

June 3, 2015

To: SFDA

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

Dear Sir,

Alcon is providing the SFDA 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 the SFDA that Alcon has initiated a product removal / recall of all lots affected in Saudi Market

Attached please find FSCA.

If you have any questions regarding this matter, please contact the following mobile number :
+966 562922233

Sincerely,

Sultan AlSnaid
Scientific Office, Regulatory Affairs and PhV Manager

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.