# Vol_013 Doc_001 User Manual Rx-Clean Copy

# User Manual

# RESPONDER® Polysaccharide Hemostat

# CONTENT

## 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 further bleeding.

## 3. INDICATIONS

RESPONDER® Polysaccharide Hemostat is intended to be used to achieve hemostasis on emergency situation for the temporary control of severe topical bleeding.

## 4. INSTRUCTIONS FOR USE

1) Tear open Responder® package.
2) Dry any excess blood using gauze.
3) Immediately apply AMP® particles liberally onto the wound site.
4) Apply firm pressure directly to wound for 5 minutes using gauze. If any bleeding persists, apply direct pressure for an additional 5 minutes.
5) Wrap and tie bandage so as to maintain pressure on the wound.
6) Seek MEDICAL CARE as soon as possible. Remove excess AMP® particles carefully and completely by irrigation and aspiration during wound cleaning procedure.

## 5. NOTE

If bleeding continues, remove excess particles and repeat the procedure.

## 6. PRECAUTIONS

This product has not been evaluated under the condition that has the underlying issues with clotting (i.e. anticoagulant or antiplatelet therapy).
If the package has been previously opened or damaged, discard and replace with a new device.

## 7.WARNINGS

Do not inject RESPONDER® into blood vessels.
RESPONDER® is intended to be used in a dry state. Contact with fluids prior to application will result in loss of hemostatic effec.
If the package has been previously opened or damaged, discard and replace with a new device.
If signs of an infection develop in the site where RESPONDER® has been used, contact a health care professional.

## 8. CONTRAINDICATIONS

RESPONDER® is contraindicated in patients who are sensitive to starch or starch-derived materials.
This product has not been evaluated under the condition that has the underlying issues with clotting (i.e. anticoagulant or antiplatelet therapy).

## 9. ADVERSE REACTIONS

None reported to date.

## 10. DOSAGE AND ADMINISTRATION

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

## 11. HOW SUPPLIED

RESPONDER® is supplied in packages of 10g and 25g.

## 12. STERILIZING METHOD & EXPIRATION DATE

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

## 13. STORAGE&EXPIRATION DATE

Store at room temperature. It should not be exposed to extreme environmental conditions for example, -40℃(-40℉) for over two weeks or 55℃(131℉) for over four months during transportation or under other special circumstances. Shelf life is three (3) years from date of manufacture. Lot number and expiration date are marked on product.

## 14. TRADEMARKS

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

Starch Medical Inc.

2150 Ringwood Ave, San Jose, California 95131 USA

Tel: 408-428-9818 Fax: 408-383-9189

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 |
|  | = Manufacturer |
|  | = Do not use if package is damaged |
|  | = Do not re-sterilize |
|  | = Consult instructions for use |
| Rx ONLY | =USA Federal law restricts this device to sale by or order of a physician |
|  | = This product is not made with natural rubber latex. |

# Vol_013 Doc_004 User Manual OTC-Clean Copy

# User Manual

# RESPONDER® Polysaccharide Hemostat

# CONTENT

## 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 further 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

1) Tear open Responder® package.
2) Dry any excess blood using gauze.
3) Immediately apply AMP® particles liberally onto the wound site.
4) Apply firm pressure directly to wound for 5 minutes using gauze. If any bleeding persists, apply direct pressure for an additional 5minutes.
5) Wrap and tie bandage so as to maintain pressure on the wound.
6) Seek MEDICAL CARE as soon as possible. Remove excess AMP® particles carefully and completely by irrigation and aspiration during wound cleaning procedure.

## 5. NOTE

If bleeding continues, remove excess particles and repeat the procedure.

## 6. PRECAUTIONS

Responder® have 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.
This product has not been evaluated under the condition that has the underlying issues with clotting (i.e. anticoagulant or antiplatelet therapy).

## 9. ADVERSE REACTIONS

None reported to date.

## 10. DOSAGE AND ADMINISTRATION

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

## 11. HOW SUPPLIED

RESPONDER® is supplied in packages of 10g and 25g.

## 12. STERILIZING METHOD & EXPIRATION DATE

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

## 13. STORAGE&EXPIRATION DATE

Store at room temperature. RESPONDER® should not be exposed to extreme environmental conditions for example, -40℃(-40℉) for over two weeks or 55℃(131℉) for over four months during transportation or under other special circumstances. Shelf life is three (3) years from date of manufacture. Lot number and expiration date are marked on product.

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