veritas®

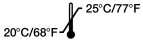
COLLAGEN MATRIX

Instructions for Use

Synovis®

Surgical Innovations

SYMBOL DEFINITIONS:

	Store at controlled room temperature
	Keep away from heat. Do not use if heat indicator is red
	Do not reuse
	Consult *Instructions for Use*
STERILE R	Sterilized using irradiation
	Do not use if the product sterilization barrier or its packaging is compromised
NaOH	This product is treated with sodium hydroxide
BOVINE	This product is derived from USDA-inspected cattle
MADE IN THE U.S.A.	Made in the U.S.A.
Rx Only	CAUTION: Federal (USA) Law restricts this device to sale by, or on the order of, a physician
CONTENT	Content
REF	Catalog number
	Use by date
LOT	Batch code
	Manufacturer
PN	SSI part number
TN	SSI tracking number
IC	SSI internal code
ID	SSI internal code

DESCRIPTION:

Veritas® Collagen Matrix is an implantable biologic mesh comprised of noncrosslinked bovine pericardium. Veritas Collagen Matrix bovine pericardium is sourced from cattle less than 30 months of age.

Veritas Collagen Matrix allows for neo-collagen formation and neovascularization of the implanted device and permits replacement of the device with host tissue, or remodeling. Veritas Collagen Matrix also minimizes tissue attachment to the device in case of direct contact with viscera.

Veritas Collagen Matrix is packaged in an inner sterile pouch and outer non-sterile pouch. The contents of the unopened, undamaged container are sterile.

INDICATIONS FOR USE:

Veritas Collagen Matrix is intended for use in reconstruction of the pelvic floor excluding transvaginal pelvic organ prolapse and for use in the repair of rectal prolapse excluding rectocele.

Veritas Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies: abdominal and thoracic wall repair, muscle flap reinforcement and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

Veritas Collagen Matrix minimizes tissue attachment to the device in case of direct contact with viscera.

CONTRAINDICATIONS:

Use of Veritas Collagen Matrix is contraindicated in patients with a known sensitivity to bovine material.

ADVERSE REACTIONS:

As with any surgical procedure, adverse reactions are possible and include but are not limited to: infection, rejection, erosion, and allergic reaction.

WARNINGS:

- Do not re-sterilize.
- This product is for single use only; discard all open and unused portions.
- Do not use product if the outer or inner pouch is damaged or if the seals are not intact.
- Veritas Collagen Matrix is not designed, sold, or intended for use except as indicated; doing so may result in surgical complications.
- Do not use if the product has been exposed (1) to solutions above room temperature, (2) to chemicals, antibiotics, or other substances other than specifically addressed in these instructions, (3) or if heat indicator has been activated as the characteristics of Veritas Collagen Matrix may change or be compromised.

CAUTIONS:

- Product must be moist at all times; place the product in a solution of room temperature saline for up to one hour if needed.
- Avoid tension on the material.
- When clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic measures should be taken to manage the contamination/infection.

STORAGE CONDITIONS:

1. Store at controlled room temperature (20° - 25°C / 68° - 77°F). The average temperature must be kept ≤ 25°C (77°F) but there may be brief temperature fluctuations between 15°C and 30°C (59° - 86°F).
2. Do not use the product if the heat indicator has been activated.

INSTRUCTIONS FOR USE:

These *Instructions for Use* are designed for proper use of this device. They are not intended to serve as a reference to surgical technique or to supersede institutional protocols or professional clinical judgement regarding patient care.

1. Check the heat indicator on the carton. Do not use the product if the heat indicator is activated.
2. Remove the pouch from the carton.
3. Inspect the outer pouch. Do not use if the outer pouch is damaged or if the seals are not intact.
4. Open the outer pouch and aseptically transfer the inner pouch into the sterile field.
5. Open the inner pouch and remove the product with a smooth forceps.
6. Veritas Collagen Matrix is ready for implantation. If the product is not to be used immediately, keep it moist by placing it in a basin of room temperature sterile saline.

Caution: Product must be moist at all times; place the product in a solution of room temperature saline for up to one hour if needed.

7. At the surgeon's discretion a room temperature, pre-implant soak in saline and antibiotics for up to one hour may be conducted. The following antibiotics have been demonstrated to not adversely affect Veritas Collagen Matrix: Ampicillin, Kanamycin, Neomycin, or Cefazolin.

IMPLANT INSTRUCTIONS:

1. Using sterile technique, tailor the configurations of the Veritas Collagen Matrix to meet the patient's needs.
2. Veritas should be placed in maximum possible contact with healthy, well-vascularized tissue; adequate overlap is recommended to ensure that the implant margin is in contact with healthy, vascularized adjacent tissue.
3. Veritas Collagen Matrix may be secured in position to the host tissue by suture, staple, tack, or other method chosen by the surgeon; when suturing, place the sutures at least 2-3 mm from the edge of the Veritas Collagen Matrix .
4. Discard any unused portion of the Veritas Collagen Matrix.

DISCLAIMER OF WARRANTIES:

Synovis Surgical Innovations (SSI), a division of Synovis Life Technologies, Inc., warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since SSI has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after it leaves its possession, SSI does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. SSI will replace any device which is defective at the time of shipment. No representative of SSI may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

Synovis®
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