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17 December 2015 FSN: 122015

URGENT – FIELD SAFETY NOTICE

XEN•45 Glaucoma Treatment System (Lots 60815, 60869)

Increased actuation force on XEN Injector

Dear Customer,

It has been reported to us that a small percentage of XEN users have encountered a higher than expected resistance when actuating the slider mechanism on some XEN•45 devices. The need for increased force to use deploy the slider may potentially lead to ocular trauma, if the slider mechanism is forced forward.

We have determined that the issue of increased resistance in the slider mechanism is limited to two batches with the following lot numbers – 60815 and 60869. No other lots are affected. The purpose of this notice is to let you know how to manage this potential issue, if you have product from these lots, and to reassure you that this issue is being resolved.

What is in this Field Safety Notice (FSN):

- An explanation of the issue and under what circumstances it may occur
- The actions that should be taken to prevent risks for patients
- The actions planned by AqueSys to resolve the issue

Explanation of the Issue:

In the two affected lots, surgeons may note an increased resistance to the slider movement which begins at approximately the midpoint of slider travel when the Injector transitions from advancing the Gel Stent to retracting the needle. This increase in resistance may be more prominent if the surgeon has rotated the needle bevel angle selector from the center channel to the left channel.

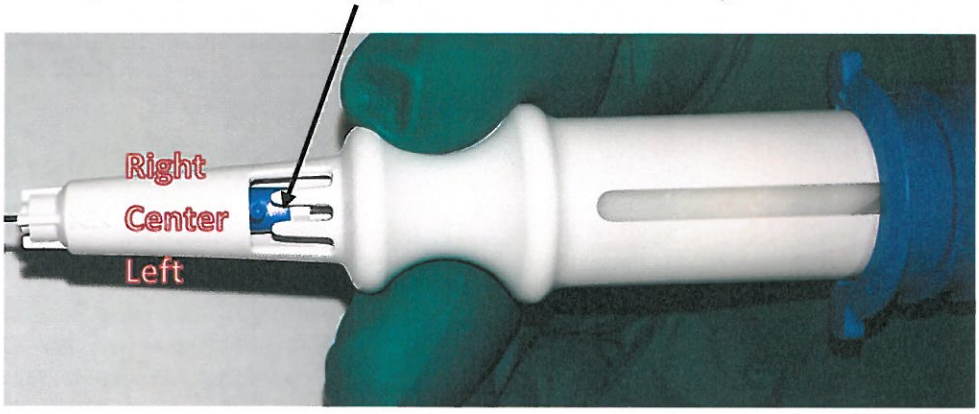
Please note that the potential risk of ocular trauma occurs only during implantation with the impacted lots, if the slider is forced forward. Successfully implanted XEN Gel Stents are not affected by the issue.

Actions that should be taken to prevent risks for patients:

To avoid encountering the increased actuation force during surgery, the following steps are recommended:

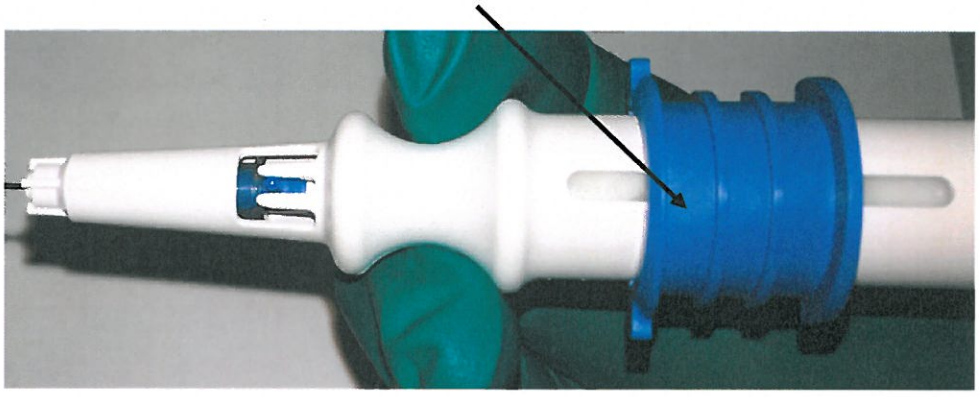
1. Follow the current instructions for use and remove the retention plug and the slider lock before inserting the injector into the eye.
2. Keep the needle of the injector tilted slightly upward to ensure the Gel Stent remains in the needle.
3. Verify that the needle bevel angle selector is in the **center position** (as shown in Figure 1).

Figure 1: Needle bevel angle selector shown in center position



4. Over a sterile tray or surface, carefully advance the slider forward to where the needle begins to retract (approximately 75% of the full travel distance as shown in Figure 2). The Gel Stent should advance but not fall out of the needle. Note: if the Gel Stent does fall onto the sterile tray, discard the system and use a new XEN system.

Figure 2: Slider advanced to just past approximately 75% of the full travel distance



Note: As the surgeon moves the slider forward, the slider should run smoothly and without undue force. If the surgeon feels the slider force is unacceptable, **immediately stop the procedure** and prepare to use a new XEN system, repeating the steps above. Please return the discarded XEN unit to AqueSys (details below).

5. Return the slider to the original position.
6. Hold the Injector vertically with the needle up. Tap the bottom of the Injector to allow the Gel Stent to slide back into the needle.
7. Proceed with the surgery.

Key points:

- **If increased resistance is noticed at any time, immediately stop the procedure and use a new XEN system as ocular trauma may result.**
- **AqueSys recommends that only the center channel (angle selector) is used for the impacted lots.**

Transmission of this Field Safety Notice:

This notice needs to be provided to anyone within your organization who needs to be aware of this issue or to any organization where the potentially affected devices have been transferred. Since the risk occurs during implantation with two lots, the surgeons using the XEN system must be provided a copy of this notice.

Actions planned by AqueSys to resolve the issue:

We have identified the cause of this issue, which has impacted only two lots of XEN product. We are working diligently to avoid this issue in future batches as well as introducing modifications to manufacturing and inspection procedures to ensure that the injector does not require increased force to safely deliver the XEN Gel Stent. This issue and the resolutions have been reported to the appropriate Regulatory Agencies.

Further information or support:

If you need any further information or support concerning this issue, please contact the following representatives:

In Europe: Dr. Cameron Hudson, CHudson@aquesys.com, +44 7951 756613

In Canada: Roger Kash, RKash@aquesys.com, +1 760 271 5958

Sincerely,

Barbara Niksch
Vice President, Regulatory & Clinical Affairs