

# **The Impella RP<sup>®</sup> System**

## **A New Way to Treat Right Heart Failure**

### **A Guide for You and Your Family**



## About This Booklet

This booklet is for people like you, who have failure of the right side of the heart (*right heart failure*) and have not been helped by medication. Your doctor can help you decide if treatment with the Impella RP<sup>®</sup> System is a good option for you.

The booklet explains:

- How the heart works
- What heart failure means
- What the Impella RP<sup>®</sup> System is
- How it is inserted into your heart
- What you can expect before, during and after the procedure
- What are the possible risks and benefits of having this treatment

Please read this booklet carefully and share it with your family and caregivers. For your convenience, a Glossary is provided in the front of the Guide. Terms that are explained in the Glossary are in *bold italics* in the text.

If you have questions about the Impella RP<sup>®</sup> System that are not answered in this booklet, please visit our website at [www.abiomed.com](http://www.abiomed.com).

*This booklet is intended for general information only. Your doctor should always be your primary source of information about your heart condition and your general health.*

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# Glossary

**Catheter:** a thin, flexible tube used in medical devices and procedures

**Console:** a special computer used to power and control a medical device

**Defibrillator:** a small device implanted in your chest that monitors the heart to detect abnormal heartbeats

**Femoral vein:** a large vein in the groin area

**Heart pump:** a pump used to support heart function and blood flow in people who have weakened hearts

**Heart transplantation:** a surgical transplant procedure that takes a working heart from a recently deceased organ donor and implants it into a patient with end-stage heart failure or severe coronary artery disease

**Inferior Vena Cava:** a large blood vessel in the chest that blood flows through as it travels from the legs back to the heart

**Intensive Care Unit:** a special department of the hospital that provides intensive care medicine

**Left atrium:** the heart chamber that receives blood from the lungs and delivers it to the left ventricle

**Left heart failure:** failure of the left side of the heart to pump enough blood

**Left ventricle:** the heart chamber that pumps blood through all of the body except for the lungs

**Medical device:** a machine or instrument used to prevent or treat disease

**Open-heart surgery:** any surgery in which the chest is opened and surgery is done on the heart muscle, valves, arteries or other parts of the heart

**Pacemaker:** a small device placed in the chest or abdomen to help control abnormal heart rhythms

**Pulmonary Artery:** the blood vessel that blood travels through to get from the heart to the lungs

**Right atrium:** the heart chamber that receives blood from the body and delivers it to the right ventricle

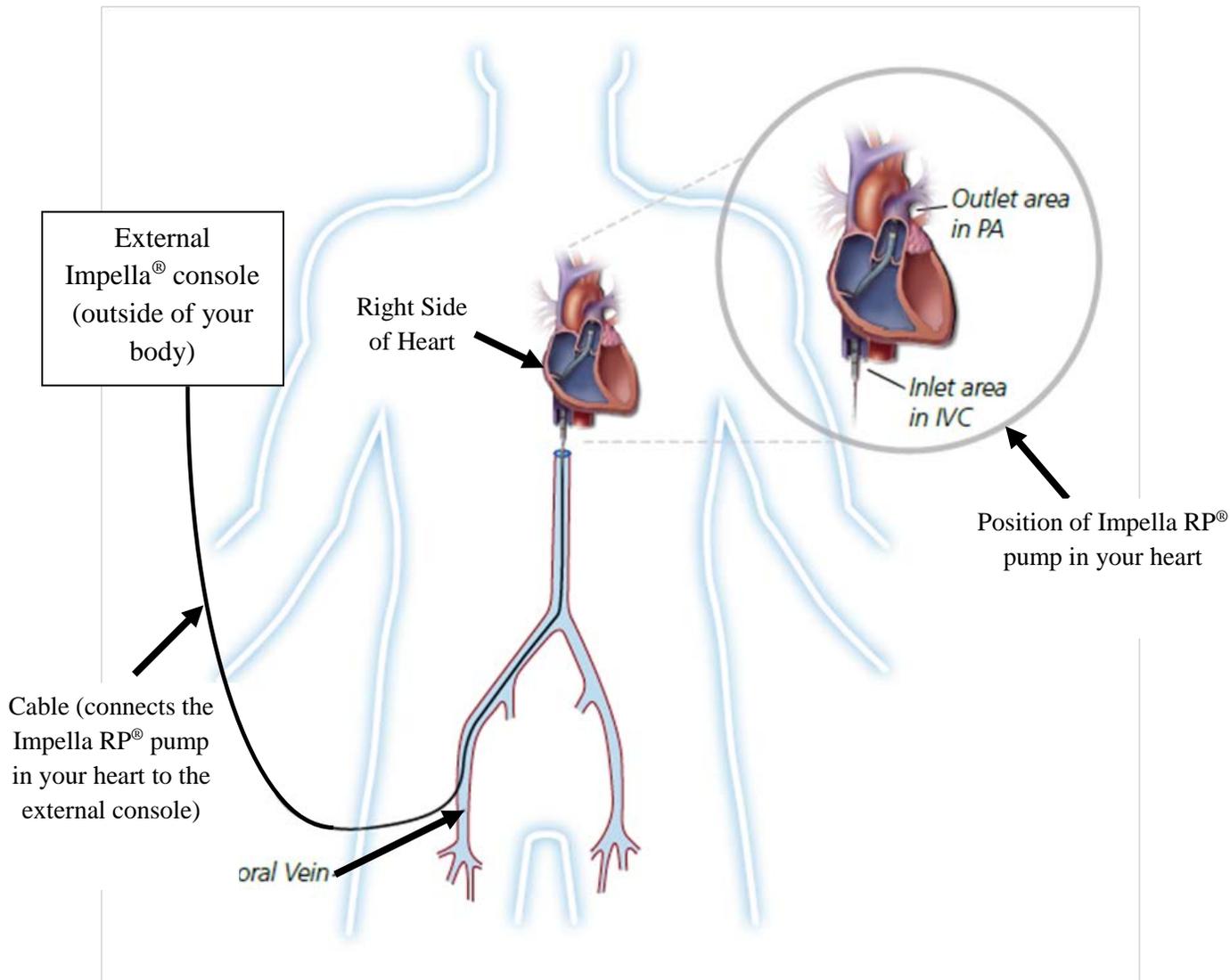
**Right ventricle:** the heart chamber that pumps blood through the lungs. In the lungs, the blood picks up oxygen from the breath and releases carbon dioxide into the breath

**Right heart failure:** failure of the right side of the heart to pump enough blood

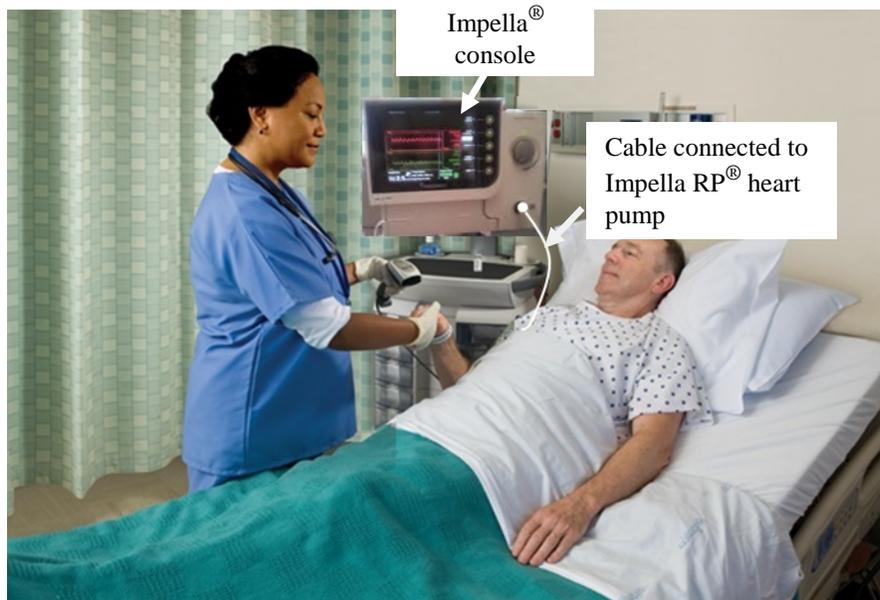
# Treating the Heart with the Impella RP<sup>®</sup> System

## The Impella RP<sup>®</sup> System

The Impella RP<sup>®</sup> System consists of three major components: the Impella RP blood pump, an external controller used to drive the blood pump, and an infusion pump used to flush the blood pump. The Impella RP blood pump is implanted through a vein in a patient's leg (*femoral vein*). Once implanted, it pumps blood for the right side of the heart. It does this by pumping blood from outside the heart, from a vessel called the *inferior vena cava* (labeled IVC in the picture below), through the heart into a vessel leading to the lungs, called the *pulmonary artery* (labeled PA in the picture below).



During your therapy, the Impella RP<sup>®</sup> blood pump will be permanently connected to the console, which will be monitored by your caregivers. The Impella RP<sup>®</sup> System and console are only approved for use in the hospital, so you cannot be discharged home from the hospital while the Impella RP<sup>®</sup> blood pump is in place.



## Who Should Use the Impella RP<sup>®</sup> System

The Impella RP<sup>®</sup> System may help patients who need emergency support of the right heart. Typical patients who may use the Impella RP<sup>®</sup> System include:

- Patients whose right heart fails after receiving a heart pump to support the left side of the heart
- Patients whose right heart fails because of a heart attack
- Patients whose right heart fails after a heart transplant
- Patients whose right heart fails after heart surgery

# **The Impella RP<sup>®</sup> System is Not Right for Everyone**

## **Who Should NOT Be Treated with the Impella RP<sup>®</sup> System**

If you have any of the conditions listed below, you may not be able to be treated with the Impella RP<sup>®</sup> System. Your doctor will determine whether you have any of these conditions:

- Defects in your veins and arteries, including calcium deposits or hardening of the vessel walls, which could block the open area available for the pump to pass
- A rigid replacement heart valve, which could block the open area available for the pump to pass
- A leaky pulmonary or tricuspid valve, which could cause blood flowing in the wrong direction and reducing the pump output
- Severe narrowing of your pulmonary or tricuspid valve, which could block the open area available for the pump to pass
- Loosely attached clot(s) in your blood vessels or heart, which may break off while the pump is in use and result in harm to you
- A filter in one of your large veins, which may block the open area available for the pump to pass

# Risks You Should Know About

All surgical procedures have risks. Many of the risks with the Impella RP<sup>®</sup> System are the same as those with the placement of any pump used to help the heart. Other problems that may happen with the Impella RP<sup>®</sup> System are the same as those that occur with any major heart surgery done with general anesthesia (when you are completely unconscious).

## Risks

The Impella RP<sup>®</sup> System has been studied clinically to determine the likelihood of some of the expected problems that may occur with the Impella RP<sup>®</sup> System. The studies looked at the most serious risks, which are:

- Death: death due to any cause
- Major bleeding: a bleeding event causing abnormal lab values or requiring blood to be put back into the body – during the trial most of the major bleeding was related to the surgery to place the Impella RP<sup>®</sup> blood pump
- Breakdown of red blood cells: damage to red blood cells caused by the pump
- Stroke: a condition when decreased blood flow to the brain causes death of brain cells
- Reduced blood flow to the leg
- Blood clot lodged in the lung
- Poorly functioning right heart valves

The following table summarizes the potential risks at 30 days or hospital discharge (whichever is longer) or to the next longer term therapy after Impella RP<sup>®</sup> blood pump placement.

Event	Number of Patients in Studies Reporting Problem at 30 Days or Hospital Discharge (whichever is longer) or to the next longer term therapy
Death	27 out of 100
Major Bleeding	48 out of 100
Breakdown of red blood cells	27 out of 100

## Other Potential Risks

In addition to the risks listed in the table above, there may be other potential risks associated with your treatment with the Impella RP<sup>®</sup> System. Specifically, while you are being treated:

- You may have an allergic reaction to the medication, for instance a blood thinner called heparin, which is used in conjunction with the Impella RP<sup>®</sup> blood pump
- Clots may develop in your blood vessels, which can travel through your blood vessels and block the blood flow to other organs, including your lungs making breathing difficult
- You may develop an infection, which could be localized or spread throughout your body
- Your heart tissue and blood vessels may be injured by the device as it is placed into your heart or during the time it sits inside your heart. The injury may result in life threatening conditions
- Your heart tissue may be irritated by the device as it is placed into your heart or during the time it sits inside your heart. The irritation may cause your heart to beat irregularly
- Your liver may not receive enough blood to function efficiently and may not function normally
- Your heart may not get better, or your heart failure condition may worsen
- The Impella RP<sup>®</sup> blood pump may have a unexpected problem requiring it to be removed, which would result in your right heart support being stopped

## What Happens If the Impella RP<sup>®</sup> System Works Poorly or Fails?

Since you will be in the hospital, your doctors and nurses will be able to continuously monitor the performance of the Impella RP<sup>®</sup> System. If the Impella RP<sup>®</sup> System begins to work poorly or fails, your doctor will be able to make changes to fix the problem. If the problem cannot be fixed, the Impella RP<sup>®</sup> blood pump will be removed. Your doctor will decide if a new Impella RP<sup>®</sup> blood pump should be used.

In addition, your doctor may decide to remove the Impella RP<sup>®</sup> blood pump, and place a different type of heart pump, for instance, if your heart needs to be supported for a longer time.

# Benefits

## How the Impella RP<sup>®</sup> System Can Help You

Your doctor is considering treating you with the Impella RP<sup>®</sup> System because the right side of your heart is very weak. Use of the device for a short time may help your right heart recover.

Based on what we currently know from clinical studies, it appears that the benefits of using the Impella RP<sup>®</sup> System include:

- Allowing your right ventricle to rest
- Improving or recovering your heart function or allowing you to be a candidate for a permanent heart pump
- Reducing complications related to your surgery to insert your permanent heart pump
- Giving your heart the chance to recover after the Impella RP<sup>®</sup> blood pump is removed
- Reducing the time it takes for your heart to recover
- Avoiding invasive operations like *open-heart surgery*

The clinical studies have shown that:

- About 3 out of 4 patients survived to either 30 days or to hospital discharge or to the next longer term therapy
- The Impella RP<sup>®</sup> blood pump was successfully implanted in 9 out of 10 patients suffering from right heart failure

However, the device did not help all of the patients treated by the Impella RP<sup>®</sup> System in the clinical studies.

## Other Right Heart Pumps are Very Invasive

There are other heart pumps that can be used to treat the right side of your heart, such as surgical right ventricular assist devices (RVADs). To implant an RVAD, doctors will need to open your chest to allow direct access to your heart. This is called *open-heart surgery* and is invasive.

## The Impella RP<sup>®</sup> System is Minimally Invasive

With the Impella RP<sup>®</sup> blood pump, doctors do not have to open your chest. The pump is inserted into a vein in your leg and moved up the vein until it reaches the heart. Only an incision in your leg is needed.

# What to Expect During Your Treatment

## Before the Procedure

Before the Impella RP<sup>®</sup> System is used, your doctor will review your medical information with you or a family member to make sure the Impella RP<sup>®</sup> System is right for you. Your doctor may also perform a test, using sound waves to look at your heart and blood vessels, to make sure you can use the Impella RP<sup>®</sup> System safely.

Some patients receive the Impella RP<sup>®</sup> System very soon after heart surgery. It's a good idea to talk to your doctor about the Impella RP<sup>®</sup> System before your surgery, to allow enough time to ask questions and decide whether you want to be treated with the Impella RP<sup>®</sup> System, if your doctor decides that you need it after your surgery.

## During the Procedure

At the beginning of the procedure, your doctor will numb your leg so no pain is felt when the pump component of the Impella RP<sup>®</sup> blood pump is inserted. The pump will be inserted into your *femoral vein* through a small incision in your leg. Then it will be advanced through the vein to your heart. A series of x-rays will be taken to help position the device. The *catheter* will be connected to the console and the pump will be turned on. The Impella RP<sup>®</sup> blood pump will remain in place and will continue pumping while your heart rests.

## After the Procedure

After the Impella RP<sup>®</sup> blood pump is inserted you will be moved to the *Intensive Care Unit* of the hospital where you will be closely monitored by your doctors and nurses. A breathing tube will probably be used for 1-3 days to help your lungs function properly. Your doctors and nurses will use the console to check on the Impella RP<sup>®</sup> blood pump. Since the pump will be connected to the console, you will not be able to get out of bed or sit up until the Impella RP<sup>®</sup> blood pump is removed.

When you become stronger, you will be moved to a regular hospital room. You may experience some pain from the incisions that were part of the medical procedure of putting in the Impella RP<sup>®</sup> blood pump. Your medical team will give you medication for your heart and pain medication as necessary. Nurses and physical therapists will work with you to help you regain your strength and freedom of movement.

When your doctor determines that your heart has recovered, he or she will gradually lower the pumping speed of the Impella RP<sup>®</sup> and allow your heart to take over. When your heart is pumping properly, without the help of the Impella RP<sup>®</sup> blood pump, the device will be removed. Your doctor may decide to give you general anesthesia (making you sleep), while the device is being removed, so that you will not experience any discomfort. The insertion site on your leg will be closed and bandaged.

You will not be able to leave the hospital until the Impella RP<sup>®</sup> blood pump is removed and your doctor determines you are well enough to go home. It is not possible to leave the hospital while you are being treated with the Impella RP<sup>®</sup> System.

# Warnings and Precautions

## Warnings for Patients and their Families



Portable and mobile radio frequency devices, such as cell phones, may affect your external console. Take special care when you or your family members are operating their portable devices near your console. If you suspect that one of these devices is interfering with your console, turn off the portable device and contact your nearest caregiver.

# About the Heart

## How the Heart Works

The heart is a muscle that pumps blood through the body. The heart pumps blood by expanding and contracting (beating) about 100,000 times each day.

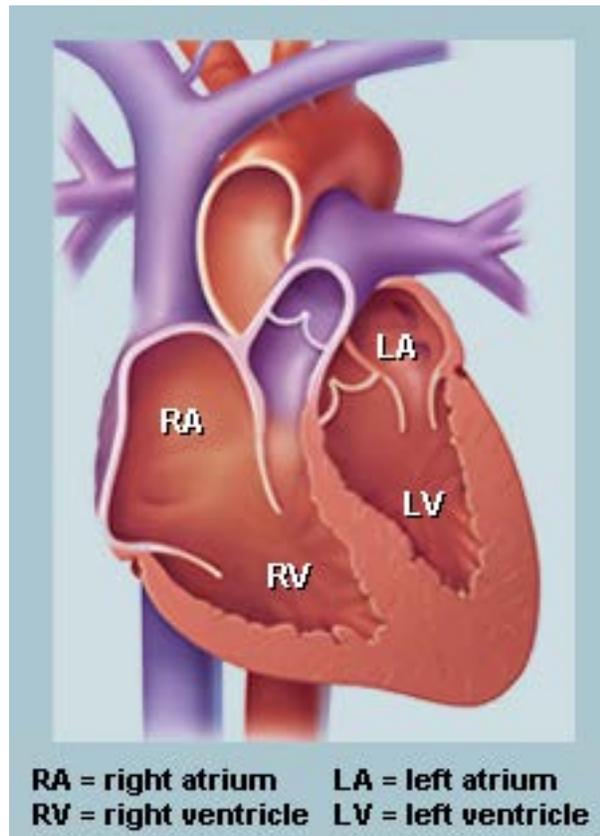
Blood pumped by the heart brings oxygen and food to every part of the body. It also removes carbon dioxide and other waste produced by the body. A healthy body depends on the heart pumping enough blood to deliver oxygen and food and to remove waste.

## The Right and Left Sides of the Heart

The heart is divided into two sides, the right side and the left side. The right side of the heart pumps blood through lungs. The left side of the heart pumps blood through the rest of the body. In a healthy heart, both sides of the heart work fine:

Each side of the heart has two chambers, an atrium and a ventricle.

- The **right atrium** receives blood from the body and delivers it to the right ventricle.
- The **right ventricle** pumps blood through the lungs. In the lungs, the blood picks up oxygen from the breath and releases carbon dioxide into the breath.
- The **left atrium** receives blood from the lungs and delivers it to the left ventricle.
- The **left ventricle** pumps blood through the rest of the body. As blood travels through the body, it releases oxygen for the body to use. It also picks up carbon dioxide that the body has produced as waste.



# Heart Failure

Heart failure occurs when the heart is not able to pump enough blood to meet the needs of the body. Common symptoms include shortness of breath, being unusually tired and swelling in the legs. Shortness of breath is usually worse when you exercise, lie down or sleep at night. You may not be able to do a lot of exercise.

Heart failure usually happens because the left side of the heart is not working properly. This is called *left heart failure*. Left heart failure may happen when the left ventricle is damaged by a heart attack, or when the valves that control blood flow through the left side of the heart do not work well.

However, in some patients, heart failure occurs because the right side of the heart is not working properly. This is called *right heart failure*. Right heart failure may happen when the right ventricle is damaged by a heart attack or when the valves that control blood flow through the right side of the heart do not work well.

## Treating Your Heart Failure

Your doctor will treat your heart failure by finding ways to make you feel better and keep your heart failure from getting worse. Your treatment may include:

- Changing what you eat and drink
- Increasing how much you exercise
- Taking medications
- Receiving a *medical device*
- Receiving a *heart transplant*

Your doctor will first suggest that you eat a healthier diet and exercise as much as possible. Your doctor will also prescribe medications to help your heart work better and to relieve your heart failure symptoms.

You may also receive a medical device such as a *pacemaker*, *defibrillator* or *heart pump*, to help your heart work better.

- A pacemaker is a device that keeps your heart beat regular
- A defibrillator is a device that corrects your heart beat if it becomes abnormal
- A heart pump is a device that pumps blood for your heart when it is severely damaged

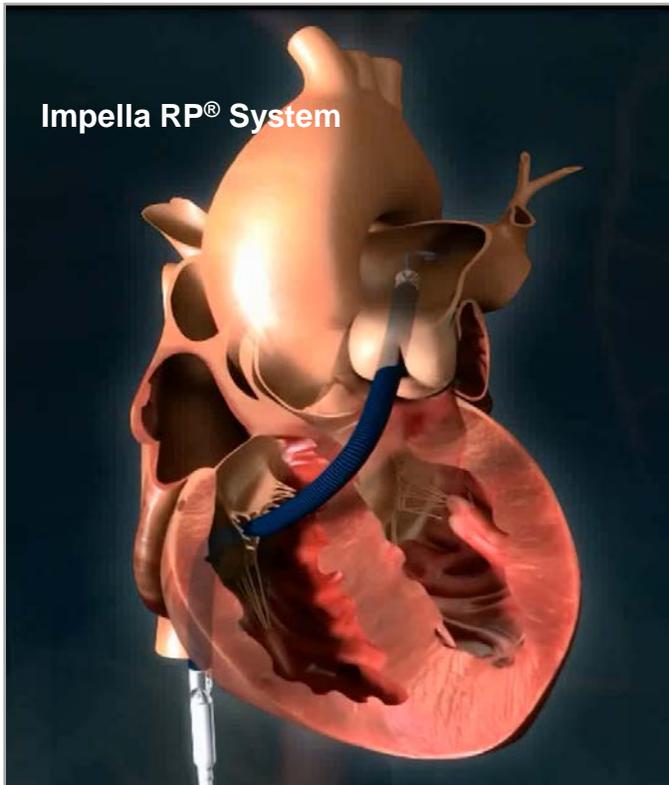
If your condition is very severe, your doctor may consider heart transplantation.

# Online Resources

Abiomed, Inc.  
visit: [www.abiomed.com](http://www.abiomed.com)

Federal Law (USA) restricts this device to sale by or on the order of a physician. Please address any questions you have about the Impella RP® System to your doctor.

Rx only.



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