

ADVISORY NOTICE ATTENTION & ACTION REQUIRED Beaver-Visitec International, Inc.

Anterior Chamber Cannula [Rycroft] .60 x 22mm (23G x 7/8 in.) REF#: 585772 LOT Numbers: 6031665 and 6035693

20 April 2021

Dear Doctor and Customer,

Beaver-Visitec International, Inc. (BVI) is providing this Advisory Notice to make you aware that the two lots of <u>Anterior Chamber Cannula [Rycroft]</u>, .60 x 22mm (23G x 7/8 in) sent to your facility have labelling that incorrectly identifies the product as <u>Viscoflow® Cannula</u>, .60 x 22mm (23G x 7/8 in).

Description of the issue:

The product contained within the packaging is the <u>Anterior Chamber Cannula [Rycroft]</u>, .60 x 22mm (22G x 7/8 in), which is a cannula with a 45-degree bend located 4mm from its tip (see Figure 1).

However, the labeling on the packaging identifies the content as the $\underline{\textit{Viscoflow}^{@} Cannula, .60 x}$ $\underline{\textit{22mm (23G x 7/8 in)}}$, which is cannula with a 45-degree bend located 9mm from its tip (see Figure 2).

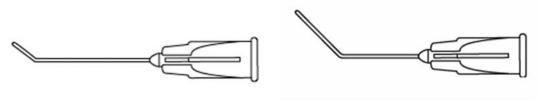


Figure 1, Anterior Chamber Cannula [Rycroft]

Figure 2, ViscoFlow® Cannula

Both the Anterior Chamber Cannula [Rycroft] and the ViscoFlow® cannulas are intended to irrigate/inject liquid and/or air during ocular surgery. BVI has determined that there is no health risk associated with the use of this incorrectly labeled product as the product contained within the packaging is the Anterior Chamber Cannula.



ADVISORY NOTICE

Anterior Chamber Cannula [Rycroft]

BVI is not requesting the product to be returned

Be Advised: You, the customer, should decide on how to proceed with product utilization or destruction. However, BVI is asking you to take the following action as part of this awareness of the incorrect identification of the Anterior Chamber Cannula [Rycroft] .60 x 22mm (23G x 7/8 in) sent to your facility.

Please complete and return this response form no later than <u>06 June 2021</u>

Please check the appropriate response(s)
STEP 1
☐ I have No product on hand [Complete information in Step 2]
OR
\square I have read the information related to this matter and understand this product Advisory Notice [Complete information in Step 2].
STEP 2
Company name:
Address:
BVI Customer Account # (if known)
If purchased through a distributor, include distributor name:
Telephone:
Contact name:
Title: Email:
Date completed:
STEP 3
Please return the completed Attachment 1-Response Form to BVI by emailing the completed attachment to BVI_FA_21_003@Stericycle.com.

Thank you for your assistance in this matter