RESPONDER® Polysaccharide Hemostat

CAUTION

RESPONDER® should only be used by a physician or other licensed practitioners.

DESCRIPTION

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

ACTION

AMP® particles have a molecular structure that rapidly 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.

INDICATIONS

RESPONDER® is intended to use as a topical hemostat for the treatment of severely bleeding wound including cuts, lacerations, burns and other traumatic injuries.

INSTRUCTIONS FOR USE

1. Visually inspect the sealed RESPONDER® package. If the package has been previously opened or damaged, discard and replace with a new packaged device.
2. Open the package, then the device is ready for use.
3. Gauze dry excess blood and quickly apply AMP® particles liberally onto the wound and then apply direct pressure.

NOTE

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

PRECAUTIONS/CONTRAINDICATIONS

RESPONDER® is contraindicated in patients who are sensitive to starch or starch-derived materials.
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 properties.
Aseptic technique should always be used.
If the package has been previously opened or damaged, discard and replace with a new packaged device.
If signs of an infection develop in the site where RESPONDER® has been used, contact a health care professional.

ADVERSE REACTIONS

None reported to date.

DOSAGE AND ADMINISTRATION

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

HOW SUPPLIED

RESPONDER® is supplied in packages of 1g, 3g, 5g, 5.5g, 10g, 25g.

STERILIZING METHOD & EXPIRATION DATE

Contents of the RESPONDER® package are sterilized by irradiation and should not be re-sterilized. Unused, open packages should be discarded properly.
If stored under the conditions specified in this manual (see Storage and Handling), this product remains sterile for three years from the date of sterilization.

STORAGE AND HANDLING

Do not store in extreme conditions, such as a temperature lower than -40°C or higher than 60°C.

TRADEMARKS

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


= Do not reuse


= Use until year & month (Expiration date)

REF = Reference number (Product code)

= Method of sterilization - Irradiation

= Lot number


= Date of manufacture


= Attention, see Instruction for Use


= CE-mark and identification number of Notified Body. Certified according to MDD (93/42/EEC)


= Manufacturer

= Authorized representative in the EU


= Temperature limitation

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