



Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية																																
Title	A potential of endobronchial combustion during therapeutic procedures using lasers or argon plasma coagulation																																	
Medical Device Description	Bronchofiberscope, Bronchovideoscope																																	
Medical Device Products Identifier	<table border="1"> <tr> <td>BF-XT40**</td> <td>BF-XT160*</td> <td>BF-H190</td> <td>BF-6C260*</td> </tr> <tr> <td>BF-P60</td> <td>BF-Q170</td> <td>BF-Q190</td> <td>BF-H290</td> </tr> <tr> <td>BF-MP60</td> <td>BF-1TQ170</td> <td>BF-XT190</td> <td>BF-Q290</td> </tr> <tr> <td>BF-1T60</td> <td>BF-P180*</td> <td>BF-1TH190</td> <td>BF-1TQ290</td> </tr> <tr> <td>BF-PE2</td> <td>BF-Q180**</td> <td>BF-260*</td> <td>* BF-H1100</td> </tr> <tr> <td>BF-TE2</td> <td>BF-Q180-AC*</td> <td>BF-F260</td> <td>BF-1TH1100</td> </tr> <tr> <td>BF-P150*</td> <td>BF-1T180*</td> <td>BF-P260F*</td> <td>BF-H1200</td> </tr> <tr> <td>BF-1T150</td> <td>BF-1TQ180*</td> <td>BF-1T260*</td> <td>BF-1TH1200</td> </tr> </table> <p>* Sales discontinued ** Sales and Service discontinued</p>	BF-XT40**	BF-XT160*	BF-H190	BF-6C260*	BF-P60	BF-Q170	BF-Q190	BF-H290	BF-MP60	BF-1TQ170	BF-XT190	BF-Q290	BF-1T60	BF-P180*	BF-1TH190	BF-1TQ290	BF-PE2	BF-Q180**	BF-260*	* BF-H1100	BF-TE2	BF-Q180-AC*	BF-F260	BF-1TH1100	BF-P150*	BF-1T180*	BF-P260F*	BF-H1200	BF-1T150	BF-1TQ180*	BF-1T260*	BF-1TH1200	العنوان اسم ووصف الجهاز/المستلزم الطبي الأرقام للجهاز/المستلزم الطبي
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Manufacturer	Olympus																																	
Authorized Representative	Salehiya Trading Est.																																	
Medical Devices Marketing Authorization (MDMA)	<table border="1"> <tr> <td>MDMA-1-2019-1564</td> </tr> <tr> <td>MDMA-1-2019-1562</td> </tr> <tr> <td>MDMA-1-2018-1065</td> </tr> <tr> <td>MDMA-1-2020-1004</td> </tr> </table>	MDMA-1-2019-1564	MDMA-1-2019-1562	MDMA-1-2018-1065	MDMA-1-2020-1004	إذن التسويق																												
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Potential /Associated risks	Endobronchial combustion during therapeutic procedures using lasers or argon plasma coagulation with the Olympus bronchoscope model BF Series. If endobronchial combustion occurs, patients may suffer internal burn in their airway or lungs, respiratory insufficiency, apnea, loss of consciousness, hospitalization or its prolongation, ICU care, or death.																																	
Recommendations	To maximize patient safety and mitigate any potential risk to patient health Olympus is providing the following recommendations related in combination with laser therapy equipment: - Only Nd:YAG laser or 810 nm diode lasers may be used with Olympus laser compatible bronchoscopes. Olympus has not evaluated any other lasers for compatibility with the indicated bronchoscope models.																																	

	<ul style="list-style-type: none"> - Do not perform laser cauterization while supplying oxygen. This may result in combustion during cauterization. This is included in the Warnings in the Operation Manual on laser cauterization with Olympus bronchoscopes. - Never emit laser radiation before confirming that an appropriate distance between the target and the endoscope's distal end with the tip of the laser probe is in the correct position in the endoscopic image. This is essential to avoid patient injury (burns, bleeding, & perforation) or damage to the device. 	
<p>For Reporting</p>	<div style="display: flex; justify-content: space-around; align-items: center;"> <div data-bbox="462 478 696 562" style="border: 1px solid black; padding: 5px;">  <p>SFDA 19999 مركز الاتصال الموحد</p> </div> <div data-bbox="745 478 967 562" style="border: 1px solid black; padding: 5px;"> <p>NCMDR</p> </div> <div data-bbox="1016 478 1230 562" style="border: 1px solid black; padding: 5px;">  <p>تيقظ Saudi Vigilance</p> </div> </div>	<p>للإبلاغ</p>