Instructions for Use

RESPONDER First Aid Kit

（for Model RKF105)

CONTENTS

1 DESCRIPTION..... 3
2. INDICATIONS 3
3. INSTRUCTIONS FOR USE 3
4. WARNINGS & CONTRAINDICATIONS..... 4
5. STERILITY STATUS & STERILIZATION METHOD.....4.
6. STORAGE & EXPIRATION DATE 4
7. TRADEMARK..... 4
8. ANNEX..... 4

1. DESCRIPTION

The RESPONDER® First Aid Kit is an advanced emergency hemostatic solution designed for the rapid and effective management of bleeding wounds. This compact kit combines cutting-edge hemostatic technology with essential first-aid components, making it an ideal choice for cyclists, outdoor enthusiasts, and general emergency use.

The components included in the RESPONDER® First Aid Kit are as follows:

Item	Specification	Quantity
Responder Powder	RP0005 (5.0g)	1 pc
Adhesive Gauze	100 × 100 mm	1 pc
Elastic Bandage	2000 mm × 25mm	1 roll
Alcohol Pad	60mm × 30mm	2 pcs

2. INDICATIONS

RESPONDER® First Aid Kit is indicated for the local management of bleeding such as lacerations, cuts and abrasions.

3. INSTRUCTIONS FOR USE

Step1- Prepare the Components Tear open all corresponding packages and remove all components from the packages.

Step2- Clean the Wound Use an alcohol pad to disinfect the wound and the surrounding area.

Step3- Apply RESPONDER® Powder Immediately and liberally apply RESPONDER® powder directly onto the wound site.

Step4- Cover and Secure the Wound Cover the wound with an adhesive wound dressing and apply gentle pressure for 1-5 minutes. If necessary, use an elastic bandage for additional compression and fixation. Seek medical care if needed.

Follow-up Care Remove excess RESPONDER® powder carefully and completely by irrigation during wound cleaning procedure.

For detailed information regarding the Instructions for Use, please refer to each IFU. See the attached documents for details.

4. WARNINGS & CONTRAINDICATIONS

Please refer to the detailed descriptions in each IFU in the attachments.

5. STERILITY STATUS & STERILIZATION METHOD

- Hemostatic Powder：Sterile
- Alcohol Pad：Sterile
- Adhesive Gauze：Sterile
- Elastic Bandage：Non-sterile

The sterilization method for each sterile component is provided in the corresponding IFUs in the attachments.

6. STORAGE & EXPIRATION DATE

Please refer to the detailed descriptions in each IFU in the attachments.

7. TRADEMARKS

RESPONDER® is a registered trademark of Starch Medical Inc.

 Starch Medical Inc.

2150 Ringwood Ave, San Jose, CA 95131 USA

Tel: 408-428-9818

Email:info@starchmedical.com

www.starchmedical.com

8. ANNEX

ANNEX 1: Symbol Explanation

ANNEX 2: Instructions for Use for the RESPONDER Powder

ANNEX 3: Instructions for Use for the Adhesive Gauze

ANNEX 4: Instructions for Use for the alcohol

ANNEX 1: Symbol Explanation

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

ANNEX 2 Instructions for Use for the RESPONDER Powder

User Manual

RESPONDER® Polysaccharide Hemostat

LIT-D-0008 0125

User Manual

RESPONDER®
Polysaccharide Hemostat

CONTENT

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

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 three (3) 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.

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

LIT-D-0008 0125

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

= This product is not made with natural rubber latex.

ANNEX 3 Instructions for Use for the Adhesive Gauze

Instruction for Use

Wound Dressing

CE 0123

[Revision No]: A/0

[Product Name]

Wound Dressing

[Intended use]

For surgery, wound surface, and IDVC application; also can be used for baby's umbilical cord wound protection.

[Model and Size]

	Size
Wound Dressing	50mm×40mm , 50mm×50mm , 70mm×35mm, 70mm×40mm, 70mm×50mm, 75mm×75mm, 80mm×40mm, 80mm×60mm, 80mm×70mm, 90mm×40mm, 90mm×60mm, 90mm×70mm, 100mm×40mm, 100mm×60mm, 100mm×70mm, 100mm×90mm, 100mm×100mm, 110mm×70mm, 150mm×90mm, 150mm×100mm, 150mm×150mm, 200mm×90mm, 200mm×100mm, 250mm×90mm, 250mm×100mm, 300mm×90mm, 300mm×100mm, 350mm×90mm, 350mm×100mm, 400mm×100mm
	Tolerance: Nominal size range＜10cm:±10% or 2mm (Whichever is greater in absolute value) Nominal size range≥10cm:±5%

[Caution]

1) This product is a one-time use product and cannot be reused.

2) This product is sterile, do not use if packing is damaged.If an allergic reaction occurs, please stop using it immediately and consult a doctor for treatment.

3) Persons with a history of allergies, please according to the doctor's advice.

[Disposal of waste]

Products after use should be destroyed and disposed of according to local/national regulations. It is strictly forbidden to discard it randomly.

[Use Method]

1) Clean the wound with physiological saline first, take out the package after it is dry, and remove the release paper (film) underneath;

2) Hold both ends of the dressing and align the dressing with the wound cover;

3) Start from the cut of the frame-shaped paper sheet or release film, and slowly tear off along the edge;

4) Peel off the transparent adhesive film to make it fixed;

5) Follow the directions, lightly press the dressing with one hand, and gently stretch it out with the other hand to separate the dressing from the surface of the skin. Continue this way and pull while pressing to slowly remove the dressing.

6) If the wound under the dressing has a large amount of exudate, it should be replaced.

7) When the applicator is found to be damaged or falling off, it should be replaced in time to ensure the barrier and fixation of the applicator.

[Contraindications]

None.

[Storage conditions]

Packed wound dressing should be stored in a dry place at normal temperature, no corrosive gas and draughty, clean place without direct sunlight.

[Shelf-life]

The product shelf-life is 5 years.

[Sterility]

EO sterilization

[Package Information]

1 pcs/pouch

[Production Date]

See on the packaging

[Definitions of Signs]

CE 0123	CE Mark: conforms to essential requirements of the Medical Device Regulation 2017/745 (EU) and EC notified body identification number
	Indicates the need for the user to consult the instructions for use
	Date of manufacture, Indicates the date when the medical device was manufactured
	Manufacturer, Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745 (EU)
EC REP	Authorized representative in the European Community
	Use-by date, Indicates the date after which the medical device is not to be used
	Do not re-use, indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
STERILE EO	Sterilized using ethylene oxide
	Do not use if package is damged, indicates a medical device that should not be used if the package has been damaged or opened
UDI	Unique device identifier
LOT	Batch code, Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Keep away from sunlight, indicates a medical device that needs protection from light sources.

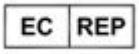
	Keep dry, indicates a medical device that needs to be protected from moisture.
	Medical Device mark

 Jinhua Jingdi Medical Supplies Co.,Ltd

Address: Building 2,Ditian Function, Xiaoshun Town, Jindong Zone,321000 Jinhua City, Zhejiang, P.R.C China

Tel.: +86-579-891167778

Fax: +86-579-89116751

 MedPath GmbH

Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

[Revision No]: A/0

ANNEX 4 ： Instructions for Use for the Alcohol Pad

Instruction for Use

Alcohol Prep Pads Medium Sterile-Isopropyl Alcohol Cloth

LABEL: ALCOHOL PREP PADS MEDIUM STERILE- isopropyl alcohol cloth cloth

VIEW PACKAGE PHOTOS

NDC Code(s): 83446-001-01
Packager: JINHUA JINGDI MEDICAL SUPPLIES CO., LTD

Category: HUMAN OTC DRUG LABEL
DEA Schedule: None

DRUG LABEL INFORMATION

Updated December 25, 2024

If you are a consumer or patient please visit this version.

CLOSE ALL SECTIONS

ACTIVE INGREDIENT

Isopropyl Alcohol, 70% v/v

CLOSE

DESCRIPTION

Use for preparation of skin prior to injection

CLOSE

INACTIVE INGREDIENT

Purified Water

CLOSE

WARNINGS

For external use only. Flammable, keep away from fire or flame.

Do not use

- with electrocautery procedures
- in the eyes

on mucous membranes
on irritated skin.

Stop use and ask a doctor if

irritation or redness develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control center right away.

CLOSE

DOSAGE & ADMINISTRATION

Apply topically as needed to cleanse intendend area;

Apply the product to the skin, take the injection or puncture site as the center, slowly rotate from the inside to the outside, and gradually apply the product for two times, the disinfection area should be more than 5cmx5cm, and the action time should be 1min.

CLOSE

INDICATIONS & USAGE

Use for preparation of skin prior to injection， apply the product to the skin, take the injection or puncture site as the center, slowly rotate from the inside to the outside, and gradually apply the product for two times, the disinfection area should be more than 5cmx5cm, and the action time should be1min.Please clean before disinfection.

CLOSE

PURPOSE

Use for preparation of skin prior to injection, to clean the skin.

CLOSE

KEEP OUT OF REACH OF CHILDREN

keep out of reach of children.

CLOSE

DO NOT USE

Do not use the product when its packaging is damaged.

CLOSE

OTHER SAFETY INFORMATION

Store at room temperature 15 - 30°C (59 - 86°F)

CLOSE

PRINCIPAL DISPLAY PANEL

CLOSE

INGREDIENTS AND APPEARANCE

ALCOHOL PREP PADS MEDIUM STERILE
isopropyl alcohol cloth cloth

PRODUCT INFORMATION			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83446-001
Route of Administration	TOPICAL		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

INACTIVE INGREDIENTS	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	30 mL in 100 mL

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83446-001-01	100 in 1 CARTON	03/01/2023	
1		100 in 1 BOX		
1		0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	03/01/2023	

LABELER - JINHUA JINGDI MEDICAL SUPPLIES CO., LTD (546604382)

REGISTRANT - JINHUA JINGDI MEDICAL SUPPLIES CO.,LTD (546604382)

ESTABLISHMENT

NAME	ADDRESS	ID/FEI	BUSINESS OPERATIONS
JINHUA JINGDI MEDICAL SUPPLIES CO.,LTD		546604382	manufacture(83446-001)

CLOSE

CLOSE ALL SECTIONS

FIND ADDITIONAL RESOURCES (also available in the left menu)

SAFETY

Report Adverse Events, FDA Safety Recalls, Presence in Breast Milk

RELATED RESOURCES

Medline Plus, Clinical Trials, PubMed, Biochemical Data Summary

MORE INFO ON THIS DRUG

View Labeling Archives, RxNorm, Get Label RSS Feed, View NDC Code(s)NEW!

ANNEX 5 Instructions for Use for the Elastic Bandage

Cohesive Bandage Instructions for Use (IFU)

1. Intended Use

The cohesive bandage is intended for:

Holding wound dressings and gauze in place.

Providing support and compression to limbs for managing swelling or mild sprains.

Securing splints and other medical devices.

It is self-adhering (sticks to itself) and does not require clips or pins. It does not adhere to skin or hair.

2. Contraindications

Do not use on patients with a known hypersensitivity or allergy to any component of the bandage (e.g., latex, acrylic adhesives).

Do not apply directly over open or weeping wounds.

Do not use in cases of severe arterial insufficiency or other circulatory disorders in the limb.

Do not use on areas with severe skin infections or compromised skin integrity.

3. Warnings and Precautions

WARNING:

Apply with appropriate tension. The bandage should be snug but not tight. Check circulation frequently (color, warmth, sensation, movement) of the fingers or toes. If signs of compromised circulation occur (numbness, tingling, pain, bluish color, coldness), LOOSEN THE BANDAGE IMMEDIATELY.

For single use only. Do not re-use.

Keep away from fire or ignition sources, as the material may be flammable.

Precautions:

Ensure the skin is clean and dry before application.

Avoid excessive stretching when applying, especially over joints.

Removal may cause discomfort in hairy areas.

Keep out of reach of children.

4. Directions for Use

Preparation: Wash hands. Prepare the bandage and any primary dressings. Clean and dry the area to be bandaged.

Apply Dressing: Cover the wound with a sterile gauze or primary dressing.

Start Wrapping:

Hold the bandage roll with the roll facing outward.

Place the starting end at an angle below the dressing and anchor it with one or two turns.

Always leave the toes or fingers exposed to allow for continuous circulation monitoring.

Wrap the Bandage:

Continue wrapping in a spiral or figure-of-eight pattern (for joints).

Each turn should overlap the previous one by approximately 1/2 to 2/3 of its width.

Maintain even, moderate tension. DO NOT STRETCH THE BANDAGE TO ITS MAXIMUM.

Finish:

After covering the desired area, tear or cut the bandage.

Press the final end firmly onto the previous layer. The cohesive property will secure it without need for pins or tape.

Ensure the end is secure and will not catch on clothing.

5. Removal

To remove, gently find the end and unwind slowly.

Peel the bandage back parallel to the skin, rather than pulling it straight up.

If the bandage is stuck to hair, moistening the edge with warm water can ease removal.

Discard the used bandage appropriately.

6. Storage

Store in a cool, dry, and dust-free place.

Protect from direct sunlight, moisture, and excessive heat.

Keep away from chemicals.

7. Product Description

The cohesive bandage is typically made from an elastic fabric (e.g., cotton, synthetic fibers) coated with a self-adhering, non-latex material.

It is available in various widths and lengths.

8. Potential Adverse Effects

Possible skin irritation or allergic reaction to the bandage material (redness, itching, rash).

Complications from improper application, such as impaired circulation, nerve compression, or skin damage if applied too tightly.

9. Manufacturer Information

Wenzhou Zhusi Medical Supplies Co., Ltd

Building 3-4, NO.887, Fazhang Road, Longgang, Wenzhou, Zhejiang, 325802

Lot Number: See package

Expiration Date: See package