

User Manual

RESPONDER[®] Polysaccharide Hemostat

(OTC)

LIT-F-0008 0926

Contents

1. DESCRIPTION	3
2. ACTION	3
3. INDICATIONS	3
4. INSTRUCTIONS FOR USE	3
5. DOSAGE AND ADMINISTRATION	3
6. PRECAUTIONS	3
7. WARNINGS	4
8. CONTRAINDICATIONS	4
9. ADVERSE REACTIONS	4
10. HOW SUPPLIED	4
11. STERILIZING METHOD	4
12. STORAGE & EXPIRATION DATE	4
13. TRADEMARKS	4
ANNEX: SYMBOL EXPLANATION	5

1. DESCRIPTION

RESPONDER® Polysaccharide Hemostat (RESPONDER®) is a medical device composed of absorbable modified polymer (AMP®) particles. AMP® particles are bio-compatible, non-pyrogenic and derived from plant starch. The device contains no human or animal components.

2. ACTION

AMP® particles have a molecular structure that absorbs water from the blood. This dehydration process causes a high concentration of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) which accelerates the normal, physiologic clotting cascade. In contact with blood, AMP® particles support the formation of a gelled, adhesive matrix which provides a mechanical barrier to stop bleeding.

3. INDICATIONS

RESPONDER® Polysaccharide Hemostat OTC is indicated for the local management of bleeding such as minor lacerations, minor cuts and minor abrasions.

4. INSTRUCTIONS FOR USE

- a. Tear open RESPONDER® package.
- b. Dry any excess blood using gauze.
- c. Immediately apply AMP® particles liberally onto the wound site.
- d. Apply firm pressure directly to wound for 5 minutes using gauze. If any bleeding persists, apply direct pressure for an additional 5 minutes.
- e. Wrap and tie bandage so as to maintain pressure on the wound.
- f. If bleeding persists, seek medical care as soon as possible.
- g. Remove excess AMP® particles carefully and completely by irrigation during wound cleaning procedure.

5. DOSAGE AND ADMINISTRATION

A liberal amount of AMP® particles should be applied to the bleeding site until hemostasis is achieved. Apply pressure if necessary.

6. PRECAUTIONS

RESPONDER® has not been clinically evaluated in patients with coagulation disorders.

7. WARNINGS

RESPONDER® is intended to be used in a dry state. Contact with fluids prior to application will result in loss of hemostatic effect.

If the package has been previously opened or damaged, discard and replace with a new device.

If signs of an infection develop at the site where RESPONDER® has been used, contact a health care professional.

Keep away from children.

8. CONTRAINDICATIONS

RESPONDER® is contraindicated in patients who are sensitive to starch or starch-derived materials.

9. ADVERSE REACTIONS

None reported to date.

10. HOW SUPPLIED

RESPONDER® is supplied in packages of 2g, 3g, 5g, 10g and 25g.

11. STERILIZING METHOD

Contents of the RESPONDER® package are sterilized by irradiation and should not be re-sterilized. Discard unused portion after opening.

12. STORAGE & EXPIRATION DATE

Store at room temperature. It should not be exposed to extreme environmental conditions for example, -40°C (-40°F) for over two weeks or 55°C (131°F) for over four months during transportation or under other special circumstances. Shelf life is five (5) years from date of manufacture. Lot number and expiration date are marked on product.

13. TRADEMARKS

RESPONDER® and AMP® are registered trademarks of Starch Medical Inc.

Manufactured for:

Starch Medical Inc.

2150 Ringwood Ave, San Jose, California 95131 USA

Tel: 408-428-9818

Email: info@starchmedical.com

www.starchmedical.com

ANNEX: SYMBOL EXPLANATION

	= Do not reuse
	= Use-by date
	= Catalogue number
	= Sterilized using irradiation
	= Batch code
	= Date of manufacture
	= Caution
	= Do not use if package is damaged
	= Do not re-sterilize
	= Consult instructions for use
	= This product is not made with natural rubber latex.