

## 退货政策

有关退货政策的详细信息，请联系您的 Lenstec 代表。退货时请附上完整的识别信息及退货原因。另请在包装上注明其为生物危害物。

## 安全和临床表现摘要

请参阅 EUDAMED。

## 患者登记和报告

包装中含有患者身份卡。该卡应在填写完毕后交给患者，并告知患者将其作为永久记录保存，以便以后咨询眼科医师时向其出示。包装中还随附自粘型晶体识别标签，以供在患者身份卡和其他临床记录中使用。

如果不良事件/投诉可合理地认为与晶状体相关，并且在性质、严重性或发生率方面先前未曾预料到，则应将这些不良事件/投诉报告给相关的欧盟成员国主管部门和 Lenstec，地址为：Airport Commercial Centre, Pilgrim Road, Christ Church, Barbados；电话：+1 246-420-6795；传真：+1 246-420-6797；电子邮件：[feedback@lenstec.com](mailto:feedback@lenstec.com)，或者联系您的 Lenstec 代表。

以下是已确认的不良反应。必须对这些已确认的不良反应和可能尚未确认的不良反应进行记录。

## 蓄积性不良反应包括但不限于：

眼内炎、眼前房出血、眼前房积脓、眼内感染、晶体脱位、囊样黄斑水肿、瞳孔阻滞、视网膜剥离、再次手术干预（排除视网膜剥离和后囊切开术）。

## 持续性不良反应包括但不限于：

角膜间质水肿、虹膜炎、囊样黄斑水肿、需要治疗的眼内压增高

## 参考文献 (Q)

## 与信息卡相关

- 身份信息的所有字段必须由医疗机构提供者填写。
- 医疗机构/医疗服务提供者有责任将带有不干胶蚀刻标志“LENSTEC”的标签贴纸粘贴到患者身份证的背面（未印刷），并将其提供给患者，以作为其植入物的记录。



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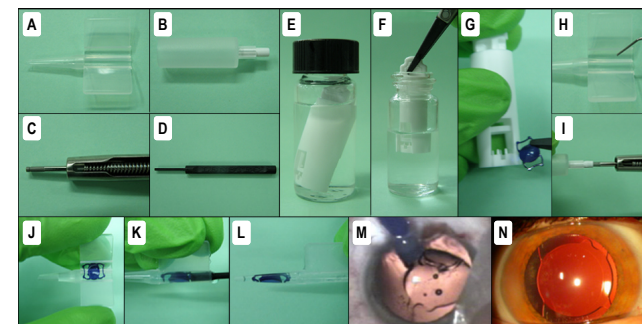
## UDI

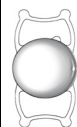
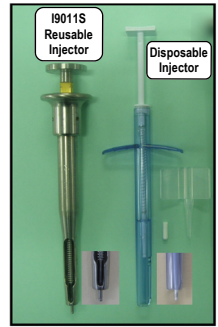
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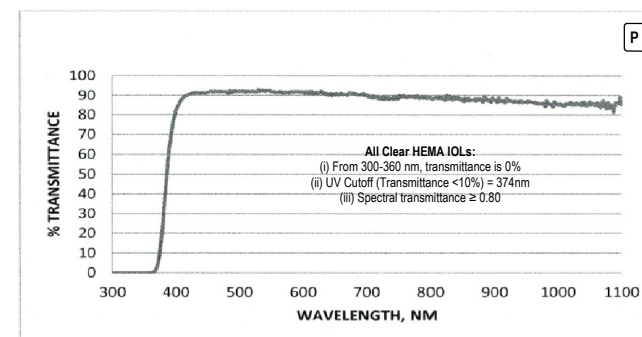


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PI32 Rev 11  
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O	Labeled Power (D)	Increments (D)	Claim Tolerances (D)	
 Tetraflex HD™	+5.0 to +14.5	0.5	±0.25	 <b>19011S Reusable Injector</b> LC16 Cart45S +5.0D to +26.0D  <b>Disposable Injector</b> LC16I +5.0D to +26.0D  LC24 +5.0D to +36.0D
	+15.0 to +25.0	0.25	±0.11	
	+25.5 to +30.0	0.5	±0.25	
	+31.0 to +36.0	1.0	±0.5	



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