

For patients with fat malabsorption  
who require enteral feeding...

---

# Hydrolyze Fats, Normalize Absorption of Fatty Acids

RELiZORB mimics the function  
of pancreatic lipase and delivers  
absorbable fats to your patients.



RELiZORB® (iMMOBILIZED LIPASE) CARTRIDGE is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula.

In clinical studies, use of RELiZORB was shown to normalize DHA/EPA plasma concentrations to levels consistent with a reference range based on healthy subjects as shown in the literature (please see IFU for full description of the studies and references).

**RELiZORB®**   
(iMMOBILIZED LIPASE) CARTRIDGE

# Essential Fatty Acids Are Indispensable Building Blocks of Human Health



## The benefits of omega-3 fatty acids (DHA and EPA) start at the cellular level

- Fatty acids are derived from medium-chain and long-chain triglycerides (MCTs and LCTs)
- When hydrolyzed, LCTs yield omega-3 fatty acids, **which benefit human health**<sup>1</sup>
  - LCTs are the **ONLY source** of omega-3 fatty acids

## Omega-3 fatty acids can ease inflammation before it causes widespread damage to the body<sup>2</sup>

- DHA and EPA may have clinically important anti-inflammatory effects in a variety of conditions associated with fat malabsorption<sup>2</sup>
- A balanced ratio of omega-6 to omega-3 fatty acids is beneficial in maintaining normal development, immunological function, and overall health



Omega-3 fatty acids **strengthen the development and functioning of organs** at the cellular level

**Brain and retina**<sup>2-4</sup>  
Have highly specialized functional roles in normal signal transduction, neurotransmission, and neurogenesis

**Cardiovascular system**<sup>5</sup>  
Help lower blood pressure and improve blood vessel function

**Play a key role in numerous metabolic processes**<sup>1,6</sup>  
In addition to acting as a source of energy

**Throughout the body**<sup>1,3</sup>  
Are released from membranes by phospholipases for conversion to mediate immune function, platelet aggregation, and lipid homeostasis

Fats can increase caloric uptake and, when compared with proteins and carbohydrates, are a **greater source of calories** (cal) [9 kcal/gram vs 4 kcal/gram for proteins and carbohydrates].<sup>7</sup>

# Deficiency of Pancreatic Lipase Is an Underlying Cause of Fat Malabsorption

Pancreatic lipase is essential to break down fats into fatty acids and accounts for a majority of fatty acid digestion.<sup>8,9</sup>

Amylase acts on starches  
Only **LIPASE** has the ability to hydrolyze fats  
Protease acts on proteins

**Fat may be the most poorly absorbed macronutrient relative to carbohydrates and proteins**

**Conditions commonly associated with fat malabsorption<sup>10</sup>:**

- Cystic fibrosis
- Pancreatitis
- Pancreatic cancer
- Gastric cancer
- Surgery/trauma
- Crohn's disease
- Celiac disease
- Other inflammatory bowel disease

**Patients with compromised pancreatic output have a higher risk for fatty acid deficiencies in plasma and tissue, which may be related to a variety of adverse physiological effects, such as altered membrane and cellular functions**

**Among patients with cystic fibrosis, fat malabsorption is associated with low BMI and poor outcomes that can have an impact on: digestive symptoms, nutritional status, physical functioning, treatment burden, body image, pain<sup>11,12</sup>**

# Fat Malabsorption Has Devastating Consequences

**In critically ill patients in the ICU, an inflammation-modulating diet enriched with EPA and γ-linolenic acid GLA resulted in<sup>13</sup>:**



**83%** risk reduction of developing new organ failures



**60%** risk reduction of 28-day in-hospital all-cause mortality



**~5** fewer days on mechanical ventilation



**~4** fewer days in the ICU

**GI symptoms associated with fat malabsorption<sup>14</sup>:**

- Diarrhea
- Steatorrhea
- Abdominal pain
- Nausea
- Bloating
- Constipation

**Overall short- and long-term health impacts are multisystemic and varied<sup>15-17</sup>**

- Weight loss
- Intestinal obstruction
- Diabetes
- Death
- Respiratory issues
- Chronic infections
- Impaired bone health (vitamin K deficiency)

# The Current Treatment Practice Cannot Adequately Address Fat Malabsorption

**Before participating in a multicenter, randomized, double-blind, crossover trial with an open-label safety evaluation period, patients had been receiving up to 1.5 L of enteral formula overnight for a mean of 6.6 years, and yet...<sup>18</sup>**

- Still had plasma concentrations of omega-3 fatty acids that were well below concentrations found in healthy humans<sup>18</sup>
- Had BMI or BMI percentiles that were below target for patients with CF<sup>18</sup>
  - These suboptimal nutrition measurements occurred despite use of a mean of 8 to 9 pancreatic enzyme replacement therapy (PERT) capsules in conjunction with enteral nutrition<sup>18</sup>

**In enteral formulas, protein can be prepared in a form that is pre-hydrolyzed, stable, and available to be readily absorbed. However, pre-hydrolyzed fatty acids and monoglycerides are not available in enteral formulas since they are not stable and spoil quickly**

# 60%

In this study, DHA and EPA plasma concentrations were approximately 60% of values observed in normal subjects.<sup>18</sup>

**This study was funded by Alcresta Therapeutics, Inc. and conducted among patients with cystic fibrosis.**

# PERT Capsules Are Not Formulated To Be Added to Enteral Feeding Systems

**PERT capsules are indicated for oral use and are not intended to be crushed or added to enteral feeding regimens<sup>19</sup>**

- Enteric-coated microspheres may separate from meal contents in the stomach and not adequately mix during delivery to the small intestine<sup>20</sup>
  - Some unprotected enzymes may fail due to prolonged exposure to gastric acid<sup>16</sup>
- Even when PERT capsules are administered in large doses, there have been no results of complete restoration of normal fat absorption<sup>20</sup>
- PERT capsules were not designed to work with enteral formula and have been shown to result in...
  - Clogged feeding tubes<sup>21</sup>
  - Activity that peaks after 30 minutes and wanes over the next 2 hours<sup>19,21</sup>
  - Only a small number of patients experiencing normalization of fat malabsorption, with many requiring individualized therapy<sup>20</sup>

**Current practices using PERT capsules with enteral nutrition have not been adequately studied for use in hydrolyzing key fats in enteral nutrition.<sup>22</sup>**

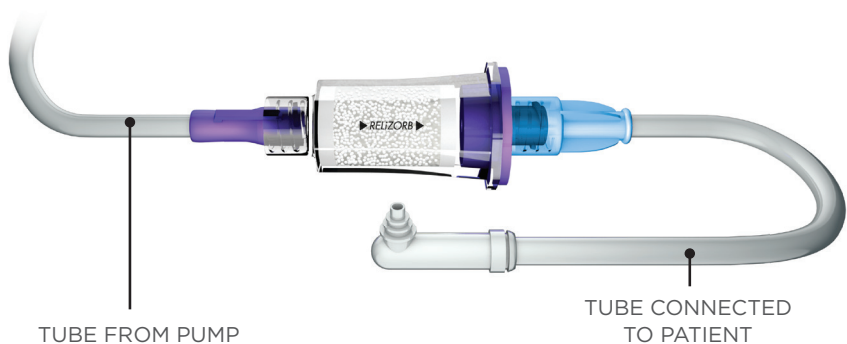
# RELiZORB Hydrolyzes Fats Prior to Ingestion

## Mimics the function of the digestive pancreatic enzyme lipase

- Lipase is covalently bound to the small white beads inside the cartridge. The lipase-bead complex, iLipase® (immobilized lipase), is retained within the RELiZORB cartridge during use by 2 filters as enteral formula flows through
- By hydrolyzing fats from enteral formulas, RELiZORB allows for the delivery of absorbable fatty acids and monoglycerides
- Like human pancreatic lipase, the iLipase in RELiZORB is intended to selectively break apart triglycerides at the sn-1 and sn-3 positions
- The lipase enzyme is not from a porcine or animal source



The RELiZORB cartridge easily connects to in-line enteral feeding systems: simple for clinicians or caregivers



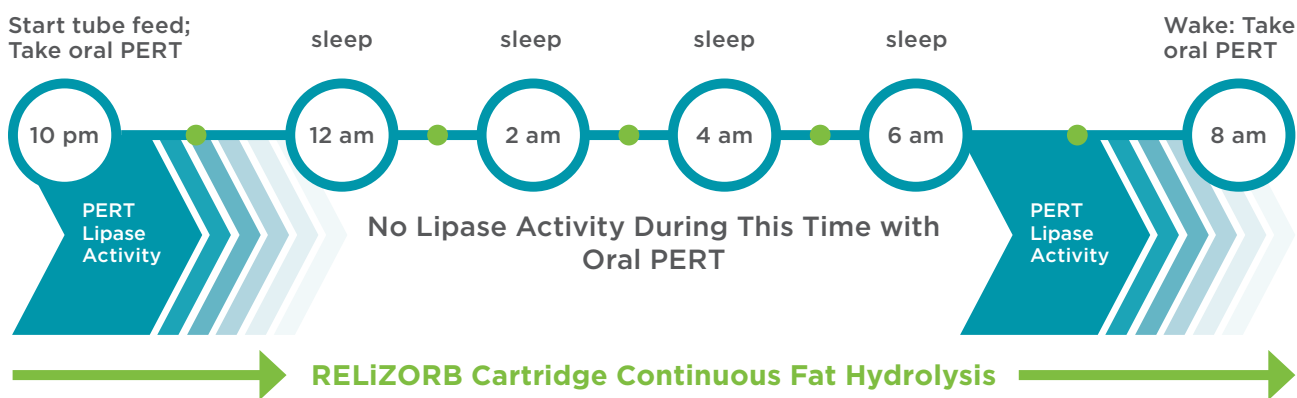
# RELiZORB Achieves Efficient Fat Hydrolysis

## RELiZORB is proven to hydrolyze available fats,\* including MCTs and LCTs

- LCTs are extremely hard to hydrolyze
- LCTs provide approximately 10% more calories than MCTs

>90%  
fat hydrolysis\* with RELiZORB

## RELiZORB is intended to provide continuous fat hydrolysis during overnight enteral feeding

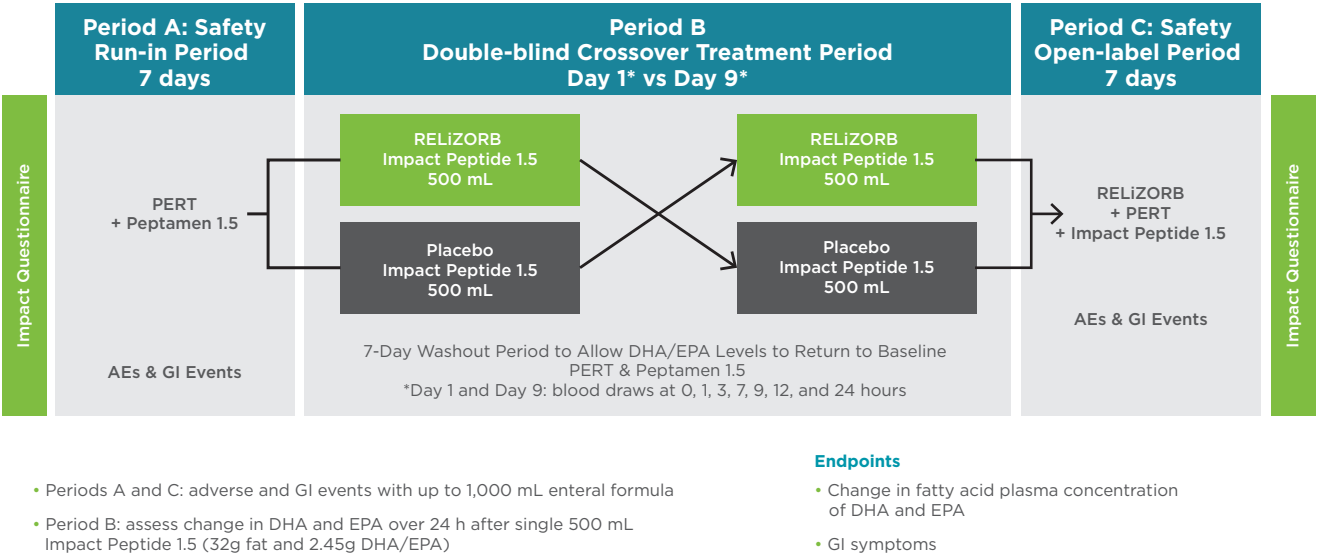


- Oral PERT is active in the GI tract for about 45-60 minutes after administration<sup>23</sup>
- Manufacturer's prescribing information and FDA safety bulletin advise against crushing PERT products and adding them to formula<sup>22</sup>

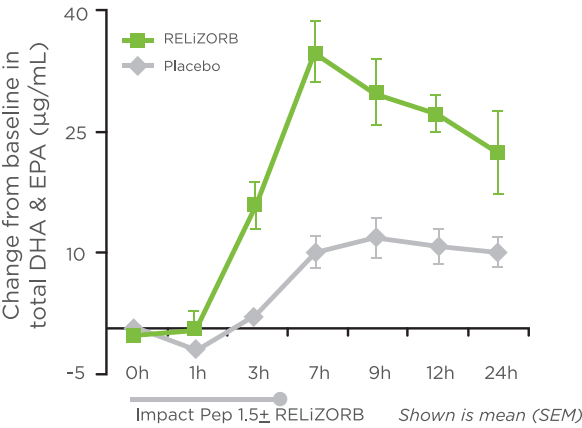
\*Greater than 90% of available fats hydrolyzed in most enteral formulas tested, including Nutren 2.0, Impact Peptide 1.5, Peptamen 1.5, Peptamen AF, and Nutren 1.0. Percentage of fat hydrolysis is estimated based on label claim for content, calculated using 500 mL of formula with a pump rate of 120 mL/hr. Formula manufacturers may change the composition of their formulas, which may affect the operation of RELiZORB. Please refer to formula product websites for recent product descriptions, ingredients, and nutritional information.

# RELiZORB Normalizes Absorption of Fatty Acids With Immediate Use

497 Study: A double-blind, placebo-controlled crossover treatment period with a follow-up safety period was used to measure endpoints<sup>18</sup>



Over 24 hours: Changes in plasma concentrations of DHA and EPA (omega-3 fatty acids)



2.8-fold

overall increase in total DHA and EPA with RELiZORB versus placebo (AUC<sub>0-24h</sub>;  $P < 0.001$ )

- DHA and EPA were used as measures in the studies as they are strongly correlated with overall fat absorption<sup>24</sup>

>50% of Patients Reported a Decrease in the Frequency of Some GI Events<sup>18</sup>

In the 497 study, overall the frequency of GI events decreased in Period C compared with Period A among 33 pediatric and adult patients with cystic fibrosis\*

57%

reduction in the incidence of diarrhea from Period A to Period C<sup>18</sup>

	OVERALL (N=33)	
	PERIOD A PERT	PERT + RELiZORB
ABDOMINAL PAIN	29 (13)	19 (10)
BLOATING	14 (5)	7 (3)
CONSTIPATION	8 (6)	0 (0)
DIARRHEA	7 (7)	3 (3)
GAS	30 (12)	38 (10)
INDIGESTION/HEARTBURN	9 (6)	4 (3)
NAUSEA	9 (6)	6 (4)
STEATORRHEA/FATTY STOOL	7 (6)	7 (3)
VOMITING	4 (3)	5 (3)
FLATULENCE	1 (1)	7 (1)
SMELLY BURPS	4 (1)	0 (0)
LARGE VOLUME STOOL	0 (0)	4 (2)
ABDOMINAL GAS PAIN	0 (0)	1 (1)
TOTAL FREQUENCY	122	101

During Period C of the trial, 42% (n=14) of patients using RELiZORB stopped taking PERT capsules<sup>18</sup>

- Despite protocol instructions to maintain their usual treatment practice

In clinical studies, use of RELiZORB was shown to normalize plasma concentrations to levels consistent with a reference range based on healthy subjects as shown in the literature (please see IFU for full description of the studies and references).

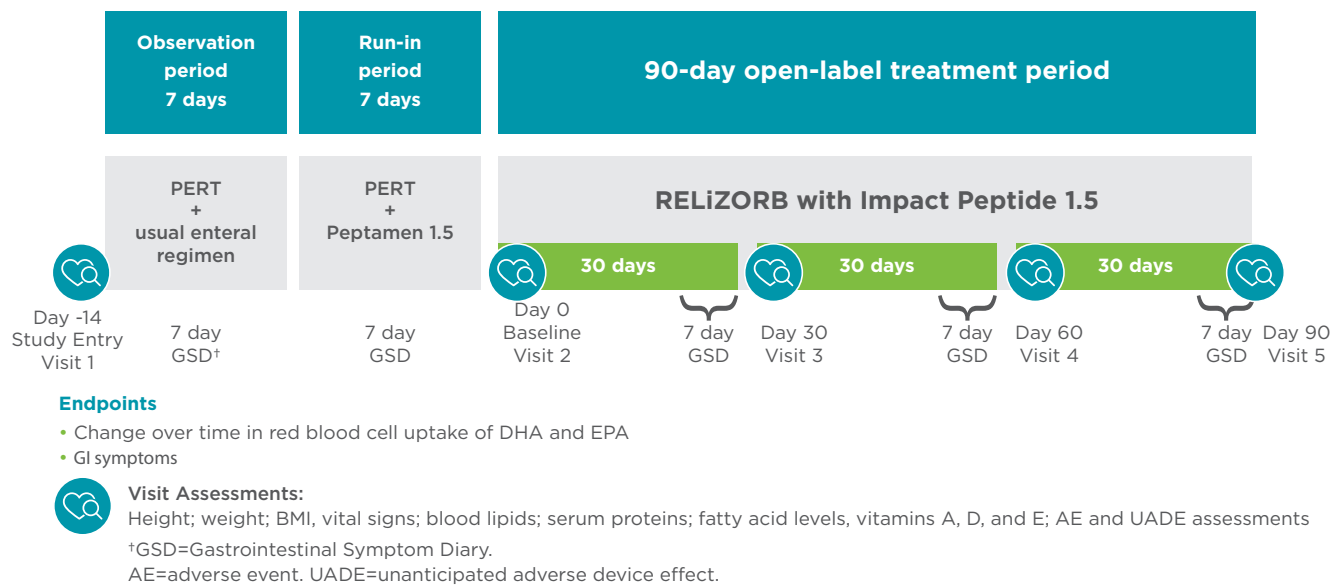
Period A=baseline run-in period. Period C=open-label safety period.

\*Gastrointestinal events are expressed as: number of events (number of patients reporting events).

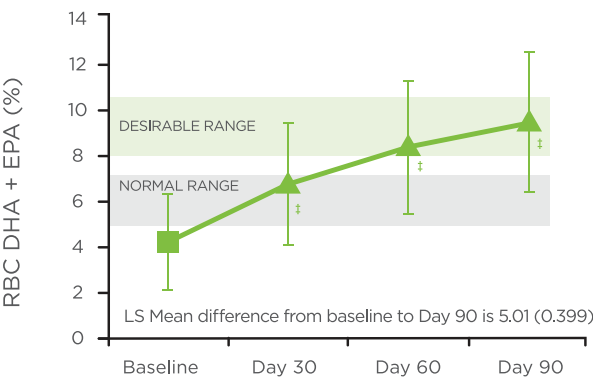
Freedman S, Orenstein D, Black P, et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with cystic fibrosis. *J Pediatr Gastroenterol Nutr.* 2017;65(1):97-101.

# RELiZORB Normalizes Absorption of Fatty Acids With Sustained Use\*

**498 ASSURE Study: A multicenter, 90-day, open-label study in which RELiZORB was used with overnight enteral nutrition<sup>25</sup>**



## Changes in Erythrocyte Membrane Fatty Acid Composition (%) for Omega-3 Index<sup>25</sup>



<sup>†</sup>P<0.001 for difference from baseline to Day 30, Day 60, and Day 90.

# Improvement in Weight Percentiles With Long-Term (90-Day) Use of RELiZORB

**61%**

**of participants demonstrated improvement in weight percentiles<sup>25</sup>**

Overall, weight and BMI z-scores and percentiles were not significantly different from baseline to 90 days. However, 20/33 (61%) patients had improvement in weight z-scores and percentiles in the intention to treat (ITT) population.<sup>25</sup>

**In the 498 study, long-term usage of RELiZORB showed<sup>25</sup>:**

- No reported incidences of diarrhea at Day 90
- Overall, the number of participants reporting GI symptoms decreased from Day 30 to Day 90
- No participants discontinued RELiZORB due to an adverse event

**All exploratory efficacy outcomes, including serum levels of fat-soluble vitamins A, D, and E in plasma as well as serum protein (total protein, prealbumin, albumin, and transferrin) levels, were within normal ranges at study entry and remained so throughout the 90-day study treatment period<sup>25</sup>**

\*Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. Absorption and Safety with Sustained Use of RELiZORB Evaluation (ASSURE) study in patients with cystic fibrosis receiving enteral feeding. *J Pediatr Gastroenterol Nutr.* 2018;Oct;67(4):527-532.

# How to Connect and Use RELiZORB With Volumes Up to 500 mL

RELiZORB is easy to set up and use

Instructional video available at [www.relizorb.com](http://www.relizorb.com)

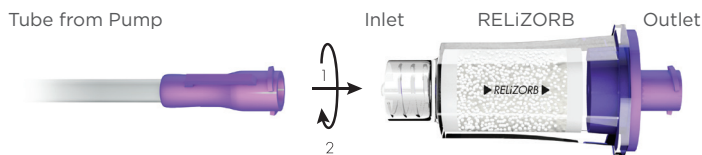


## RELiZORB Setup Procedure and Use

Patients and patient caregivers should review the following RELiZORB installation instructions before use.

- 1 Set up the pump and enteral feeding pump tubing set per the pump manufacturer's instructions. Prime the enteral feeding pump tubing per the manufacturer's instructions.
- 2 Remove the 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 Remove the RELiZORB from its pouch. Examine the RELiZORB. Do not use the RELiZORB cartridge if:
  - the RELiZORB is damaged
  - the RELiZORB has been previously used
- 4 Secure the RELiZORB to the end of the enteral feeding pump tubing set by inserting the outlet fitting from the pump tubing into the inlet of the RELiZORB with a twisting motion until secure.

FIGURE 1: Securing RELiZORB inlet to outlet fitting from pump tubing.



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

- 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 outlet fitting to the inlet fitting of the patient extension set or enteral feeding tube that connects to the patient.

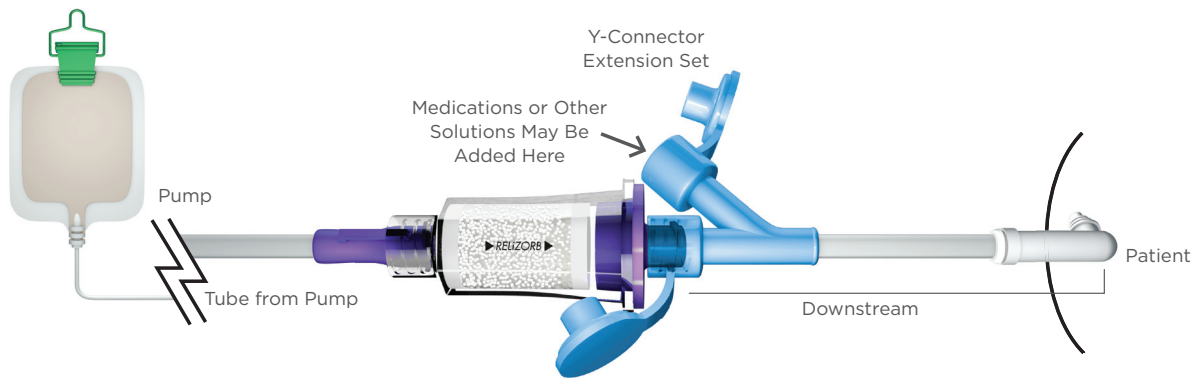
FIGURE 2: Connecting RELiZORB outlet to inlet fitting of patient extension set or enteral feeding tube that connects to patient.



- 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.
- 8 Set the pump to the prescribed flow rate and proceed with feeding.

**WARNING:** If medications, saline flushes or other non-enteral formula materials are to be added, they must be introduced **AFTER** RELiZORB (ie, between RELiZORB and the patient). They may be added to the side-port of a Y-Connector extension set located between the RELiZORB and the patient as shown in Figure 3.

FIGURE 3: Medications may be added between RELiZORB and patient.



**NOTE:** If medications or flush solutions are added BEFORE the RELiZORB cartridge, then RELiZORB, all tubing and formula must be discarded. You may re-start feeding using a new RELiZORB and patient extension set. Please follow Steps 1-7 to re-start the process.

**NOTE:** If a second RELiZORB is required to be installed to replace an existing RELiZORB, use the following steps:

- Pause the pump following the pump manufacturer's instructions
- Disconnect the current RELiZORB from the patient extension set or enteral feeding tube
- Remove the current RELiZORB from the enteral feeding pump tubing set
- Connect the new RELiZORB to the enteral feeding pump tubing set following Step 4
- Prime the enteral formula through to the end of the RELiZORB following Step 5
- Connect the new RELiZORB to the patient extension set or enteral feeding tube following Step 6
- Follow Step 7 if a patient extension set is being used
- Follow Step 8 to re-start enteral formula delivery

# How to Connect and Use Tandem RELiZORB With Volumes of 500-1000 mL

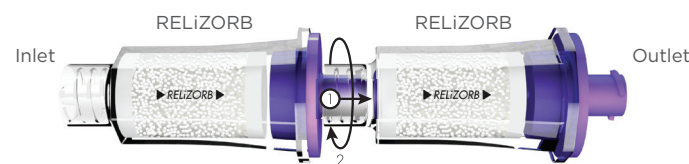
For volumes greater than 500 mL and up to 1000 mL, you can connect 2 RELiZORBs together in a tandem configuration. The tandem configuration (2 cartridges) is limited to 1 such use per day. Tandem RELiZORB may also be referred to as “piggybacking.”

For complete product use information, including indications for use, warnings and precautions, please refer to the Instructions for Use (IFU) and Patient Guide you received in the RELiZORB packaging, or visit [www.RELiZORB.com](http://www.RELiZORB.com).

## Tandem RELiZORB Setup Procedure and Use

- 1 Set up the pump and enteral feeding pump tubing set per the pump manufacturer’s instructions. Prime the enteral feeding pump tubing per the manufacturer’s instructions.
- 2 Remove 2 RELiZORB pouches from the carton. 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 Remove the RELiZORBs from their pouches. Examine each RELiZORB. 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 1**.

**FIGURE 1:** Connecting 2 RELiZORB cartridges together to form a tandem RELiZORB.



- 5 Secure the tandem RELiZORB to the end of the enteral feeding pump tubing set 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 2**.

**FIGURE 2:** 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 patient extension set or enteral feeding tube that connects to the patient, as shown in **Figure 3**.

**FIGURE 3:** Connecting tandem RELiZORB outlet to inlet fitting of tube that connects to patient.



- 8 If a patient extension set is being used, 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 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 4**.

**FIGURE 4:** 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 and all tubing and formula must be discarded. You may re-start feeding using a new RELiZORB and a patient extension set. Please follow Steps 1-7 to re-start the process.

# RELiZORB Warnings and Cautions

RELiZORB® (IMMOBILIZED LIPASE) CARTRIDGE is indicated for use in pediatric patients (ages 5 years and above) and adult patients to hydrolyze fats in enteral formula. RELiZORB is for use with enteral feeding only; do not connect to intravenous or other medical tubing. Medications should not be administered through RELiZORB. Please see Instructions for Use for full safety information at [www.relizorb.com](http://www.relizorb.com).

## Warnings

- RELiZORB is for use with enteral feeding only.
- RELiZORB should not be connected to any intravenous (IV) line, setup, or system.
- Medications should not be administered through the RELiZORB cartridge. Do not add medications to the enteral feed line in between the pump and RELiZORB (before RELiZORB). The passage of medications through RELiZORB may adversely affect the medications or the ability of RELiZORB to hydrolyze fats.
- Fibrosing Colonopathy - Fibrosing colonopathy is a rare, serious adverse reaction associated with high-dose use of pancreatic enzyme replacement therapy in the treatment of patients with cystic fibrosis. The underlying mechanism of fibrosing colonopathy remains unknown. Patients with fibrosing colonopathy should be closely monitored because some patients may be at risk of progressing to stricture formation. RELiZORB contains lipase enzyme that is not from a porcine source. The lipase is bound to the beads, and this lipase-bead complex (iLipase) is retained within the RELiZORB cartridge. Continue to follow your physician's guidance and porcine pancreatic enzyme labeling regarding porcine pancreatic enzyme use when used in conjunction with RELiZORB.

## Cautions and Precautions

- Do not re-use RELiZORB. RELiZORB is a single-use product. Re-use may result in contamination of the product. If re-used, RELiZORB may not effectively hydrolyze fats.
- Do not break, alter, or place excess pressure on any part of the RELiZORB cartridge. Any compromise of the structural integrity of RELiZORB may lead to improper connection to enteral feeding pump tubing sets and patient extension sets or enteral feeding tubes, enteral formula leakage or risk of contamination.
- Do not use RELiZORB after the date marked on the pouch.
- Enteral formulas containing insoluble fiber (including blenderized formulas) should NOT be used. Insoluble fiber may clog the RELiZORB cartridge. A detailed listing of enteral formulas compatible with RELiZORB can be found at [www.relizorb.com/formulas](http://www.relizorb.com/formulas).
- RELiZORB is designed for use with enteral feeding pump systems with low flow/no flow alarms. RELiZORB is NOT intended for use with gravity feed systems. A detailed listing of pumps, enteral feeding pump tubing sets and patient extension sets or enteral feeding tubes compatible with RELiZORB can be found at [www.relizorb.com/pumps](http://www.relizorb.com/pumps).
- In order to ensure product performance, store RELiZORB in its pouch either refrigerated or at room temperature (2°C to 27°C; 36°F to 80°F).
- RELiZORB is indicated for use with enteral feeding only; patients should follow physician's guidance for pancreatic enzyme replacement therapy (PERT) use for meals and snacks. Patients and patient caregivers should follow physician's guidance regarding the need for pancreatic enzyme replacement therapy (PERT) during enteral feeding.

# Fat Malabsorption Is a Debilitating Problem

- **Long-chain omega-3 fatty acids are crucial to human health** and have been shown to exert clinically important anti-inflammatory effects<sup>1-6</sup>
- **Fats are a greater source of calories** than proteins and carbohydrates (9 kcal/gram vs 4 kcal/gram) but are the most poorly absorbed<sup>7</sup>
- **The impact of fat malabsorption can be devastating**, especially for patients with cystic fibrosis and critically ill patients<sup>11-17</sup>
- **The current treatment paradigm is lacking**—does not adequately address fat malabsorption and under-delivers on clinical outcomes<sup>18-21</sup>



# Hydrolyze Fats, Normalize Absorption of Fatty Acids With RELiZORB

## 497 Study demonstrated:

- **2.8-fold increase** in the plasma concentrations of omega-3 fatty acids (DHA and EPA)
- **>50% of participants reported a decrease** in the frequency of some GI events with RELiZORB (Period C)<sup>18</sup>
  - Overall, the frequency of GI events decreased in Period C compared with Period A
  - 57% reduction in the incidence of diarrhea from Period A to Period C

## 498 ASSURE Study demonstrated:

- **2.1-fold increase** in red blood cells of DHA and EPA<sup>25</sup>
- **61% of participants** demonstrated improvement in weight percentiles<sup>\*25</sup>
- **No incidences** of diarrhea at Day 90<sup>25</sup>
- RELiZORB was found to be **well tolerated**<sup>25</sup>
  - No participants discontinued RELiZORB due to adverse events

In clinical studies, use of RELiZORB was shown to normalize plasma concentrations to levels consistent with a reference range based on healthy subjects as shown in the literature (please see IFU for full description of the studies and references).

\*20/33 patients had improvements in weight z-scores, and percentiles. Not significantly different from baseline to Day 90.



## Assistance You Can Rely On

### YOUR PATIENT

will be assigned a dedicated RELiZORB Program Coordinator who is available by phone or email to help with:



Understanding how to use RELiZORB



Insurance assistance



Delivery and shipments of RELiZORB



Financial assistance, including out-of-pocket assistance program<sup>†</sup>

### YOUR PRACTICE

will have access to a Program Coordinator dedicated to helping you and your office staff along the way with:



Insurance verification



Claims management and appeals assistance



Prior authorization, reimbursement, and financial assistance



Eligibility of your patient for the RELiZORB Out-of-Pocket Assistance Program

Support is just a phone call away at  
**1-844-632-9271**

<sup>†</sup>Eligible patients in the US only.

References

1. National Institutes of Health Website. Omega-3 fatty acids: fact sheet for professionals <https://ods.od.nih.gov/factsheets/omega3FattyAcids-HealthProfessional/>. Accessed October 16, 2017.

2. Calder PC. Omega-3 fatty acids and inflammatory processes. *Nutrients*. 2010;2:355-374.

3. Abedi E, Sahari MA. Long-chain polyunsaturated fatty acid sources and evaluation of their nutritional and functional properties. *Food Sci Nutr*. 2014;2(5):443-463.

4. Uauy R, Mena P, Rojas C. Essential fatty acids in early life: structural and functional role. *Proc Nutr Soc*. 2000;59(1):3-15.

5. Harvard School of Public Health Website. The Nutrition Source. Omega-3 fatty acids: an essential contribution. <https://www.hsph.harvard.edu/nutritionsource/omega-3-fats/>. Accessed October 16, 2017.

6. Prentice AM, Paul AA. Fat and energy needs of children in developing countries. *Am J Clin Nutr*. 2000;72(5):1253S-1265S.

7. Cleveland Clinic Website. Fat and calories. <https://my.clevelandclinic.org/health/articles/fat-and-calories>. Accessed October 16, 2017.

8. Whitcomb DC, Lowe ME. Human pancreatic digestive enzymes. *Dig Dis Sci*. 2007;52:1-17.

9. Carriere F, Barrowman JA, Verger R, Laugier R. Secretion and contribution of lipolysis of gastric and pancreatic lipases during a test meal in humans. *Gastroenterology*. 1993;105:876-888.

10. MedlinePlus Website. Malabsorption. <https://medlineplus.gov/ency/article/000299.htm>. Accessed October 16, 2017.

11. Bodnar R, Kadar L, Holics K, et al. Factors influencing quality of life and disease severity in Hungarian children and young adults with cystic fibrosis. *Ital J Pediatr*. 2014;2:40-50.

12. Sawiki GS, Rasouliyan L, McMullen AH, et al. Longitudinal assessment of health-related quality of life in an observational cohort of patients with cystic fibrosis. *Pediatr Pulmonol*. 2011;46(1):36-44.

13. Pontes-Arruda, A, et al. The use of an inflammation-modulating diet in patients with acute lung injury or acute respiratory distress syndrome: a meta-analysis of outcome data. *JPEN*. 2008;32(6)596-605.

14. Blaauw R. Malabsorption: causes, consequences, diagnosis and treatment. *S Afr J Clin Nutr*. 2011;24(3):125-127.

15. Mayo Clinic Website. Cystic fibrosis: symptoms and causes. <http://www.mayoclinic.org/diseases-conditions/cystic-fibrosis/symptoms-causes/dxc-20211893>. Accessed October 16, 2017.

16. Kalnins D, Wilschanski M. Maintenance of nutritional status in patients with cystic fibrosis: new and emerging therapies. *Drug Des Devel Ther*. 2012;6:151-161.

17. Dominguez-Munoz JE. Pancreatic exocrine insufficiency: diagnosis and treatment. *J Gastroenterol Hepatol*. 2011;26(2):12-16.

18. Freedman S, Orenstein D, Black P, et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with cystic fibrosis. *J Pediatr Gastroenterol Nutr*. 2017;65(1):97-101.

19. Berry AJ. Pancreatic enzyme replacement therapy during pancreatic insufficiency. *Nutr Clin Pract*. 2014;29(3):312-321.

20. Trang T, Chan J, Graham DY. Pancreatic enzyme replacement therapy for pancreatic exocrine insufficiency in the 21st century. *World J Gastroenterol*. 2014;20(33):11467-11485.

21. Ferrie S, Graham C, Hoyle M. Pancreatic enzyme supplementation for patients receiving enteral feeds. *Nutr Clin Pract*. 2011;26(3):349-351.

22. Schwarzenberg SJ. Enteral tube feeding for individuals with cystic fibrosis: Cystic Fibrosis Foundation Evidence-Informed Guidelines. *Journal of Cystic Fibrosis* 2016;15(6):724-735.

23. Cystic Fibrosis Foundation. <https://www.cff.org/Life-With-CF/Daily-Life/Fitness-and-Nutrition/Nutrition/Taking-Care-of-Your-Digestive-System/Enzymes/>. Accessed April 19, 2018.

24. Harris WS, Sands SA, Windsor SL, et al. Omega-3 fatty acids in cardiac biopsies from heart transplantation patients: correlation with erythrocytes and response to supplementation. *Circulation* 2004;110:1645-1649.

25. Stevens J, Wyatt C, Brown P, Patel D, Grujic D, Freedman SD. Absorption and Safety with Sustained Use of RELiZORB Evaluation (ASSURE) study in patients with cystic fibrosis receiving enteral feeding. *J Pediatr Gastroenterol Nutr*. 2018;Oct;67(4):527-532.

**RELiZORB®**   
(iMMOBILIZED LIPASE) CARTRIDGE

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



RELiZORB, iLipase, the Alcresta capstone, and Alcresta Therapeutics are registered trademarks of Alcresta Therapeutics, Inc.

©2020 Alcresta Therapeutics, Inc. All rights reserved.

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

REL20-314