

令和 8年 2月24日作成

医療機器回収の概要
(クラスII)

1. 一般的名称及び販売名

一般的名称： 腹腔鏡用ガス気腹装置

販売名： (1) 高速気腹装置 UHI
(2) 高速気腹装置 UHI-2
(3) 高速気腹装置 UHI-3

2. 対象ロット、数量及び出荷時期

型番： UHI

シリアル番号

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型番： UHI-2

シリアル番号

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型番 : UHI-3
シリアル番号 :

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台数 : 合計 3485台

出荷時期 : 1994年6月23日～2024年4月1日

3. 製造販売業者等名称

製造販売業者の名称 : オリンパスメディカルシステムズ株式会社 八王子事業所
製造販売業者の所在地 : 東京都八王子市石川町2951番地
許可の種類 : 第一種医療機器製造販売業
許可番号 : 13B1X00277
製造業者 : 白河オリンパス株式会社

4. 回収理由

UHI-1、UHI-2、UHI-3に搭載されたソフトウェアアルゴリズムが腹腔過圧を引き起こす可能性があることが発覚しました。
この状況を踏まえて回収を決定しました。

5. 危惧される具体的な健康被害

有害事象および苦情の調査を含む健康被害リスク評価から、過剰送気は処置中に以下の様々な患者危害を引き起こす可能性があります。(空気塞栓症、不整脈(徐脈、心停止、または心停止)、気胸、腎臓または尿路の問題、低酸素症、皮下気腫、治療遅延、および処置の複雑化)
なお、当該製品は医療従事者の管理下で使用されることから、直ちに適切な医学的処置が

なされることにより、
重篤な健康被害には至らないと考えます。

6. 回収開始年月日
令和8年2月18日

7. 効能・効果又は用途等

本製品は、腹腔鏡下外科手術において、腹腔内にCO₂ ガスを送気すると共に、自動吸引、排煙動作を行うことにより、手術・観察に必要な空間及び視野を確保することを目的とする。

8. その他

本製品の出荷先はすべて把握しておりますので、回収する旨を文書にて通知の上、対象品を回収します。

9. 担当者及び連絡先

担当者 : Quality Assurance FCA Japan
連絡先 : オリンパスメディカルシステムズ株式会社
東京都八王子市石川町2951
電話番号 : 03-6901-4014
FAX番号 : 03-4567-2363