Alcon Nordic A/S
Edvard Thomsens Vej 14
DK-2300 Copenhagen S, Denmark

URGENT: VOLUNTARY MEDICAL DEVICE CORRECTION	
Description	**Handling guidance for specific catalog numbers of Alcon Phaco Tips when used with included plastic wrench**
Relevant Product	**Alcon Phaco Tips** (see Attachment 1)
Alcon Record ID	**2023.011**

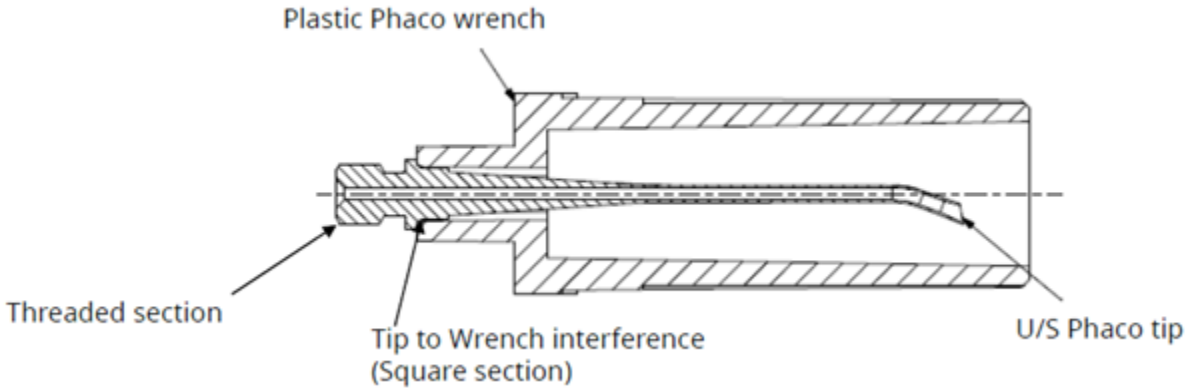
July 4, 2023

«Ship_to_Name»
«Address»
«City_», «State» «Zip_Code»
Account «Account»

Dear Healthcare Professional,

Alcon has become aware of the potential for the Phaco Tip wrench to generate plastic shaving particles if the Phaco Tip is over-tightened to the handpiece to the point where the wrench slips over the tip-to-wrench interface.

Please review the following information regarding specific catalog numbers of Alcon Phaco Tips and packs or kits containing those Phaco Tips. The purpose of this letter is to provide you with additional guidance on handling of the plastic wrench when tightening the Phaco Tip to mitigate the risk of generating plastic particles.



Alcon has reported this issue to Health Authorities in accordance with applicable regulations. Our records indicate that you have received or may receive an Alcon product containing a Phaco Tip with a plastic wrench, see *Attachment 1* for a list of relevant catalog numbers.

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Reason for the Voluntary Medical Device Correction:

Alcon has detected an increase in complaints of plastic particles associated with Phaco Tips. Laboratory analysis of retrieved particles revealed that the composition of the particles is consistent with the plastic wrench material. Globally, complaints of plastic particles associated with Phaco Tips represent less than 0.01% of Phaco Tips sales volume. Alcon has received a limited number of reports of adverse events associated with this issue.

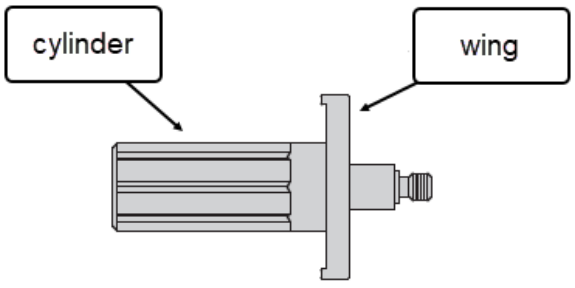
Potential patient impact

If particles are generated from the plastic wrench by overtightening the Phaco Tip and those particles subsequently enter the patient's eye during surgery, there is a potential risk of intra- and/or post-operative complications, including intraocular tissue damage, bleeding, and/or associated inflammation.

Actions to be taken by the Customer / User:

A. In order to mitigate the potential for the wrench to be damaged by overtightening the Phaco Tip and associated generation of plastic particles, Alcon is advising customers of the following precautions:

- To fasten the tip into the handpiece, grasp the plastic wrench by the cylindrical part of the wrench. Overtightening by leveraging the wings can increase the likelihood that the wrench may slip over the tip-to-wrench interface, causing damage to the wrench, and has the potential to generate plastic particles which may remain on the exterior of the Phaco Tip and/or distal end of the phaco handpiece.



TIP WRENCH

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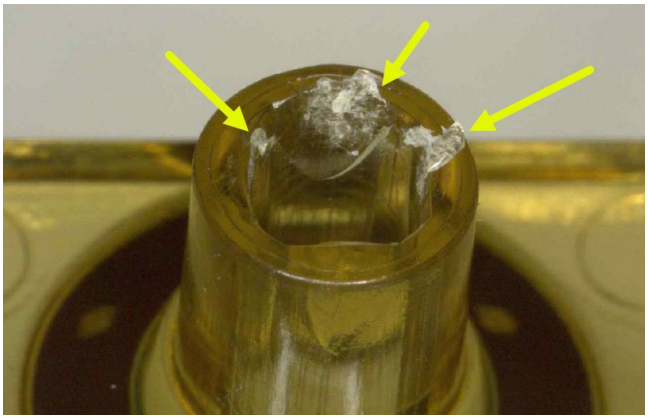
- If the wrench slips, or you suspect that the wrench may have slipped, during the process of threading the tip to the handpiece, do not apply the infusion sleeve over the Phaco Tip.



- Thoroughly flush the tip using the console irrigation functionality.
- Inspect the Phaco Tip and distal end of the phaco handpiece for particle presence under magnification and illumination.
- If particles are present on the Phaco Tip and/or phaco handpiece, use the console irrigation functionality to flush the tip again.
- After flushing, inspect again to verify no particles are present. Upon confirming that the observed particle(s) is no longer present, proceed with application of the infusion sleeve and instrument setup.

B. To acknowledge your receipt of this Voluntary Medical Device Correction notification, please take the following steps:

1. Forward this notification to all departments or organizations using Alcon Phaco Tips.
2. See *Attachment 1* for the list of relevant Alcon catalog numbers. You may receive shipments containing Phaco Tips manufactured prior to issuance of this Voluntary Medical Device Correction.
3. Follow the risk mitigation precautions provided in this notice when using identified catalog numbers of Phaco Tips, procedure pack, or Alcon Custom Pak®.
4. Please complete the attached *"Response Form"* indicating your understanding of the included instructions and **return the attached *"Response Form"* via email to Alcon.**
5. Keep *Attachment 1* for your records.

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon via email (qa.complaints@alcon.com) or by phone (+4535153952).

Alcon Nordic A/S
Edvard Thomsens Vej 14
DK-2300 Copenhagen S, Denmark

Should you have any questions or concerns about this matter, please feel free to call our Customer Service or contact your Alcon Sales Representative.

Sincerely,

Heather Attra
Senior Vice President, Quality and Regulatory Affairs

Alcon Nordic A/S
Edvard Thomsens Vej 14
DK-2300 Copenhagen S, Denmark

RESPONSE FORM	
MA 2023.011 **Handling guidance for specific catalog numbers of Alcon Phaco Tips when used with included plastic wrench**	«Ship_to_Name» «Address» «City_», «State» «Zip_Code» Account «Account»

Please follow these important steps:

To acknowledge your receipt of this Voluntary Medical Device Correction notification, please take the following steps:

1. Forward this notification to all departments or organizations using Alcon Phaco Tips.
2. See *Attachment 1* for the list of relevant Alcon catalog numbers. You may receive shipments containing Phaco Tips manufactured prior to issuance of this Voluntary Medical Device Correction.
3. Follow the risk mitigation precautions provided in this notice when using identified catalog numbers of Phaco Tips, procedure pack, or Alcon Custom Pak®.
4. Please complete the attached *"Response Form"* indicating your understanding of the included instructions and **return the attached *"Response Form"* via email to Alcon.**
5. Keep *Attachment 1* for your records.

Email: qa.nordic@alcon.com

Your signature below attests that you have read and understood Alcon's request and instructions.

Signature of Facility Representative:

Printed Name and Title:

Date:

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Edvard Thomsens Vej 14
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Attachment 1: List of relevant products and catalog numbers

Below products and Custom Paks and Procedure Paks containing these products are within the scope of this Voluntary Medical Device Correction.

Catalog Number	Item Description
8065752066	0.9MM ABS MINI 45K TIP
8065750958	ASSY,SHIP,CONSTELLATN FRAG TIP
8065750852	ASSY,SHIP,TIP MINI FL 30K
8065752200	CEN FMS PACK,ACT,.9U 30 BAL
8065752201	CEN FMS PACK,ACT,.9U 45 BAL
8065752193	CEN FMS PAKC,ACT,.9U 45K MF
C08561-33	DK-AALBORG SYGEHUS
C29192-01	DK-AALBORG SYGEHUS - CENTURION
C16609-13	DK-CATARACT
C17954-12	DK-CATARACT PACK
C17500-09	DK-CATARACT PACK - KELMAN
C24037-06	DK-CATARACT PAK
C24037-07	DK-CATARACT PAK
C21680-16	DK-CATARACT PAK
C16466-18	DK-CATARACT PAK
C27592-02	DK-CATARACT PAK 2
C18107-10	DK-CATARACT PAK TIL INFINITI
C18107-11	DK-CATARACT PAK TIL INFINITI
C28940-02	DK-CENTURION C PAK GRENÅ
C29188-01	DK-CENTURION CUSTOM PAK OUH
C25913-03	DK-ØJENLÆGERNES CENTER REGION
C20169-11	DK-PHACO CUSTOM PAK-HESTETORVET
C20169-12	DK-PHACO PAK-HESTETORVET
C25899-05	DK-RANDERS CENTURION PAK
C25899-06	DK-RANDERS CENTURION PAK
C28979-02	DK-REGION HS - KATARAKT - CENTURION

Catalog Number	Item Description
C29188-02	DK-CENTURION CUSTOM PAK OUH
C25148-05	DK-CENTURION PAK MORTZOS
C25148-06	DK-CENTURION PAK MORTZOS
C18963-12	DK-CENTURION PHACO PAK
C18963-13	DK-CENTURION PHACO PAK M/IA HP
C28370-05	DK-CONSTELLATION 25+ GAUGE COMBI
C28370-06	DK-CONSTELLATION 25+ GAUGE COMBI
C22508-06	DK-CPKB CONSTELLATION PHACO
C14835-22	DK-CPKB ODENSE INFINITI PAK
C23202-10	DK-HANNE ROED CATARACT
C25340-08	DK-HOLSTEBRO CENTURION PAK
C29071-02	DK-HØRSHOLM PRIVATKLINIK CPAK
C25341-04	DK-INFINITI JENS ØSTERGAARD
C25148-04	DK-INFINITI PAK MORTZOS
C20360-13	DK-KATARAKT PAK
C19124-07	DK-KATARAKT PAKKE
C13888-16	DK-KATARAKT PAKKE
C18706-13	DK-NÆSTVED SYGEHUS
C18706-14	DK-NÆSTVED SYGEHUS
C28216-05	DK-ØJENKLINIKKEN MORS
C26453-06	DK-SUSANNE TVEDE CPAK
C25327-08	DK-VENDSYSSEL KATARAKT PAK
C27573-05	S-MEMIRA CPAK 1 - CENTURION BAL30
8065750853	TS TIP,45KT,MINI FL AB 0.9MM
C25325-06	DK-SEC CATARACT CENTURION
n/a	n/a

If you have any questions about Alcon products, please feel free to call your Alcon Sales Representative.