

June 4, 2015

Sundhedsstyrelsen
Axel Heides Gade 1
2300 Kbh S
Denmark

Re: **Accurus[®] Standalone Probe**
Model: Models are tabulated in attachment 1

Dear Sir/Madam:

Alcon is providing Sundhedsstyrelsen with a communication regarding the recall of specific lots and catalog numbers of its Alcon Accurus[®] Vitrectomy Probes as documented in the attached FSCA.

Alcon is conducting a voluntary recall for specific lots and catalog numbers of its Accurus[®] Vitrectomy Probes after quality review processes discovered an insufficient seal on the outside packaging, potentially affecting the sterility of the product. We are conducting this voluntary medical device recall due to the fact that the possibility exists that the use of the non-sterile probes in surgery may pose a safety risk to patients. The use of non-sterile vitrectomy probes in ophthalmic surgery has the potential to result in patient infection and inflammation. No adverse events or complaints have been confirmed related to the Accurus[®] Vitrectomy Probe lots impacted by this voluntary recall.

The purpose of this communication is to inform Sundhedsstyrelsen that Alcon has initiated a product removal / recall of all lots affected in Denmark.

Attached please find FSCA.

If you have any questions regarding this matter, please contact Rúbia Cristina Gilbert Poulsen.

Sincerely,



Rúbia Cristina Gilbert Poulsen

Nordic Quality & Vigilance Manager

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Attachment 1
Tabulation of impacted lots and catalog numbers.

| Lot Number | Core Pak ID | Pak Description |
|-------------------|--------------------|--|
| 14010428X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14010429X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14010430X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14012984X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14012985X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14012987X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14014736X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14014737X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14014738X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14014739X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14016477X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14016577X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14017451X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14017452X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14017912X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14018320X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14020246X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14020280X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14020282X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14020283X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14022920X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14022921X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14022922X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14022923X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14024168X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14024219X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14026030X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14026031X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14026032X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14026034X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14028440X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14028553X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14028554X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |

| Lot Number | Core Pak ID | Pak Description |
|------------|-------------|--|
| 14028555X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14029477X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14031263X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14031264X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14033830X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14033831X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14033832X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14033833X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14036297X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 14036306X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 14036315X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 14036319X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 14038094X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 15010056X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 15010057X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 15010058X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 15010059X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 15012798X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 15012799X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 15013290X | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 15013291X | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 15014227X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 15015699X | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |
| 15015746X | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 15015749X* | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 15015753X* | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 15019245X* | 8065741018 | ACCURUS® 2500 STAND-ALONE VITREOUS PROBE |
| 15019246X* | 8065751122 | ACCURUS® 25+ 2500 CPM STAND-ALONE VITREOUS PROBE |
| 15019247X* | 8065803650 | ANTERIOR ACCURUS® PROBE WITH INFUSION NEEDLE |
| 15019248X* | 8065750821 | ACCURUS® 23 GA STANDALONE VITREOUS PROBE |

* These lots are still within Alcon control, and have not been distributed.