

# RELiZORB<sup>®</sup>

(iMMOBILIZED LIPASE) CARTRIDGE



Patient Guide

ENFit<sup>®</sup>  
Compatible

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## 2 GLOSSARY OF TERMS

**Digest (digesting; digestion)**—Breaking down food so it can be used (absorbed) by the body.

**Digestive enzyme (enzyme)**—Substance made by the body that breaks down food so it can be absorbed.

**Enteral feeding pump tubing set**—The tubing set that is connected to the enteral tube feeding bag. An enteral feeding pump tubing set is threaded through the enteral tube feeding pump and connects to the inlet of RELiZORB.

**Enteral tube feeding**—A way to provide food through a tube placed in the nose, stomach or small intestine. The enteral feeding tube can be a G (gastrostomy) or J (jejunostomy) tube that is surgically placed in the patient's body.

**Exocrine pancreatic insufficiency**—A health condition where the body does not produce enough digestive enzyme or produces enzyme that does not work properly.

**Fats**—A type of nutrient in food. The body uses fat as an energy source (calories).

**Fatty acids; monoglycerides**—The forms of fat that the body can easily absorb and use for energy and other health benefits/functions.

**Fibrosing colonopathy**—Rare bowel disease where thickening can form in the large intestine.

**Fat hydrolysis**—The breakdown of fats (triglycerides) into forms that the body can absorb.

**iLipase®**—The combination of the lipase enzyme attached to the white beads in RELiZORB.

**Lipase**—A digestive enzyme that breaks down fats (triglycerides) into absorbable fatty acids and monoglycerides.

**Omega-3 and omega-6 fats**—Important fats that provide energy (calories) and other important health benefits. Omega-3 fatty acids are key for normal development and growth. Omega-3 fats include DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid). Omega-6 fats include AA (arachidonic acid).

**Pancreas**—An organ in the body that produces digestive enzymes, which are needed to break down food.

**Patient caregiver**—Parent, relative, family member or friend responsible for assisting patient with use of RELiZORB.

**Patient extension set (enteral tubing set)**—The tubing that connects RELiZORB outlet to the enteral feeding port (low-profile button) on the patient's body.

**Triglycerides**—The form of fat that is used in enteral feeding formulas. The body cannot absorb this form of fat until enzymes break the fats down into fatty acids and monoglycerides.

### 3 INTRODUCTION

Your doctor believes that you or a patient you provide care for might benefit from RELiZORB because you or a patient you provide care for may need help breaking down (digesting) fats from your enteral tube feeding formula.

Read all of this RELiZORB Patient Guide before you or a person you care for starts using RELiZORB. Reread the RELiZORB Patient Guide each time you get a new supply of RELiZORB in case there is new information in the guide.

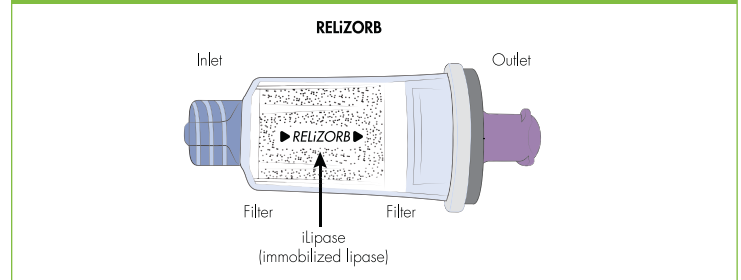
Use RELiZORB as directed by your doctor or healthcare provider. Do not make changes to the feeding care plan for you or the patient you provide care for without first speaking with your doctor or healthcare provider.



### 4 WHAT IS RELiZORB?

RELiZORB is a digestive enzyme cartridge that contains the enzyme lipase. RELiZORB is used with enteral tube feeding to help break down the fats. Lipases are enzymes that are normally made in the body to break down (digest) fats (triglycerides) into an absorbable form (fatty acids and monoglycerides). The lipase enzyme used in RELiZORB is attached to the white beads (iLipase), which are visible through the side of the cartridge. The RELiZORB cartridge is shown in Figure 1.

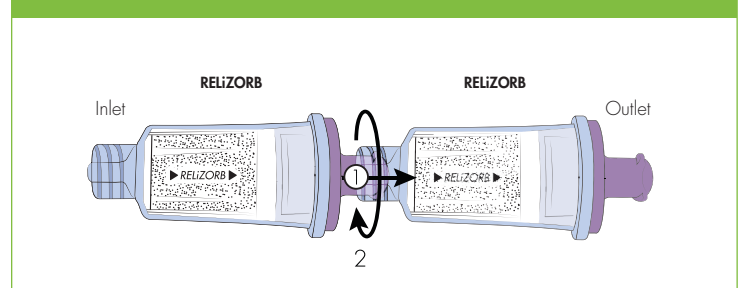
FIGURE 1: RELiZORB digestive enzyme cartridge.



### 5 HOW TO USE RELiZORB WITH ENTERAL TUBE FEEDING?

A single RELiZORB may be used for up to 500 mL of enteral formula, and up to 2 RELiZORBs can be used in a day (24-hour period). For enteral tube feeding formula volumes greater than 500 mL and up to 1000 mL, connect 2 RELiZORBs together in a tandem configuration, as shown in Figure 2. The tandem configuration (2 cartridges) is limited to 1 such use per day. More details provided in the Setup Procedure and Use in Section 18.

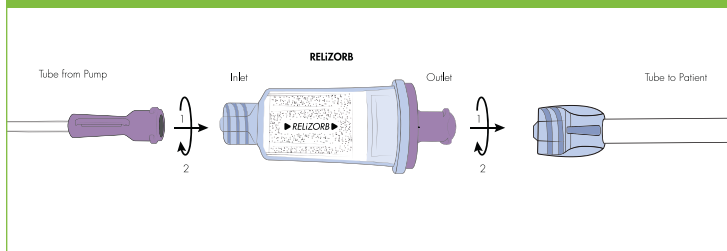
FIGURE 2: Connecting 2 RELiZORB cartridges together to form a tandem RELiZORB.



## 6 HOW DOES RELiZORB CONNECT INTO MY FEEDING PUMP?

RELiZORB connects to your enteral feeding pump tubing setup and the patient extension set or enteral feeding tube as shown in Figure 3. The tube from the enteral pump tubing set (left) connects to the inlet of RELiZORB. The patient extension set or enteral feeding tube to patient (right) connects to the outlet of RELiZORB. More details on tubing setup are provided in the Setup Procedure and Use in Section 18.

**FIGURE 3:** Single RELiZORB connected to an enteral feeding pump tubing set and patient extension set or enteral feeding tube.



## 7 WHO IS RELiZORB DESIGNED FOR?

RELiZORB is designed for use by people who have trouble breaking down (digesting) fats and need enteral tube feeding. People who may benefit from RELiZORB cannot properly make digestive enzymes. If fats are not broken down, you can have stomach pain, gas, oily or foul smelling stools, an unusually full feeling in the stomach or feel like throwing up. Fats that are not broken down (digested) could result in getting fewer calories, weight loss, shortage of key fats (omega-3 fats), and lower levels of some vitamins.

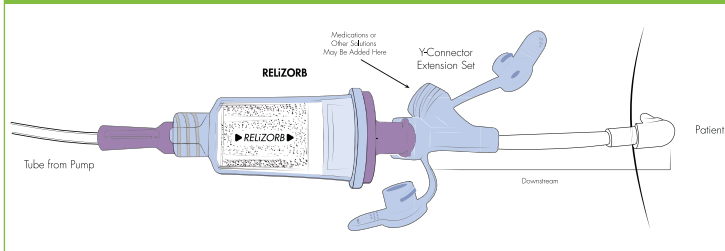
## 8 WHAT MUST YOU BE AWARE OF WHEN USING RELiZORB TO AVOID INJURY?

**WARNINGS:** Using RELiZORB other than as directed may result in RELiZORB not working properly or may cause serious injury.

- DO NOT connect RELiZORB to IV (intravenous) or other non-enteral tubes or lines. RELiZORB is ONLY for use with enteral tube feeding.
- DO NOT place medicines in the enteral tube feeding bag or anywhere else before the RELiZORB cartridge. Passing medicines through RELiZORB may change how the medicine works or how RELiZORB breaks down fats. If medicines or flush solutions are accidentally added before RELiZORB, then the RELiZORB and all tubing and formula must be thrown away. Restart feeding using a new RELiZORB and enteral feeding pump tubing set and patient extension set (if used). Medicines or saline flushes may only be added to the enteral feed line after RELiZORB. Medicines may be added to the side port of a Y-Connector extension set located between RELiZORB and the patient as shown in Figure 4.



**FIGURE 4:** Medications may be added between RELiZORB and patient (single cartridge configuration shown).



- Fibrosing colonopathy is a rare bowel disease. The chance of having fibrosing colonopathy could increase with use of high dose pancreatic enzyme replacement therapy (PERT). PERTs are usually tablets or capsules that contain enzymes and are ingested orally. RELiZORB contains a digestive enzyme lipase which is not the same as in PERT. The lipase in RELiZORB stays attached to the white bead (ilipase) so it remains in the cartridge and does not enter the body with the enteral tube feeding formula. Follow your healthcare provider's instructions on PERT product dosing when used with RELiZORB. Fibrosing colonopathy is a serious problem that may require surgery. Call your healthcare provider right away if you have any unusual or severe stomach area pain.

## 9 WHAT ARE POTENTIAL RISKS WITH USE OF RELiZORB?

In clinical studies with RELiZORB, the most common complaints were stomach related symptoms that are typical in people who have trouble breaking down fats and need enteral tube feeding. The most commonly reported symptoms were stomach pain and gas.

## 10 WHAT MUST I DO TO AVOID DAMAGING RELiZORB AND USE IT CORRECTLY?

**CAUTIONS:** Using RELiZORB other than as directed may result in RELiZORB not working properly.

- Do not reuse RELiZORB. Each RELiZORB should only be used once. At the end of the feeding, throw away the RELiZORB. RELiZORB may not break down fats properly if reused.
- Do not break or place excess pressure on any part of the RELiZORB cartridge. Any cracks or breaks may cause RELiZORB to not connect properly to the enteral feeding pump tubing set or patient extension set or enteral feeding tube and may lead to formula leaking.
- Do not use enteral tube feeding formulas containing insoluble fiber (including blenderized formulas) as this may block the cartridge. Check the label of your feeding formula for something called insoluble fiber.
- Use RELiZORB only with a pump that has a low flow or no flow alarm. RELiZORB has not been tested for use with gravity feed systems (systems that have no pumps). If you use a pump system without a low flow/no flow alarm, you may not notice if the flow of the feeding slows down or stops.
- Do not use more than 2 RELiZORBs in a day (a 24-hour period). You can use 2 RELiZORBs, 1 right after the other, or space out the timing of their use.
- Each RELiZORB may be used for up to 500 mL of enteral tube feeding formula. Do not use a single RELiZORB for more than 500 mL in a feeding, as it may not work as well to break down all the fat. If you use less than 500 mL of formula in a feeding, you must throw away the RELiZORB after use.

- Use only with flow rates from 10 to 120 mL/hr when using single RELiZORB and 24 to 120 mL/hr when using tandem RELiZORB. RELiZORB has not been tested using flow rates greater than 120 mL/hr or less than 10 mL/hr (single) or 24 mL/hr (tandem).

Using a flow rate outside of this flow rate range may affect how well RELiZORB breaks down fat.

- RELiZORB has been tested for up to a 1-hour stop in feeding and shown not to change flow rate or how well RELiZORB breaks down fat.
- Do not freeze RELiZORB. Store RELiZORB in its pouch either refrigerated or at room temperature (2°C to 27°C; 36°F to 80°F) until you are ready to use it. Storing RELiZORB in a hot place (greater than 27°C or 80°F) may affect how well RELiZORB breaks down fat.
- Do not use RELiZORB after the “use by” date marked on the pouch. If RELiZORB is used after the “use by” date, RELiZORB may not break down fats as well.

## 11 HOW WILL USING RELiZORB HELP WITH ENTERAL FEEDING?

You or the patient you care for may need enteral tube feeding to gain or maintain weight because of trouble breaking down (digesting) and absorbing the fats needed. During laboratory testing, RELiZORB has been shown to break down fats in enteral tube feeding formulas. RELiZORB may help to break down fats in enteral tube feeding formula before it goes into the body, so the fats are absorbable.

In clinical studies, RELiZORB was shown to increase the amount of fat that the body absorbs from enteral tube feeding formulas, particularly omega-3 fats, which are described in Section 14.

## 12 WHY DOESN'T MY ENTERAL TUBE FEEDING FORMULA CONTAIN ABSORBABLE FATS?

Fats that are broken down into their absorbable form are not stable and spoil quickly. Therefore, enteral tube feeding formulas are made with fat in triglyceride form, which does not spoil as quickly but also is not absorbable by the body. RELiZORB breaks down the fats into absorbable forms (fatty acids and monoglycerides) during enteral tube feeding.

## 13 HOW DOES RELiZORB WORK?

Inside the RELiZORB cartridge, there are small white beads. You can see these beads through the clear cartridge (see Figure 1 on page 3). The lipase enzyme, which helps break down fats, is attached to the small white beads. The lipase and bead combination is called iLipase. As the enteral tube feeding formula passes through RELiZORB, it makes contact with the iLipase and the fat in the formula is broken down to its absorbable form (fatty acids and monoglycerides).

The iLipase stays inside RELiZORB as the enteral tube feeding formula flows through the cartridge. As a result, you do not consume (or ingest) the lipase. You or the person you care for consumes (or ingests) the formula with the absorbable fats that the lipase has broken down.

## 14 WHY ARE OMEGA-3 AND OMEGA-6 FATS IMPORTANT, AND HOW DOES RELiZORB BREAK DOWN OMEGA-3 AND OMEGA-6 FATS?

Omega-3 and omega-6 fats are special fats that provide energy and are important for normal development and growth. The lipase in RELiZORB helps break down the fat in enteral tube feeding formula (which is in triglyceride form) into its absorbable (usable) forms (fatty acids and monoglycerides), which may help the body use omega-3 and omega-6 fats. People who have problems digesting and absorbing fats usually have reduced levels of omega-3 and omega-6 in their body.



## 15 WHAT ENTERAL TUBE FEEDING FORMULAS CAN I USE WITH RELiZORB?

For a listing of formulas that can be used with RELiZORB, visit [www.relizorb.com/formulas](http://www.relizorb.com/formulas). RELiZORB was tested in a laboratory with different enteral tube feeding formulas.

## 16 WHAT PUMPS AND FEEDING SETS CAN I USE WITH RELiZORB?

RELiZORB must be used with enteral tube feeding pumps that have low flow/no flow alarms. RELiZORB has not been tested for use with gravity feed systems (systems that have no pumps).

Examples of the pumps tested with RELiZORB are listed in Table 1.

**TABLE 1:** Pumps that work with RELiZORB.

Pump Name	Pump Manufacturer
EnteraLite® Infinity®	Moog
Kangaroo™ Joey	Covidien
Kangaroo™ ePump	Covidien

For a detailed listing of pumps, enteral feeding pump tubing sets and patient extension sets tested with RELiZORB, visit [www.relizorb.com/pumps](http://www.relizorb.com/pumps).

EnteraLite® and Infinity® are registered trademarks of Zevex, Inc. Kangaroo™ Joey and ePump are trademarks of Covidien.

## 17 WHEN TAKING RELiZORB, CAN I ALSO USE PERT (PANCREATIC ENZYMES)?

RELiZORB is to be used with enteral feeding only; patients should follow physician's guidance for PERT (pancreatic enzymes) use for meals and snacks. In clinical studies, the use of RELiZORB was shown to hydrolyze fat as intended when used during enteral feeding.

## 18 RELiZORB SETUP PROCEDURE AND USE

There are 2 different setup procedures depending on the feeding volume:

- (A) Feeding volume up to 500 mL using 1 single cartridge.
- (B) Feeding volume greater than 500 mL and up to 1000 mL using 1 tandem configuration.

RELiZORB in single and tandem configurations have been evaluated with enteral pump flow rates listed in the table:

	Single RELiZORB* 2 cartridges/day	Tandem RELiZORB* One tandem configuration (2 cartridges)/day
ENTERAL FORMULA VOLUME:	Up to 500 mL	500-1000 mL
ENTERAL PUMP FLOW RATE:	10-120 mL/hr	24-120 mL/hr

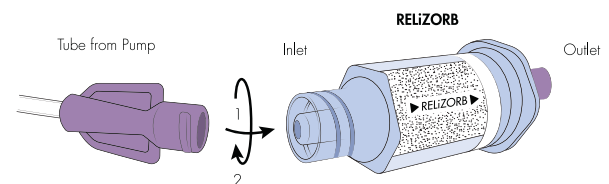
\*Do not exceed use more than 24 hours in either single or tandem configuration.



### A. SETUP PROCEDURES FOR RELiZORB USE WITH UP TO 500 mL

- 1 Set up the enteral tube feeding tubing set and feed set according to the pump manufacturer's instructions. Prime the enteral feeding pump tubing set according to the manufacturer's instructions.
- 2 Remove a RELiZORB pouch from its carton. Examine the RELiZORB pouch. Do not use the RELiZORB if:
  - the pouch seal is broken
  - the current date is past the expiration date shown on the pouch
- 3 Tear open the RELiZORB pouch from either end and remove the RELiZORB from its pouch. Do not use the RELiZORB cartridge if:
  - the RELiZORB is damaged
  - the RELiZORB has been previously used
- 4 Connect the RELiZORB cartridge to the end of the enteral feeding pump tubing set. Insert the outlet fitting from the enteral feeding pump tubing set into the inlet of the RELiZORB cartridge. Use a twisting motion until the connection is tight as shown in Figure 5.

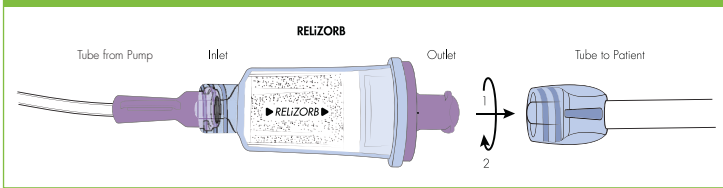
**FIGURE 5:** Securing the enteral feeding pump tubing set to the RELiZORB cartridge inlet.





- 5 Manually prime the enteral formula through the RELiZORB, up to the outlet by holding the prime button on the enteral feeding pump.
- 6 Connect the RELiZORB cartridge outlet to the inlet of the patient extension set or enteral feeding tube that connects to the patient as shown in Figure 6.

**FIGURE 6:** Connecting RELiZORB outlet to the patient extension set or enteral feeding tube that connects to patient.



- 7 If a patient extension set is being used, follow the pump manufacturer's instructions to prime the feeding formula to the end of the patient extension set. Connect the patient extension set to the enteral feeding port (button).
- 8 Set the pump to the prescribed flow rate and proceed with feeding.

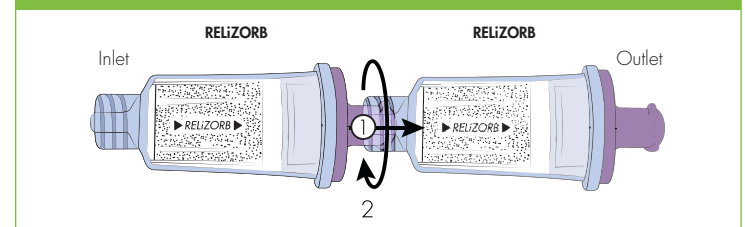
## B. SETUP PROCEDURES FOR RELiZORB USE WITH VOLUMES GREATER THAN 500 mL AND UP TO 1000 mL

For enteral tube feeding formula volumes greater than 500 mL and up to 1000 mL, connect 2 RELiZORBs together in a tandem configuration. The tandem configuration (2 cartridges) is limited to 1 such use per day. Tandem RELiZORB configuration may also be referred to as "piggybacking."

## TANDEM RELiZORB SETUP PROCEDURE AND USE

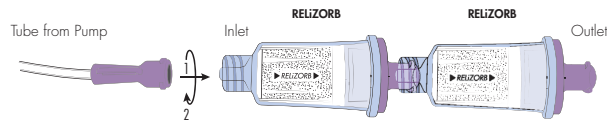
- 1 Set up the pump and feed set per the pump manufacturer's instructions. Prime the feed set per the manufacturer's instructions.
- 2 Remove 2 RELiZORB pouches from their cartons. Examine the RELiZORB pouches. Do not use the RELiZORB if:
  - the pouch seal is broken
  - the current date is past the expiration date shown on the pouch
- 3 Tear open the RELiZORB pouches from either end and remove the RELiZORBs from their pouches. Do not use the RELiZORB cartridge if:
  - the RELiZORB is damaged
  - the RELiZORB has been previously used
- 4 Join the 2 RELiZORB cartridges by inserting the outlet fitting from the first RELiZORB into the inlet of the second RELiZORB with a twisting motion until secure as shown in Figure 7.

**FIGURE 7:** Connecting 2 RELiZORB cartridges together to form a tandem RELiZORB.



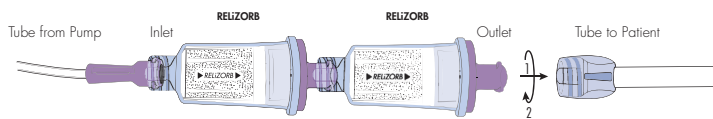
- 5 Secure the tandem RELiZORB to the end of the feed set tubing by inserting the outlet fitting from the pump tubing into the inlet of the tandem RELiZORB with a twisting motion until secure as shown in Figure 8.

**FIGURE 8:** Securing tandem RELiZORB inlet to outlet fitting from pump tubing.



- 6 Manually prime the enteral formula through the RELiZORB, up to the outlet by holding the prime button on the enteral feeding pump.
- 7 Connect the tandem RELiZORB outlet fitting to the inlet fitting of the pump extension set that connects to the patient as shown in Figure 9.

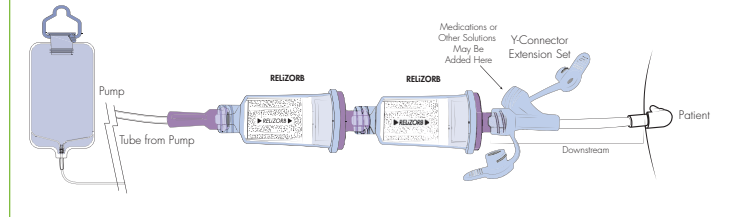
**FIGURE 9:** Connecting tandem RELiZORB outlet to inlet fitting of tube that connects to patient.



- 8 Follow the pump manufacturer's instructions to prime the feeding formula to the end of the pump extension set.
- 9 Set the pump to the prescribed flow rate between 24 and 120 mL/hr and proceed with feeding.

**WARNING:** If medications, saline flushes, or other non-enteral formula materials are to be added, they must be introduced **AFTER** the tandem RELiZORB (ie, between tandem RELiZORB and the patient). They may be added to the side-port of a Y-Connector extension set located between the tandem RELiZORB and the patient as shown in Figure 10.

**FIGURE 10:** Medications may be added between the tandem RELiZORB and patient.



**NOTE:** If medications or flush solutions are added BEFORE the tandem RELiZORB, then both RELiZORB cartridges, all tubing, and formula must be discarded.

## 19 RELiZORB DISASSEMBLY AND DISPOSAL

When feeding is complete, disconnect the RELiZORB from the patient extension set or enteral feeding tube and enteral feeding pump tubing set.

Throw away the RELiZORB after use in your trash.

## 20 TROUBLESHOOTING

Symptom	Probable Cause(s)	Correction(s)
Flow Error Alarm	See pump instructions for the cause of the alarm.	If none of the actions in the pump instructions fix the Flow Error Alarm, remove the RELiZORB and replace it with a new RELiZORB.
Leakage From Connections	Improper connection of inlet or outlet fitting.	Disconnect and re-connect RELiZORB with a twisting motion until the connection is tight.
Incomplete Priming	Auto prime may not pump formula completely through the cartridge.	Use manual prime to completely prime the RELiZORB and patient extension set.



## 21 ADDITIONAL INFORMATION

If you would like more information, talk to your doctor or healthcare professional.

For more information, or to report a problem with RELiZORB, visit [www.relizorb.com](http://www.relizorb.com) or call toll-free at 1-844-632-9271.

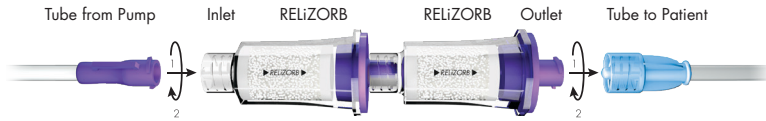
## 22 QUICK GUIDE TO RELiZORB SETUP

- 1 For volumes up to 500 mL, connect 1 RELiZORB cartridge to the end of the primed feeding pump tubing set. For volumes greater than 500 mL and up to 1000 mL, connect 2 RELiZORB cartridges in tandem configuration, then connect to the end of the primed feeding pump tubing set.
- 2 Connect RELiZORB outlet to the patient extension set or enteral feeding tube and manually prime through the device(s).

### Single RELiZORB setup for volumes up to 500 mL



### Tandem RELiZORB setup for volumes 500-1000 mL



**NOTE:** Do not overtighten the enteral feeding pump tubing set when connecting to RELiZORB. A small gap between the flange on the enteral feeding pump tubing set and the RELiZORB is normal.

- 3 If using a patient extension set, prime the feeding formula to the end of the patient extension set, and connect to the feeding port (button).
- 4 Set the pump to the prescribed flow rate. Proceed with feeding. For detailed setup instructions, see Section 18.

**To learn more about RELiZORB,  
please visit or call:**



[www.relizorb.com](http://www.relizorb.com)



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Patents: <http://www.alcresta.com/patents>

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