

Closing letter - FSN plastic plug chest support by R82

In March 2020 R82 A/S received feedback from market that the plastic plug on the chest support for Mustang and Rabbit/Rabbit Up could come loose without use of a tool. The safety of the user is of utmost importance and as such R82 created a Field Safety Notice adding safety information (“This product contains small parts which could present a choking hazard if removed from their intended placing.”) regarding small parts to the existing Instructions for Use.

The chest support was manufactured in the period 01-04-2017 to 10-02-2020.

Chest support for Rabbit/Rabbit Up (3 sizes): 861810, 861820, 861830,

Chest support for Mustang (3 sizes): 869810, 869820, 869830

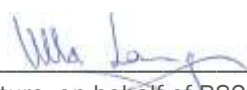


The Field Safety Notice was for informational purposes only. The updated Instructions for Use are available on www.etac.com

Field Safety Notice letters were sent out to all affected distributors with the obligation to pass this field safety notice to all those who need to be aware within their organization or to any organization where potentially affected devices have been transferred. Confirmation of the receipt of the letter and transferring of the information has been requested by R82 A/S.

Sufficient effort, follow up, and response has been obtained and R82 A/S is now closing the case. From heron, non-responders take responsibility if the information is not transferred as requested.

Place	Gedved, Denmark
Date of issue	01. November 2021
Name and function	Ulla Lange, Director of QA and Regulatory Affairs



Signature, on behalf of R82 A/S