

## URGENT FIELD SAFETY NOTICE

### RESOLVE® HALO

FSCA – 032021

#### STERILE PACKAGING INSPECTION INSTRUCTIONS

January 2022

#### AFFECTED DEVICES

| Product Variant          | Item Number | Description                    | GTIN           |
|--------------------------|-------------|--------------------------------|----------------|
| Closed Back Kit          | 505300T     | CB Ring Kit Ti Sm              | 05690977305885 |
|                          | 505400T     | CB Ring Kit Ti Std             | 05690977305892 |
|                          | 505500T     | CB Ring Kit Ti Lg              | 05690977305908 |
| Halo Trays               | 540C        | ReSolve Halo Comp Tray         | 05690977165335 |
|                          | 540D        | OB ReSolve Component Tray      | 05690977197404 |
|                          | 540V2       | Sterile V2 Component Tray      | 05690977192348 |
| Ossur Halo               | 515300T     | CB Ring Kit Ti Sm-No App       | 05690977334960 |
|                          | 515400T     | CB Ring Kit Ti Std-No App      | 05690977319035 |
|                          | 515500T     | CB Ring Kit Ti Lg-No App       | 05690977326200 |
|                          | 553CB       | CB Ring Tray Sm                | 05690977343269 |
|                          | 554CB       | CB Ring Tray Std               | 05690977343283 |
|                          | 555CB       | CB Ring Tray Lg                | 05690977343306 |
| ReSolve Closed Back Halo | 510300CH    | CB Resolve Glass Ring Sml      | 05690977192355 |
|                          | 510400CH    | CB Resolve Glass Ring Std      | 05690977192645 |
|                          | 510500CH    | CB Resolve Glass Ring Lge      | 05690977192362 |
|                          | 515300C     | CB ReSolve Ring Kit Sm-No App  | 05690977308596 |
|                          | 515400C     | CB ReSolve Ring Kit Std-No App | 05690977308626 |
|                          | 515500C     | CB ReSolve Ring Kit Lg-No App  | 05690977308633 |
| ReSolve Open Back Halo   | 510400DH    | OB Resolve Ring Nonsterile Std | 05690977311145 |
|                          | 510500DH    | OB N/S Resolve Ring Lg         | 05690977307407 |
|                          | 505300D     | OB ReSolve Sterile Unit Sml    | 05690977197312 |
|                          | 505400D     | OB ReSolve Sterile Unit Std    | 05690977197329 |
|                          | 505500D     | OB ReSolve Sterile Unit Lge    | 05690977197336 |
|                          | 515300D     | OB ReSolve Ring Kit Sm-No App  | 05690977308640 |
|                          | 515400D     | OB ReSolve Ring Kit Std-No App | 05690977308657 |
|                          | 515500D     | OB ReSolve Ring Kit Lg-No App  | 05690977308664 |
| V2 Open Back Kit         | 505300V2    | OB V2 Ring Kit Ti Sm           | 05690977305915 |
|                          | 505400V2    | Open Back Glass Halo Std       | 05690977305922 |
|                          | 505500V2    | OB V2 Ring Kit Ti Lg           | 05690977223370 |
|                          | 515300V2    | OB V2 Ring Kit Ti Sm-No App    | 05690977308671 |
|                          | 515400V2    | OB V2 Ring Kit Ti Std-No App   | 05690977308688 |
|                          | 515500V2    | OB V2 Ring Kit Ti Lg-No App    | 05690977308695 |

## DEVICE ISSUE

Össur is committed to providing safe, high-quality medical devices to its customers. Össur's Halo devices have sterile barrier systems that contain high impact polystyrene trays with sealed Tyvek lids. It has been identified that the high impact polystyrene trays of Resolve® Halo Rings and Össur Halo Rings may crack or puncture during transit, leading to a potential failure of the sterile barrier system. As such, Össur is implementing a Field Safety Corrective Action in relation to the sterility risk and the packaging inspection steps required for the affected Halo devices.

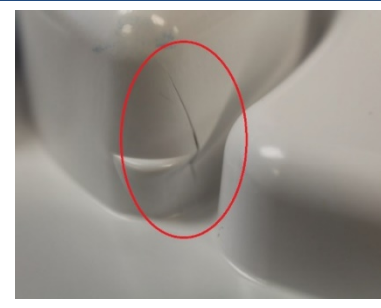
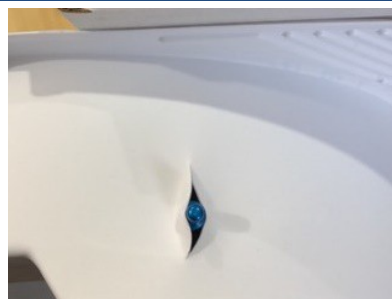
### PICTURE OF THE AFFECTED DEVICE



### PICTURE OF THE DEVICE PACKAGING



### EXAMPLES OF PACKAGING FAILURES



The recommended actions in relation to this case are outlined below:

## ACTION - ORGANISATIONS

### ACTION REQUIRED:

1. Please ensure the polystyrene trays are inspected for any cracks or punctures prior to using the listed Halo devices. Please contact Össur Customer Service should you have devices with compromised packaging and a failure of the sterile barrier system.
2. Please pass this notice to those who need to be aware within your organisation or to any organisation where the listed devices have been transferred.
3. Please retain this letter in a prominent position for an appropriate period.
4. If you have further distributed this product, please identify your customers, and notify them at once of this Field Safety Notice. We recommend that you include a copy of this notice.
5. Complete and return the attached Customer Acknowledgement Form to the address provided, even if your facility is no longer in possession of any of the listed device as we require this information to reconcile this process.

This notice is to be communicated to all those within your organisation, and to any other organisation where affected devices may have been provided or serviced.

Please maintain awareness of this notice and recommended actions.

Please contact customer service for further information and assistance. A list of the contact numbers is provided at the end of this notice.



Hulda Hallgrímsdóttir  
Vice President, Quality & Regulatory

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