COMPLAINT REPORT (PN100103/100295/100299)

PN 100103

PN 100295/100299

INSTRUCTIONS: (1) Describe the incident or event in *Section A*. **(2)** For leaking, gastrointestinal, or clogging related issues please also complete *Sections B-D*, as applicable. **(3)** Add in the complainant (source of complaint) information, onto *Section E*. **(4)** If patient related, add the patient or user's information onto *Section F*. **(5)** Add the patient's healthcare provider/caregiver info onto *Section G*. **(6)** Add the patient's formula and pump information onto *Section H*. **(7)** Add who to contact if Alcresta feedback is needed onto *Section I*. **(8)** If available, please indicate if defective samples may be returned to Alcresta and if replacement product is needed onto *Section J*. **(9)** If you are filling out this form, please enter your contact information onto *Section K.*

Once completed, return this form to Alcresta Quality Assurance < QForms@alcresta.com >

SECTION A - COMPLAINT AND PRODUCT INFORMATION

A1. Complaint Description: *Describe the incident/event which lead up to the complaint in detail*

A2. Event Date: *(On what date did the incident occur?)* ***Month*** _____ ***Day*** _____ ***Year*** _____

A3. Product Name: RELiZORB	**A4. Lot Number:**

SECTION B - LEAKING RELATED ISSUE (LK - Leakage)

Is this a leaking related issue? ☐ Yes ☐ No (*If 'Yes', please answer B1 – B10)*

B1. Is the leak coming from the feeding tube or extension set connected to the RELiZORB?	☐ Yes ☐ No ☐ N/A
B2. Is there visible damage or cracking on the cartridge?	☐ Yes ☐ No ☐ N/A
B3. Is the RELiZORB cartridge leaking?	☐ Yes ☐ No ☐ N/A
B4. Is the leaking visible at the initial connection?	☐ Yes ☐ No ☐ N/A
B5. Is the user waking up and finding that it was leaking?	☐ Yes ☐ No ☐ N/A
B6. Is an ENFit transition connector used?	☐ Yes ☐ No ☐ N/A
B7. Has there been any leaking when using the feeding tube or extension set without the RELiZORB?	☐ Yes ☐ No ☐ N/A
B8. Are connections clean and dry prior to setting up?	☐ Yes ☐ No ☐ N/A
B9. Is anything added to the formula or are non-enteral formula liquids put through the cartridge? (If 'Yes', specify what was added in B10)	☐ Yes ☐ No ☐ N/A

B10. Comments:

SECTION C – GASTROINTESTINAL ISSUE (GI – Gastro Issue)

Is this a gastrointestinal related issue? ☐ Yes ☐ No (*If 'Yes', please answer C1 – C3)*

C1. Are these new symptoms? (If 'Yes', add details in C3)	☐ Yes ☐ No ☐ N/A
C2. Have symptoms increased with use of RELiZORB? (If 'Yes', add details in C3)	☐ Yes ☐ No ☐ N/A

C3. Comments:

SECTION D – FLOW RATE/CLOGGING ISSUE (FR – Flow Rate)

Is this a flow rate or clogging related issue? ☐ Yes ☐ No (*If Yes, please answer D1 – D4)*

D1. Additives to formula? (If 'Yes', specify what was added and the amount in D1a-D1b)	☐ Yes ☐ No ☐ N/A
D1a. Name of additive(s): _____ **D1b.** Amount added: _____	
D2. Two (2) RELiZORB used in tandem configuration? (If 'Yes', answer D2a)	☐ Yes ☐ No ☐ N/A
D2a. Priming through both cartridges?	☐ Yes ☐ No ☐ N/A
D3. One (1) RELiZORB used with more than 500 mL of formula? (If 'Yes', answer D3a)	☐ Yes ☐ No ☐ N/A
D3a. Primed through the second cartridge when replacing after the first 500 mL?	☐ Yes ☐ No ☐ N/A

D4. Comments:

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SECTION E - COMPLAINANT INFORMATION (Fill in who originated, or the source of the complaint)		
E1. Name:	**E2. Title:**	**E3. Email:**
E4. Telephone:	**E5. Address:**	

SECTION F – PATIENT/USER AND IMPACT INFORMATION (Complete this section if the issue is patient-related)		
F1. Patient Name or Patient ID #:	**F2. Disease State:**	**F3. Age:**
F4. Alleged Device Failure and/or Impact to Patient/User:		
F5. Extent of Patient/User Harm: ☐ N/A – No Patient / User Harm Reported		
F6. Extent of Medical Intervention Required: ☐ N/A – No Patient / User Harm Reported		

SECTION G – PHYSICIAN/HEALTHCARE FACILITY CONTACT INFORMATION (Add the patient's provider info)		
G1. Name:	**G2. Title:**	**G3. Address:**
G4. Telephone:	**G5. Email:**	

SECTION H – FORMULA and PUMP INFORMATION (Add the patient's formula and pump info)				
H1. Formula Brand Name / Manufacturer: **H2. Formula Lot Number:**	**H3. Amount of Formula Used:**	**H4. Pump Model:**	**H5. Pump Speed / Rate:**	**H6. IFU was adequate?** ☐ **Yes** ☐ **No**

SECTION I – FEEDBACK REQUEST INFORMATION	
I1. Is feedback/response requested for this incident/event? (select one) ☐ ***Yes (please answer I2 and I3. Alcresta QA will provide feedback/response)*** ☐ ***No***	
I2. Respond by Date:	**I3. Send Response to (name, phone/email, and best time to contact):**

SECTION J – DEFECTIVE PRODUCT RETURN AND REPLACEMENT INFORMATION
J1. Is the defective product available for return to Alcresta upon request? ☐ **Yes** ☐ **No** **J2. Is a photo of the defective product available?** ☐ **Yes** ☐ **No** ☐ **N/A** **J3. If defective product is available for return to Alcresta, has the product been used?** ☐ **Yes** ☐ **No** ☐ **N/A**
J4. Is replacement product requested and the patient/user is enrolled in the RELiZORB Support program? ☐ ***Yes (note - you must contact RELiZORB Support Services at 1-844-632-9271 to fulfill this request)*** ☐ ***No***

SECTION K – REPORTER INFORMATION (Enter your information, the preparer of this form)		
K1. Your Name:	**K2. Your Title:**	**K3. Your Email:**
K4. Your Address:		**K5. Your Telephone:**
K6. Alert Date: *(On what date were you aware of the incident?)* ***Month*** _____ ***Day*** _____ ***Year*** _____		

Thank you for completing this report. Please send to <QForms@alcresta.com>
Alcresta Quality Assurance representative will contact you if additional information or follow-up is required.