



Vitasure™

Absorbable Hemostat
Flexible Extended Applicator

Instructions for Use (REF# 2114-1000)
Single Use Only. Provided Sterile--Do Not Resterilize.

CAUTION

Federal (USA) Law restricts this device to sale by or on the order of a physician or licensed practitioner.

DESCRIPTION

A single use, malleable and disposable, manual apparatus, the Vitasure Flexible Extended Applicator is designed to deliver Orthovita's Vitasure Absorbable Hemostatic Particles for use as an adjunct to hemostasis for control of capillary, venous, and arteriolar bleeding when conventional procedures are ineffective or impractical. **Please see the instructions for use for Vitasure for complete information on the absorbable hemostat.** Upon contact with blood, the hemostatic particles act as molecular sieves and enhance natural hemostasis by concentrating blood solids such as platelets, red blood cells, and blood proteins on the particle surfaces to form a gelled matrix.

Two (2) Vitasure Flexible Extended Applicators are supplied in each sterile pouch. Vitasure is available separately.

INDICATIONS

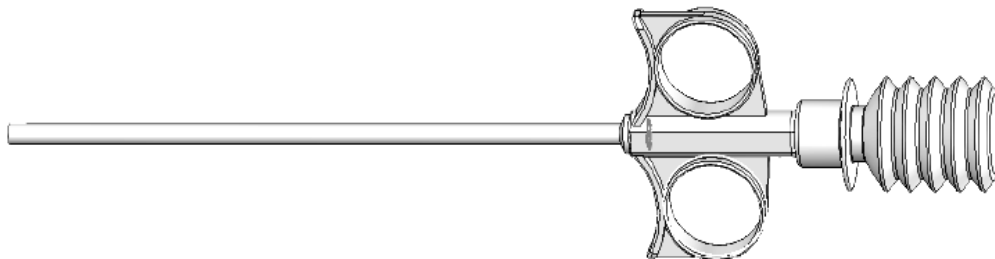
- The Vitasure Flexible Extended Applicator is intended for the application of Vitasure Hemostat onto surgical wounds.
- Vitasure is indicated in surgical procedures (except neurological, ophthalmic, and urological) as an adjunctive hemostatic device to assist when control of capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is ineffective or impractical.

Note: Carefully read the Directions for Use prior to application.

DIRECTIONS FOR USE

APPLICATOR ASSEMBLY

- Prior to initiating the procedure, visually inspect the package containing the Vitasure Flexible Extended Applicators for any signs of damage. If damage is visible, do not use the Applicators.
- Remove the Vitasure Flexible Extended Applicators from the packaging.
- Remove the Vitasure from its packaging and then bend and twist off its protective cap.
- Firmly press the Vitasure bellows applicator into the mouth of a Vitasure Flexible Extended Applicator handle. The Vitasure Flexible Extended Applicator is now ready for deployment.
- The Applicator should be assembled as depicted below.



CLINICAL APPLICATION

- After a bleeding lesion has been identified, blot, wipe, or suction the bleeding tissue. It is important to remove excess blood so that Vitasure may be applied immediately and directly to the site of active bleeding.
- Immediately position the Vitasure Flexible Extended Applicator tip at the site of bleeding within the wound, as close to the source of bleeding as possible, and begin delivering Vitasure by successively pumping the bellows applicator. Avoid direct contact between the applicator tip and blood at the surgical site to minimize the potential for clotting the tip during Vitasure application.

Note that the Vitasure Flexible Extended Applicator can be easily trimmed in the event that tip clotting occurs. It is important to use a sharp scissors to avoid crushing the tip.

- Immediately after application of a liberal amount of Vitasure to completely cover the wound, apply wound-appropriate, direct pressure over the treated site.
- If bleeding or oozing continues, remove excess Vitasure and reapply.
- Once hemostasis is achieved, remove excess Vitasure from the surgical site by irrigation and aspiration.

CONTRAINDICATIONS

- Do not inject Vitasure into blood vessels as potential for embolization and death may exist.

WARNINGS

- Vitasure in conjunction with the Vitasure Flexible Extended Applicator is not intended as a substitute for meticulous surgical technique.
- The Vitasure Flexible Extended Applicator is supplied as a sterile (single use only) product and cannot be resterilized.

PRECAUTIONS

- Do not use Vitasure Flexible Extended Applicator if the product packaging has been opened or damaged.
- To prevent product contamination prior to application, always follow aseptic techniques.
- The safety and efficacy of the combined use of Vitasure Flexible Extended Applicator with other hemostatic agents has not been clinically evaluated and is therefore not recommended.

ADMINISTRATION

Aseptic technique should always be followed. A liberal amount of Vitasure should be applied to the bleeding site using the Vitasure Flexible Extended Applicator (see DIRECTIONS FOR USE) followed by pressure until hemostasis is achieved. After hemostasis is achieved, excess Vitasure should be removed by irrigation and/or aspiration.

Please see the instructions for use for Vitasure for complete information on the absorbable hemostat.


STORAGE AND HANDLING


The Vitasure Flexible Extended Applicator should be stored at room temperature. Once the product is opened, contents are subject to contamination. It is recommended the product contents be used as soon as opened and unused contents discarded.

DISCLAIMER

Neither Medafor, Inc. nor Orthovita, Inc. shall be liable for any direct, incidental, or consequential damages other than as specifically provided under applicable law or contract. No individual has the authority to bind Medafor, Inc. to any representation or claim except as specifically set for herein. Descriptions or specifications are presented to generally describe the Vitasure Flexible Extended Applicator and related procedures, and do not constitute any expressed claims or practices.

DEFINITION OF SYMBOLS

 Sterilized using irradiation

 Do not reuse

 Latex Free

 Prescription Only

Distributed by:



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The Vitasure Flexible Extended Applicator is manufactured by Medafor, Inc. Vitasure is manufactured under U.S. Patent #6,060,461. Other Patents related to the Vitasure Flexible Extended Applicator are pending.