Mallinckrodt™ Pharmaceuticals

# INSTRUCTIONS FOR USE - US

## RaplixaSpray™ (Raplixa™ Delivery Device)

6014/1 (01)

**INSTRUCTIONS FOR USE - US**
**RaplixaSpray™ (Raplixa™ Delivery Device)**

For the application of Raplixa powder to stop bleeding. Raplixa is a hemostatic fibrin sealant. It is a powder formulation in a vial and supplied separately.

## 1. FIELD OF APPLICATION

The RaplixaSpray device has been designed for the application of Raplixa powder. The spray device can deliver Raplixa powder to bleeding sites as an adjunct to hemostasis in adults undergoing open surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical.

### 1.1. Intended use

RaplixaSpray device is intended for the topical application of the hemostatic agent Raplixa via spraying with propellant gas to control delivery of powder onto the wound surface. The accessory, the flexible nozzle, is intended to enable the RaplixaSpray device to be used in difficult to reach areas.

## 2. DESCRIPTION

Raplixa Delivery Kit, consisting of [1]:

- 1 RaplixaSpray Delivery Device with integrated in-line gas filter (insufflation filter) and attached removable fixed (rigid) nozzle
- 1 flexible nozzle

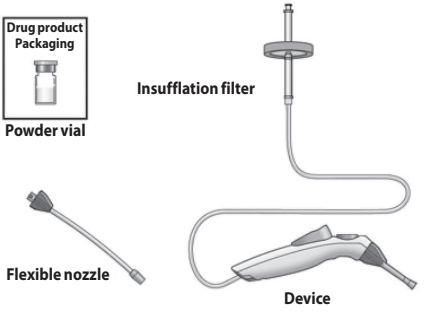


**Figure 1: Raplixa Delivery Kit**

### 2.1. Principle

The RaplixaSpray device must be operated via a RaplixaReg $CO_2$ pressure regulator (for open surgery) connected to a $CO_2$ gas supply (or a medical grade $CO_2$ tank) located in the operating room (OR) or a RaplixaReg air pressure regulator (for open surgery) connected to pressurized air from a central air supply (or a medical grade air tank). A RaplixaReg gas pressure regulator (for open surgery) must be used in order to supply gas at a reduced pressure to the RaplixaSpray device. The Raplixa vial is opened and attached to the spray device. When the operating button on the device is pushed down, the valve opens within the device allowing gas flow from the supply line (via the regulator) into the device. The gas flow has two functions: it creates vibration that mobilizes the Raplixa powder, and transports the Raplixa powder out of the spray device onto the bleeding site via the nozzle. The majority of the gas flow is released from the rear of the device and ≤ 4% of the incoming gas flow is used to deliver the Raplixa powder to the bleeding site.

[1] Raplixa is packaged and supplied separately

The RaplixaSpray device must only be used with Raplixa powder.

The RaplixaSpray may not be used with liquid (or other) hemostatic agents.

The RaplixaSpray device with integrated insufflation filter, and its accessory, the flexible nozzle, are packed in a blister. The blister is covered by a foil lid and is gamma irradiated.

For single use only. DO NOT RE-STERILIZE.

### 2.2. Frequency of Administration

The RaplixaSpray device must only be used during the course of one surgery and must always remain in the sterile field when not in use. Up to two vials of Raplixa may be used to cover a specified area with one device. The maximum total Raplixa dose allowed per patient is 3 grams.

The dose of Raplixa can vary based on the size of the area to be treated. In clinical trials, smaller bleeding sites (< 10 $cm^2$) used 0.5 g to 1.0 g on average. Larger bleeding sites used 1.0 to 2.0 grams (10 - 100 $cm^2$).

The dose of Raplixa based on the size of the bleeding surface area to be treated is shown in the table below:

| **Maximum Surface Area Application Using RaplixaSpray** | **Raplixa Package Size** |
|---|---|
| 50 $cm^2$ | 0.5 g |
| 100 $cm^2$ | 1.0 g |
| 200 $cm^2$ | 2.0 g |

**Table 1: Dose of Raplixa**

Total number of vials used with one RaplixaSpray device may not be more than two vials. Raplixa may be used at multiple bleeding sites in the same patient.

**Note:**
- The maximum total Raplixa dose allowed per patient is 3 grams

If the device is removed from the sterile area it may NOT be used again.

### 2.3. Storage Instructions

Store at room temperature. Once device has been used DO NOT Store or RE-USE.

## 3. OPERATING INSTRUCTIONS

### 3.1. Set-up Gas Pressure Regulator

Prior to the procedure, prepare the RaplixaReg gas regulator by connecting the regulator hose to the gas supply, see also IFU RaplixaReg regulator.

For $CO_2$ use the RaplixaReg $CO_2$ pressure regulator (for open surgery) as indicated on the regulator.

For medical air, use the RaplixaReg air pressure regulator (for open surgery) as indicated on the regulator.

The regulator must be connected to the gas supply in the OR while the right knob is set to "O" (off) and must be placed and remain outside the sterile field (see also Quick Reference Guide).

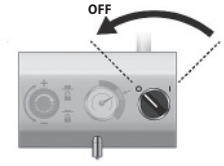


**Figure 2a: Check regulator is set OFF 'O'**

**Figure 2b: Pull out the control knob and adjust the pressure to 22 psi (1.5 bar). Push the control knob back in**

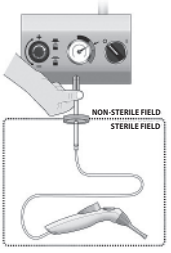


**Figure 2c: Connect the filter to the regulator**

Unlock the pressure adjustment knob by lifting it away from the surface of the regulator and adjust the pressure to 1.5 bar (22 psi) by rotation. Lock the knob by pushing it toward the surface of the regulator box until it locks with a snap. The right knob must remain set to "O" (off).

### 3.2. Connect the RaplixaSpray Device

Uncoil the tubing with the integrated insufflation filter in the sterile field. Connect the other end of the gas filter to the regulator (located in the non-sterile field).

Avoid nicking and blocking the tubing. The regulator's right knob must still be set to "O" (off).

### 3.3. Test Device

Check the device function prior to attaching a Raplixa vial. Turn on the gas flow by switching the right knob on the regulator to "I" (on). Press the operating button on the RaplixaSpray device. A continuous uniform vibration should be apparent as a buzzing sound. The delivery rate can be controlled with this button. Turn off the gas flow by switching the right knob on the regulator to "O" (off) until the device is ready to be used and set the device within the sterile field until needed.

### 3.4. Select Nozzle

If the bleeding site is difficult to reach, the fixed (rigid) nozzle that comes attached with the device, can be replaced by the flexible nozzle.

The nozzle can be changed at any time during a procedure. First set the regulator to "O" (off).

Twist to remove the fixed (rigid) nozzle. Attach flexible nozzle by twisting until it clicks into place.

Bend the flexible nozzle to desired position.

**Note:**
- Do not bend the flexible nozzle more than 90 degrees.

### 3.5. Attach Vial and Switch Regulator On

Remove the Raplixa vial from the aluminum pouch.

Raplixa is hygroscopic (readily takes up and retains moisture), only remove the crimp and rubber stopper from the vial prior to application.

Remove the rubber stopper from the Raplixa vial, holding the vial upright.

Invert the device. Holding the device upside down, snap the powder vial into the rubber cup.

The device is then turned upright, in order to deliver Raplixa and can be handed to the surgeon for use.

Just before application of Raplixa, activate the gas flow by turning the right knob on the regulator from "O" (off) to "I" (on).

**Note:**
- Be careful not to push the RaplixaSpray device operating button when handing the device to the surgeon.

### 3.6. Powder Delivery

Check that the pressure is 1.5 bar (22 psi) and the needle of the pressure indicator gauge on the RaplixaReg regulator is within the green band. This is indicated on the regulator with an arrow (see figure 2b).

Hold the device upright. Ensure the vial is kept within 45° of vertical at all times.

Hold the nozzle at a minimum distance of 5 cm (2 inches) from the bleeding site. Start application by gently pressing the operating button and cover the bleeding site with a thin layer of powder. The powder should cover the bleeding surface as a uniform thin coating. Application of Raplixa should be done rapidly.

**Note:**
- Be careful not to touch the tip of the device on anything wet, to avoid clogging the nozzle. In the unlikely event that blockage occurs, discard the device and prepare a new one.

Immediately after Raplixa application is completed, place a gelatin sponge, trimmed to the approximate size, on top of the Raplixa. The gelatin sponge may be used dry or moistened with sterile saline. A moistened sponge molds more easily to irregularly-shaped and contoured bleeding areas. Hold the gelatin sponge in place with manual pressure using sterile gauze.

### 3.7. Using a 2nd vial of Raplixa

Switch the regulator to the "O" (off) position. Hold device upside down, carefully remove the empty vial, and snap the second opened powder vial into the rubber cup and follow Section 3.5. Operate the device as described in Section 3.6.

## 4. CONTRAINDICATIONS

Do not administer Raplixa intravascularly.

Do not use for the treatment of severe or brisk arterial bleeding.

## 5. WARNINGS

Only use the RaplixaSpray device with the Raplixa powder.

Only use the RaplixaSpray device with a RaplixaReg $CO_2$ pressure regulator (open surgery) or a RaplixaReg air pressure regulator (open surgery).

Only use RaplixaSpray accessories. The use of accessories of other manufacturers is not permitted.

A RaplixaSpray device can be used with at most two vials. To administer a third vial, a new device must be opened. The maximum total dose per patient is 3 grams.

The RaplixaSpray device and accessory must be used within 1 hour of opening the device package.

Raplixa powder must be used within 1 hour of opening the vial.

Air or gas embolism can occur using air- or gas-pressurized sprayers to administer fibrin sealants. Operate the device according to the manufacturer's instructions.

Be sure to take appropriate measures to exclude these risks, by control of maximum pressure of 1.5 bar (22 psi) and minimum distance of 5 cm (2 inches). Do not touch the tip against the bleeding site. Do not bend the flexible nozzle more than 90 degrees.

Ensure the vial is kept within 45° of vertical at all times.

Do not cut the nozzle to length.

Be careful not to push the RaplixaSpray device operating button when handing the device to the surgeon.

Do not re-use the device. The Raplixa powder contains human blood derived materials and might remain in the device after use. To prevent contamination the device or its accessory must not be reused.

**Caution:**

- There is the potential for powder loss from the nozzle tip during or after usage. Minor leakage/drop of powder from the nozzle tip can occur when transferring the device back to the table. After the blue button is released and application of Raplixa powder is stopped some minor powder is still present in the nozzle. A single occurrence of powder leakage during transfer of device after use during Phase 3 clinical trial was noticed. The hazard is trivial and the user may not even be aware of it.

## 6. ACCESSORIES

RaplixaReg $CO_2$ pressure regulator (open surgery) and RaplixaReg air pressure regulator (open surgery).

Manufacturer:
Mallinckrodt Pharmaceuticals Ireland Limited,
College Business & Technology Park,
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For adverse events and technical support, please contact
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E: globalpv@mallinckrodt.com

## US

*Explanation of symbols used in the labelling*

| | |
|---|---|
|  | Single use only |
|  | Use by |
|  | Read the instructions for use |
| LOT | Batch number |
| REF | Article number |
| STERILE R | Sterilisation by gamma irradiation |
|  | Temperature limit |
| Rx | Prescription Use only |
|  | Manufacturer |

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6014/1 (01)

# Global Labeling Operations

## JOB INFORMATION

| | |
|---|---|
| **Product Brand and Descriptor:** | Raplixa™ Delivery Kit |
| **GTIN:** | None |
| **GBU:** | Pharmaceuticals |
| **REV:** | 11/2016 |

## ADDITIONAL JOB INFORMATION

| | | | |
|---|---|---|---|
| Job #: | 160514 | Dimensions: | 3.937″ W x 7.874″ H (approx) |
| Artwork/Part #: | 6014/1 (01) | Metric Dimensions: | 100.00 mm W x 200.00 mm H |
| Print Process: | Offset Lithography | Package Type: | Blister Instructions for Use (IFU) |
| Barcode Format: | None | File Name: | 0020xx-if0000-us1116.indd |

Check here if: ■ US Only ☐ Generic Artwork ☐ Country Specific

Notes:

## NUMBER OF COLORS

■ Black

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## TECHNICAL INFORMATION

| | |
|---|---|
| **Application:** | InDesign |
| **Linked Images:** | Mallinckrodt_standard_TM.eps<br>Figure_1_2016_020_GS.jpg<br>Figure_2a_2016_020_GS.jpg<br>Figure_2b_2016_020_GS.jpg<br>Figure_2c_2016_020_GS.jpg |
| **Fonts Used:** | Myriad Pro Family<br>Helvetica Neue LT Std Family |

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## GBU-SPECIFIC INFORMATION

| | |
|---|---|
| Manufacturing Site: | Wesley Coe |
| Print Vendor: | CCL Label Ltd |
| Country: | United States |
| Graphic Designer | rr/nk3 |
| Date: | February 22, 2017 |

## OTHER INFORMATION

Additional Notes: