

Physician Administration Guide

This guide is intended to provide ophthalmologists with information regarding the administration of DURYSTA™ (bimatoprost implant). This is a step-by-step guide for administration. Please refer to the full Prescribing Information for additional information regarding DURYSTA™.

FOR OPHTHALMOLOGISTS

INDICATIONS AND USAGE

DURYSTA™ (bimatoprost implant) is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DURYSTA™ is contraindicated in patients with: active or suspected ocular or periocular infections; corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy); prior corneal transplantation or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]); absent or ruptured posterior lens capsule, due to the risk of implant migration into the posterior segment; hypersensitivity to bimatoprost or to any other components of the product.

Please see additional Important Safety Information throughout this piece and click [here](#) for full Prescribing Information.

Inside This Guide to DURYSTA™

DURYSTA™ Overview.....	3
DURYSTA™ delivery and applicator	4
General dosing and administration information	5
Setting Up for Administration	6
Preparing the patient for DURYSTA™	6
Preparing DURYSTA™ for administration	7
Intracameral Administration of DURYSTA™	8
Administration instructions	8
DURYSTA™ Post-Administration	12
Typical implant behavior.....	12
Patient instructions.....	13
Troubleshooting Scenarios	14
Implant adheres to the needle tip.....	14
Implant becomes lodged in the corneal administration track	15
Implant floats in the anterior chamber	16
Implant removal from the eye	17
Integrating DURYSTA™ Into Your Practice	18
How supplied/storage and handling.....	18
Support and resources	19

List of Figures

Figure 1. DURYSTA™ Biodegradable Intracameral Implant.....	4
Figure 2. The DURYSTA™ Applicator	5
Figure 3. Visual Inspection of the DURYSTA™ Applicator.....	7
Figure 4. Examples of Functioning vs Damaged Needles	8
Figure 5. The Corneal Entrance Site.....	9
Figure 6. How to Release the Implant.....	10
Figure 7. Proper Placement of the DURYSTA™ Implant.....	12
Figure 8. Implant Adheres to the Needle Tip.....	14
Figure 9. Implant Becomes Lodged in the Corneal Administration Track	15
Figure 10. Implant Floats in the Anterior Chamber.....	16



DURYSTA™ Overview

DURYSTA™ is a biodegradable implant for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT) containing bimatoprost 10 mcg. DURYSTA™ is believed to lower IOP by increasing the outflow of aqueous humor through both the trabecular meshwork (conventional) and uveoscleral (unconventional) routes.¹

This step-by-step guide provides information for DURYSTA™ intracameral administration. Please review this information before performing the administration. For additional support, please contact your Allergan representative.

Contact your Allergan representative to learn more about DURYSTA™.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

The presence of DURYSTA™ implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Administration of DURYSTA™ should be limited to a single implant per eye without retreatment. Caution should be used when prescribing DURYSTA™ in patients with limited corneal endothelial cell reserve.

DURYSTA™ should be used with caution in patients with narrow iridocorneal angles (Shaffer grade < 3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.

Macular edema, including cystoid macular edema, has been reported during treatment with ophthalmic bimatoprost, including DURYSTA™ intracameral implant. DURYSTA™ should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Prostaglandin analogs, including DURYSTA™, have been reported to cause intraocular inflammation. DURYSTA™ should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

DURYSTA™ delivery and applicator

Biodegradable implant (Figure 1)

- A sterile intracameral implant containing 10 mcg of bimatoprost, a prostaglandin analog¹
- Solid polymer sustained-release drug delivery system¹

Drug delivery system

- Polymer matrix similar to material used in biodegradable sutures
- Implants are not permanent and will biodegrade¹

Figure 1. DURYSTA™ Biodegradable Intracameral Implant



IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

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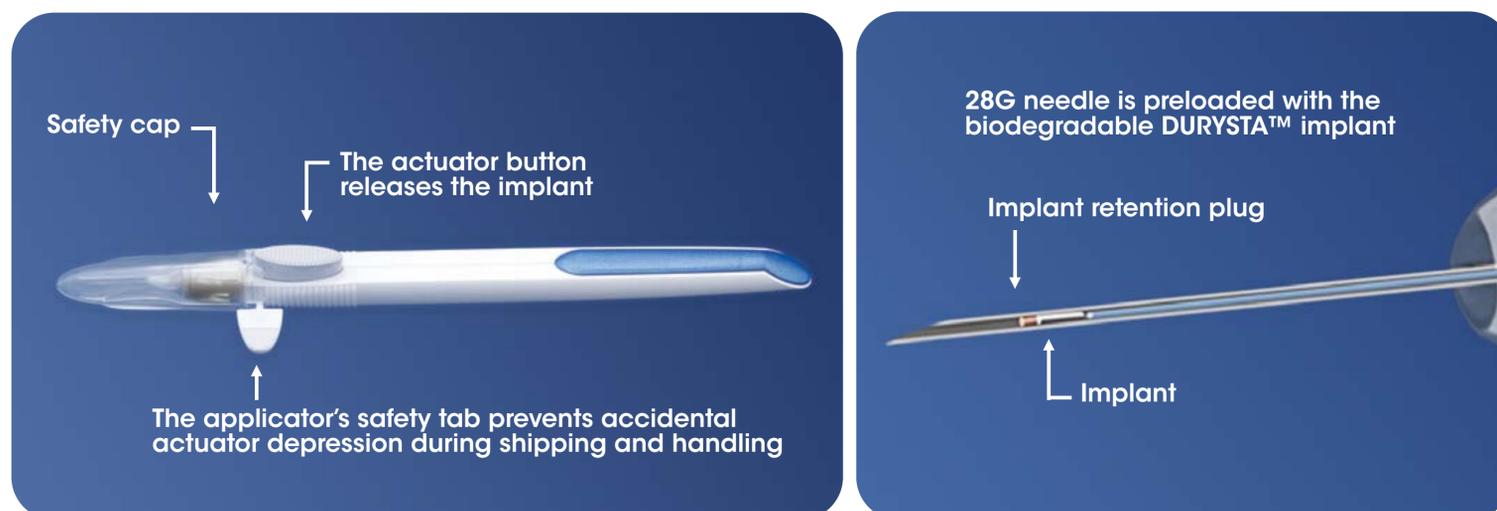
DURYSTA™

(bimatoprost implant) 10 mcg

DURYSTA™ applicator (Figure 2)

- Designed for single-use application in 1 eye¹
- 28G needle preloaded with the biodegradable implant and implant retention plug to keep the biodegradable implant from falling out of needle tip during shipping and handling

Figure 2. The DURYSTA™ Applicator



General dosing and administration information

DURYSTA™ is an ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant. DURYSTA™ should not be readministered to an eye that received a prior administration of DURYSTA™.¹

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

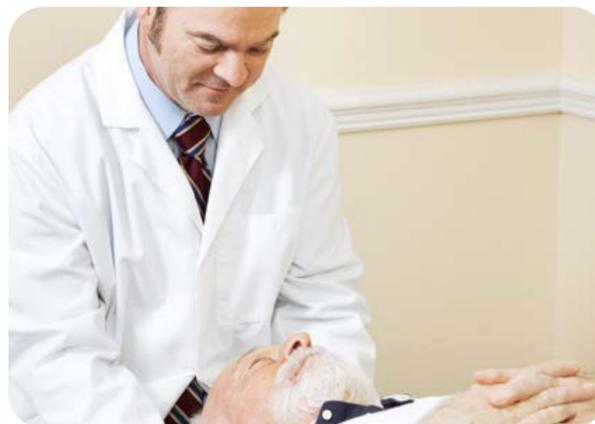
Intraocular surgical procedures and injections have been associated with endophthalmitis. Proper aseptic technique must always be used with administering DURYSTA™, and patients should be monitored following the administration.

Setting Up for Administration

The administration must be performed under magnification that allows clear visualization of the anterior chamber structures and should be carried out using standard aseptic conditions for intracameral procedures.¹

Preparing the patient for DURYSTA™¹

- 1** Follow your standard protocol for aseptic preparation for intracameral procedures
- 2** Place the patient's head in a stabilized position
- 3** Ensure the magnification enables clear visualization of the anterior chamber structures



CAUTION: The eye should not be dilated prior to the administration.

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

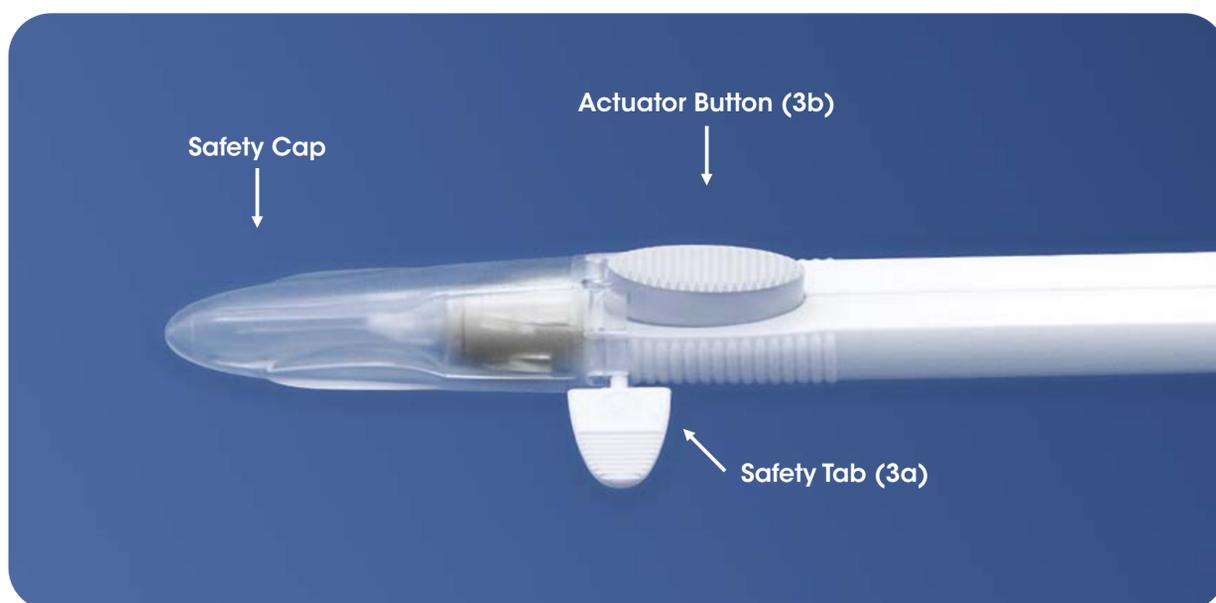
In controlled studies, the most common ocular adverse reaction reported by 27% of patients was conjunctival hyperemia. Other common adverse reactions reported in 5%–10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, iritis, and headache.

Preparing DURYSTA™ for administration¹

- 1 Set up the materials needed for performing an intracameral administration in standard aseptic conditions
- 2 Remove the foil pouch containing the DURYSTA™ applicator from the carton and examine for any damage
- 3 Open the foil pouch over a sterile field and gently drop the applicator on a sterile tray. Use promptly after opening
- 4 Perform a detailed visual inspection of the applicator and ensure:
 - The safety tab is in place (**Figure 3a**)
 - The actuator button is not prematurely depressed (**Figure 3b**)

INFORMATION: The safety tab prevents the actuator button from depressing prematurely.

Figure 3. Visual Inspection of the DURYSTA™ Applicator

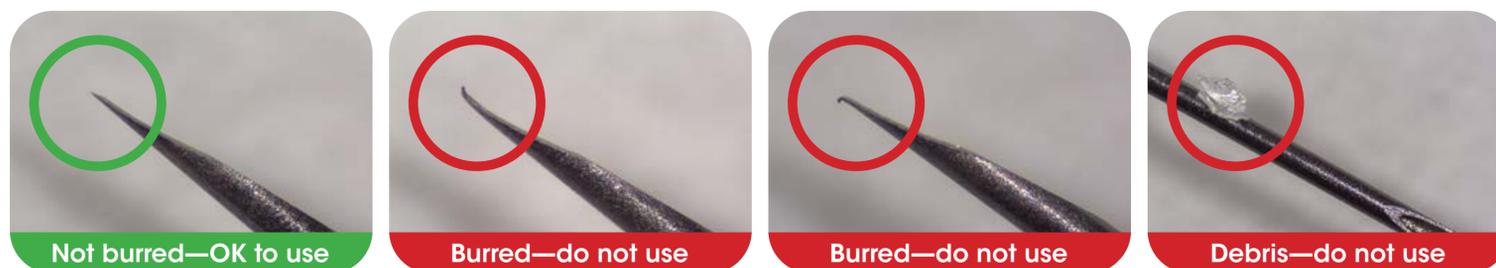


Intracameral Administration of DURYSTA™

Administration instructions¹

- 1** Carefully remove the plastic safety cap of the applicator, avoiding any contact with the needle tip
- 2** Inspect the needle tip for damage under magnification prior to use (**Figure 4**); the implant retention plug may be visible in the bevel and should not be removed
- 3** Prior to use, remove the safety tab by pulling it out perpendicular to the long axis of the applicator. Do not twist or bend the tab

Figure 4. Examples of Functioning vs Damaged Needles



CAUTION: If the needle tip is burred and/or has debris, do not use. Contact your Allergan sales representative for instructions on how to return the product.

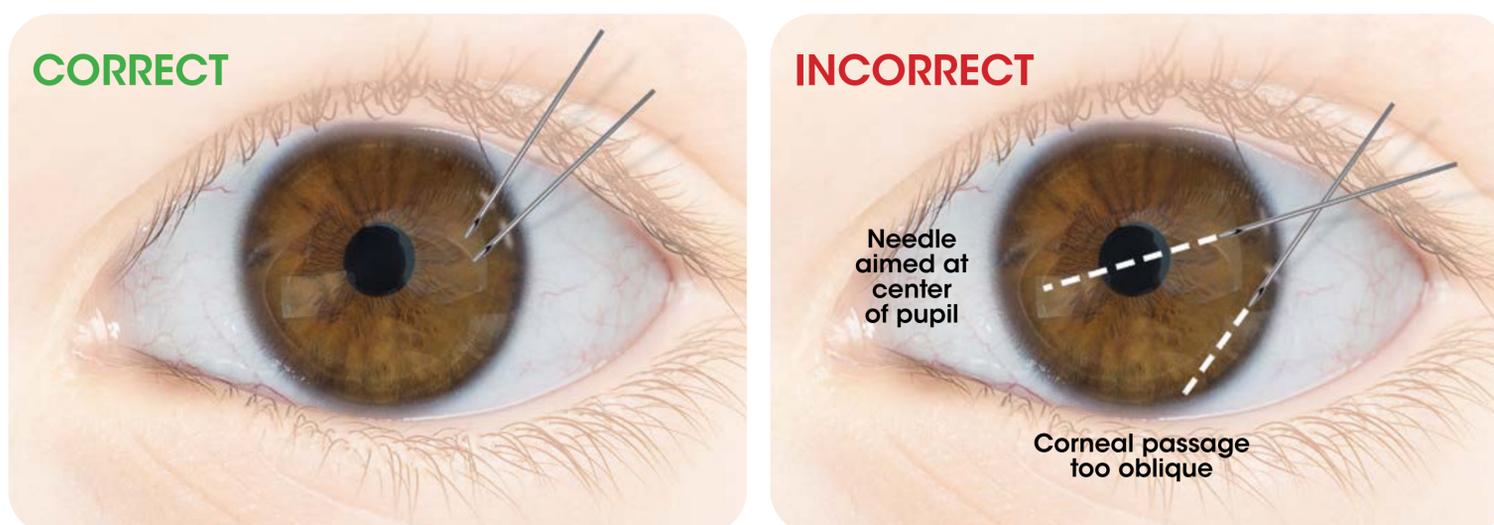
IMPORTANT SAFETY INFORMATION (CONTINUED)

CONTRAINDICATIONS

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- 4 Stabilize the eye as the needle is advanced through the cornea
- 5 Enter the anterior chamber with the needle bevel visible through clear cornea. Enter parallel to the iris plane, adjacent to the limbus through clear cornea in the superotemporal quadrant (Figure 5)

Figure 5. The Corneal Entrance Site



CAUTION: Do not aim needle towards the pupil.

IMPORTANT SAFETY INFORMATION (CONTINUED)

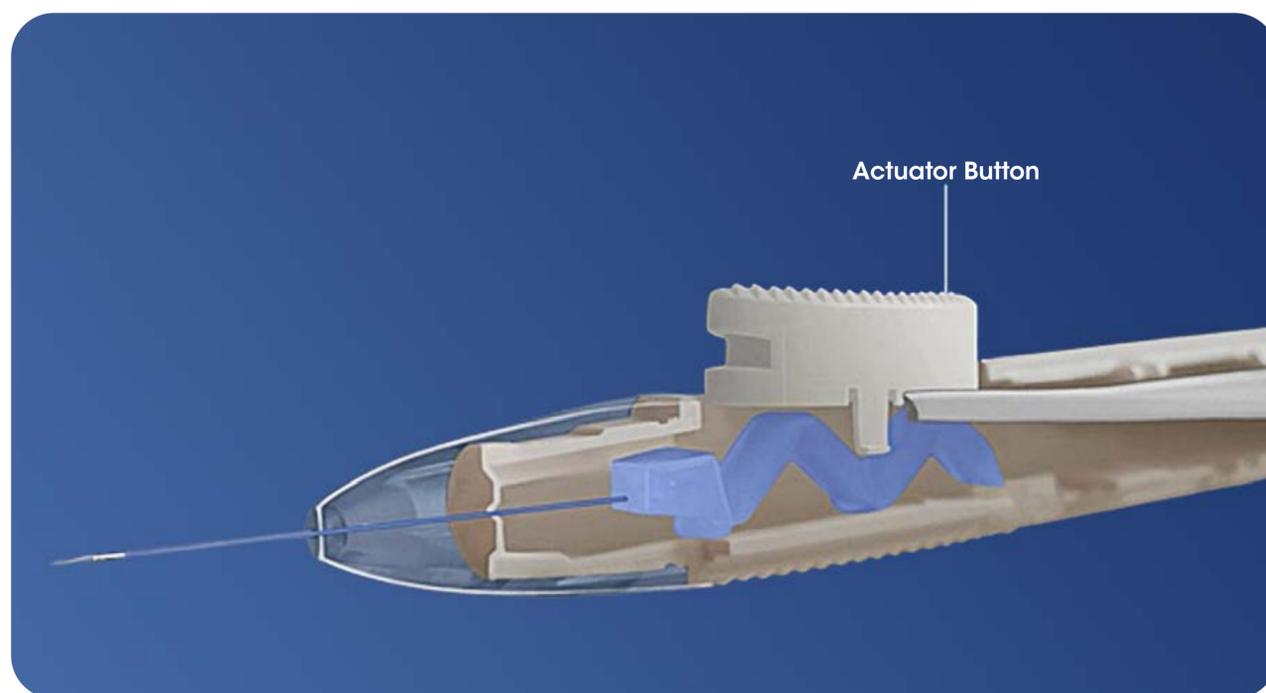
WARNINGS AND PRECAUTIONS

The presence of DURYSTA™ implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Administration of DURYSTA™ should be limited to a single implant per eye without retreatment. Caution should be used when prescribing DURYSTA™ in patients with limited corneal endothelial cell reserve.

DURYSTA™ should be used with caution in patients with narrow iridocorneal angles (Shaffer grade < 3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.

- 6 The needle should be inserted approximately 2 bevel lengths with the bevel completely within the anterior chamber; avoid positioning the needle bevel directly over the pupil
- 7 Ensure the needle is not bent before depressing the actuator button
- 8 To release the implant, depress the **back half** of the actuator button (**Figure 6**) firmly until an audible and/or palpable click is noted

Figure 6. How to Release the Implant



IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Macular edema, including cystoid macular edema, has been reported during treatment with ophthalmic bimatoprost, including DURYSTA™ intracameral implant. DURYSTA™ should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Prostaglandin analogs, including DURYSTA™, have been reported to cause intraocular inflammation. DURYSTA™ should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

CAUTION: In some cases, the implant may adhere to the needle tip. See the Troubleshooting Scenarios beginning on page 14, for guidance on what to do if the implant adheres to the needle tip.

- 9 Following the release of the implant, remove the needle via the same track in which it was inserted and tamponade the opening. The implant should not be left in the corneal injection track
- 10 Check the injection site for leaks and make sure it is self-sealing and the anterior chamber is formed
- 11 After injection, **do not** recap the needle. Safely dispose the used applicator in a sharps disposal container and in accordance with local requirements
- 12 Instruct the patient to remain upright for at least 1 hour after the procedure so the implant can settle
- 13 Inform the patient that some degree of eye redness and discomfort is expected following administration. However, it is recommended to instruct patients that if the eye becomes progressively red, sensitive to light, painful, or develops a change in vision, they should immediately contact the physician

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Ophthalmic bimatoprost, including DURYSTA™ intracameral implant, has been reported to cause changes to pigmented tissues, such as increased pigmentation of the iris. Pigmentation of the iris is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. While treatment with DURYSTA™ can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

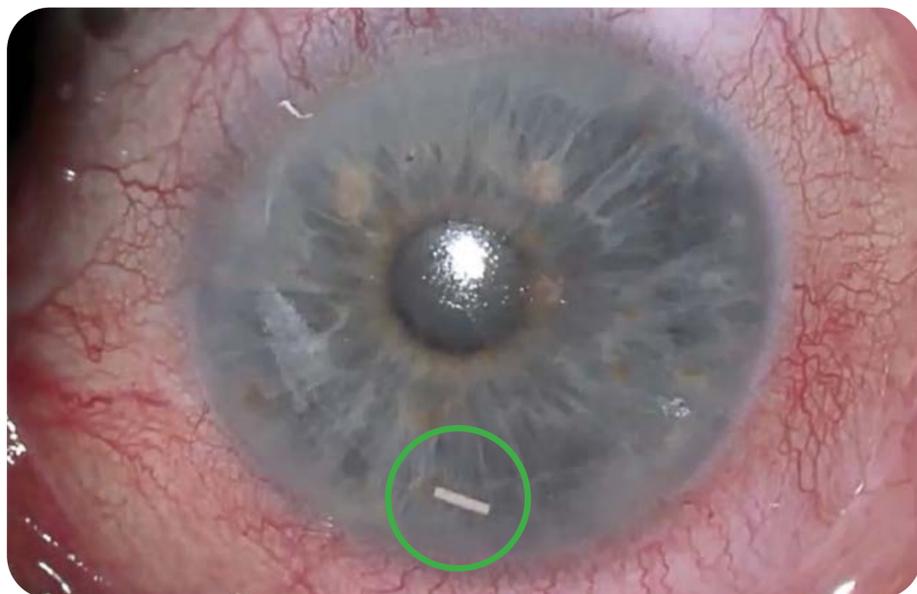


DURYSTA™ Post-Administration

Typical implant behavior

Allow the implant to settle into the inferior position. The patient should be instructed to remain upright for at least 1 hour after the administration so the implant can settle (**Figure 7**).¹

Figure 7. Proper Placement of the DURYSTA™ Implant



CAUTION: DURYSTA™ should be used with caution in patients with narrow iridocorneal angles (Shaffer grade <3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.¹

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Intraocular surgical procedures and injections have been associated with endophthalmitis. Proper aseptic technique must always be used with administering DURYSTA™, and patients should be monitored following the administration.

Patient instructions

- 1** Inform patients that some degree of eye redness and discomfort is expected following administration¹
- 2** Instruct patients to contact the physician immediately if they experience any of the following in the treated eye:¹
 - Progressive redness
 - Sensitivity to light
 - Pain
 - Change in vision
- 3** Provide instructions for physical activities, medications, and set up a follow-up appointment to check on the patient's response to DURYSTA™

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

In controlled studies, the most common ocular adverse reaction reported by 27% of patients was conjunctival hyperemia. Other common adverse reactions reported in 5%–10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, iritis, and headache.

CONTRAINDICATIONS

DURYSTA™ is contraindicated in patients with: active or suspected ocular or periocular infections; corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy); prior corneal transplantation or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]); absent or ruptured posterior lens capsule, due to the risk of implant migration into the posterior segment; hypersensitivity to bimatoprost or to any other components of the product.

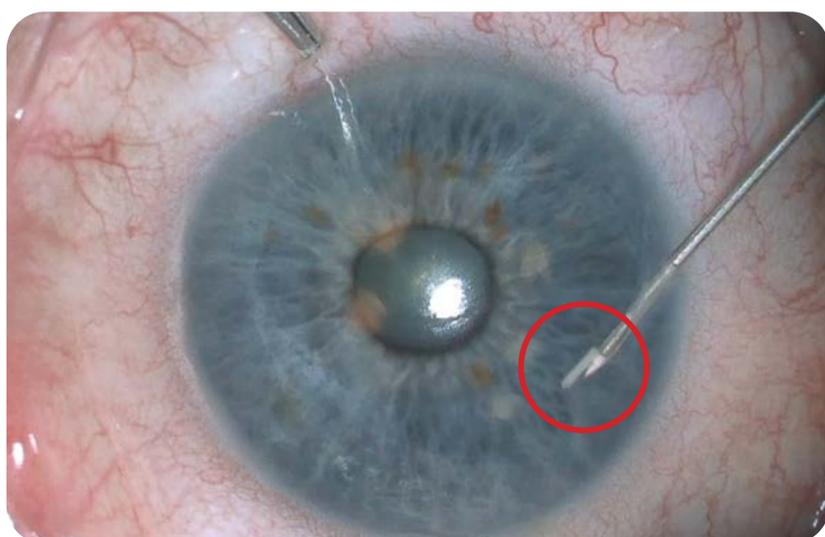


Troubleshooting Scenarios

These troubleshooting scenarios are not found in the Prescribing Information. The information in this section has been gained through clinical experience and therefore offers suggestions that are ultimately up to the physician's judgment. Remember to always follow the instructions found in the Prescribing Information completely.

Implant adheres to the needle tip

Figure 8. Implant Adheres to the Needle Tip



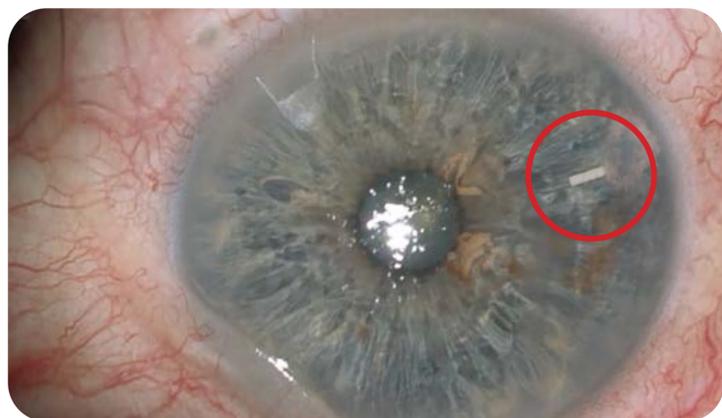
What to do:

- 1 Wait 5 seconds to allow the implant to disengage from the needle tip
- 2 If the implant still does not disengage, gently press the implant against the anterior iris to engage it and slightly rotate the applicator to disconnect the implant from the needle tip
- 3 If step 2 doesn't work, withdraw the needle from the anterior chamber. Contact with the inner lip of the administration track may release the implant from the needle tip

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Implant becomes lodged in the corneal administration track

Figure 9. Implant Becomes Lodged in the Corneal Administration Track



What to do:

- 1 Implants should not be allowed to remain lodged in or in contact with the administration track as they may cause an inflammatory response
- 2 Try to gently tap the cornea over the administration track to cause the implant to drop down
- 3 If step 2 doesn't work, use an Anterior Chamber Probe to dislodge the implant from the administration track by advancing approximately 4 mm into the anterior chamber

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

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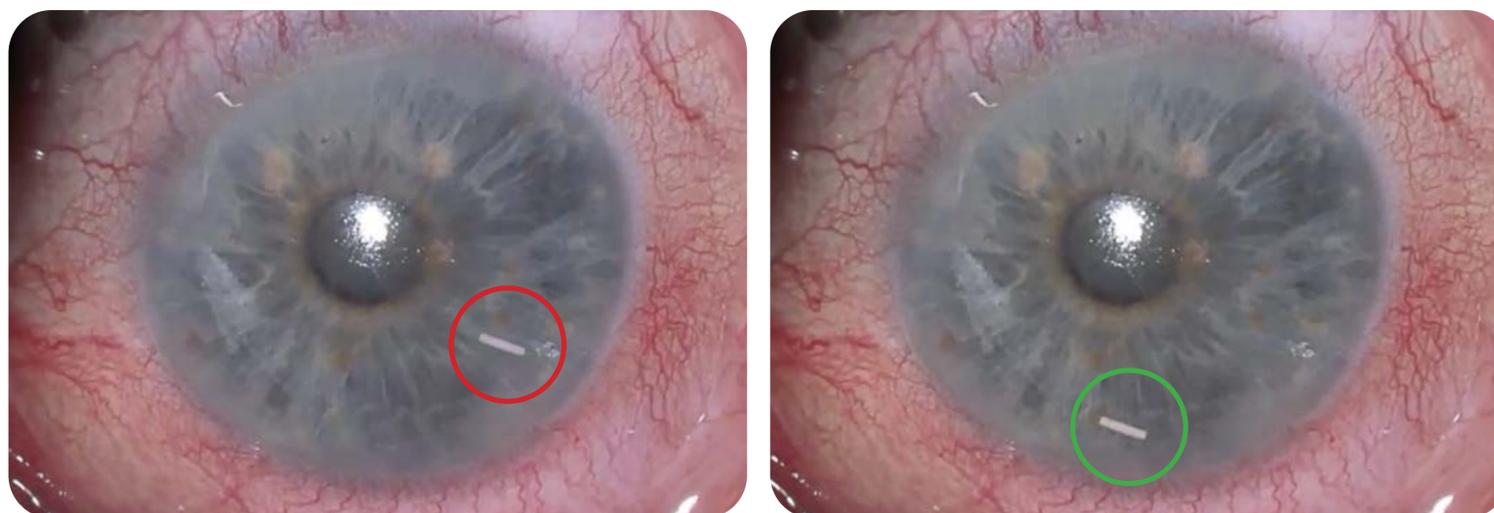
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Implant floats in the anterior chamber

Figure 10. Implant Floats in the Anterior Chamber



What to do:

- 1 During the observation period, allow the implant to settle into the inferior position without manipulating it
- 2 If the implant is floating in the anterior chamber because of an air bubble, the air bubble should dissipate on its own

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

DURYSTA™ should be used with caution in patients with narrow iridocorneal angles (Shaffer grade < 3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.

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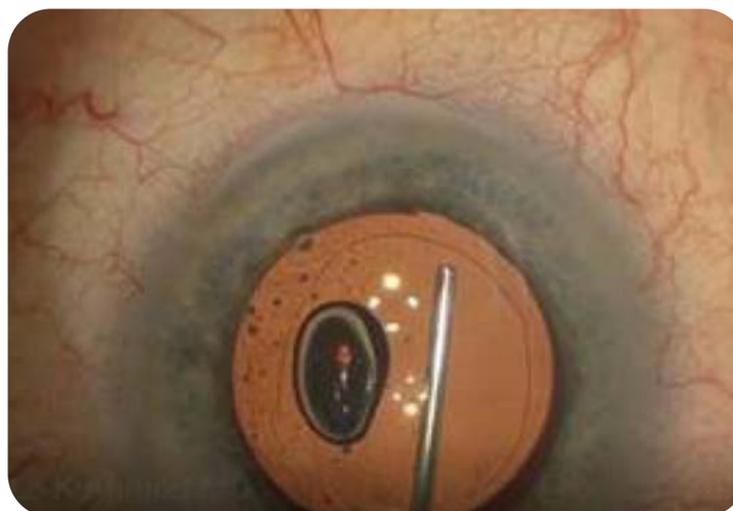
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Implant removal from the eye

What to do: If for any reason you need to remove the implant from the eye, first create a clear corneal incision with a keratome, using standard aseptic technique for intraocular procedures. Then, perform an anterior chamber washout with a sterile intraocular irrigating solution. Close the incision using your preferred closure method.



IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

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Integrating DURYSTA™ Into Your Practice

How supplied/storage and handling¹

DURYSTA™ contains a 10 mcg bimatoprost intracameral implant in a single-use applicator that is packaged in a sealed foil pouch containing desiccant.

DURYSTA™ must be refrigerated at 2°C to 8°C (36°F to 46°F).

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

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Support and resources

Allergan is committed to providing you and your practice with the resources you need for success with DURYSTA™.

Visit www.durystahcp.com for this guide and other resources for you and your staff.

IMPORTANT SAFETY INFORMATION (CONTINUED) WARNINGS AND PRECAUTIONS

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Reference: 1. DURYSTA™ (bimatoprost implant) 10 mcg [prescribing information]. Madison, NJ: Allergan, Inc. 2020.



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DURYSTA™

(bimatoprost implant) 10 mcg

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