

PMS 2020 05 FSN Explanatory email

R82 A/S has received feedback from market that the plastic plug on the chest support for Mustang and Rabbit/Rabbit Up can come loose without use of a tool and on this background we have decided to issue a Field Safety Notice as the loose plastic plug on the chest support can potentially put the user at risk of choking.

The chest support has been 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 safety of the user is of utmost importance to us and we have decided to make an FSN on 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. Updated Instructions for Use will be available on www.r82.org/support/

The field safety notice is for informational purposes only.
It is not necessary to return devices or plastic plugs.
Replacement plug (2504000) can be ordered, if required.

R82 A/S will notify all applicable national regulatory authorities about this matter.

This field safety notice must be passed to all those who need to be aware within your organization or to any organization where potentially affected devices have been transferred.

For information, reply forms to document information passed on can be found at:

Distributor reply form <https://ec.europa.eu/docsroom/documents/32517>

Customer reply form <https://ec.europa.eu/docsroom/documents/32516>

Please return your filled-in attached distributor reply form to ula@r82.com or mkg@r82.com within 1 month from receipt of this email.

We sincerely regret any difficulties this may cause you. R82 A/S remains dedicated to patient safety and will continue to monitor device performance to ensure the product integrity and usage.