



Date: January 11, 2024

URGENT: MEDICAL DEVICE REMOVAL

Product: EVIS EXERA II and EVIS EXERA III Colonovideoscopes

Models: CF-H180AL, CF-HQ190I, CF-HQ190L, CF-Q180AL, PCF-H180AL, PCF-H190DL, PCF-H190L, PCF-H190TL, PCF-HQ190L, PCF-Q180AL

Serial: See attachment 1 for specific list of serial numbers

Subject: Variable Stiffness Mechanism Repair

ATTENTION: ENDOSCOPY DEPARTMENT

Dear Health Care Provider:

Olympus has become aware of an issue that requires your attention. This letter pertains to specific model and serial numbers of EVIS EXERA II and EVIS EXERA III colonovideoscope units listed above that have been repaired by the Olympus America Repair Center.

These devices are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve). These instruments are intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

Reason for action:

Olympus became aware that specific colonovideoscope units repaired at our Olympus America Repair facility were assembled without an adhesive, specifically a thread locking compound in the variable stiffness mechanism. The purpose of the thread locking compound is to provide additional assembly security for pins and screws located in the variable stiffness mechanism and protect them from certain physical conditions such as high levels of vibration, fluctuation in temperature or severe shock loads.

Loose pins and screws could cause the device's variable stiffness mechanism to malfunction, causing stiffness/resistance in the locking ring mechanism and could potentially cause the insertion tube to become locked in the last mode set by the clinician.

Risk to Health:

The potential harms that could occur due to a malfunction in the variable stiffness mechanism include unspecified tissue injury, surgical delay or prolongation, pain, and/or perforation.

Olympus has not received any reports of adverse events associated with this phenomenon.



Action steps to be taken by the end user:

Olympus has determined based upon our repair records that your facility is in possession of one or more affected units shown in Attachment 1. Olympus requires that you take the following actions:

1. Inspect your inventory for the referenced products and identify any devices with the model number and serial number specified in Attachment 1. Please check all areas of the hospital to determine if any of these products remain in inventory. Quarantine and stop using the device.
2. Our Olympus Customer Solutions team will contact you to arrange a no-charge return, and a loaner as necessary. Olympus will perform an inspection of your device, repair the variable stiffness mechanism if required, and return your device at no charge to you.

Note: If other issues which require repair are identified during the inspection process, our Customer Solutions team will follow your service agreement without approval or contact you to approve additional repair work.

3. Olympus requests that you acknowledge receipt of this matter through our recall portal:
 - a. Go to <https://olympusamerica.com/recall>.
 - b. Enter the recall number "0437"
 - c. Complete the form as instructed.
4. If you have distributed these devices outside your facility, please provide a copy of this letter to those facilities immediately.

Please report to Olympus any adverse events and/or irregularities associated with the use of the devices by contacting the Olympus Technical Assistance Center at 1-800-848-9024, option 1. Adverse events experienced with the use of this product may also be reported to the Food and Drug Administration MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me at 647-999-3203 or Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas

Attachment 1

URGENT – MEDICAL DEVICE REMOVAL

Affected Models and Serial Numbers for Variable Stiffness Mechanism Repair

	Model Number	Serial Number		Model Number	Serial Number		Model Number	Serial Number
1)	CF-H180AL	2001426	51)	PCF-H180AL	2801450	101)	CF-HQ190L	2417755
2)	CF-H180AL	2001524	52)	PCF-H180AL	2801763	102)	CF-HQ190L	2418202
3)	CF-H180AL	2001614	53)	PCF-H180AL	2802289	103)	CF-HQ190L	2418754
4)	CF-H180AL	2002139	54)	PCF-Q180AL	2808983	104)	CF-HQ190L	2418843
5)	CF-H180AL	2002212	55)	PCF-H180AL	2903612	105)	CF-HQ190L	2419006
6)	CF-H180AL	2002285	56)	PCF-H180AL	2903746	106)	CF-HQ190L	2419007
7)	CF-H180AL	2103817	57)	PCF-H180AL	2903896	107)	CF-HQ190L	2419105
8)	CF-H180AL	2104137	58)	PCF-H180AL	2904201	108)	CF-HQ190L	2510489
9)	CF-H180AL	2104581	59)	PCF-H180AL	2904811	109)	CF-HQ190L	2510795
10)	CF-H180AL	2105255	60)	PCF-Q180AL	2909332	110)	CF-HQ190L	2510801
11)	CF-H180AL	2105976	61)	CF-HQ190L	2082724	111)	CF-HQ190L	2511164
12)	CF-H180AL	2107112	62)	CF-HQ190L	2082896	112)	CF-HQ190L	2512292
13)	CF-H180AL	2207880	63)	CF-HQ190L	2082936	113)	CF-HQ190L	2512458
14)	CF-H180AL	2207929	64)	CF-HQ190L	2083461	114)	CF-HQ190L	2512470
15)	CF-H180AL	2207940	65)	CF-HQ190L	2083765	115)	CF-HQ190L	2512569
16)	CF-H180AL	2309317	66)	CF-HQ190L	2084560	116)	CF-HQ190L	2512817
17)	CF-H180AL	2601078	67)	CF-HQ190L	2085050	117)	CF-HQ190L	2513285
18)	CF-H180AL	2601096	68)	CF-HQ190L	2186261	118)	CF-HQ190L	2524619
19)	CF-H180AL	2601255	69)	CF-HQ190L	2187110	119)	CF-HQ190L	2524916
20)	CF-H180AL	2601368	70)	CF-HQ190L	2187274	120)	CF-HQ190L	2625144
21)	CF-H180AL	2601700	71)	CF-HQ190L	2187811	121)	CF-HQ190L	2635605
22)	CF-Q180AL	2602060	72)	CF-HQ190L	2188037	122)	CF-HQ190L	2635832
23)	CF-Q180AL	2603763	73)	CF-HQ190L	2188206	123)	CF-HQ190L	2636020
24)	CF-H180AL	2702380	74)	CF-HQ190L	2200530	124)	CF-HQ190L	2636500
25)	CF-H180AL	2702460	75)	CF-HQ190L	2201625	125)	CF-HQ190L	2636782
26)	CF-H180AL	2702478	76)	CF-HQ190L	2201677	126)	CF-HQ190L	2637892
27)	CF-H180AL	2702805	77)	CF-HQ190L	2201844	127)	CF-HQ190L	2659060
28)	CF-H180AL	2703697	78)	CF-HQ190L	2202345	128)	CF-HQ190L	2659357
29)	CF-H180AL	2704366	79)	CF-HQ190L	2263354	129)	CF-HQ190L	2759754
30)	CF-H180AL	2704490	80)	CF-HQ190L	2288483	130)	CF-HQ190L	2761671
31)	CF-H180AL	2806996	81)	CF-HQ190L	2288940	131)	CF-HQ190L	2762243
32)	CF-H180AL	2807975	82)	CF-HQ190L	2289129	132)	CF-HQ190L	2772492
33)	CF-H180AL	2900004	83)	CF-HQ190L	2289391	133)	CF-HQ190L	2773247
34)	CF-H180AL	2900185	84)	CF-HQ190L	2289421	134)	CF-HQ190L	2773259
35)	CF-H180AL	2900249	85)	CF-HQ190L	2289572	135)	CF-HQ190L	2773324
36)	CF-H180AL	2908770	86)	CF-HQ190L	2290978	136)	CF-HQ190L	2773552
37)	CF-H180AL	2909110	87)	CF-HQ190L	2291472	137)	CF-HQ190L	2874236
38)	CF-H180AL	2909884	88)	CF-HQ190L	2303312	138)	CF-HQ190L	2875490
39)	PCF-H180AL	2005061	89)	CF-HQ190L	2304024	139)	CF-HQ190L	2875615
40)	PCF-H180AL	2007000	90)	CF-HQ190L	2304070	140)	CF-HQ190L	2875616
41)	PCF-H180AL	2108388	91)	CF-HQ190L	2314598	141)	CF-HQ190L	2875656
42)	PCF-H180AL	2108779	92)	CF-HQ190L	2315390	142)	CF-HQ190L	2876636
43)	PCF-H180AL	2109211	93)	CF-HQ190L	2391750	143)	CF-HQ190L	2876811
44)	PCF-H180AL	2109849	94)	CF-HQ190L	2391772	144)	CF-HQ190L	2876877
45)	PCF-Q180AL	2200140	95)	CF-HQ190L	2391857	145)	CF-HQ190L	2877237
46)	PCF-H180AL	2200674	96)	CF-HQ190L	2392281	146)	CF-HQ190L	2877319
47)	PCF-H180AL	2201253	97)	CF-HQ190L	2417328	147)	CF-HQ190L	2877901
48)	PCF-H180AL	2301680	98)	CF-HQ190L	2417450	148)	CF-HQ190L	2978291
49)	PCF-Q180AL	2603268	99)	CF-HQ190L	2417702	149)	CF-HQ190L	2978331
50)	PCF-H180AL	2800321	100)	CF-HQ190L	2417736	150)	CF-HQ190L	2978640

Attachment 1

URGENT – MEDICAL DEVICE REMOVAL

Affected Models and Serial Numbers for Variable Stiffness Mechanism Repair

	Model Number	Serial Number
151)	CF-HQ190L	2979287
152)	CF-HQ190L	2979510
153)	CF-HQ190L	2980281
154)	CF-HQ190L	2980304
155)	CF-HQ190L	2980541
156)	CF-HQ190L	2981322
157)	CF-HQ190L	2982038
158)	CF-HQ190L	2982143
159)	PCF-HQ190L	2000569
160)	PCF-HQ190L	2001007
161)	PCF-H190DL	2046148
162)	PCF-H190DL	2046377
163)	PCF-HQ190L	2101185
164)	PCF-HQ190L	2101301
165)	PCF-HQ190L	2101313
166)	PCF-HQ190L	2101860
167)	PCF-HQ190L	2102339
168)	PCF-HQ190L	2102634
169)	PCF-HQ190L	2102740
170)	PCF-HQ190L	2103215
171)	PCF-HQ190L	2103257
172)	PCF-HQ190L	2103483
173)	PCF-HQ190L	2103614
174)	PCF-HQ190L	2103674
175)	PCF-H190TL	2110150
176)	PCF-H190L	2201678
177)	PCF-H190L	2201735
178)	PCF-HQ190L	2203899
179)	PCF-HQ190L	2203915
180)	PCF-HQ190L	2204096
181)	PCF-HQ190L	2204400
182)	PCF-HQ190L	2204659
183)	PCF-HQ190L	2204820
184)	PCF-HQ190L	2205238
185)	PCF-HQ190L	2205684
186)	PCF-HQ190L	2206065
187)	PCF-HQ190L	2206501
188)	PCF-H190L	2301759
189)	PCF-H190L	2301775
190)	PCF-H190L	2301929
191)	PCF-H190L	2301930
192)	PCF-H190L	2302159
193)	PCF-H190L	2302280
194)	PCF-H190L	2302281
195)	PCF-H190L	2302380
196)	PCF-H190L	2302506
197)	PCF-H190L	2303832
198)	PCF-H190L	2303927
199)	PCF-HQ190L	2307200
200)	PCF-HQ190L	2307709

	Model Number	Serial Number
201)	PCF-HQ190L	2307713
202)	PCF-HQ190L	2308226
203)	PCF-H190L	2404124
204)	PCF-H190L	2404132
205)	PCF-H190L	2404806
206)	PCF-H190L	2404888
207)	PCF-H190L	2404967
208)	PCF-H190L	2405012
209)	PCF-H190L	2405253
210)	PCF-H190L	2405290
211)	PCF-H190L	2405353
212)	PCF-H190DL	2500549
213)	PCF-H190DL	2501714
214)	PCF-H190L	2517013
215)	PCF-H190L	2517120
216)	PCF-H190L	2517422
217)	PCF-H190L	2517440
218)	PCF-H190L	2517541
219)	PCF-H190L	2517616
220)	PCF-H190L	2517649
221)	PCF-H190L	2517705
222)	PCF-H190DL	2602501
223)	PCF-H190DL	2602549
224)	PCF-H190DL	2602675
225)	PCF-H190DL	2602884
226)	PCF-H190DL	2603086
227)	PCF-H190DL	2605185
228)	PCF-H190DL	2605189
229)	PCF-H190DL	2605279
230)	PCF-H190DL	2605338
231)	PCF-H190DL	2605343
232)	PCF-H190DL	2615621
233)	PCF-H190L	2628544
234)	PCF-H190DL	2716237
235)	PCF-H190DL	2716306
236)	PCF-H190DL	2716379
237)	PCF-H190DL	2727123
238)	PCF-H190DL	2727529
239)	PCF-H190DL	2737897
240)	PCF-H190DL	2738603
241)	PCF-H190DL	2839269
242)	PCF-H190DL	2839284
243)	PCF-H190DL	2839580
244)	PCF-H190DL	2840038
245)	PCF-H190DL	2840130
246)	PCF-H190DL	2840639
247)	PCF-H190DL	2840669
248)	PCF-H190DL	2840719
249)	PCF-H190DL	2840798
250)	PCF-H190DL	2840928

	Model Number	Serial Number
251)	PCF-H190DL	2842302
252)	PCF-H190DL	2942674
253)	PCF-H190DL	2942814
254)	PCF-H190DL	2943131
255)	PCF-H190DL	2943193
256)	PCF-H190DL	2943240
257)	PCF-H190DL	2943296
258)	PCF-H190DL	2943451
259)	PCF-H190DL	2943708
260)	PCF-H190DL	2943820
261)	PCF-H190DL	2944426
262)	PCF-H190DL	2944690
263)	PCF-H190DL	2944765
264)	PCF-H190DL	2944939
265)	PCF-H190DL	2945260