

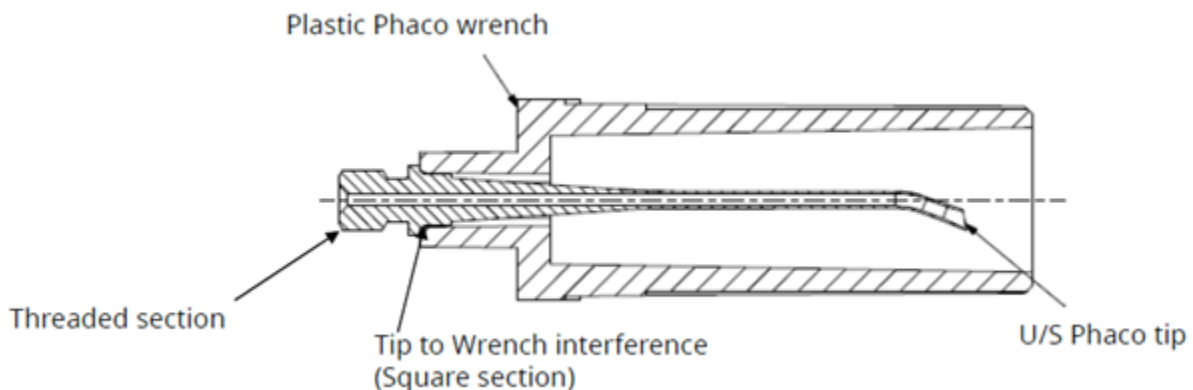
| <b>URGENT: VOLUNTARY MEDICAL DEVICE CORRECTION</b> |  |
|--|--|
| <b>Description</b>                                 | <b>Handling guidance for specific catalog numbers of Alcon Phaco Tips when used with included plastic wrench</b> |
| <b>Relevant Product</b>                            | <b>Alcon Phaco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

July 3, 2023

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.

**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

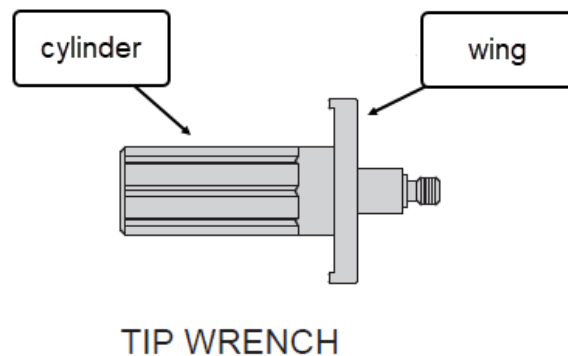
consistent with the plastic wrench material. Globally, complaints of plastic particles associated with Phaco Tips represent less than 0.01% of Phaco Tips sales volume. Alcon has received a limited number of reports of adverse events associated with this issue.

## Potential patient impact

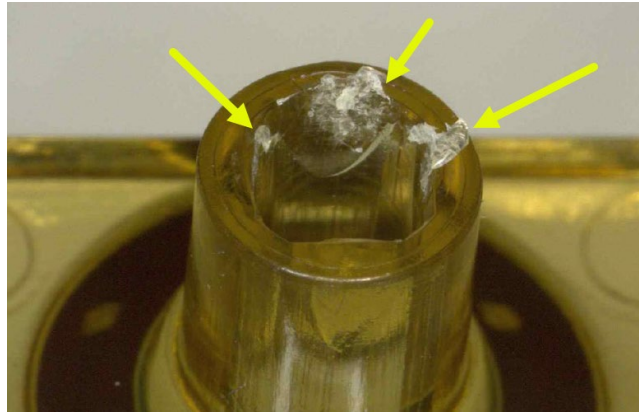
If particles are generated from the plastic wrench by overtightening the Phaco Tip and those particles subsequently enter the patient's eye during surgery, there is a potential risk of intra- and/or post-operative complications, including intraocular tissue damage, bleeding, and/or associated inflammation.

## 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.



- 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<sup>®</sup>.
4. Please complete the attached "*Response Form*" indicating your understanding of the included instructions and **return the attached "*Response Form*" via fax or 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 ([msus.safety@alcon.com](mailto:msus.safety@alcon.com)) or by phone (1-800-757-9780, Option 5).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA MedWatch Adverse Event Reporting program either online (<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>), by regular mail or by fax.

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,

A handwritten signature in black ink, appearing to read 'Heather Attra', with a long horizontal flourish extending to the right.

Heather Attra  
Senior Vice President, Quality and Regulatory Affairs

| RESPONSE FORM  |
|--|
| <p style="text-align: center;"><b>MA 2023.011</b></p> <p style="text-align: center;"><b>Handling guidance for specific catalog numbers of Alcon Phaco Tips when used with included plastic wrench</b></p>  |
| <p><b>Please follow these important steps:</b></p> <p>To acknowledge your receipt of this Voluntary Medical Device Correction notification, please take the following steps:</p> <ol style="list-style-type: none"><li>1. Forward this notification to all departments or organizations using Alcon Phaco Tips.</li><li>2. See <i>Attachment 1</i> 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.</li><li>3. Follow the risk mitigation precautions provided in this notice when using identified catalog numbers of Phaco Tips, procedure pack, or Alcon Custom Pak<sup>®</sup>.</li><li>4. Please complete the attached "<i>Response Form</i>" indicating your understanding of the included instructions and <b>return the attached "<i>Response Form</i>" via fax or email to Alcon.</b></li><li>5. Keep <i>Attachment 1</i> for your records.</li></ol> <p style="text-align: center;"><b>Fax: 817-302-4337    Email: <a href="mailto:Market.Actions@alcon.com">Market.Actions@alcon.com</a></b></p> <p style="text-align: center;"><b><i>Your signature below attests that you have read and understood Alcon's request and instructions.</i></b></p> |
| <b>Signature of Facility Representative:</b>   |
| <b>Printed Name and Title:</b>   |
| <b>Date:</b>   |



**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                          | Catalog Number | Item Description |
|----------------|---|----------------|------------------|
| 8065752201     | CEN FMS PACK,ACT,.9U 45 BAL               |                |                  |
| 8065750853     | TS TIP,45KT,MINI FL AB 0.9MM              |                |                  |
| 8065750958     | ASSY,SHIP,CONSTELLATN FRAG TIP            |                |                  |
| 8065752087     | PACK,INT PL 0.9MM ULTRA MF 45K            |                |                  |
| AS14152-03     | MAL-H PANTAI B PAHAT PHACO PAK BATU PAHAT |                |                  |
| 8065752217     | CEN FMS PACK,GRV,.9U 45BAL                |                |                  |
| 8065752200     | CEN FMS PACK,ACT,.9U 30 BAL               |                |                  |
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*If you have any questions about Alcon products, please feel free to call our Customer Service at 1-800-862-5266 or contact your Alcon Sales Representative.*