

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.

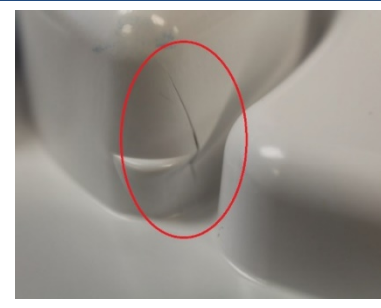
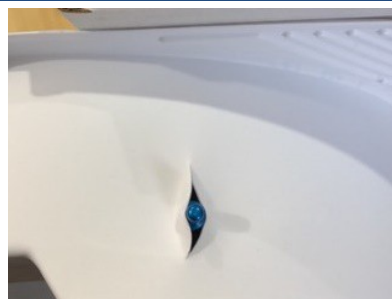
PICTURE OF THE AFFECTED DEVICE



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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