

## Customer Bulletin

### ***Bausch +Lomb Phaco Packs: Enhanced Packaging for Needle Wrench***

May26, 2017

Dear Valued Bausch + Lomb Customer,

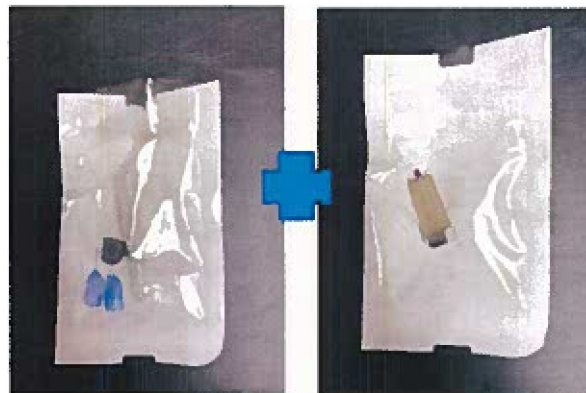
We are writing to inform you of a change we are making to the phacoemulsification packs for our Bausch + Lomb Stellaris® Vision Enhancement System. We have begun packaging the needle wrench assembly in a separate pouch from the silicone irrigation sleeves, test chambers and cassette stopper as noted in the illustrations below. In addition, we have implemented an enhanced cleaning process for the needle wrench to reduce the potential for the transfer of microscopic particulate to the irrigation sleeves that may be associated with the metal cap of the phaco needle wrench.

We are taking these steps to address several observations of microscopic particulate left in the corneal incision following cataract surgery. There have been no reported adverse events related to these observations. Scientific literature indicates that intraocular microscopic particulates commonly occur in eyes following cataract surgery using phacoemulsification and we have performed a thorough analysis of the microscopic particulate to confirm biocompatibility.

Although our findings have determined all product meets specification we have taken these continuous improvement measures to minimize the occurrence of the reported sightings of microscopic particulate to improve the customer experience with our Phacoemulsification packs. The specific products impacted by this enhancement are listed in Attachment 1 (see page 3). We anticipate distribution of most of the enhanced products to customers beginning later this year.



Current Configuration



New Configuration

Please contact the Bausch + Lomb Customer Service team with any questions or comments regarding this product improvement. As always, if you note any complications related to the use of a Bausch + Lomb product, please inform our Customer Service team immediately.

Bausch + Lomb Customer Service Center  
Email: [kundenservice@bausch.com](mailto:kundenservice@bausch.com)  
Tel: 0800- 589 31 14  
Contact: Alina Rachow

Sincerely,

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**[Redacted Signature]**

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# ATTACHMENT 1

## Products Affected By This Change

PACKS
CX4320
CX5310
BL5110
BL5111
BL5112
BL5120
BL5121
BL5123
BL5123A
BL5113
BL5113A
BL5114
BLV2260000
BLV3220000
BLV4180000
BLV128MP30
BLV126MF30
BLV322MM30
BLS226TI30

PACKS
BL5323W
BL5523W
BL5323WV
BL5523WV
BL5325W
BL552SW
BL5325WV
BL5525WV
BL5300
BL530W X
BL5323WVX
BL5325WV
BL5325WVX
BLSSOO
BL5520WX
BLSS23WVX
BL5525WVX
BL5115-4
BL5114A