BAERVELDT® Glaucoma Implants

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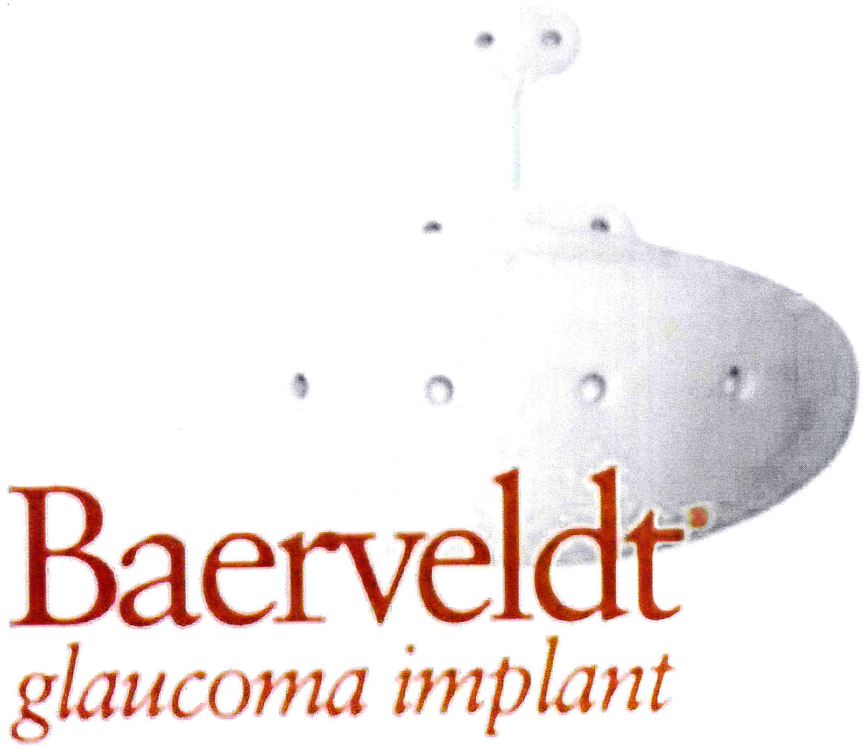

Instructional Guides

Directions for Use (PDF)

Description

Easing the Pressure

The BAERVELDT® BG 103-250, BAERVELDT® BG 101-350 and BAERVELDT® Pars Plana BG 102-350

Glaucoma Implants

Provide pressure control with a minimally invasive **BAERVELDT®** Glaucoma Implant. Its fenestration system is designed to control bleb height and volume while a patented larger surface area enhances IOP control.[1,2] When traditional glaucoma therapy can't help the rising IOP, provide control with a **BAERVELDT®** Glaucoma Implant.

Glaucoma Control

Large plate implants, such as **BAERVELDT®** Implants, facilitate aqueous outflow to help provide IOP control.[3]

- Allows improved aqueous filtration
- Maximizes pressure relief

Minimally Invasive

BAERVELDT® Implants only require single-quadrant insertion, allowing for better IOP control than competing implants.[4,5]

The **BAERVELDT®** Implants' patented bleb control mechanism allows fibrotic tissue growth through the fenestrations in the plate, controlling bleb height and volume.[2,6]

- Minimizes the likelihood of ocular motility disturbances[5]
- Helps ensure a low profile for better globe fit

Specifications

	BAERVELDT® BG 103-250 Glaucoma Implant	**BAERVELDT®** BG 101-350 Glaucoma Implant	**BAERVELDT®** Pars Plana BG 102-350 Glaucoma Implant
Surface Area:	250 mm^2	350 mm^2	350 mm^2
Plate Length:	22 mm	32 mm	32 mm
Tube Length:	32 mm	32 mm	7 mm
Fenestrations:	4	4	4
Placement:	Anterior chamber	Anterior chamber	Posterior chamber (Pars Plana)
Drainage Mechanism:	Open tube	Open tube	Open tube with Hoffman Elbow

REFERENCES

1. Gedde S, Schiffman J, Feuer W, et al. Treatment outcomes in the tube versus trabeculectomy study after on year of follow-up. Am J Ophthalmol.2007;143(1):9-22.
2. Lloyd MA, Baerveldt G, Fellenbaum PS, et al. Intermediate-term results of a randomized clinical trial of the 350 - versus the 500 mm2 Baerveldt Implant. Ophthalmology. 1994;101(8):1456-1464.
3. Gedde, S. et al. Treatment outcomes in the tube versus trabeculectomy (TVT) study after five years of follow

up. Am J Ophthalmol. 2012;153(5).
4. Heuer DK, Lloyd MA, Abrams DA, et al. Which is better? One or two? A randomized clinical trial of single-plate versus double-plate Molteno implantation for glaucomas in aphakia and pseudophakia. Ophthalmology. 1992;99(10):1512-1519.
5. Fellenbaum PS, Sidoti P, Heuer DK, Minckler DS, Baerveldt G, Lee PP. Experience with the Baerveldt implant in young patients with complicated glaucomas. J Glaucoma. 1995;4(2):91-97.
6. Hodkin MJ, Goldblatt WS, Burgoyne CF, Ball SF, Insler MS. Early clinical experience with the Baerveldt implant in complicated glaucomas. Am J Ophthalmol. 1995(1);120:32.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR BAERVELDT® GLAUCOMA IMPLANTS

Rx Only

INDICATIONS

For use in patients (with prior vitrectomy for Pars Plana) with medically uncontrollable glaucoma and poor surgical prognosis, such as, but not limited to: neovascular glaucoma, aphakic/pseudophakic glaucomas, patients who have failed conventional surgery, congenital glaucomas and secondary glaucomas due to uveitis, epithelial downgrowth, etc.

CONTRAINDICATIONS

Bacterial conjunctivitis, bacterial corneal ulcers, endophthalmitis, orbital cellulitis, bacteremia or septicemia, active scleritis and/or no light perception.

WARNINGS

Do not use the device if sterile package integrity has been compromised. Do not resterilize the implant by any method. Do not reuse the implant. Do not store at temperatures above 45°C (113°F). Johnson & Johnson Surgical Vision single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user. The reuse of/resterilization/reprocessing of single- use Johnson & Johnson Surgical Vision, Inc. medical devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility. JJSV single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user.

COMPLICATIONS/ADVERSE EVENTS

The complications during and after surgery include, but are not limited to: chorodial hemorrhage, hyphema, serous choroidal effusion, hypotony, flat anterior chamber, phthisis bulbi, retinal detachment, endophthalmitis, tube erosion, tube touch to cornea, tube block by iris or vitreous, bullous keratopathy, uveitis and diplopia.

ATTENTION

Reference the labeling for a complete listing of Indications and Important Safety Information.

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