VersaWrap Sheet is supplied sterile, non-pyrogenic, for single use, in double peel pouches. The VersaWrap Solution is applied to the Sheet to render the Sheet a gelatinous, tissue adherent layer (gel in situ). The aqueous citrate Solution is provided sterile, non-pyrogenic, for single use, in a dropper, packaged in a double peel pouch.

INDICATIONS

VersaWrap is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The device may also be used in the management and protection of surrounding tissues such as skeletal muscle and ligament.

VersaWrap is indicated for the management of peripheral nerve (including nerve root) injuries in which there has been no substantial loss of nerve tissue.

CONTRAINDICATIONS

- VersaWrap is not designed, sold, or intended for use except as described in the indications for use and is contraindicated for patients with known hypersensitivity to citrate, alginate, or hyaluronate materials.
- VersaWrap is contraindicated for use as a mechanical support to repair nerve or to function as a nerve conduit

PRECAUTIONS

- DO NOT RESTERILIZE. Discard all opened and unused portions of VersaWrap
- Based on in vivo animal studies in a rat sciatic nerve injury model, VersaWrap can displace or move after placement on the target tissue. Patient mobility should be considered to mitigate the risk of device movement post-implant.
- While VersaWrap may be placed in proximity to dura, VersaWrap is not intended for use as a dura replacement or sealant.
- Excess Solution (more than the recommended volume) may accelerate bioresorption. Not enough Solution (less than the recommended volume) may retard bioresorption and reduce tissue adherence

INSTRUCTIONS FOR USE

If irrigation of the surgical site is desired, then irrigation should be conducted prior to the application of VersaWrap. Always handle VersaWrap using aseptic technique.

Preparation

- Peel open the outer pouch and remove the two inner sterile pouches (Component A: VersaWrap Sheet, and Component B: VersaWrap Solution) and place the two pouches flat onto a sterile surface.
- Peel open the VersaWrap Sheet pouch. Remove the VersaWrap Sheet, which is clear, from the inner pouch carefully with dry, gloved fingers or blunt tools. **Handle with care as the Sheet is fragile.** Discard the backing material (carrier) which is white and opaque. (See photo)
- Determine the appropriate size of Sheet needed to extend the entire target area and cut Sheet. Multiple sheets or pieces of sheet(s) may be used as needed to ensure complete coverage of the entire target tissues. For example, one tendon / nerve may be wrapped and/or covered with multiple sheets.
- Sheet may be placed onto a dry, room temperature, sterile area or in sterile water until application.
- Peel open the VersaWrap Solution pouch. VersaWrap Solution is supplied in a single use, sterile dropper. Remove dropper cap before using.

Application Method 1: Sheet placement prior to adding Solution

Component A: VersaWrap Sheet

1. Sheet may be applied dry or may be dipped in sterile water or saline before use. Do not soak in saline.
2. Gently lift tissues to place the Sheet on, under, or around the target tissues. Avoid pulling on Sheet. Backing material may be used to help guide the Sheet and prevent tearing.
3. Wrap the ends of the Sheet around the affected region, ensuring complete coverage.
4. After wrapping, trim or overlap the excess Sheet as desired.
5. Smooth with gloved finger or blunt tool, if needed. Sheet must be in contact with tissue or itself to adhere.

Component B: VersaWrap Solution. After the Sheet is positioned, the Solution is applied to the entire visible surface of the Sheet. Avoid direct contact of the Sheet with the dropper tip.

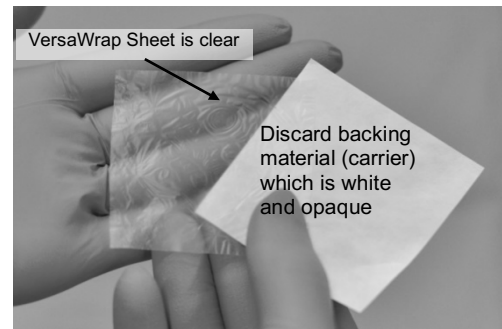
6. Add the VersaWrap Solution dropwise to the positioned Sheet. Use enough Solution to adequately wet the entire Sheet surface, including edges. **Sheet will become gelatinous and will conform to underlying tissues when the recommended volume of Solution is delivered. This transition is visible.** There may be excess Solution as the volume provided is adequate for the full, uncut Sheet. For example, a 1 cm x 2 cm piece of Sheet would require approximately 2-4 drops of Solution. Do not manipulate the Sheet after application of the Solution.
 - a. Excess Solution (more than the recommended volume) is acceptable, however may accelerate bioresorption.
 - b. Not enough Solution (less than the recommended volume) is acceptable, however may retard bioresorption and reduce tissue adherence.
 - c. Use of Solution is recommended for significant Sheet overlap.
 - d. Saline is a mild chelator and performs similarly to the Solution in greater volumes. No data with saline has been generated for overlapped Sheets.
7. No further wound irrigation should be conducted after application of VersaWrap Solution.

WARNINGS

- VersaWrap is not indicated to replace, to repair, or to reinforce the strength or closure of target tissues such as tendon, ligament, or skeletal muscle
- VersaWrap is sterile if the package is unopened and undamaged. Do not use if the package seal is broken or if the packaging/product is otherwise compromised.
- VersaWrap should not be applied until bleeding is controlled
- VersaWrap should not be applied in the presence of infection

ADVERSE EVENTS

- Possible complications that can occur with any implanted device or surgical procedure such as nerve repair include pain, infection, foreign body response, decreased or increased nerve sensitivity, and complications associated with the use of anesthesia



Application Method 2: Solution added to Sheet prior to placement

Component A + B: VersaWrap Sheet + VersaWrap Solution.

1. Sheet may be applied dry or may be dipped in sterile water or saline before use. Do not soak in saline.
2. Place Sheet on provided backing material or in a sterile container (such as a syringe)
3. Add the VersaWrap Solution dropwise to the entire Sheet surface; adequately wet the entire Sheet surface, including edges; approximately 0.5 mL (25-50 drops) applied to the uncut 5 cm x 5 cm Sheet. **Sheet will become gelatinous; This transition is visible and may take 3-5 minutes.**
4. There may be excess Solution as the volume provided is adequate for the full, uncut Sheet.
 - a. Excess Solution (more than the recommended volume) is acceptable, however may accelerate bioresorption.
 - b. Not enough Solution (less than the recommended volume) is acceptable but may prevent complete gelatinous transition, and may retard bioresorption and reduce tissue adherence. Saline is a mild chelator and performs similarly to the Solution in greater volumes.
5. Gently apply the gelatinous layer on, under, or around the target tissues, ensuring complete coverage.
6. Smooth with gloved finger or blunt tool, if needed. VersaWrap must be in contact with tissue or itself to adhere.
7. No further wound irrigation should be conducted after application of VersaWrap Solution.

Post-Application

Application of VersaWrap does not modify postoperative treatment. The surgeon must determine motion and strength limitations according to standard practice based on the extent of the repair.



HOW SUPPLIED

VersaWrap is supplied dry, sterile, in single use, double peel packages. Inner pouches remain sterile when handled with proper sterile technique.

STORAGE

Store at room temperature. Avoid excessive heat (greater than 40°C). Avoid freezing.

CAUTION

Federal law restricts this device to sale by or on the order of a physician or practitioner.

SYMBOL GLOSSARY

Symbol	Symbol Title	Description of Symbol	Standard Reference	Standard Title
Symbols Derived from Standards				
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC.	ISO 15223-1 Symbol 5.1.1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Symbol 5.1.4	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Batch code	Indicates the manufacturer’s batch code so that the batch or lot can be identified.	ISO 15223-1 Symbol 5.1.5	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Catalogue number	Indicates the manufacturer’s catalogue number so that the medical device can be identified.	ISO 15223-1 Symbol 5.1.6	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 Symbol 5.2.4	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened. This symbol may also mean “Do not use if the product sterile barrier system or its packaging is compromised.”	ISO 15223-1 Symbol 5.2.8	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Packaging unit	Indicate the number of pieces in the package.	ISO 7000 Symbol 2794	Graphical symbols for use on equipment
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1 Symbol 5.3.2	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 Symbol 5.3.4	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 Symbol 5.3.7	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Symbol 5.4.2	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Symbol 5.4.3	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	MR Safe	An item which poses no known health hazards resulting from exposure to any MR environment.	ASTM F2503-20 Fig. 4	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
	Prescription Only	Requires prescription in the United States. Caution: Federal (USA) law restricts this device to sale	21 CFR 801.15	Part 801 Labeling, Section 801.15 Medical devices; prominence of required label statements; use of symbols in labeling

Returned goods policy

- Authorization, from customer service, must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packaged to prevent damage. Custom or special order products will not be accepted for credit.
- Credit will be issued for goods returned prior to ninety days from ship date with a restocking charge. This credit assumes that the product returned is not damaged and can be verified to have not been used or opened

Product information disclosure: Alafair has exercised reasonable care in the selection of materials and the manufacture of these products. Alafair excludes all warranties except its applicable standard warranty, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Alafair shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Alafair neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products. Alafair intends that this device should be used only by physicians having received proper training in the use of the device.